

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Early value assessment guidance document

### Digitally enabled therapies for adults with depression: early value assessment

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 technology advisory committee has considered the evidence and the views of clinical and patient experts. This topic is one of the pilots using the new EVA approach. EVA guidance recommendations are conditional while more evidence is generated to address uncertainty in their evidence base. Although there are uncertainties, they do not suggest a risk to patient safety. 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 within 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 any new research and make a recommendation on the routine adoption of these technologies 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 evidence generation recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read with the [evidence for this EVA](#) (an EVA report, cost and resource use report).

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

- Has all of the relevant evidence been considered?

Draft guidance – Digitally enabled therapies for adults with depression: early value assessment

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- Are the summaries of clinical effectiveness, costs and resource use reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for EVA 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 people with a particular disability or disabilities.

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 digitally enabled therapies for adults with depression. The conditional recommendations in section 1 and the accompanying points on evidence generation in section 4 may change after consultation.**

After consultation, NICE will consider the comments received. The final recommendations will be the basis for NICE's EVA guidance on using the technologies with evidence generation.

## **Key dates:**

Closing date for comments: **15 March 2023**

# 1 Recommendations

1.1 Three digitally enabled therapies can be used as treatment options for adults with depression while further evidence is generated. The therapies should be used with support from a trained practitioner in NHS Talking Therapies Services. These technologies can be used once they have Digital Technology Assessment Criteria (DTAC) approval and an NHS Talking Therapies digitally enabled therapies assessment from NHS England. The technologies are:

- Beating the Blues (365 Health Solutions)
- Deprexis (Ethypharm Digital Therapy)
- Space from Depression (SilverCloud).

1.2 Further evidence should be generated on:

- rates of recovery
- rates of reliable recovery
- rates of reliable improvement
- rates and reasons for stopping treatment
- rates of relapse
- adverse effects and stepping up of care
- patient experience
- health-related quality of life
- resource use during and after therapy, including level of guidance provided (defined by healthcare professional grade and time)
- baseline data including demographics of the people using the technology and their risk classification.

Find out more in the [evidence generation section](#) in this guidance.

1.3 The following technologies should only be used in research for treating depression in adults:

- Iona Mind (Iona Mind)
- Minddistrict (Minddistrict)
- Wysa (Wysa).

## Potential benefits of early access

- **Access:** Digitally enabled therapies offer another treatment option for adults with depression. People using them will be supported by psychological wellbeing practitioners or therapists. The technologies will particularly benefit anyone who needs more flexible access to treatment or who prefers digitally-enabled therapy to face-to-face therapy.
- **Clinical benefit:** The clinical evidence suggests that digitally enabled therapies may reduce symptoms of depression. They may help people to better manage their depression and treatment choices, which could increase autonomy and empowerment.
- **Resources:** Digitally enabled therapies may need less practitioner or therapist time for delivery than standard care psychological interventions in NHS Talking Therapies services. This could reduce demand on some mental health services by freeing up resources that could be allocated elsewhere in the service. There is preliminary evidence that digitally enabled therapies may be cost effective compared with standard care.

## Managing the risk of early access

- **Clinical assessment:** In NHS Talking Therapies services, digitally enabled therapies would be offered after assessment (which includes a risk assessment).
- **Clinical support:** Digitally enabled therapies in NHS Talking Therapies services must be delivered with practitioner or therapist support including monitoring and managing patient safety and progress. This means that if the treatment is not working and symptoms worsen, it will be identified quickly.
- **Individual choice:** Digitally enabled therapies can be offered as a treatment option for adults with depression. Some people may choose not to use digitally enabled therapies and may prefer another treatment option such as face-to-face therapy. Everyone has the right to make informed decisions about their care. People should be offered another treatment option if they do not want to or cannot use digitally enabled therapies.

- **Equality:** Digitally enabled therapies may not be accessible to everyone. Adults with limited access to equipment, internet connection or low digital literacy skills are unlikely to benefit and may prefer another treatment option.
- **Costs:** Results from the early economic analysis suggest that the technologies could be cost effective based on current prices and evidence. This guidance will be reviewed within 4 years and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.
- **Care pathway:** This guidance focuses on using digitally enabled therapies for treating depression in adults who have been referred to NHS Talking Therapies. Digital therapies may be used elsewhere in the NHS care pathway, but this is outside the scope of this assessment.

## 2 The technology

### Technologies

2.1 Digitally enabled therapies are a treatment option for adults with depression. They are technologies, used online or through apps, that deliver a substantial portion of therapy through their content. They are delivered with support from a trained practitioner in NHS Talking Therapies Services who facilitates the self-help intervention, encourages completion, and reviews progress and outcomes. Six digitally enabled therapies which include materials based on structured cognitive behavioural therapy (CBT) were included in this evaluation:

- Beating the Blues (365 Health Solutions) is an online CBT programme comprising of 8 modules.
- Deprexis (Ethypharm Digital Therapy) is an online CBT programme comprising of 10 modules.
- Iona Mind (Iona Mind) is an app-based CBT programme which uses machine learning to anticipate and adapt the programme to a person's needs.

