NICE National Institute for
Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Virtual reality for treating agoraphobia and agoraphobic avoidance: early value assessment
Final scope

March 2023

1   Introduction

The topic has been identified by NICE for early value assessment (EVA). The objective of EVA is to identify promising technologies in health and social care where there is greatest need and enable earlier conditional access while informing further evidence generation. The evidence developed will demonstrate if the expected benefits of the technologies are realised and inform a final NICE evaluation and decision on the routine use of the technology in the NHS.

NICE's topic selection oversight panel ratified virtual reality (VR) for treating agoraphobia and agoraphobic avoidance as potentially suitable for an EVA by the medical technologies evaluation programme (MTEP). A list of abbreviations is provided in appendix A.

2   Description of the technologies

This section describes the properties of the VR technologies based on information provided to NICE by manufacturers and experts and information available in the public domain. NICE has not carried out an independent evaluation of this description.

2.1   Purpose of the medical technology

Agoraphobia is an anxiety disorder characterised by marked and excessive fear of being in situations where escape may be difficult or help may not be available ([World Health Organization (WHO) 2022](#)). Some people may describe this experience as feeling threatened or worried about going out. It involves fear and avoidance of places or situations that might cause panic and feelings of being trapped, helpless or embarrassed. This anxious avoidance of everyday situations may occur with other mental health disorders including panic disorder, depression, social anxiety and psychosis.

Improving and widening services for mental health is a commitment of the NHS, given the high prevalence of these conditions and the importance of early intervention (NHS Long Term Plan). The most recent Adult Psychiatric Morbidity Survey reports that only 1 in 3 people with a common mental health disorder accesses treatment (McManus et al. 2016). There may be considerable barriers to accessing face-to-face treatments such as individual cognitive behavioural therapy (CBT), including a shortage of trained healthcare professionals and limited clinical resources. Agoraphobia may further impact a person's ability to access mental health services and support. Clinical experts advised that agoraphobia is often untreated or undertreated when it occurs with other mental health conditions because treatment tends to focus on the more severe or prominent disorder. Some people with agoraphobia or agoraphobic avoidance may also discontinue treatment because of difficulty tolerating techniques such as exposure therapy, which gradually increases a person's exposure to situations they fear and avoid.

VR may increase access to care by offering another treatment option for people with agoraphobia or agoraphobic avoidance. VR is a simulated 3-dimensional environment with scenes and objects that people can explore and interact with, most typically using a VR headset. This creates an immersive experience that can trigger emotional responses similar to those in real-world situations. VR may be used as a tool in therapy sessions or as a digital intervention with the support of a mental health worker. It allows 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 and confidence in completing interventions.

VR would support remote delivery of treatment which would allow some people to receive treatment in their own home. This could increase access to care for those who are unable or prefer not to attend face-to-face treatment. Clinical experts suggested that this may help with quicker management of symptoms and could help people work towards accessing face-to-face treatment in the future if needed. VR interventions are scalable and may allow mental health professionals to treat more people in less time. This could save time and resources compared with standard care interventions for agoraphobia and agoraphobic avoidance.

2.2   Product properties

This scope focuses on VR for treating agoraphobia and agoraphobic avoidance. For this EVA, NICE will consider VR that:

- can be used to treat agoraphobia and agoraphobic avoidance either as a digital intervention with the support of a mental health worker or as a tool in face-to-face therapy or teletherapy
- meet the standards within the digital technology assessment criteria (DTAC), including the criteria to have a CE or UKCA mark where required. Products may also be considered if they are actively working towards required CE or UKCA mark and meet all other standards within the DTAC
- are available for use in the NHS.

In total, 4 VR technologies for treating agoraphobia and agoraphobic avoidance are included in the scope. The final list of included technologies may be subject to change.

