

Digital health technologies to help manage symptoms of psychosis and prevent relapse in adults and young people: 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.

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1 Recommendations

Adults

1.1 Three digital health technologies can be used as an option in the NHS while more evidence is generated, to help manage symptoms of psychosis or prevent relapse for adults. The technologies are:

- AVATAR Therapy, for managing auditory verbal hallucinations (hearing voices)
- SlowMo, for managing distressing thoughts or paranoia
- CareLoop, for monitoring symptoms of psychosis to prevent relapse.

These technologies should be delivered or supported by a mental health professional trained in the technology. They can only be used once they have appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

1.2 The companies 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 companies 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 technologies can be routinely adopted in the NHS.

Young people

1.4 Research is needed on 3 digital health technologies to help manage symptoms of psychosis or prevent relapse for young people. The technologies are:

- AVATAR Therapy, for managing auditory verbal hallucinations (hearing voices)

- SlowMo, for managing distressing thoughts or paranoia
- CareLoop, for monitoring symptoms of psychosis to prevent relapse.

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

Evidence generation and more research

1.6 Evidence generation and more research are needed on:

- change in the target symptoms managed by the technology, including long-term benefits and who may benefit most from using the technologies
- rates of relapse or worsening of symptoms
- the effect of the technology on functional outcomes, including social functioning and personal recovery (for example, the person's perception of how they are feeling)
- adverse events
- resource use, including healthcare professional grade and time needed to deliver treatment or support
- implementation and training costs associated with the use of the technology
- resource costs associated with relapse, such as hospital stay costs
- adherence, including frequency of use and completion rates.

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.

Potential benefits of use in the NHS with evidence generation for adults

- **Access:** Access to psychological interventions for psychosis, such as cognitive behavioural therapy for psychosis (CBTp) varies and is very limited for some people. Digital health technologies for managing symptoms of psychosis offer another option for adults with psychosis who may otherwise not have psychological interventions. Technologies for monitoring symptoms may detect early signs of relapse, which could allow quicker access to treatment when needed. This could particularly benefit people having treatment in early intervention in psychosis (EIP) services.
- **Clinical benefit:** Clinical evidence suggests that digital health technologies may improve symptoms of psychosis or prevent relapse in adults.
- **Resources:** AVATAR Therapy and SlowMo may use less staff resources and time than CBTp. CareLoop may detect relapse and enable earlier treatment, which could reduce hospital stays and demand on crisis intervention services.

Managing the risk of use in the NHS with evidence generation for adults

- **Clinical assessment:** Digital health technologies should only be offered after assessing symptoms of psychosis and if the technology is suitable for the person. Some people may choose not to use digital health technologies and may prefer another treatment option, particularly people whose psychotic symptoms relate to digital technology. Everyone has the right to make informed decisions about their care.
- **Clinical support:** Digital health technologies must be delivered or supported by a mental health professional trained in the technology. Services should have protocols for delivering digital health technologies, including for initial clinical assessment and matching the right treatment to people's needs and preferences. This includes ongoing monitoring and managing the safety and progress of people using them. This means that worsening symptoms can be identified quickly and appropriate action taken. For CareLoop, additional clinical support should be set up to monitor and respond to alerts.
- **Adverse events:** The clinical experts advised that adverse events may occur with any treatment when managing severe mental illnesses such as psychosis,

regardless of the delivery method. Some serious adverse events have been reported in the published studies for all the technologies. All adverse event data should be collected for these technologies as part of further evidence generation.

- **Costs:** Early results from the economic modelling show that the technologies could be cost effective. But there is considerable uncertainty because of the limited evidence. This guidance will be reviewed within 3 years and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.
- **Equality:** Digital health 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. People's ethnic, religious, and cultural background as well as their personal experiences of healthcare may affect their views of mental health services and digital health technologies. Other treatment options may be more appropriate for some people.

NICE also recommends that 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. See [NICE's early value assessment on virtual reality technologies for treating agoraphobia or agoraphobic avoidance](#) for the full recommendations and guidance.

