

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

Health technology evaluation

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[www.nice.org.uk/guidance/hte8](https://www.nice.org.uk/guidance/hte8)

## 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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This guidance replaces MIB215.

# 1 Recommendations

1.1 Two digitally enabled therapies can be used as treatment options for adults with depression while further evidence is generated on their clinical and cost effectiveness. The therapies should be used with support from a trained practitioner or therapist in NHS Talking Therapies for anxiety and depression services. These technologies can be used once they have Digital Technology Assessment Criteria (DTAC) approval and an [NHS Talking Therapies for anxiety and depression digitally enabled therapies assessment from NHS England](#). The technologies are:

- 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 of reliable deterioration
- 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 treatment, including the average number of treatment sessions and level of guidance provided (defined by healthcare

professional grade and time)

- baseline data, including the demographics and symptom severity of the people using the technology, and their risk classification.

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

1.3 The following technologies should only be used as part of a research study that has been approved by an ethics committee, once they have appropriate regulatory approval:

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

Find out more in the [research only recommendations](#) section of this guidance.

### Potential benefits of early value assessment

- **Access:** Digitally enabled therapies offer another treatment option for adults with depression. People using them will be supported by an appropriately trained NHS Talking Therapies for anxiety and depression (formerly Improving Access to Psychological Therapies, or IAPT) practitioner or therapist, including psychological wellbeing practitioners. 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 better manage their symptoms and their treatment choices, which could increase their 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 for anxiety and depression services. This could free up resources that could be allocated elsewhere in the services to increase access or reduce waiting times. There is preliminary evidence that suggests digitally enabled therapies may be cost effective compared with standard care.

### Managing the risk of early value assessment

- **Clinical assessment:** In NHS Talking Therapies for anxiety and depression services, digitally enabled therapies would be offered after assessment (which includes a risk assessment).
- **Clinical support:** Digitally enabled therapies in NHS Talking Therapies for anxiety and depression services must be delivered with practitioner or therapist support, including monitoring and managing the safety of patients and their progress. This means that if the treatment is not working and symptoms worsen, it can 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.

- **Equality:** Digitally enabled therapies may not be accessible to everyone. Adults with limited access to equipment or to an internet connection, or who are less comfortable or skilled at using digital technologies, are less likely 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 using NHS Talking Therapies for anxiety and depression. Digital therapies may be used elsewhere in the NHS care pathway, but this is outside the scope of this assessment.

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.

## 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 or therapist in NHS Talking Therapies for anxiety and depression services (formerly Improving Access to Psychological Therapies, or IAPT). The practitioner or therapist facilitates the intervention, encourages completion, recommends complementary material, and reviews progress and outcomes. The full criteria for technologies to be included in this early value assessment can be found in the [scope on the NICE website](#). Six digitally enabled therapies that 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 8 modules. This technology is no longer available to the NHS.
- Deprexis (Ethypharm Digital Therapy) is an online CBT programme comprising 10 modules.
- Iona Mind (Iona Mind) is an app-based CBT programme that uses machine learning to anticipate and adapt the programme to a person's needs.
- Minddistrict (Minddistrict) is an online CBT programme comprising 8 modules.
- Space from Depression (SilverCloud) is an online CBT programme comprising 5 modules.
- Wysa (Wysa) is an artificial intelligence-based app with a CBT-based self-help programme.



## Care pathway

- 2.2 NHS Talking Therapies for anxiety and depression services provide 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 guideline on depression in adults: treatment and management](#) recommends several treatment options that can be used as first-line treatments for less severe and more severe depression. Guided self-help (including digitally enabled therapies) is an option for treating less severe and more severe episodes of depression. It should be considered first for most people with less severe depression because 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 guideline on depression in adults: treatment and management](#). These treatments are delivered by NHS Talking Therapies for anxiety and depression services.

## 3 Committee discussion

NICE's medical technologies advisory committee considered evidence on digitally enabled therapies for treating depression in adults from several sources, including an early value assessment 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. 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 digitally enabled therapies can provide flexible access to therapy and remove barriers to treatment such as travel-related issues and having to take time off work, and may give access to people who are not able to leave the house. They also said that early access to treatment could alleviate mild symptoms of depression and prevent their symptoms getting worse. The use of these technologies could free up clinical resources and time that could be used to support those who need or would prefer face-to-face care. The committee concluded that there is an unmet clinical need and that access to effective mental health treatments needs to be improved.