- Minddistrict (Minddistrict) is an online CBT programme comprising of 8 modules.
- Space from Depression (SilverCloud) is an online CBT programme comprising of 5 modules.
- Wysa (Wysa) is an artificial intelligence-based app with a CBT-based self-help programme.

## Care pathway

2.2 NHS Talking Therapies (formerly Improving Access to Psychological Therapies or IAPT) provides NICE recommended psychological therapies for depression using a stepped care approach. For adults with depression, treatment options should be discussed and the choice of treatment matched to their clinical needs and preferences. [NICE's clinical guideline on depression in adults: treatment and management](#) recommends several treatment options which can be used as first-line treatments for less and more severe depression. Guided self-help (including digitally enabled therapies) is an option for treating both less severe and more severe episodes of depression. It should be considered first for most people with less severe depression as it is the least intrusive and least resource intensive treatment option. Although guided self-help is also recommended for adults with more severe depression, other treatment choices with more therapist contact should be considered first. Monitoring for treatment concordance, side effects, and suicidal ideation should be done by a healthcare professional. Routine outcome monitoring and follow up should be considered.

## Comparator

2.3 The comparators are the treatments offered for a new episode of less severe depression or more severe depression as described in [sections 1.5 and 1.6 in NICE's clinical guideline on depression in adults:](#)

[treatment and management](#). These treatments are delivered by NHS Talking Therapies services.

### 3 Committee discussion

#### Unmet need

- 3.1 Mental health services are in high demand and the availability of treatment options that need higher levels of therapist involvement can involve long waiting times. Digitally enabled therapies can increase the treatment options available and reduce the time needed by mental health professionals to deliver treatment.
- 3.2 Patient experts noted that early access to treatment could alleviate mild symptoms of depression and prevent escalation. Digitally enabled therapies can also provide flexible access to therapy and remove barriers to treatment such as travel-related issues, taking time off work and give access to people who are not able to leave the house. The use of these technologies could free up clinical resources and time that could be used to support those who need more personalised face-to-face care. The committee concluded that there is an unmet clinical need and access to effective mental health treatments needs to be improved.

#### Implementation

- 3.3 Digitally enabled therapies will be used in NHS Talking Therapies with existing service protocols. All the technologies included in this assessment are being used in the NHS or have planned pilots for their use. The committee acknowledged that a recommendation for use with further evidence generation would support adoption of these technologies and provide a mechanism for collecting real world clinical efficacy data.
- 3.4 Practitioners and therapists need training and support to effectively deliver digitally enabled therapies. The clinical experts advised that

practitioners and therapists also need to be comfortable using digital technologies and need to have access to the necessary systems. Technologies should be integrated into a service's system rather than being a standalone technology. This would assist with data collection and reporting.

## **Patient considerations**

- 3.5 Treatment options should be discussed by healthcare professionals, the person considering treatment and (when appropriate) carers. Discussions should consider clinical assessment, the person's preferences and needs, and the level of support needed. Clinical and patient experts agreed that personal choice should be a main consideration when offering a digitally enabled therapy. People who want to use a digitally enabled therapy are more likely to engage with the content. This may allow people to feel they are taking responsibility for their treatment which may create a sense of achievement. Clinical experts also said that other factors including risk and depression severity should also be considered. This is because anyone at high risk (such as those with suicidal ideation) or those with reduced ability to engage with a digitally enabled therapy (such as people with reduced concentration) would be better suited to therapies with more therapist involvement. The committee concluded that personal choice and clinical judgement is of most importance when deciding on the suitability of the use of digitally enabled therapies.
- 3.6 Patient experts said that people need to be reassured that their care can be escalated or an alternative treatment offered without being put to the end of a waiting list, if a digitally enabled therapy does not improve symptoms. Clinical experts confirmed that symptom scores would be routinely monitored and if symptom severity is not improving, further therapist support or an alternative intervention should be considered.

- 3.7 Patient experts said that appropriate privacy and security measures should be in place to reassure people using the technology. People would also need to be told about any additional support measures in place, especially when the technology is used outside of working hours.

## Clinical-effectiveness overview

- 3.8 The evidence shows that Space from Depression, Deprexis and Beating the Blues have a potential benefit for adults with depression. There was limited or no evidence within the scope of this assessment for Minddistrict, Iona Mind and Wysa. The evidence base consists of 46 papers, reporting on 32 studies. There were 14 randomised controlled trials, 1 meta-analysis, 1 non-randomised pilot study and 13 non-comparative studies. Of these, 12 studies were done in the UK using Beating the Blues or Space from Depression. The external assessment group (EAG) noted that the populations were broadly relevant but in 18 of the 32 studies the population was not restricted to depression and included adults with anxiety and other affective disorders. Most comparative studies also had waitlist or usual care controls. Some of the evidence was done outside of the UK which may limit the generalisability of the evidence. The committee concluded that the evidence base is sufficient to recommend use of Space from Depression, Deprexis and Beating the Blues, while further evidence is generated. But, there was not enough evidence for Minddistrict, Iona Mind and Wysa to make a recommendation for use. See the [assessment report](#) for further details.

