

Be Mindful for adults with depression

13 May 2019

Summary

- The **technology** described in this briefing is Be Mindful. It is an online mindfulness-based cognitive therapy (MBCT) course, designed to treat depression, stress and anxiety.
- The **scope** for this briefing is to consider the use of Be Mindful in a therapist-guided model of care, in adult IAPT services, to treat mild to moderate and moderate to severe depression.
- The **intended place in therapy** would be as step 1 and step 2 therapy, as an alternative to face-to-face MBCT or other psychological interventions.
- The **main points from the evidence** summarised in this briefing are from 1 randomised controlled trial including 118 adults in the UK. The results show that Be Mindful is more effective than waiting list control (no treatment) in people with depression.
- **Key uncertainties** around the evidence or technology are that the population in the study may not be fully representative of users in adult IAPT services. There is no evidence comparing Be Mindful with face-to-face MBCT in a therapist-guided model of care.
- The **cost** of Be Mindful is typically around £46 per person. This includes course costs of £36 (including VAT) and 30 minutes of a psychological wellbeing practitioner's time. IAPT services may be eligible for volume discounts depending on uptake. The **resource impact** would be less than face-to-face MBCT and using Be Mindful may free up staff time.
- The IAPT expert panel **did not recommend** Be Mindful for the evaluation in practice phase of the NICE and NHS England IAPT assessment programme. The panel concluded that Be Mindful did not match the eligibility criterion for a therapist-guided model of care needed to progress to evaluation in practice.

The technology

Be Mindful (Wellmind Media) is an online, mindfulness-based cognitive therapy (MBCT) course for treating depression, stress and anxiety. Be Mindful can be used as a standalone self-help tool but this briefing focuses on its use in a therapist-guided model of care.

The course comprises 4 modules that are designed to be completed over 4 consecutive weeks:

- Week 1 – Stepping out of autopilot: routine activity, mindful eating and body scan.
- Week 2 – Reconnecting with body and breath: mindful movement, event awareness and mindful breathing.
- Week 3 – Working with difficulties: breathing space, stress awareness and sitting meditation.
- Week 4 – Mindfulness in daily life: activity awareness, breathing space and action step and stress strategies.

Users are first introduced to the course and invited to complete a questionnaire to classify severity of their symptoms ('Getting started'). At the end of the course, users complete the same questionnaire to see how their symptoms have changed and are given a certificate and further resources ('Going forward').

The course includes 12 practical assignments and each module includes videos and interactive exercises. Users receive automated emails to help keep them on track and remind them about the assignments.

Both users and therapists can view automatically generated progress summaries. Users also have access to a personal symptom diary and notes pages (which the therapist can't see), as well as additional mindfulness resources that can be accessed as needed after the course is completed.

Regulatory status

The technology owner of Be Mindful states that the program is not currently within the remit of any UK regulation.

Current usage and reach

Be Mindful has been available in the UK since 2011. Since 2012 it has been used by 9 IAPT services in the NHS in England, with around 1,000 people enrolled by NHS IAPT therapists.

Current care pathway

Be Mindful is aligned to the NHS England [Adult Improving Access to Psychological Therapies \(IAPT\)](#) programme. IAPT services provide evidence-based treatments for people with anxiety and depression. IAPT services offer evidence-based psychological therapies given by accredited practitioners, with routine monitoring and regular outcomes-focused supervision.

The care pathway for depression is described in NICE guidelines on [depression in adults](#), [depression in adults with a chronic physical health problem](#) and [common mental health problems: identification and pathways to care](#). NICE recommends a [stepped-care model](#) for treating depression, in which the least intrusive, most effective intervention is provided first; if a person does not benefit from the intervention initially offered, or declines an intervention, they should be offered an appropriate intervention from the next step.

NICE recommends MBCT for people with depression who are currently well but have had 3 or more previous episodes of depression.

Be Mindful can be used in a therapist-guided care model in primary care, secondary care, or in IAPT services as a step 1 or step 2 therapy. Be Mindful would be offered as an alternative to other therapies and it is not anticipated that any changes would be needed to the current care pathway.

Population, setting and intended user

Be Mindful could be used in any setting in which the user has access to the internet, including at home or in outpatient clinics. It can be used on any internet-enabled device including smartphones and tablets.

