NICE National Institute for Health and Care Excellence

NICE guidance

Virtual reality technologies for treating agoraphobia or agoraphobic avoidance: early value assessment

Health technology evaluation

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

Can be used in the NHS with evidence generation

1.1 gameChangeVR (a virtual reality [VR] technology) can be used in the NHS while more evidence is generated, to treat severe agoraphobic avoidance in people with psychosis aged 16 and over. It should be used with the support of a mental health professional.

1.2 The company must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan) and contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance if these conditions are not met.

1.3 At 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 the evidence and assess if the technology can be routinely adopted in the NHS.

Can only be used in research

1.4 More research is needed on the following VR technologies:

- Amelia Virtual Care to treat agoraphobia
- gameChangeVR to treat mild to moderate agoraphobic avoidance in people with psychosis
- XR Therapeutics to treat agoraphobia.

1.5 Access to the technologies for the indications in section 1.4 should be through company, research, or non-core NHS funding, and clinical and financial risks should be appropriately managed.

The technologies can only be used once they have appropriate regulatory approval.

Evidence generation and research

1.6 More evidence generation and research are needed on:

- clinical effectiveness, including long-term benefits and who may benefit most from using VR technologies
- rates of relapse or worsening of symptoms, including use and effectiveness of extra VR therapy sessions
- adverse effects
- resource use, including maintenance and lifespan of the hardware, and mental health professional grade and time needed to deliver treatment or support.

Potential benefits of using gameChangeVR in the NHS with evidence generation

- **Unmet need:** Agoraphobia is often untreated or undertreated, especially when its symptoms occur with other mental health conditions, such as agoraphobic avoidance in people with psychosis. Access to psychological interventions such as cognitive behavioural therapy (CBT) for treating psychosis varies and is very limited for some people. gameChangeVR is a virtual reality (VR) technology that delivers VR therapy using CBT techniques. It offers a treatment option for people aged 16 and over, who have psychosis and severe agoraphobic avoidance, who may otherwise not have psychological treatment.
- **Clinical benefit:** The clinical evidence suggests that gameChangeVR has potential benefits for treating severe agoraphobic avoidance in people with psychosis.
- **Resources:** gameChangeVR can be delivered and supported by mental health professionals working in lower pay bands than staff who are delivering other psychological treatments for psychosis with agoraphobic avoidance. gameChangeVR may also need less mental health professional time for delivery and support than other psychological treatments.

Managing the risk of using gameChangeVR in the NHS with evidence generation

- **Clinical assessment:** gameChangeVR should only be offered after assessing and identifying severe agoraphobic avoidance in people with psychosis. People with psychosis who are having difficulty leaving the house should be assessed in line with the World Health Organization's International Classification of Diseases (ICD)-10 classification of agoraphobia. Mental health professionals may use assessment tools to help identify the presence and severity of agoraphobic avoidance. They should also assess a person's safety, and if VR therapy is suitable for them.
- **Evidence generation:** There are uncertainties about the clinical and cost effectiveness of gameChangeVR for treating agoraphobic avoidance in people with psychosis because of the limited evidence. There is only 1 key effectiveness study for the technology. A secondary analysis on gameChangeVR suggests that there are benefits in treating agoraphobic avoidance in people with psychosis,

but only when the agoraphobic avoidance is severe. Primary evidence is needed to confirm this finding.

- **Costs:** Cost modelling suggests that gameChangeVR may be cost effective in people with psychosis who have severe agoraphobic avoidance, but there is considerable decision uncertainty in the modelling. gameChangeVR is unlikely to be cost effective for treating mild to moderate agoraphobic avoidance in people with psychosis.
- **Equality:** VR technologies may not be accessible to everyone. Additional support and resources may be needed for people who are unfamiliar with digital technologies or who do not have access to the internet. Other treatment options may be more appropriate for some people with agoraphobic avoidance. Everyone has the right to make informed decisions about their care.

The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

2 The technologies

2.1 Virtual reality (VR) is a simulated environment with scenes and objects that people can explore while wearing a headset or viewing a screen. This creates an immersive experience that can trigger emotional responses like those in real-world situations. Some VR technologies are designed to be used by a qualified therapist as a tool in therapy sessions to support the delivery of face-to-face or remote cognitive behavioural therapy (CBT). Other VR technologies are designed to be a standalone digital intervention that can be used with the support of a wider range of mental health professionals, such as assistant psychologists, peer support workers or therapists. VR technologies can help deliver treatments such as exposure therapy, by allowing people to immerse themselves in real-world situations while being in the safety of their home or clinic. Virtual environments can be adjusted based on a person's needs and individual treatment plan. This could allow more gradual exposure to stressful situations and increased comfort in completing interventions.