## Equality considerations

- 3.9 Digitally enabled therapy may not be suitable for everyone. Adults with limited access to equipment, internet connection or low digital literacy skills may be less likely to benefit from digitally enabled therapies. The committee concluded that face-to-face treatment options may be more appropriate for some adults.

3.10 Additional support and resources may also be needed for people with visual or hearing impairments, problems with manual dexterity or who are unable to read or understand English. The companies said that they have taken steps to improve accessibility of their technologies, including having a low reading age for the content, audio recording options, and consideration of diversity and inclusivity in their content design. One technology, Deprexis, is also available in 9 languages.

## Costs and resource use

3.11 The economic modelling on Beating the Blues, Deprexis and Space from Depression showed that they could be a cost-effective option for people with less severe depression. For more severe depression, only Deprexis could be included in the model. The results showed that Deprexis and generic computerised CBT with support could be cost-effective options for people with more severe depression. But, the technologies are less likely to be the most cost-effective treatment option when compared with other standard care treatment options. The EAG noted that the main cost drivers are the effectiveness of the treatment and the follow-up treatment for people whose symptoms have not improved with a digitally enabled therapy. There was not enough clinical evidence on Iona Mind, Minddistrict or Wysa to evaluate the technologies quantitatively in the economic model. The committee concluded that there was enough evidence to recommend the use of Beating the Blues, Deprexis and Space from Depression while further evidence is generated. Evidence on measures of clinical effectiveness as well as resource use is needed to reduce uncertainty in the economics modelling.

## Evidence gap overview

3.12 The most important evidence gaps for the technologies relate to the comparator and the outcomes reported. The main evidence gaps are:

- A minority of the studies were done in an NHS Talking Therapies service setting and some evidence was collected outside of the UK.

Most comparative studies used waitlist or usual care as a control rather than the standard care options used in NHS Talking Therapies services. The committee concluded that the quality and quantity of the evidence for 3 of the technologies was enough to demonstrate that the technologies had promise of a clinical benefit. Evidence generation within an NHS Talking Therapies setting, with appropriate comparators, would be needed.

- Over half of studies included people with depression and other affective disorders. The clinical experts advised that the co-morbidity of depression and anxiety is high and so this would not be a major limitation of the evidence base. The committee acknowledged that data collection in an NHS Talking Therapies service should include baseline measures of depression and anxiety symptoms.
- Published evidence was not available for some outcomes listed within the scope of this evaluation and there was some heterogeneity in how outcomes were reported. Further evidence generation should collect a wide range of outcomes to assess clinical effectiveness of the treatments, the level of rates and reasons for stopping treatment, adverse events, further treatment, and patient experience data.
- The evidence did not report any adverse events related to the use of the technologies. The committee considered that few studies reported adverse events and more evidence is needed. The clinical experts said that they did not expect to see more adverse events for digitally enabled therapies compared with standard care once these were used with local service protocols. This includes offering digitally enabled therapies as one of a range of treatment options for people who do not need regular in-depth safety reviews or face-to-face care.
- The EAG noted that the economic modelling is limited by a lack of clinical evidence comparing the technologies with treatment as usual within an NHS Talking Therapies service. Longer follow up of up to 2 years, depression severity subgroup analyses of treatment effects and reporting of resource use after treatment with digitally enabled therapies would also address uncertainty in the model. The economic

model was also limited by not including costs relating to set up, training and administration.

## 4 Further evidence

### Evidence generation

- 4.1 Further evidence will be generated while the 3 recommended technologies are used in the NHS to address the immediate unmet need, with appropriate safety processes in place. The clinical experts stressed the importance of managing clinical risk. The companies advised that they have risk management systems in place but that risk should be managed according to local care protocols. All the technologies are supported by trained practitioners in NHS Talking Therapies Services that check in with users on a weekly or fortnightly basis by telephone calls or messaging. These digitally enabled therapies are a way to increase access to treatment with support from a healthcare professional. The committee concluded that Space from Depression, Deprexis and Beating the Blues can be used as options for adults with depression if used with appropriate risk management processes in place while evidence is generated. The main outcomes prioritised by the committee for evidence generation are outlined in [section 1.2](#).

### Research only recommendations

- 4.2 There was not enough evidence to recommend Minddistrict, Iona Mind and Wysa for early access in the NHS. They should be used only in research. Research should be within the scope of this assessment and include well-designed and adequately powered studies with appropriate comparators in NHS Talking Therapies services. Studies should address the evidence gaps outlined in this guidance and demonstrate the benefit of using these technologies for adults with depression.

## 5 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 technology 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](#), which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

### NICE project team

Each medical technologies guidance 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.

#### **Charlotte Pelekanou**

Health technology assessment analyst

#### **Kimberley Carter**

Health technology assessment adviser

#### **Elizabeth Islam and Harriet Wilson**

Project managers

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