Amelia Virtual Care (Amelia Virtual Care)

Amelia Virtual Care (AVC) is a VR platform designed to be used by therapists to support the treatment of mental health disorders. It is delivered under the guidance of a therapist in clinical settings or remotely using AVC's smartphone app. It also offers a homework feature with virtual mindfulness and relaxation sessions. AVC helps therapists to facilitate the delivery of evidence-based treatment including gradual exposure, mindfulness-based cognitive therapy and desensitisation. AVC has over 100 virtual environments that can be configured and personalised to a patient's needs using a simple control panel.

gameChange (Oxford VR)

gameChange is designed to treat agoraphobia and agoraphobic avoidance in people with psychosis. It delivers VR cognitive therapy and is compatible with a range of VR equipment that use 6 degrees of freedom tracking. This includes the HTC Vive, Meta Quest and Pico Neo headsets. The treatment includes repeated behavioural experiments using the headset to simulate different real-life situations (including visiting a café, shop, pub, street, doctor's office and bus) to help people test their fear expectations. It is delivered in around 6 weekly 30-minute sessions. Treatment is facilitated by a virtual coach to support the use of techniques and assist people to overcome their difficulties. It should also be supported by a mental health worker either remotely or in the room during sessions to help people maximise their learning from gameChange in the real world. It may be used with outpatients in clinics or at home. The company advises that it may also benefit people in inpatient settings.

Invirto (Invirto)

Invirto offers app-based cognitive behavioural therapy (CBT) content and exposure exercises in VR using a VR headset. The programme includes psychoeducation via the app, interoceptive exposure, situational exposure with VR, anxiety diary, monitoring and progress reports, and relaxation and mindfulness exercises. Its programme for agoraphobia includes over 15 situational exposure scenarios such as driving a car, using an elevator, public transport and shopping. These are prepared and followed up as behavioural experiments in the app. Invirto also has programmes for panic disorder and social phobia.

XR Therapeutics (XR Therapeutics)

XR Therapeutics (XRT) offers VR treatment to help reduce anxieties and to treat phobias including agoraphobia. It is designed to be combined with face-to-face CBT and 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. Digital scenes can also be personalised in line with a person's background and cultural preferences. XRT does not require the use of a VR headset. VR technology is used to project digital scenes onto a curved white screen to recreate situations such as being in a supermarket in a safe setting. The company said this is easy to install, operate and maintain.

3   Target conditions

The target population for this assessment is people aged 16 years and over with agoraphobia or agoraphobic avoidance. This includes agoraphobia and agoraphobic avoidance that occurs with other common mental health problems or severe mental illness. This EVA includes a subpopulation of people with psychosis who have agoraphobia or agoraphobic avoidance but does not exclude any other co-occurring mental health conditions.

Agoraphobia is an anxiety disorder characterised by marked and excessive fear of being in situations where escape may be difficult or help may not be available (WHO 2022). Some people may describe this as feeling threatened or worried about going out. This may include fear of travelling on public transport, visiting shops, being in crowds or queues and leaving home. If faced with a stressful situation, a person with agoraphobia will usually have symptoms of a panic attack. This includes rapid heart rate, hyperventilation, feeling hot, sweaty and sick. People with agoraphobia have ongoing anxiety about being in these situations because of a fear of specific negative outcomes or symptoms. This can result in active avoidance of situations that

cause anxiety ([NHS 2018](#)). Symptoms continue for at least several months and are severe enough to cause significant distress or impairment in personal, social, educational, occupational and daily functioning.

Clinical experts advised that many people with mental health problems including severe mental illness have agoraphobia or agoraphobic avoidance. For some people, agoraphobia develops as a complication of panic disorder. Panic disorder is an anxiety disorder where people have repeated and unexpected attacks of intense anxiety followed by persistent worry of future attacks. Up to 2 in 100 people in the UK have panic disorder, with about a third going on to develop agoraphobia ([NHS Wales 2021](#)).