2.2 NICE has assessed 2 VR technologies for treating agoraphobia (Amelia Virtual Care and XR Therapeutics), and 1 VR technology for treating agoraphobic avoidance in people with psychosis (gameChangeVR). The assessment included VR technologies that are designed to be used as tools in therapy sessions and VR technologies that are standalone digital interventions. The criteria for including technologies in this assessment are in the final scope for this guidance on the NICE website. The technologies are:

- Amelia Virtual Care (Amelia Virtual Care) for treating mental health conditions including agoraphobia. This is a software-only VR technology that delivers VR therapy using a VR headset. It is designed to be used by qualified therapists as a tool to support treatment in clinics or at home. Amelia Virtual Care helps therapists to deliver evidence-based treatment including gradual exposure, mindfulness-based cognitive therapy and desensitisation.
- gameChangeVR (Oxford VR) for people with schizophrenia spectrum disorders or affective disorders with psychotic symptoms, who have agoraphobic avoidance (difficulties leaving home because of anxiety). This is a software-only VR technology that delivers VR therapy using a VR headset.

The intervention is delivered in around 6 weekly 30-minute sessions. There is an automated virtual therapist within the VR environment that guides the person through the treatment for agoraphobic avoidance using CBT techniques. This is supported by a mental health professional remotely or in person.

- XR Therapeutics (XR Therapeutics) for treating anxiety disorders including agoraphobia. This uses a fully immersive screen-based VR studio and is delivered in person by a qualified therapist in combination with face-to-face CBT. It allows therapists to tailor digital scenes to a person's individual needs. Treatment can be adapted in real time, allowing therapists to manage the rate of exposure and the intensity of situations.

  During scoping, NICE also identified Invirto (Invirto) for treating anxiety disorders including agoraphobia. The company did not respond to requests for information, and no evidence was identified. So, this technology was not assessed and was excluded from recommendations.

Care pathway

The target population for this early value assessment is people aged 16 years and over with agoraphobia. This includes agoraphobia that occurs with other common mental health problems or severe mental illness, including psychosis with agoraphobic avoidance. More information on the target conditions and care pathways can be found in the final scope for this guidance on the NICE website.

Agoraphobia without complex or severe mental health conditions

2.3 In people aged 18 and over, agoraphobia without complex or severe mental health conditions is usually treated in primary care or in NHS Talking Therapies for anxiety and depression services. NICE's guideline on common mental health problems recommends a stepped-care approach for treating common mental health disorders in adults, such as panic disorder with or without agoraphobia. The first step is identification and assessment, including identifying any comorbidities. This is used to develop a treatment plan, which may involve lifestyle changes and guided self-help based on CBT that is delivered with the

support of a practitioner or therapist. If needed or preferred, more intensive treatments should be offered. NICE's guideline on generalised anxiety disorder and panic disorder in adults recommends that adults with moderate to severe panic disorder with or without agoraphobia should be considered for referral for CBT or an antidepressant. Antidepressants may be considered if the disorder is long-standing or if the person has not benefited from or has declined psychological intervention. The NHS Talking Therapies for anxiety and depression programme offers evidence-based psychological therapies for adults, including CBT, guided self-help and counselling. Agoraphobia with co-occurring complex or severe mental health conditions would not be treated in primary care or NHS Talking Therapies for anxiety and depression services, but most likely in community mental health services or inpatient services. There is no NICE guideline on treating agoraphobia in young people aged under 18. Young people with symptoms of anxiety may be assessed and treated in a range of settings, including school mental health teams, single point of access teams, voluntary sector teams and children and young people's mental health services (CYPMHS).

Agoraphobic avoidance in people with psychosis

2.4 Treatment and care for psychosis in adults is usually managed in community mental health services including early intervention in psychosis services and community mental health teams. NICE's guideline on psychosis and schizophrenia in adults recommends that adults with a first episode or first presentation of psychosis should have an assessment and treatment in early intervention in psychosis services. Longer-term treatment and care are usually then provided by community mental health teams. NICE's guideline on psychosis and schizophrenia in children and young people recommends that young people with a first presentation of sustained psychotic symptoms should be urgently referred to child and adolescent mental health services or an early intervention in psychosis service. Longer-term treatment and care may then be provided in primary care or secondary care, including early intervention in psychosis services. The clinical experts advised that there is no established care pathway for agoraphobic avoidance within psychosis services. Treatment for agoraphobic avoidance in psychosis would be integrated within standard care treatment for psychosis. People with psychosis should be offered oral antipsychotic medicine and psychological interventions including CBT and family intervention. The clinical

and patient experts advised that access to CBT for psychosis varies and is limited for some people. Most adults with psychosis who are having treatment outside of early intervention in psychosis services do not have the psychological treatment recommended by NICE's guideline on psychosis and schizophrenia. They are more likely to be offered antipsychotic medicine and monitoring from their mental health service.