### Implementation

- 3.3 Digitally enabled therapies will be used in NHS Talking Therapies for anxiety and depression 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 The committee carefully considered the safety and risks of using these technologies while further evidence is generated. The clinical experts advised that NHS Talking Therapies for anxiety and depression services have established protocols, which include initial clinical assessment, matching the right treatment to people's needs and preferences, and ongoing monitoring and management of patient safety. Some digitally enabled therapies also have inbuilt functionalities to promote safety; for example, technologies may alert the practitioner or therapist of potential concerns so that they can contact the patient when needed. The practitioner or therapist may also contact the patient if they see worsening in patient-reported outcomes or if the patient has stopped using the programme. Decline in mental health or functioning while using digitally enabled therapies should be identified by the practitioner or therapist and treatment should be increased when needed, in line with the stepped care approach.
- 3.5 Practitioners and therapists need training and support to effectively deliver digitally enabled therapies. Healthcare professionals working in NHS Talking Therapies for anxiety and depression have ongoing supervision to ensure the quality of treatment and to provide support to practitioners and therapists in the delivery of assessments and treatment. 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 help with data collection and reporting. More information on the implementation of digitally enabled therapies can be found in the [adoption report within the supporting documentation on the NICE website](#).

## Patient considerations

- 3.6 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 such as 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 are most important when deciding on the suitability of using digitally enabled therapies.

- 3.7 Patient experts said that people need to be reassured that their level of care can be increased 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.
- 3.8 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. People should discuss any concerns about using digitally enabled therapies with their practitioner or therapist before starting treatment.

## Equality considerations

- 3.9 Digitally enabled therapy may not be suitable for everyone. Adults with limited access to equipment or to an internet connection, or who are less comfortable or skilled at using digital technologies, 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 with depression.
- 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 the accessibility of their technologies, including having a low reading age for the content and audio recording options, and considering diversity and inclusivity in their content design. One technology, Deprexis, is also available in 9 languages.

## Clinical effectiveness overview

3.11 The evidence shows that Beating the Blues, Deprexis and Space from Depression have potential benefits for adults with depression. There was limited evidence for Wysa and no evidence for Iona Mind or Minddistrict within the scope of this assessment. 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 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 collected outside the UK, which may limit the generalisability of the evidence. The committee concluded that the evidence base was sufficient to recommend use of Beating the Blues, Deprexis and Space from Depression while further evidence is generated. These technologies can be used once they have Digital Technology Assessment Criteria (DTAC) approval and an [NHS Talking Therapies for anxiety and depression digitally enabled therapies assessment from NHS England](#). But there was not enough evidence for Iona Mind, Minddistrict and Wysa to make a recommendation for their use. Further evidence is needed on these technologies, so they should only be used as part of formal research studies. See the [assessment report on the NICE website](#) for further details.

## Costs and resource use

3.12 The economic modelling on Beating the Blues, Deprexis and Space from Depression showed that they could be cost-effective options 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 cognitive behavioural therapy 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 economic model included the licence costs, NHS clinicians' time, the cost of access to a computer, and the internet and costs associated with comparator treatment. Training, set-up and administrative costs

for NHS staff were not included. 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

3.13 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 for anxiety and depression service setting and some evidence was collected outside the UK. Most comparative studies used waitlist or usual care as a control rather than the standard care options used in NHS Talking Therapies for anxiety and depression services. The committee concluded that the quality and quantity of the evidence for 3 of the technologies was enough to show that the technologies had promise of a clinical benefit. Evidence generation within an NHS Talking Therapies for anxiety and depression 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 comorbidity of depression and anxiety is high, so this would not be a major limitation of the evidence base. The committee acknowledged that data collection in an NHS Talking Therapies for anxiety and depression 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 rates and reasons for stopping treatment, adverse effects, 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 for anxiety and depression 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 main outcomes prioritised by the committee for evidence generation are outlined in [recommendation 1.2](#).
- 4.2 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 or therapists in NHS Talking Therapies for anxiety and depression services, who check in with users every week or every 2 weeks by telephone calls or messaging. The committee concluded that using digitally enabled therapies in NHS Talking Therapies for anxiety and depression services could increase access to treatment and support while ensuring the safety of patients through continued monitoring and review.

### Research only recommendations

- 4.3 The committee concluded that there was not enough evidence to recommend Minddistrict, Iona Mind or Wysa for early use in the NHS. They should only be used in formal research that has been approved by an ethics committee.
- 4.4 Research should be within the scope of this assessment and include well-designed and adequately powered studies with appropriate comparators in NHS Talking Therapies for anxiety and depression services. The main outcomes prioritised by the committee for evidence generation are outlined in [recommendation 1.2](#). Studies should address the evidence gaps outlined in this guidance and show 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

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## Update information

**December 2023:** 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.

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