NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

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

Final Scope

September 2023

1 Introduction

The topic has been identified by NICE for consideration 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 where the evidence base is still emerging. It will provide an early indication to the system that they could be used while evidence is generated. The process will enable the technologies to be recommended for use only if further data is collected before NICE makes a final evaluation. NICE's topic selection oversight panel ratified this topic as potentially suitable for an EVA by the HealthTech programme.

The technologies identified for this assessment are those used to help manage symptoms of psychosis and prevent relapse.

The purpose of this EVA evaluation is to map the evidence that is available on the technologies; assess their potential clinical and cost-effectiveness and to identify evidence gaps to help direct data collection and further research. This evaluation will inform Committee recommendations on the conditional use of these technologies in the NHS while further evidence is generated.

2 Description of the technologies

This section describes the digital health technologies used to help manage symptoms of psychosis and prevent relapse. The information is based on information provided to NICE by technology developers 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

The demand for psychological therapy for people with psychosis in the NHS outstrips the available capacity to provide this in a timely manner (Mind report on access to talking therapies). In addition, the use of antipsychotic medication is a contributor to poor physical health in people living with psychosis and so there is a need to provide non-drug intervention alternatives. The prolonged use of antipsychotic medication causes obesity, diabetes, hypertension and hypercholesterolaemia. An area of priority is enabling access to approved interventions quickly after diagnosis, as early intervention has been shown to improve outcomes. Digital health technologies are available that could help clinical teams in the effective management of psychosis by providing specialist support to manage symptoms of psychosis or by providing remote monitoring to help prevent relapses by alerting healthcare professionals to deterioration.

2.2 Product properties

This scope focuses on digital health technologies for symptom management and relapse prevention of psychosis. For this EVA, NICE will consider technologies that:

- are digital health interventions designed to provide specialist support for managing symptoms of psychosis or to prevent relapse in people with psychosis who are receiving care from healthcare professionals.

- 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 digital health technologies were identified which met the selection criteria above. One of the technologies, gameChange, is currently being evaluated as an EVA topic in virtual reality for treating agoraphobia and agoraphobic avoidance and so will not be included in the decision problem of this EVA. The final list of included technologies may be subject to change.

AVATAR Therapy

AVATAR Therapy [Avatar Therapy] is treatment for distressing auditory verbal hallucinations ('voices') for people with psychosis. This therapy aims to reduce the distress that can be experienced when hearing voices by facilitating a three-way conversation between the patient, their distressing voice and the therapist. This technology uses digital avatars which are a digital representation, both visual and auditory, of the distressing voice created by the patient supported by the therapist. Whilst supported by the therapist in a different room or remotely, using video conferencing, the patient engages in dialogue with the avatar (voiced by the therapist) to take power and control within the conversation. The treatment is provided over 6 to 12 sessions and may be provided as a stand-alone treatment or as one component of CBT for psychosis therapy, where persecutory voices are part of the overall condition.

CareLoop

CareLoop [CareLoop Health] is a remote monitoring system for people with psychosis that facilitates early identification and intervention when symptoms escalate. It includes a patient-facing app where users record symptoms daily,

using proprietary questionnaires, and can add journal entries of their thoughts and feelings. The daily symptom data based in the questionnaire responses are transferred to the cloud-based CareLoop system for storage and processing. The CareLoop system includes an algorithm that is designed to recognise changes in a person's mental health, identifying deterioration and predicting acute events before they occur. The daily symptom data is also used to generate information on the app for patients which shows how their symptoms have changed over time. It is also shared with the patient's clinical team. Output from the algorithm is expected to provide early warning signs for clinical teams to flag a patient's deterioration and to generate insights at an individual level to optimise treatment and care- for example in medication management. A web-based dashboard is used for symptom monitoring by the clinical team.

SlowMo

SlowMo [King's College London] is a blended digital therapy which aims to reduce distressing worries or paranoia by supporting people with psychosis to notice and slow down their unhelpful fast thinking habits. The blended approach combines face-to-face therapy sessions with interactive digital content on a webapp and mobile app. The SlowMo webapp has modules for each session with interactive stories and games. Users can also record personalised messages. From each module, personalised session content is synchronised with a SlowMo mobile app that supports people with paranoia to use strategies to combat fast thinking in daily life.

SlowMo can be used as an alternative to conventional CBT for psychosis where paranoia is the main presenting problem. However, it has the flexibility to be integrated into a longer course of conventional CBT for psychosis, which is also targeting other psychosis symptoms such as auditory hallucinations.