Some people with psychosis also have anxiety towards everyday situations, which may develop into agoraphobia or heightened feelings of threat. Agoraphobia in people with psychosis may be underdiagnosed in part because agoraphobic avoidance may be confused with negative symptoms of psychosis. Less than 1 in 100 adults in England are diagnosed with a psychotic disorder in any given year ([McManus et al. 2016](#)). Prevalence of agoraphobia in people with schizophrenia spectrum disorders (based on diagnostic criteria excluding self-report) ranges from 0% to 28% ([Achim et al. 2011](#)). This may be as high as 65% when considering self-reported symptoms ([Freeman et al. 2019](#)). Agoraphobia usually starts between the ages of 18 and 35 years.

4   Care pathway

Psychological treatments for agoraphobia include self-help programmes and CBT with exposure therapy. Treatment is usually delivered in primary care services such as NHS Talking Therapies for anxiety and depression (formerly Improving Access to Psychological Therapies or IAPT) services. Agoraphobia and agoraphobic avoidance may also be treated in secondary care mental health services and inpatient settings, but this could be due to co-occurring complex or severe mental health problems being treated in these settings rather than primary care.

The NHS recommends a stepped care approach for treating agoraphobia and any underlying panic disorder ([NHS 2022](#)). The first step involves recognition and accurate diagnosis, including identification of any comorbidities. Treatment for agoraphobia and agoraphobic avoidance may encourage self-help techniques and lifestyle changes such as exercise to help people relieve and manage their symptoms. People may be offered individual guided self-help which is based on CBT and delivered with the support of a therapist. If needed or preferred, more intensive treatments should be offered such as CBT or applied relaxation.

[NICE's clinical guideline on generalised anxiety disorder and panic disorder in adults](#) recommends that people with moderate to severe panic disorder with or without agoraphobia should be offered CBT or an antidepressant. CBT is delivered weekly for a total of 7 to 14 hours of treatment. Antidepressants may be offered if the disorder is long-standing or if the person has not benefited from or has declined psychological intervention. This may include selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs). Escitalopram, sertraline, citalopram, paroxetine and venlafaxine are licensed for the treatment of panic disorder ([British National Formulary 2022](#)).

Agoraphobia and agoraphobic avoidance in people with psychosis

[NICE's clinical guideline on psychosis and schizophrenia in adults](#) recommends that people with psychosis should be offered oral antipsychotic medication along with psychological interventions including family intervention and individual CBT. Clinical and patient experts advised that access to CBT is limited and only a minority of people have the NICE recommended treatment. People with psychosis who have agoraphobia or agoraphobic avoidance may instead be offered antipsychotic medication and simple contact and monitoring with services. Peer support workers may also support people who have agoraphobic avoidance or difficulty leaving home. But more resources and recognition of agoraphobia is needed to support the delivery of effective interventions for this population.

Treatment and care for psychosis is usually managed in early intervention in psychosis services or specialist integrated community-based teams. People with psychosis whose symptoms have responded well to treatment may have their care transferred to primary care, with referral to specialist services for suspected relapse as needed. Clinical experts advised that most people with psychosis are not treated in NHS Talking Therapies for anxiety and depression services.

Potential place of VR in the care pathway

VR for treating agoraphobia and agoraphobic avoidance would be offered after clinical assessment and diagnosis. It would be an alternative or addition to standard care psychological interventions for agoraphobia and agoraphobic avoidance. VR may be delivered by a therapist as part of face-to-face therapy or teletherapy. It may also be used as a standalone intervention with the support of a mental health worker such as an assistant psychologist, peer support worker or therapist. The level of support provided may vary depending on the intervention and the person's needs.

The place in the care pathway depends on the specific disorder and comorbidities. This may differ for agoraphobia and agoraphobic avoidance with or without other mental health disorders such as psychosis. VR for treating agoraphobia and agoraphobic avoidance is not intended to replace other treatments for psychosis such as antipsychotic medications. It may not be suitable for use during an acute episode. Treatment options should be discussed by healthcare professionals, patients and (when appropriate) carers and should consider clinical assessment and judgement, patient preferences and risk, and the level of support needed.

