

Guidance assessment consultation document for GID-HTE10020 Digital health technologies to help manage symptoms of psychosis and prevent relapse: early value assessment

18 January 2024

Guidance development process

Early value assessment (EVA) guidance rapidly provides recommendations on promising health technologies that have the potential to address national unmet need. NICE has assessed early evidence on these technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated.

The medical technologies advisory committee has considered the evidence and the views of clinical and patient experts. EVA guidance recommendations are conditional while more evidence is generated to address uncertainty in their evidence base. NICE has included advice in this guidance on how to minimise any clinical or system risk of early access to treatment.

Further evidence will be generated over the next 3 years to assess if the benefits of these technologies are realised in practice. NICE guidance will be reviewed to include this evidence and make a recommendation on the routine adoption of this technology across the NHS.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the [evidence](#) (an EVA report).

The advisory committee is interested in receiving comments on the following:

Draft guidance – Digital health technologies to help manage symptoms of psychosis and prevent relapse

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- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for guidance to the NHS?

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. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on disabled people.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on digital health technologies to help manage symptoms of psychosis and prevent relapse. The recommendations in section 1 may change after consultation.

After consultation, NICE will consider the comments received. The final recommendations will be the basis for NICE's early value guidance.

Key dates:

Closing date for comments: 1 February 2024

1 Recommendations

Adults

1.1 Three digital health technologies can be used 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 and meet standards within NHS England's Digital Technology Assessment Criteria (DTAC).

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.

Children and young people

1.4 More research is needed on using the following digital health technologies to help manage symptoms of psychosis or prevent relapse for children and young people:

- 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 symptoms targeted by the technology, including longer-term benefits and who may benefit most from using these technologies
- rates of relapse or worsening of symptoms, including patient safety monitoring, frequency and effectiveness of continued or repeated use
- effect of the technology on functional outcomes, including social functioning and personal recovery (for example, the person's perception of how they are feeling)
- intervention-related 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 in the clinical pathway
- resource consequences associated with relapse such as hospitalisation
- adherence, including frequency of use and completion rate.

Potential benefits of early use 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.
- **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 enable earlier treatment, which could reduce hospitalisations and demand on crisis intervention services.

Managing the risk of early use 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. 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. This includes monitoring and managing the safety of patients and their progress. This means that worsening of symptoms can be identified quickly and appropriate action taken.
- **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. This may be particularly important for people from ethnic minority backgrounds or from areas of high socioeconomic deprivation. Other treatment options may be more appropriate for some people.

2 The technologies

2.1 NICE has assessed 3 digital health technologies for managing symptoms of psychosis or preventing relapse. All 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 a symptom of psychosis, fast thinking and reasoning, and helps slow down thoughts. It is delivered in 8 sessions by a mental health professional, trained in use of this technology, who can access modules and interactive features using the SlowMo web app. Content is also synchronised to a mobile app on the patient's smartphone for use 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 of symptoms. People 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

2.2 The scope for this early value assessment included a target population of people aged 14 years and over with primary psychosis. Treatment and care for psychosis in people aged 18 years and over 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 children and young people who present

for the first time with sustained psychosis 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. For adults, children and young people, inpatient hospital care may be considered by care providers for subsequent acute episodes of psychosis.

2.3 People with psychosis should be offered 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.

2.4 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 early intervention in psychosis services do not have the psychological interventions recommended by NICE's guideline on psychosis and schizophrenia. Digital health technologies may increase access to care by offering another option for managing symptoms of psychosis. Some technologies are designed to monitor symptoms and to help detect relapses earlier, so people could be treated sooner. Digital health technologies would be used as an alternative or addition to standard care.

The comparator

2.5 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.

2.6 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](#).

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 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 children and

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. So, they can be delivered by a wider range of mental health professionals than 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 (RCT) 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 symptoms targeted. 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 children and 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 this group of people were unknown. It concluded that research was needed in children and 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 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 limited 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 the 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 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 were 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. For SlowMo, people with psychosis can continue using the app after therapy. The company said this was being explored in an implementation study. The committee concluded that more evidence was needed on the longer-term effects of the technologies, including the effects of repeat use.
- 3.8 For CareLoop, training is done at an organisational 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 organisations should have a system in place such that adequate and timely professional support is provided to react to alerts and outputs from 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 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 when managing severe mental illnesses such as psychosis. Services should have protocols for delivering digital health technologies, including initial clinical assessment, matching the right treatment to people's needs and preferences, and ongoing monitoring and management of patient 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 intervention-related adverse events should be collected for these technologies as part of further evidence generation.

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 the technologies are suitable for what the person has presented with. 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 stated 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 high socioeconomic deprivation.
- 3.12 People from some ethnic minority backgrounds may have negative views of mental health services for various reasons including, for example, that the services are not culturally adapted. They are also more likely to have restrictive interventions and 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. People's ethnic, religious, and cultural background 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 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. But 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 children and 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 psychosis symptoms targeted by the technology, longer-term impact, intervention-related adverse events, relapse rates, real-world

implementation including patient and staff experiences, adherence, completion, clinical and functional outcomes and resource use. For CareLoop, this should include data on resource consequences associated with relapse, such as hospitalisation.

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 test 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

Dr Isabel Ellory

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Dr Jihad Malasi

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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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