2 The technologies

- 2.1 Four digital health technologies were identified at scoping which met the selection criteria for this topic. One of the technologies, gameChangeVR was evaluated in [NICE's early value assessment \(EVA\) on virtual reality technologies for treating agoraphobia or agoraphobic avoidance](#) and so was not included in the decision problem for this EVA.
- 2.2 NICE has assessed 3 digital health technologies for managing symptoms of psychosis or preventing relapse. All the technologies are delivered or supported by a mental health professional trained in the technology. The criteria for including technologies in this assessment are in the [final scope for this guidance on the NICE website](#). The technologies are:
- AVATAR Therapy for managing distressing auditory verbal hallucinations (hearing voices). It allows people to create a digital representation (an avatar) of their distressing voice. Over 6 to 12 sessions, the person is encouraged to engage in dialogue with this avatar to take power and control within the conversation. The avatar is voiced by a mental health professional, trained in this technology. This allows a 3-way conversation between the person hearing voices, the avatar and the mental health professional. AVATAR Therapy can be delivered as a standalone intervention by a trained mental health professional. It can also be used as a component of standard care psychological interventions such as cognitive behavioural therapy for psychosis (CBTp).
 - SlowMo for managing distressing thoughts and paranoia in people with psychosis. It is a blended digital therapy that helps people to be aware of symptoms of psychosis, fast thinking and reasoning, and helps slow down thoughts. It is delivered in 8 sessions by a mental health professional, who is trained in the use of this technology, and who can access modules and interactive features using the SlowMo web app. People using SlowMo can also synchronise the content to a mobile app on their smartphone, for them to use it outside of sessions. SlowMo can be delivered as a standalone intervention by a trained mental health professional. It can also be used as a component of standard care psychological interventions such as CBTp.

- CareLoop for remote monitoring of symptoms of psychosis. It aims to prevent relapse by identifying worsening symptoms. People using it regularly record symptoms, thoughts and feelings in an app using questionnaires and journal entries. CareLoop includes an algorithm that aims to recognise worsening mental health and potential relapse. This information is shared with mental health professionals who can then provide early interventions to prevent relapse.

Care pathway

- 2.3 The scope for this early value assessment included a target population of people aged 14 and over with primary psychosis. Treatment and care for psychosis in people aged 18 and over is usually managed in community mental health services including early intervention in psychosis (EIP) 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 an EIP service. After 3 years of treatment in an EIP service, 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 children and young people who present for the first time with sustained psychosis symptoms should have an urgent referral to child and adolescent mental health services or an EIP service. Longer-term treatment and care may then be provided in primary care or secondary care. For adults, children, and young people, inpatient hospital care may be considered by care providers for acute episodes of psychosis.
- 2.4 People with psychosis should be offered oral antipsychotic medicine and psychological interventions including CBTp and family intervention. If a person's symptoms respond well to treatment and remain stable, they should be offered the option to return to primary care for further management. Monitoring for relapse prevention varies across NHS services. It usually involves regular follow-ups with a care coordinator and reviews with a psychiatrist. The clinical experts advised that there is no formal relapse prevention process. People may be at high risk of relapse if there are changes to their medicine or other parts of their treatment or support. If relapse is suspected, treatment should be provided in line

with a person's crisis plan, and referral to secondary care may be considered.

- 2.5 Clinical and patient experts advised that access to CBTp varies and is limited for some people. Most adults with psychosis who are having treatment outside of EIP services do not have access to the psychological interventions recommended by NICE's guideline on psychosis and schizophrenia. Digital health technologies may increase access to care by offering a non-medicine intervention for managing symptoms of psychosis. Some technologies are designed to monitor symptoms and to help detect relapses earlier, so people could have treatment sooner. Digital health technologies would be used as an alternative or addition to standard care, which may include CBTp to manage other symptoms of psychosis not covered by the technology.

The comparator

- 2.6 The comparator for digital health technologies for managing symptoms of psychosis (AVATAR Therapy and SlowMo) is CBTp. Other psychological interventions such as group therapy or supportive counselling may be offered instead for some people on waiting lists to have CBTp. In some areas, people on waiting lists may not be offered any psychological support. Clinical experts advised that digital health technologies would not be offered instead of antipsychotic medicine. So, this was not a comparator in this assessment.
- 2.7 The comparator for digital health technologies for preventing relapse (CareLoop) is healthcare professional follow-ups and reviews.

3 Committee discussion

NICE's medical technologies advisory committee considered evidence on digital health technologies to help manage symptoms of psychosis or prevent relapse from several sources, including an early value assessment (EVA) report by the external assessment group (EAG) and an overview of that report. Full details are in the [project documents for this guidance on the NICE website](#).