5 Patient issues and preferences

VR technologies provide more treatment options and increased access to care. They can be used in a person's home with the support of a mental health worker in person or remotely. This may be especially beneficial for people with agoraphobia or agoraphobic avoidance who have difficulty leaving their homes to access standard care. VR technologies may also help people to test their fear expectations in a setting where they feel safe. People may feel more comfortable completing behavioural experiments in VR and this could increase their confidence in performing these tasks in real-world settings. People may be more motivated to use and engage with VR if they have sufficient digital skills and prefer remote or digital interventions to face-to-face therapy.

Some people may choose not to use VR technologies and may prefer face-to-face treatment. There may be some concerns about the level of support provided and uncertainty around how treatment may be delivered. Some people may also prefer blended care using both VR and face-to-face treatment. People have the right to make informed decisions about their care, including the use of VR. Patient experts advised that some people may be disappointed if scenes in VR interventions are not photorealistic. Healthcare professionals and patients should discuss what to expect when using these technologies and how they work before use.

6 Comparator

VR technologies would be offered as an alternative or in addition to psychological interventions for people with agoraphobia or agoraphobic avoidance. The comparator is standard care which may include guided self-help, CBT with exposure therapy, applied relaxation, antidepressants and/or simple contact and monitoring with services.

7 Scope of the assessment

Table 1 Scope of the assessment

Population	People aged 16 years and over with agoraphobia or agoraphobic avoidance
Subgroups	If the evidence allows the following subgroups will be considered: • people with psychosis who have agoraphobia or agoraphobic avoidance • agoraphobia or agoraphobic avoidance that occurs with other mental health problems including but not limited to severe mental illness • high or severe agoraphobic avoidance
Interventions (proposed technologies)	Virtual reality (VR) for agoraphobia and agoraphobic avoidance, delivered with the support of a mental health worker or as part of face-to-face therapy or teletherapy. Namely: • Amelia Virtual Care (Amelia Virtual Care) • gameChange (Oxford VR) • Invirto (Invirto) • XR Therapeutics (XR Therapeutics) VR interventions would be offered in addition to standard care for co-occurring mental health conditions.
Comparators	Standard care which may include any combination of: • Guided self-help • Cognitive behavioural therapy (CBT) • Exposure therapy • Applied relaxation • Antidepressants licensed for the treatment of panic disorder • Oral antipsychotic medication • Simple contact and monitoring with services.
Healthcare setting	Outpatient clinics, inpatient settings or home-based care
Outcomes	Intermediate measures for consideration may include: • Patient choice and preferences • Acceptability and satisfaction • Accessibility and digital access • Intervention adherence and completion • Intervention-related adverse events

	• Device-related adverse events
	Clinical outcomes for consideration may include: • Change in agoraphobia symptoms • Change in other psychological symptoms • Global functioning and work and social adjustment • Rates of recovery, time to recovery • Rates of relapse or deterioration, time to relapse or deterioration
	Patient-reported outcomes for consideration may include: • Health-related quality of life • Recovering quality of life • Patient experience • Social contact

	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration should include:
	• Costs of the standalone VR headsets
	• Costs of the technologies including license fees
	• Healthcare professional grade and time
	• Cost of other resource use (e.g. associated with managing anxiety, adverse events or complications):
	   ○ GP or mental health team appointments
	   ○ Healthcare professional training

Time horizon	The time horizon for estimating the clinical and economic value should be sufficiently long to reflect any differences in costs or outcomes.

8 Other issues for consideration

Population

- This EVA is focused on people with agoraphobia or agoraphobic avoidance. Other subgroups of interest may include people with:

  - comorbidities such as panic disorder, other anxiety disorders and mood disorders
  - severe mental illness who have difficulties leaving home because of anxiety
  - recurring or longer-term agoraphobia or agoraphobic avoidance
  - varying levels of digital literacy or access
  - a greater interest in and willingness to try VR
  - protected characteristics.