The technology owner has stated that only basic computer skills are needed to use Be Mindful, so users need no specific training. Therapists need setup instructions and to familiarise themselves with the course; the Be Mindful client services team can provide setup instructions, usually by phone.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Digital technologies such as Be Mindful may be unsuitable for people with visual impairment or learning disabilities. Disability is a protected characteristic under the Equality Act. The technology owner states that Be Mindful can reach people who may be unable or unwilling to attend face-to-face or group MBCT.

The content

The care model

When Be Mindful is used in a therapist-guided model of care, the therapist enrolls the user who then accesses the modules by logging into a website.

The therapist and user agree if they will have phone or face-to-face contact during the course. There is no regular schedule for contact between the therapist and user and no messaging system in Be Mindful itself.

The therapist can view users' activity, progress and symptom scores (collected at the start, end and 1 month after completing the course) using the website. The therapist does not review any assignments directly and cannot access the user's symptom diary or notes.

Be Mindful includes automated support and progress messages which appear on screen and are sent to the user by email. The therapist can provide feedback to the user on their course progress, direct them to assignments in the resources library or discuss any concerns (by email or by prearranged phone or face-to-face contact).

Outcome measures

Be Mindful uses the PHQ-9 and GAD-7 outcome measures, which are needed for use in IAPT services.

Content assessment

The therapeutic content of Be Mindful was assessed using a framework designed to measure how closely its content maps to the standard principles of mindfulness and MBCT. Both the therapist view and user view of Be Mindful were considered in this assessment.

The content assessors reported that Be Mindful is generally well aligned to appropriate therapeutic approaches for MBCT. They noted that the video

presentations are clear and appropriately paced and show the techniques in use.

However, the assessors concluded that Be Mindful is not consistent with the therapist-guided model of care required for eligibility to this programme and that it is closer to a self-help programme. There is little in the way of direct contact between the user and therapist, and no system in place to alert the therapist if the user's symptoms deteriorate or if there is a risk of suicide. There is also no therapist manual describing the blended care approach.

The assessors noted that NICE guidance recommends MBCT only for use in people who are currently well but who have had recurrent depression in the past. The technology owner recommends that Be Mindful can be used for people with mild to moderate depression and moderate to severe depression, which is broader than NICE's recommendation for MBCT.

The assessors noted the following points about Be Mindful:

- It is well scripted and easy to follow.
- MBCT usually includes an explanation of 'thinking errors'; there is only passing reference to this in Be Mindful.
- It does not include a significant discussion on relapse. This is important, given that this kind of therapy is recommended for people whose depression has previously relapsed.
- The introductory sections do not explain (or give a rationale for) the introductory mindfulness exercises and how they may help users.
- It is important to manage user expectations and make them aware that Be Mindful may not work for everyone. For this reason, including the claim that 'completers of the course report... an over 50% reduction in their levels depression and anxiety' is unhelpful.

Scalability

The technology owner has stated that Be Mindful is designed to be scalable to handle large numbers of users.

Technical standards

Technical assessment

Be Mindful has undergone a technical evaluation using relevant sections from version 2.1 of the [Digital Assessment Questions \(DAQ\)](#), a tool developed by NHS Digital and currently available to developers in beta form. The evaluation included 6 domains of the DAQ: clinical safety, data protection, security, usability and accessibility, interoperability and technical stability. Questions from the DAQ on technologies for children, and questions about the evidence base were omitted from this evaluation.

Be Mindful met the digital standards set out in the DAQ. The technology assessors noted 1 minor concern in the usability section and 1 concern in the technical stability section of the DAQ, but these were resolved in the technology owner's remediation plan.

Be Mindful is in the [NHS apps library](#).

Clinical evidence

A literature search was carried out for this briefing in accordance with the [process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology.

This briefing summarises 1 study including 118 patients. [Table 1](#) summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

Querstret et al. (2018) used Be Mindful in a therapist-supported care model, which is likely to be representative of how it would be used in IAPT services. However, the trial compared the program with 'waiting list control' (that is, no treatment) rather than with standard care. Studies comparing Be Mindful with another active intervention, such as face-to-face MBCT, would be more informative.

The author provided PHQ-9 scores for both groups at 3- and 6-month follow up, but it was not possible to compare these because by this time patients in the control group had gone on to have Be Mindful (that is, they had moved from the waiting list).