Access to care

2.5 Agoraphobia and agoraphobic avoidance may further affect a person's ability to access mental health services and support. The clinical and patient experts advised that agoraphobia is often untreated or undertreated especially when its symptoms occur with other mental health conditions, such as agoraphobic avoidance in people with psychosis. Some people may also stop treatment because they have difficulty tolerating treatments such as exposure therapy. VR technologies may increase access to care by offering another treatment option for agoraphobia, or agoraphobic avoidance in people with psychosis. It would be used as an alternative or in addition to standard care. It is not intended to replace treatment for co-occurring mental health conditions.

The comparator

2.6 The comparator for Amelia Virtual Care and XR Therapeutics is standard care for agoraphobia, and for gameChangeVR, it is standard care for agoraphobic avoidance in people with psychosis. This may vary depending on a person's individual needs and preferences, comorbidities and the treatment setting. Standard care treatments for agoraphobia without complex or severe mental health conditions may include guided self-help, CBT or antidepressants. Standard care treatments for agoraphobic avoidance in people with psychosis may include CBT, antidepressants or monitoring from community mental health services. Clinical experts advised that VR technologies for treating agoraphobic avoidance in people with psychosis would not be offered instead of antipsychotic medicine. So, this was not a comparator in this assessment.

3 Committee discussion

NICE's medical technologies advisory committee considered evidence from several sources on virtual reality (VR) technologies for treating agoraphobia, or agoraphobic avoidance with psychosis, in people aged 16 and over, including an early value assessment (EVA) report by the external assessment group (EAG) and an overview of that report. Full details are in the documents for this guidance on the NICE website.

Unmet need and patient considerations

3.1 Mental health services are in high demand and access varies widely across the NHS. Because of this high demand, many people are not getting the treatment and support they need. The clinical and patient experts advised that people with agoraphobia may have even greater difficulty accessing treatment. They explained that some people with agoraphobia may have difficulty leaving their home or using public transport to attend face-to-face appointments. Also, some people may have felt that their previous experiences of healthcare services were negative. This may affect their willingness and ability to seek treatment when needed. One clinical expert recalled the challenges of treating agoraphobia in Improving Access to Psychological Therapies services (now named NHS Talking Therapies for anxiety and depression) because some people did not come to sessions. The committee considered that some VR technologies can be delivered remotely, which would allow some people to get help in their homes. People may be more comfortable and willing to engage with VR therapy rather than attending face-to-face treatment in a clinic. The clinical experts advised that this could be a first step to getting further help and accessing other healthcare services in the future if needed.

3.2 People with complex or severe mental health conditions like psychosis may have even greater difficulties accessing psychological treatments for agoraphobia or agoraphobic avoidance. The clinical and patient experts advised that access to cognitive behavioural therapy (CBT) for psychosis varies and is limited for some people. Most adults with psychosis who are having treatment outside of early intervention in psychosis services do not have psychological treatment. Access to therapy may be limited by NHS workforce pressures, including not having

enough trained staff to deliver CBT in community mental health teams. gameChangeVR can be delivered and supported by a wider range of mental health professionals than standard care, including assistant psychologists and peer support workers, not just qualified therapists. The committee considered that this may increase access to treatment because less training is needed to support delivery.

Potential benefits of the technologies

New treatment option

3.3 VR technologies may offer a new treatment option that allows people with agoraphobia, or psychosis with agoraphobic avoidance, to safely encounter threatening situations and challenge their fear response. The clinical experts advised that this offers a different way of delivering treatment and support, which has the potential for quick effect. The clinical and patient experts considered that VR technologies may help some people reduce their symptoms of agoraphobia. This could have wider benefits on their social engagement, daily living and overall wellbeing. Benefits in reducing anxiety and paranoia could help people leave their homes to go to work, or access education and other healthcare services. This could have a positive knock-on effect on people's lives. For example, it could improve their quality of life. But the clinical and patient experts advised that this benefit may not be fully captured using standard health-related quality-of-life measures.