Characteristics of VR

- VR can be used as a tool in therapy sessions to deliver techniques such as exposure therapy. Some technologies may also offer more comprehensive VR interventions which include a virtual therapist and can be delivered with the support of a mental health worker either in person or remotely. VR may be delivered by different types of mental health workers, including assistant psychologists, peer support workers or therapists. The specific VR intervention and its intended use will determine its place in the care pathway.

Evidence

- This assessment will look across a range of evidence types including RCTs and real-world evidence. Evidence considered will include evidence of clinical effectiveness, comparative outcomes to standard care interventions and adverse effects.

- This assessment will evaluate the clinical and potential cost effectiveness of VR technologies as an alternative to standard care in the NHS. This will include evaluating whether VR technologies have equal or superior outcomes to alternative treatments offered in NHS services for the same disorder.

9 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

People using these technologies at home would be provided with the device through their mental health service. Some VR technologies need Wi-Fi to use the intervention or to upload content. Additional support and resources may be needed for people who are unfamiliar with digital technologies or do not have access to good internet connectivity. People with visual or cognitive impairment, problems with manual dexterity, a learning disability or who are unable to read or understand health-related information (including people who cannot read English) may need additional support to use the technologies. Some people would benefit from VR in languages other than English. People's ethnicity, religious or cultural background may affect their views of mental health problems and interventions. Healthcare professionals should discuss the language and cultural content of VR with patients before use.

VR may not be suitable for use by people with photosensitive epilepsy; significant visual, auditory, or balance impairment; organic mental disorder;

primary diagnosis of alcohol or substance disorder or personality disorder; significant learning disability; or active suicidal plans. Some VR interventions may involve moving around the room or standing. This may be difficult for some people with physical disabilities or additional accessibility needs.

Agoraphobia can significantly affect people's daily living. Under the Equality Act 2010, a person has a disability if they have a physical or mental impairment that has a substantial and long-term effect on their ability to do typical day-to-day activities. Age, disability, race and religion or belief are protected characteristics under the Equality Act (2010).

10 Potential implementation considerations

NICE's adoption and implementation team spoke to clinical experts with experience of VR for treating agoraphobia and agoraphobic avoidance. Key considerations raised in the adoption of these technologies include:

Safety and comfort

Potential safety considerations are based on reports in the clinical evidence. This includes concerns with possible side effects such as dizziness and motion sickness. This may be less of a concern with more recent versions of devices. There were also concerns with the space needed to use VR and issues with bumping into things in the room. Experts advised that a couple of metres is enough to use these technologies. Other considerations are whether the headset used is comfortable to wear over glasses or use if the person's eyes are sensitive to glare. If people have any discomfort or concerns with using VR, they can remove the headset or leave the immersive setting. Mental health workers cannot see the visuals the patient is seeing, but devices may be able to be casted to a laptop if needed.

Patient selection

VR can be used as a standalone intervention if there is appropriate and careful patient selection. Some interventions include virtual coaches that guide the person through the intervention. But interventions have been found to work best with a facilitator who especially helps with patient engagement. VR may not be suitable for everyone. Healthcare professionals and patients should discuss treatment options before use.

Acceptability

Preliminary implementation work and input from people with lived experience shows good patient acceptability towards using VR for agoraphobia and agoraphobic avoidance. People reported good immersive quality of the technologies. They were also motivated to try the interventions because they

wanted a solution to their difficulties. Anecdotal reports suggest some people have quick progress and improvement of symptoms including increase in real-world activities. Clinical experts suggested that people with more severe symptoms may have greater response to treatment. Healthcare professionals may be a little hesitant to using VR initially but demonstrations, training and ongoing support can help.

11 Authors

Dionne Bowie
Topic Lead

Amy Crossley
Technical Adviser

March 2023

Appendix A   Abbreviations

CBT	Cognitive behavioural therapy
DTAC	Digital technology assessment criteria
EVA	Early value assessment
MTEP	Medical technologies evaluation programme
VR	Virtual reality