The patients in the trial may not be fully representative of users in adult IAPT services: they were recruited through electronic mail-outs and social media only, and were mainly public sector workers who went to university.

Table 1 [Querstret et al, 2018](#) Summary of evidence

Study size, design and location	Randomised controlled trial (n=127 randomised, n=118 completed), UK.
Intervention and comparator(s)	Online MBCT (Be Mindful) compared with WLC. Patients in the control group also had Be Mindful after a 6-week delay.
Population	Recruited using mail-outs to organisations with known relationship to the university and mail-outs using social media and LinkedIn. Patients were having no other psychological therapy and had no previous experience of mindfulness or meditation. Around half of the patients had moderate to severe levels of depression or anxiety at baseline, but only 5 self-identified as having depression or anxiety (2 of these were taking medication). No exclusion criteria were provided. Patients were mainly public sector workers. Almost 70% went to university.

Key outcomes	<p>Primary outcomes were depression, perceived stress and anxiety.</p> <p>Patients in the Be Mindful arm had a statistically significant reduction in PHQ-9 depression, stress and anxiety scores compared with patients in the WLC arm.</p> <p>When comparing PHQ-9 depression scores post-intervention with those of the WLCs, the intervention group had statistically significantly reduced scores. This was also the case for stress and anxiety.</p> <p>ITT analysis only reported.</p> <p>Mean depression (PHQ-9) scores (SD):</p> <p>Intervention group 11.10 (6.24) pre-treatment, 4.10 (4.10) at post-treatment.</p> <p>WLC group 9.91 (5.93) pre-treatment, 9.28 (5.57) at end of waitlist period.</p> <p>The between-group effect size comparing intervention to WLC at post-treatment was large: $d = -1.06$ (95% CI -1.44 to -0.67) $p < 0.001$.</p> <p>A similarly large effect size was obtained when comparing treatment and WLC groups for perceived stress and anxiety.</p> <p>Perceived stress: $d = -1.25$ (95% CI -1.64 to -0.85) $p < 0.001$.</p> <p>Anxiety: $d = -1.09$ (95% CI -1.47 to -0.98) $p < 0.001$.</p> <p>Within-group effect sizes were reported before and after the course, and at 3- and 6-month follow up. Differences for depression were statistically significant with reportedly large effect sizes.</p> <p>PHQ 9 scores (mean (SD)) were:</p> <p>Intervention group Pre-treatment 11.10 (6.24) At course completion 4.10 (4.10) At 3 months 6.45 (6.55) At 6 months 5.15 (4.87)</p> <p>WLC group Pre-treatment 9.91 (5.93) At 3 months (no treatment) 9.28 (5.57) At this point the WLC were provided access to Be Mindful: At course completion 3.73 (3.82) 3 months after completion 4.19 (5.02) 6 months after completion 3.52 (5.64)</p>
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Strengths and limitations	<p>The study compared Be Mindful with WLC rather than standard care options such as face-to-face MBCT. This may inflate a general treatment effect.</p> <p>High baseline scores for depression mean the study population had a greater capacity for change.</p> <p>After completing the course, 15 of 60 patients were lost to follow up in the treatment group (rising to 17 at 6 months) and 16 of 58 patients were lost to follow up in the WLC group (rising to 18 at 6 months).</p> <p>The patients in the trial may not be fully representative of users in adult IAPT services because they were recruited through mail-outs and social media only and were mainly public sector workers who went to university.</p>
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Abbreviations: MBCT, mindfulness-based cognitive therapy; WLC, waiting list control.

Recently completed and ongoing studies

No recent, ongoing or in-development trials on the use of Be Mindful for people with depression were identified in the preparation of this briefing.

Cost and resource impact

There are currently no published economic analyses available.

Technology costs

The licence fee for Be Mindful is £36 (including VAT). In addition, the technology owner estimates that approximately 30 minutes of band 5 psychological wellbeing practitioner (PWP) time would be needed for each course of treatment, costing £10. So, the total cost of Be Mindful will be around £46 per person.