Acceptability and reduced rates of stopping treatment

3.4 Clinical and patient experts said that there is high interest in and acceptability of VR technologies for treating agoraphobia, or agoraphobic avoidance in people with psychosis. A patient expert advised that people seemed to prefer VR technologies to medicines because medicines often have side effects. VR technologies were particularly acceptable to people with more severe agoraphobia. They may offer another treatment option for people on waiting lists, or who cannot have or do not want treatment with medicines. The clinical experts

advised that VR technologies for treating agoraphobic avoidance in people with psychosis would not be offered instead of antipsychotic medicine.

Clinical effectiveness

Limited evidence

3.5 The committee considered that there was limited evidence for all the assessed VR technologies for treating agoraphobia, or agoraphobic avoidance in people with psychosis. The relevant evidence consisted of 4 studies reported in 9 publications, specifically 1 randomised controlled trial (for gameChangeVR), 2 non-comparative studies (for Amelia Virtual Care and XR Therapeutics) and 1 design process study (for gameChangeVR). The EAG reported that there was some evidence of potential benefits for agoraphobia symptoms for gameChangeVR. But there were uncertainties about the interpretation and reliability of these findings.

Significant effects only for severe agoraphobic avoidance

3.6 The evidence for gameChangeVR suggested that there are benefits only in people with psychosis who have severe agoraphobic avoidance at baseline. The randomised controlled trial (Freeman et al. 2022a) showed that gameChangeVR plus usual care was more effective than usual care alone in reducing agoraphobic avoidance and distress at 6 weeks. But there were no statistically significant differences in the primary outcomes between groups at the 6-month follow up. There was also no statistically significant difference in quality of life or other psychological symptoms except perceived recovery at 6 weeks. Post-hoc analysis showed that treatment benefits were only seen in people with high and severe agoraphobic avoidance at baseline, and these benefits were maintained at 6 months. An additional secondary analysis of the randomised controlled trial (Freeman et al. 2022b) supported the finding that people who have psychosis with severe agoraphobic avoidance showed the greatest benefits of gameChangeVR. Details of these findings can be found in the assessment report and assessment report overview on the NICE website. The committee considered

that gameChangeVR had potential benefit in people who have psychosis with severe agoraphobic avoidance. But more research is needed on the long-term effects of VR technologies because the durability of their effects is unknown.

Unknown effects as a tool in therapy for agoraphobia

3.7 There was no evidence on the clinical effectiveness of VR technologies when used as a tool in therapy for treating agoraphobia in people aged 16 years and over. The relevant evidence for XR Therapeutics (Maskey et al. 2019) was limited to autistic people with fears and phobias but there was no evidence in agoraphobia. The evidence showed equivocal improvement in target behaviour in people with fears and phobias that may be relevant to agoraphobia. The relevant evidence for Amelia Virtual Care (Gelabert and Giner 2018) reported rates of completing treatment and satisfaction but did not report any clinical outcomes. The committee concluded that evidence is needed on the effectiveness of VR technologies in people aged 16 and over with agoraphobia.

Adherence and stopping treatment

3.8 The evidence showed good satisfaction and completion of VR therapy for all technologies. Freeman et al. (2022c) reported that 66% of people were very satisfied with gameChangeVR and 31% were mostly satisfied. For Amelia Virtual Care, Gelabert and Giner (2018) found that 82% of people completed the entire treatment protocol with an average satisfaction rating of 68%. Retention and participation were also achieved for all sessions of XR Therapeutics (Maskey et al. 2019). The committee concluded that VR technologies showed promise in improving treatment adherence and completion, but more evidence is needed. See the assessment report for this guidance on the NICE website for further details on the clinical evidence.

Costs and resource use

3.9 The base-case results from the exploratory decision analytical model showed

that gameChangeVR was not a cost-effective treatment for the overall population of people with mild to severe agoraphobic avoidance and psychosis. This was from an NHS and Personal Social Services (PSS) perspective using the conventional willingness to pay range of £20,000 to £30,000 per quality-adjusted life year (QALY) gained. The EAG advised that there was substantial decision uncertainty in the modelling. The exploratory model suggested that gameChangeVR had around 26% probability (at £20,000 per QALY gained) and 31% probability (at £30,000 per QALY gained) of being a cost-effective treatment. These probabilities were for the overall population (people with mild to severe agoraphobic avoidance and psychosis) from an NHS and PSS perspective. The probability of gameChangeVR being cost effective was higher in people with psychosis who have severe agoraphobic avoidance. gameChangeVR had around 63% probability of being a cost-effective treatment for people with severe agoraphobic avoidance at £20,000 per QALY gained, and 70% at £30,000 per QALY gained. The incremental cost-effectiveness ratios (ICERs) cannot be reported here because the price of gameChangeVR is considered commercial in confidence.