3 Target conditions

3.1 Psychosis

Psychosis is a state of mind where a person's abilities to understand and test reality are impaired. Conditions with psychosis as a main feature are called psychotic disorders and these are characterised by "positive" and "negative" symptoms, not caused by a substance or medication, and not secondary to another medical condition or mood disorder. Psychosis caused by medications or medical conditions is called "secondary psychosis". Positive symptoms of psychosis include delusions or hallucinations where an individual believes implausible ideas usually with strong paranoia or hearing voices. Negative symptoms include impaired ability to perform everyday tasks, language impairment, abnormal motor behaviour and negative symptoms such as avolition (decreased ability to initiate tasks), alogia (inability to speak) and anhedonia (decreased ability to experience pleasure).

In England, the prevalence and incidence of psychosis are 0.7% and 24.2 per 100,000 population per year respectively (Psychosis Data Report). The prevalence and incidence of psychosis in England varies by geographical location and are associated with inequalities. Geographical variation in prevalence and incidence of psychosis is likely to be linked to the nature of the development of psychosis and its association with poverty and access to life chance opportunities.

There is evidence linking the onset of psychotic disorders with the social environment, such as: inner city living, deprivation, population density, social fragmentation and ethnic density; and individual life experiences such as childhood adversity and abuse, early experience of alcohol or substance use and abuse, discrimination and adult social disadvantage (Psychosis Data Report).

3.2 Care pathway

NICE clinical guideline for psychosis and schizophrenia treatment and management provides recommendations on the management of the condition

at different stages. Management of psychosis usually requires early intervention in psychosis (EIP) specialist teams for the first episode, or a specialist community mental health team (CMHT) for longer-term psychosis. EIP services should be accessible to all people with a first episode or first presentation of psychosis, irrespective of the person's age or the duration of untreated psychosis. In both EIP and CMHT, people living with psychosis should be offered a full range of pharmacological, psychological, social, occupational, and educational interventions.

Current practice for treatment of psychosis is with an antipsychotic medication alongside psychological and social support. NICE clinical guideline for psychosis and schizophrenia treatment and management states that standard psychological support should include provision of cognitive based therapy (CBT) to all people with psychosis delivered on a one-to-one basis over at least 16 planned sessions. It should follow a treatment manual and be led by a healthcare professional with an appropriate level of competence in delivering the intervention to people with psychosis and schizophrenia who is regularly supervised by a competent supervisor.

A person with psychosis can be discharged back to their GP if they have responded effectively to treatment and remain stable. Acute episodes of psychosis may require psychiatric hospitalisation or crisis management services.

Potential place of technologies in the care pathway

The proposed technologies for symptom management would usually be used as part of the psychological support provided by the EIP team or the CMHT. If these technologies are used as a component of the CBT for psychosis programme, they could reduce the number of CBT for psychosis sessions required. The trained therapist who would deliver the digital technologies could be less specialised than the therapists providing CBT for psychosis. Expert advice is that there is significant unmet demand for CBT for psychosis within the NHS. These technologies could also be used for people waiting to receive CBT for psychosis.

CareLoop would be used for remote monitoring of symptoms by both the EIP teams and those working in the CMHT treating people with long-term psychosis.

3.3 Patient issues and preferences

Digital health technologies to help manage symptoms of psychosis such as Avatar and SlowMo could be an option for some patients who do not have access or have limited access to specialist psychological therapy because of a lack of resources. These interventions have been designed to be used by a range of trained healthcare professionals and to be used as a component of broader psychological therapy.

CareLoop could be an option for patients who are willing to engage in remote monitoring. It may help them better understand their condition and provide their clinical teams with useful insights and the ability to intervene if there are signs of relapse or deterioration.

People may have some of the following concerns when considering whether they want to use a digital technology as part of their psychosis symptom management or relapse prevention:

- ability to use the technology
- unpredictable nature of their co-morbidities
- possible costs incurred from using digital technologies, for example mobile data charges
- level of human support provided during digitally supported management of psychosis symptoms or relapse prevention
- data security and quality control

People should be supported by healthcare professionals to make informed decisions about their care, including the use of digital technologies. Shared

decision making should be supported so that people are fully involved throughout their care (see the NICE guideline for shared decision making)

4 Comparator

The comparator for this assessment is standard care relevant to the prevailing symptoms and relapse prevention. Current standard care for psychosis is based on NICE clinical guideline for psychosis and schizophrenia treatment and management (see summary in section 3.2 above). Access to CBT for psychosis varies depending on location, and some people are on waiting lists to access services. Other forms of psychological therapy such as group therapy, supportive counselling could be available to people on the waiting list. In some areas people on waiting lists may not be offered any form of psychological support.

Monitoring of patients for relapse prevention varies across NHS services. It usually involves regular follow-ups with a care co-ordinator alongside periodic reviews by a psychiatrist. Clinical experts advised there is no formal relapse prevention process. People are often considered at high risk of relapse when there are changes to their medication or other aspects of their treatment and support.