Unmet need

- 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 access to cognitive behavioural therapy for psychosis (CBTp) varies and is limited for some people. Most adults with psychosis who are having treatment outside of early intervention in psychosis (EIP) services do not have access to psychological interventions. Access to therapy may be limited by NHS workforce pressures, including not having enough trained staff to deliver CBTp in community mental health teams. The committee recognised that managing symptoms in young people may be different from adults. Digital health technologies offer another option for people with psychosis who may otherwise not have psychological interventions. Mental health professionals would not need specialised training in CBTp to deliver digital health technologies for managing symptoms of psychosis. This may then widen the range of appropriate mental health professionals who are able to deliver it, in comparison with standard care. Digital health technologies may also reduce the number of sessions needed when used with standard care CBTp.
- 3.2 Monitoring for relapse prevention varies across NHS services. People usually have regular follow-ups and psychiatric reviews, but the clinical experts advised that there is no formal relapse prevention process. They also noted that relapse prevention could reduce acute psychosis episodes and associated hospital admissions. Digital health technologies could help people to better monitor their symptoms of psychosis. They could also detect relapse earlier than standard care, so people can be offered treatment and support sooner.

Clinical effectiveness

- 3.3 All the technologies had relevant published evidence showing a potential benefit for adults with psychosis. The relevant evidence consisted of 12 studies reported in 13 publications, specifically 6 randomised controlled trials (RCTs) and 6 sub-studies. There was evidence comparing each technology with treatment as usual, and AVATAR Therapy with supportive counselling. But there was no evidence comparing AVATAR Therapy or SlowMo with CBTp. The EAG reported that there was good-quality evidence from large studies suggesting that AVATAR Therapy and SlowMo were effective at reducing the specific targeted symptoms. AVATAR Therapy was found to reduce auditory verbal hallucinations in adults with psychosis, while SlowMo reduced paranoia and delusions. The evidence suggested that these reductions can last up to 24 weeks after intervention. Both technologies also improved quality of life. The EAG considered that there was some evidence suggesting that CareLoop was effective at detecting and reducing relapses. People who used CareLoop were also less worried about having a relapse than people who had treatment as usual.
- 3.4 There was no evidence on the effects of using the technologies in young people. Clinical experts advised that evidence from adults, many of whom have had psychosis for years, was not generalisable to this younger population. So, the committee considered that the benefits and risks for young people were unknown. It concluded that research was needed in young people before the technologies could be used in the NHS for this age group.

Costs and resource use

- 3.5 There is some economic evidence, based on clinical trial data in adults, that shows cost effectiveness for AVATAR Therapy and CareLoop. Preliminary results of the EAG's early economic modelling for CareLoop suggested that the technology is more effective and less costly than standard care. The EAG said that there was not enough data to adequately populate an economic model for AVATAR Therapy and SlowMo. The cost consequence analysis for AVATAR Therapy and SlowMo showed that the staff time needed to deliver the intervention was the key driver of costs for both technologies. The committee concluded that more evidence was needed on healthcare resource use.

Implementation

- 3.6 Digital health technologies to help manage symptoms of psychosis or prevent relapse must be delivered or supported by mental health professionals trained in the technology. All of the companies provide training to mental health professionals on how to use the technologies. For AVATAR Therapy, this includes self-directed training followed by supervised use of the technology in practice. For SlowMo, training is around 1 to 3 days depending on the person's level of experience. Training for both technologies has been designed for use by mental health professionals without specialist training in CBTp.
- 3.7 The evidence suggested that digital health technologies are acceptable and have good adherence in adults with psychosis who choose to engage with them. But the EAG considered that more evidence was needed on why people turned down or did not complete the interventions. There were also uncertainties around whether people would need extra sessions and the effectiveness of repeating the interventions after relapse. The company for AVATAR Therapy said that the trials were not designed to offer additional sessions beyond the protocol, but this could be considered in clinical practice. The company for SlowMo said that this was being explored in an implementation study. For SlowMo, people will be able to continue using the app after the sessions with a mental health professional have ended. The committee concluded that more evidence was needed on the long-term effects of the technologies, including the effects of repeat use.
- 3.8 For CareLoop, training is done at an individual NHS service level and includes onboarding, categorising early warning signs of relapse, how to support people with psychosis using the app, and what to do when early warning signs and relapse occur. The committee concluded that services should have a system in place that provides adequate and timely professional support in response to alerts and outputs from people using the technology.