3.10 It was not possible to model the cost effectiveness of Amelia Virtual Care or XR Therapeutics because there was no clinical-effectiveness evidence for their use in agoraphobia. See the assessment report for this guidance on the NICE website for a detailed description of the model.

3.11 The EAG's model included incremental utility, relapse rates, and costs to deliver VR technology plus standard care, compared with standard care alone. Costs included licence fees, costs of the VR headset, healthcare professional costs based on staff grade and time, and other health service use costs. The assumptions used in the model are outlined in section 10.3.4 of the assessment report on the NICE website. The EAG noted that the main drivers of the model were incremental utility, licence fees, relapse rates and effectiveness of subsequent VR therapy. Sensitivity and scenario analyses suggested that there were scenarios in which gameChangeVR may be cost effective, particularly with lower licence costs or in people with psychosis with high and severe agoraphobic avoidance. But there was considerable uncertainty around this, so the EAG advised that more evidence is needed to confirm these findings. The committee concluded that limitations and uncertainties in the clinical evidence created limitations and uncertainties in the economic model. Further research on clinical

and cost effectiveness is needed.

Implementation

Healthcare professional resources

3.12 The committee considered that healthcare professional resources including staff grade and time are likely to impact the cost effectiveness of VR technologies. Mental health professional grade and time needed to deliver or support the delivery of VR technology varies across the technologies. Amelia Virtual Care and XR Therapeutics are designed to be used by qualified therapists to support the delivery of CBT. gameChangeVR features an automated virtual therapist to guide the user within the VR therapy session. So, it can be used with the support of a wider range of mental health professionals, such as assistant psychologists, peer support workers or therapists. One clinical expert advised that they had trained staff from band 3 to band 5 to deliver gameChangeVR, with supervision provided within the clinical teams. They advised that the staff training on how to use and support the delivery of gameChangeVR took half a day and that staff quickly learnt the skills needed for implementation.

Technical considerations

3.13 The clinical experts and patient experts advised on technical issues that should be considered when implementing VR technologies in the NHS. Some VR technologies need Wi-Fi to deliver the intervention or to upload content. Two of the 3 VR technologies are software-only technologies that could be delivered using a range of commercially available VR headsets. The committee discussed that NHS services should consider how to maintain, recycle and responsibly dispose of broken headsets in order to minimise electronic waste and maximise potential cost effectiveness.

Use in the NHS

3.14 One clinical expert advised that although mental health professionals were interested in using VR technologies, they were unsure how this would be rolled out in the NHS. There were uncertainties around how many sessions would be needed in clinical practice and whether people would need extra sessions. The clinical experts advised that clinical effectiveness would likely vary depending on how VR technologies were used. The committee considered that more evidence was needed on the use of VR technologies for treating agoraphobia, or agoraphobic avoidance in people with psychosis in different clinical settings.

3.15 The committee considered that it is important to identify who may benefit most from using VR technologies to treat agoraphobia, or agoraphobic avoidance in people with psychosis. Clinical experts advised that people should be referred to mental health services if they are having difficulty leaving the house. This should be followed by clinical assessment to help identify the presence and severity of agoraphobia or agoraphobic avoidance. Mental health professionals should also assess a person's safety and if VR therapy is suitable for them. The trial for gameChangeVR used a self-report questionnaire (Oxford Agoraphobic Avoidance Scale [O-AS]) to measure symptoms and severity of agoraphobic avoidance. The clinical experts said that this could be used in clinical practice. But standard care in the NHS varies and specific measures for agoraphobia or agoraphobic avoidance may not be widely used in some services. Mental health professionals may instead develop treatment plans based on a person's presenting problem during clinical assessment rather than based on scores on a specific scale.

Managing risks

3.16 The committee carefully considered the safety of VR technologies for treating agoraphobia, or agoraphobic avoidance in people with psychosis. Evidence on adverse events was limited and included only 1 study on gameChangeVR (Freeman et al. 2022a). This showed no serious adverse events related to the use of gameChangeVR for treating agoraphobic avoidance in people with psychosis. One clinical expert advised that their NHS trust used the safety data from the clinical trial to inform their use of gameChangeVR for people with psychosis who have agoraphobic avoidance. There is interest in using gameChangeVR in

agoraphobia without psychosis, but there is currently no evidence to support this use.