Resource consequences compared with standard care

Table 2 Costs of Be Mindful per treatment course per person compared with current treatment options

Treatment	Existing cost	Cost using Be Mindful (including VAT)	Cost/saving
Group MBCT	£114	£46	£68 saved
Individual MBCT	£687	£46	£641 saved
Course of SSRI	£75	£46	£29 saved

Abbreviations: MBCT, mindfulness-based cognitive therapy; SSRI; selective serotonin reuptake inhibitor.

The following costing assumptions have been made for Be Mindful:

- Be Mindful is expected to cost around £46 per person (including VAT).
- Be Mindful may be delivered by a PWP; costs include 30 minutes of their time per person.
- There will be no extra cost for training.

Overall impact

Using Be Mindful is unlikely to deliver cash-releasing savings but it may free staff time which could in turn reduce waiting times and increase access to care. For example, a reduction in face-face MBCT would release therapist time.

Cost and resource impact statement from the technology owner

The technology owner has stated that Be Mindful reduces costs because less therapist time is needed compared with face-to-face MBCT.

The technology owner has indicated that it would offer volume discounts for Be Mindful licences.

IAPT expert panel considerations

The expert panel considered the assessments of therapeutic content, digital technological factors, clinical evidence and resource impact in making their decision that Be Mindful should not progress to the evaluation in practice phase of this programme.

The panel noted the public interest in and demand for mindfulness-based treatments, and considered that a digital MBCT therapy such as Be Mindful may be popular with service users.

Technical assessment

The panel noted the technical assessment and the technical assessors' conclusion that Be Mindful met the appropriate digital standards. The panel also noted that Be Mindful is in the NHS apps library, so is available for users to access outside of IAPT services.

Content assessment

The panel considered the care model offered by Be Mindful, noting that there was no inbuilt secure messaging system, no regular schedule for contact between the therapist and user, no risk-flagging capacity and no regular user assignments that could be reviewed by the therapist. The panel concluded that Be Mindful did not match the eligibility criterion for a therapist-guided model of care needed to progress to evaluation in practice.

The panel discussed whether Be Mindful fits the eligibility criterion of being in line with NICE guidance. The panel concluded that Be Mindful could be used as a self-help programme in line with NICE guidance (that is, to deliver MBCT for people who are currently well but who have had 3 or more previous episodes of depression). However, few people attend IAPT services looking for treatments to prevent further relapses. The panel also noted that the technology owner recommends Be Mindful for treating mild to moderate and moderate to severe depression, which is broader than NICE's recommendation for MBCT.

Clinical evidence

The panel considered the main points from the evidence from 1 randomised controlled trial including a total of 118 adults in the UK and noted its strengths and limitations.

Cost and resource impact

The panel acknowledged the low cost of Be Mindful and the minimal cost associated with therapist time. The panel noted that this cost reflected the minimal involvement of the therapist in using Be Mindful.

Development of this briefing

This briefing was developed by NICE for NHS England's [assessment of digitally enabled psychological therapies for IAPT](#). The briefing was presented to NICE's IAPT expert panel, who considered Be Mindful for this assessment programme. The [process and methods statement](#) sets out the process for selecting topics, and how the briefings are developed, quality-assured and approved for publication.

Panel members

- Professor Tim Kendall (chair), national clinical director for mental health, NHS England and NHS Improvement.
- Ms Lauren Aylott, lay member.
- Professor Peter Bower, professor of health services research, Manchester University.
- Professor Chris Hollis, professor of child and adolescent psychiatry, University of Nottingham.
- Ms Toni Mank, clinical director for planned and scheduled care and head of IAPT, Sheffield Health and Social Care NHS Foundation Trust.
- Dr Ifigeneia Mavranouzouli, senior health economist, University College London.
- Dr Nicholas McNulty, primary care psychologist, South London & Maudsley NHS Trust.

- Professor Steve Pilling, professor of clinical psychology and clinical effectiveness, University College London.
- Dr Georgina Ruddle, Acting Associate Director Mental Health, Maternity and Children, and Interim Transforming Care Partnerships Lead, NHS Wiltshire Clinical Commissioning Group, NHS Wiltshire Clinical Commissioning Group

Specialist contributors

The following specialist commentators provided content for this briefing:

- Professor Tony Roth, professor of clinical psychology, University College London.
- Professor Paul Salkovskis, director of the Oxford Institute of Clinical Psychology Training and Oxford Centre for Cognitive Therapy.