Managing risks

- 3.9 The committee carefully considered the safety of using digital health technologies to help manage symptoms of psychosis or prevent relapse while further evidence is generated. Four studies reported adverse events, 1 study on

AVATAR Therapy, 1 on SlowMo and 2 on CareLoop. Unpublished results from the AVATAR2 trial were also shared with the committee as academic-in-confidence evidence. For all the technologies, there were a few serious adverse events that were possibly related to the technology. The clinical experts advised that adverse events may occur with any treatment when managing severe mental illnesses such as psychosis, regardless of the delivery method. Services should have protocols for delivering digital health technologies, including for initial clinical assessment, matching the right treatment to people's needs and preferences, and ongoing monitoring and management of people's safety. CareLoop uses an algorithm to recognise worsening mental health and potential relapse. The committee considered that services would need staff and resources to monitor and respond to these alerts, and to escalate care when needed. It also agreed that adverse event data should be collected for these technologies as part of further evidence generation to help assess and understand which are related to the technologies.

Patient considerations

- 3.10 The committee considered that it was important to identify who may benefit most from using digital health technologies to help manage symptoms of psychosis or prevent relapse. Each technology for managing symptoms of psychosis is indicated for specific symptoms, so mental health professionals should assess if each technology is suitable for each person's symptoms. The clinical and patient experts advised that some people with psychosis may have persecutory delusions or triggers related to digital technology. This was supported by the responses to a small patient survey. Some people who completed the survey said that they have difficulty using digital technology when their symptoms worsen. Only a few people who completed the survey had been offered digital health technologies to help manage their psychosis, with some not finding it helpful. The patient experts highlighted the need to have a range of treatment options available.

Equality considerations

- 3.11 Digital health technologies could increase access to care by providing another option for people with psychosis. Patient experts advised that people with mental health conditions sometimes experience shame. They may face a lot of stigma and discrimination, and this is more prevalent in areas of social deprivation.
- 3.12 A clinical expert suggested that some people may have negative views of mental health services. They suggested various reasons for these views, for example people from ethnic minority backgrounds are more likely to have experienced restrictive interventions while in hospital. They may also be less likely to have psychological therapy, or when they do, are more likely to have fewer sessions. A patient expert advised that some people from ethnic minority backgrounds engage with services later and may prefer using digital health technologies. Some people may feel that services are not adapted to understand and accommodate some aspects of their culture. People's ethnic, religious, and cultural backgrounds may affect their views of digital health technologies. Some people would benefit from digital health technologies in languages other than English. Healthcare professionals should discuss the language and cultural content of the technologies with people before use.
- 3.13 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.
- 3.14 Digital health technologies may not be suitable for everyone. They are delivered using a smartphone, tablet or computer. For monitoring technologies such as CareLoop, people need regular access to a device with internet access to use the technologies. People with limited access to these technologies or who are less comfortable or skilled at using digital technologies may be less likely to benefit. [Hardy et al. \(2022\)](#) found that people's experiences of using SlowMo were not affected by their level of digital literacy. But adherence was associated with people using smartphones more frequently at baseline and being more confident using them.

Evidence gap review

3.15 For all the technologies, there were evidence gaps related to the population, intervention, comparators and outcomes. The committee considered that there were uncertainties about the clinical and cost effectiveness of digital health technologies to help manage symptoms of psychosis or prevent relapse because of the limited evidence. There was enough evidence of potential benefits of all the technologies for adults with psychosis for them to be used in the NHS while further evidence is generated. Important evidence gaps for the technologies are:

- Population: the relevant evidence for all the technologies was in adults. There was no evidence of the effects of using the technologies in young people. So, research is needed on the benefits and risks of using digital health technologies for this age group. The EAG advised that evidence is also needed on using the technologies in people with newly diagnosed psychosis.
- Intervention: there was limited evidence for all the technologies. There was only 1 fully powered RCT for AVATAR Therapy and SlowMo, and 1 feasibility RCT for CareLoop. There are ongoing studies for all 3 technologies that may address their evidence gaps.
- Comparators: for AVATAR Therapy and SlowMo, a key evidence gap was the comparators used in the trials. The most common comparator was treatment as usual but there was no evidence comparing either technology with CBTp. Both technologies can also be used with CBTp. So, evidence is also needed on their effectiveness when used in addition to standard care.
- Outcomes: for all the technologies, evidence is needed on change in target psychosis symptoms managed by the technology, long-term impact, adverse events, relapse rates, real-world implementation including experiences of staff and people using the technologies, adherence, completion, clinical and functional outcomes and resource use. For CareLoop, this should include data on resource costs associated with relapse, such as hospital stay costs.

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.

Additional specialist committee members took part in the discussions and provided expert advice for this topic:

Specialist committee members

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NICE project team

Each 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.

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Accreditation