3.17 The clinical experts said that adverse effects were generally mild and transient. These included reports of dizziness, motion sickness and mild headaches. One clinical expert noted that VR technologies were used for a relatively short time of about 20 minutes. If someone felt unwell while using VR technologies, they could remove the headset or leave the immersive studio. A patient expert advised that some people may have difficulty transitioning from VR environments to the real world. A clinical expert said that they had protocols for delivering VR therapy, which included grounding exercises to help people reorient after using VR technologies. VR technologies for treating agoraphobia, or agoraphobic avoidance in people with psychosis, may not be suitable for everyone. Mental health professionals should discuss treatment options with the person being offered treatment, and their carers if appropriate. The discussion should consider clinical assessment, individual risk, personal preferences and needs, and the level of support needed.

Equality considerations

3.18 VR technologies may increase access to care for people who otherwise would not access treatment. Patient experts advised that there are limited treatment options for people with agoraphobia, particularly when presenting with co-occurring serious mental health problems like psychosis. They suggested that options for self-referral would further increase access to treatment for people who are less likely to engage with mental health services. The patient experts shared that some people from some ethnic backgrounds may feel uncomfortable accessing mental health services and may prefer using VR technologies.

3.19 Additional support and resources may be needed for people who are unfamiliar with digital technologies or who do not have access to the internet. Additional support and resources may also be needed for people with visual or hearing impairments, cognitive impairment, problems with manual dexterity, a learning disability or who are unable to read or understand English. Some people would benefit from VR technologies in languages other than English. XR Therapeutics has adapted its intervention for autistic people and people with a learning

disability. The company said that its VR studio is also accessible for disabled people, including people using a wheelchair. The committee considered that other treatment options may be more appropriate for some people with agoraphobia.

Evidence gap overview

3.20 For all the technologies, the evidence gaps are related to the population, intervention, comparators and outcomes. The committee considered that there were uncertainties about the clinical and cost effectiveness of VR technologies for treating agoraphobia, or agoraphobic avoidance in people with psychosis, because of the limited evidence. But there was enough evidence of potential benefits of gameChangeVR for it to be used in the NHS to treat severe agoraphobic avoidance in people with psychosis aged 16 and over, while further evidence is generated to address these gaps. Important evidence gaps for all the technologies are:

- **Population:** The relevant clinical evidence for XR Therapeutics included 2 people with phobias that the EAG considered to be relevant to agoraphobia. But there was no evidence in people aged 16 and over with agoraphobia. Secondary analysis on gameChangeVR suggested benefits in people with psychosis who have severe agoraphobic avoidance, but primary evidence is needed to confirm this finding. More evidence on the clinical effectiveness of all the technologies is needed to guide patient selection on who may benefit most from using VR technology for treating agoraphobia, or agoraphobic avoidance in people with psychosis, including more information on patient demographics and experiences of using VR technologies.
- **Intervention:** There is limited evidence for all of the technologies, with only 1 key study for each technology. There was no evidence on Invirto (so it was not included in this assessment) and no clinical effectiveness evidence for Amelia Virtual Care. There was also no comparative evidence on XR Therapeutics. There were no ongoing or unpublished studies that would address the evidence gaps for any of the included technologies.
- **Comparators:** More research is needed on the clinical effectiveness of VR technologies compared with standard care in the NHS.

- **Outcomes:** Published evidence was not available for some outcomes. There was also heterogeneity in how clinical measures were reported. It was unclear whether some statistically significant differences were clinically meaningful. There was no evidence on the durability of the effect or relapse rates for any of the VR technologies. Evidence on adverse events was limited and was reported in only 1 study on gameChangeVR.
- **Decision modelling:** Evidence gaps for the economic modelling mostly related to the limited clinical evidence, quality-of-life outcomes, utilities and relapse rates. The uncertainties would be reduced with further research addressing the outlined evidence gaps including longer-term data on durability of effect and the repeat use of VR technologies.

4 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technologies to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee meetings, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Specialist committee members

Additional specialist committee members took part in the discussions for this topic:

Professor Robert Dudley
Consultant clinical psychologist, Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

Dr Elizabeth Murphy
Research clinical psychologist, Greater Manchester Mental Health NHS Foundation Trust

Dr Immanuel Rhema
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Ms Eva Roberts
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NICE project team

Each medical technologies early value assessment topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

Dionne Bowie and Oyewumi Afolabi
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