Table 1 Scope of the assessment

Population	• People aged 14 and over living with primary psychosis Where data permits, subgroups will be considered based on: • Severity of psychosis • High risk of relapse • Age
Interventions (proposed technologies)	Digital health technologies which help manage the symptoms of psychosis including: • AVATAR Therapy for auditory hallucinations • SlowMo for paranoia

	or which provide remote monitoring of symptoms to help prevent a relapse including: • CareLoop
Comparator	<u>For AVATAR and SlowMo</u> Standard psychological care for managing symptoms of psychosis. This may include: • CBT for psychosis. The intervention could be used to replace symptom-specific components of a CBT for psychosis programme. • Psychological support whilst waiting for CBT for psychosis • No access to psychological support <u>For CareLoop</u> Standard care for monitoring people at risk of a relapse of psychosis.
Healthcare setting	• Outpatient clinic • Inpatient care • Home based care
Outcomes.	Outcomes for consideration include: <u>Symptom management</u> <u>High priority outcomes</u> • Change in targeted psychotic symptoms such as paranoia, agoraphobia, hearing distressing voice etc • Intervention adherence and completion • Health related quality of life • Patient experiences and well being • Intervention-related adverse events Other outcomes • Healthcare professional acceptance • Changes in other psychological symptoms

	• Changes in medications or appointments • Impact on carers and family <u>Relapse prevention</u> <u>High priority outcomes</u> • Rates of relapse or deterioration • Time to relapse or deterioration • Severity of relapse • Intervention adherence and completion • Patient experiences and well being • Health related quality of life • Intervention-related adverse events Other outcomes • Healthcare professional acceptance • Changes in other psychological symptoms • Impact on carers and family
Costs	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Cost of the technology including licence fees and training • Cost of healthcare professional time (various grades) to deliver therapy (both intervention and comparator) • Health service use • Cost of relapse treatment (including costs of any adverse events and hospitalisation, GP visits and mental health appointments)
Time horizon	The time horizon for estimating the clinical and economic value should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

5 Other issues for consideration

Eligible digital health technology excluded from the scope

- gameChange is a virtual reality device designed for the treatments of agoraphobia associated with paranoia. This technology is within scope but has already been assessed under virtual reality for treating agoraphobia and agoraphobic avoidance.

Characteristics of digital technologies

- The digital technologies are likely to have periodic updates and upgraded versions as new functionality becomes available. These updates may have an impact on the effectiveness of the technology. This means that evidence based on the earlier versions of the technology may not accurately reflect the effectiveness of the current versions. Evidence in older technology versions should be examined to see if it is relevant to the decision question.

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, adverse effects and clinician and patient perspectives.

6 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.

Prevalence of psychosis differs between socio-economic groups. The incidence and prevalence of psychosis are higher in deprived communities. A significantly higher percentage of black men are diagnosed with psychotic disorder than white men. CORE20PLUS5, a national NHS England approach to inform action to reduce healthcare inequalities at both national and system level, lists severe mental illness (SMI) as one of the five priority areas.

Digital health technologies to help manage symptoms of psychosis and prevent relapse are accessed via a mobile phone, tablet, or computer. People may need regular access to a device with internet access to use the technologies. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies or people who do not have access to smart devices or the internet. People with visual, hearing, 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) or neurodivergent people may need additional support to use digital health interventions. Some people would benefit from digital health technologies in languages other than English. People's ethnic, religious, and cultural background may affect their views of digital health interventions. Healthcare professionals should discuss the language and cultural content of digital health interventions with patients before use.

Age, disability, race, and religion or belief are protected characteristics under the Equality Act 2010.

7 Potential implementation issues

Training

Training is needed for healthcare professionals to work through and fully understand the intervention modules and content. Knowledge of the technologies will vary across healthcare professionals, within services, and across regions. This will impact the delivery and effectiveness of the interventions.

Cost

Costs may differ between technologies. Smaller service areas may have higher costs per user because fewer licences are needed. Digital health interventions may be chosen based on the balance between costs and expected outcomes.

Risk of harm

Digital health technologies must be able to identify potential risks for patients. Initial assessment is important to ensure people get access to the right care at the right level. Some digital health interventions have inbuilt processes to flag the need for more intervention. This is important to consider when choosing digital health technologies.

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Appendix C Abbreviations

CBT: Cognitive Behavioural Therapy

CE: Conformité Européene (European Conformity)

CMHT: Community Mental Health Team

DTAC: digital technology assessment criteria

EIP: Early Intervention in Psychosis

EVA: Early Value Assessment

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

SMI: Severe Mental Illness

UKCA: United Kingdom Conformity Assessed