Velibra for adults with general anxiety disorder

15 July 2019

Summary

- The **technology** described in this briefing is Velibra. It is an online programme designed to treat generalised anxiety disorder (GAD), panic disorder or social anxiety disorder.
- The **scope** for this briefing is to consider the use of Velibra to treat mild-to-moderate GAD in a therapist-guided model of care, in adult Improving Access to Psychological Therapies (IAPT) services, for the NHS England evaluation of digitally enabled psychological therapies for IAPT.
- The **intended place in therapy** would likely be as a step-2 therapy, as an alternative to guided or unguided self-help, or as an adjunct to step-3 therapies. The user would be supported by a therapist to help them to work through the programme and give feedback and guidance.
- The **main points from the evidence** summarised in this briefing are from 1 randomised controlled trial set in Germany, Austria and Switzerland, and including 139 adults with anxiety disorders (36 with a primary diagnosis of GAD and a further 22 with a comorbid diagnosis of GAD). The study reported that Velibra used without therapist guidance alongside usual care was more effective than usual care alone in people with GAD.
- **Key uncertainties** around the evidence and technology are that the study used Velibra without therapist guidance, which is different to how it would be used in IAPT. Concurrent usual care was not recorded so whether it affected the study results is unclear.
- The estimated **cost** of Velibra is £343 per person. This includes a licence fee of £324 (including VAT) and 1 hour of psychological wellbeing practitioner (PWP) time. The **resource impact** would be similar to standard care but may free staff time to deal with more dependent people.
- The IAPT expert panel **did not recommend** Velibra to treat GAD for the evaluation in practice phase of the NICE and NHS England IAPT

assessment programme. The panel concluded that Velibra did not match the eligibility criterion of having content that mirrors the NICE recommended psychological therapy for GAD.

The technology

Velibra (Gaia Group) is an online programme using the principles of cognitive behavioural therapy (CBT), which is designed to treat GAD, panic disorder, or social anxiety disorder. Velibra can be used as a standalone self-help tool or in a therapist-guided model of care. This briefing focuses on its use in a therapist-guided model of care for treating GAD.

The content of Velibra is delivered in 6 modules that explain and provide examples of CBT techniques, and allow the user to practise them. People are encouraged to complete all the modules, although they may get benefits without completing them all. The modules are:

- Session 1: Introduction – This explains the purpose of Velibra and how it works. It includes psychoeducation about anxiety, introduces CBT, and identifies the user's symptom focus (GAD, panic disorder or social anxiety disorder).
- Session 2: Coping with anxiety-related cognitions – This helps the user learn to identify and understand automatic thoughts and cognitive distortions, and to challenge unhelpful thoughts.
- Session 3: Learning mindfulness and relaxation exercises – This explains why these are used. The user can learn and practise specific exercises.
- Session 4: Understanding and practising exposure – This explains about exposure for treating anxiety. It gives disorder-specific instructions for self-guided exposure exercises.
- Session 5: Social skills, social support and interpersonal relationships – This looks at support networks and anxiety-related social situations.
- Session 6: Summary and relapse prevention – This takes the form of a quiz to review and test knowledge, and review key principles. It also contains an illustrated case study to reinforce key principles.

Users have access to Velibra for 180 days after registration. The intention is that users complete the course in about 2 months (although this can be adjusted to suit user circumstances). The content is delivered using short passages of text, with pictures, audio recordings and downloadable PDF documents. Users can choose to receive automated daily messages by SMS text message or email.

In each module, the user reads information and then selects 1 of several pre-set responses. The programme selects the subsequent material to match this response (in what is described as an 'individually tailored dialogue') to tailor the content to the user. This tailoring adjusts the content in later modules to meet user preferences and characteristics, such as what their current symptoms are and whether they would like to see more background detail in each section.

The programme can be accessed on any device that has internet access. Users log into the programme through an encrypted website, using their own login and password.

Regulatory status

Velibra is CE marked as a class 1 medical device.

Current usage and reach

The German language version of Velibra has been offered online since 2013 and has been used by about 800 people with anxiety disorders. The English language version was completed in 2017, although to date it has not been available in the UK.

Current care pathway

The NHS England Adult Improving Access to Psychological Therapies (IAPT) programme aims to provide evidence-based treatments for people with common psychological conditions such as 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 GAD is described in NICE guidance on generalised anxiety disorder and panic disorder in adults. NICE recommends a stepped-care model for treating GAD, 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.

Velibra could be used in a therapist-guided care model in primary care, secondary care or in IAPT services as a step 2 therapy or as an adjunct to step 3 therapy. It is not anticipated that any changes would be needed to the current care pathway.

Population, setting and intended user

Velibra could be used in any setting in which the user has access to the internet, including at home or in outpatient clinics. It would be used by adults with mild-to-moderate GAD, with an appropriately trained therapist. In IAPT services this would likely be an appropriately trained PWP.

The technology owner states that the user needs no training to use Velibra and that only basic computer skills are needed. It has produced information and instruction documents for therapists and recommends a 1-day training session with PWPs on the use of Velibra.

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 Velibra may be unsuitable for people with a visual impairment or learning disability. Disability is a protected characteristic under the Equality Act.

The content

The care model

Velibra can be used as a standalone therapy or in a therapist-guided care model. Currently the therapist-guided care model involves regular phone support from the therapist, with additional brief face-to-face therapist sessions arranged depending on the user's needs. The technology owner states that this care model has been well-received by therapists and has been working well for users.

Currently, there is no capacity with Velibra for a therapist to log into the programme to monitor progress and symptom scores, or to send secure messages. The technology owner has stated that these functions could be added if Velibra is selected for the NHS England evaluation in practice stage of the programme. The proposed additional functions would be similar to that provided by the technology owner's depression CBT programme, Deprexis.

The technology owner has stated that it would take around 6 to 8 weeks to build and implement these additional functions.

Outcome measures

Currently, Velibra uses 2 symptom measures: the depression, anxiety and stress-21 item (DASS-21) questionnaire, and a 6-item mood questionnaire developed by the technology owner. It has stated that other outcome measures could be added to Velibra if needed, although this could affect user experience and create data burden. The required IAPT outcome measures for GAD are Patient Health Questionnaire-9 (PHQ-9) and GAD-7.

The technology owner has stated that each outcome of the DASS-21 (depression, anxiety and stress) and the mood questionnaires can be viewed by therapists for each patient.

Content assessment

The therapeutic content of Velibra was assessed using a framework designed to measure how closely its content maps to the standard principles of CBT for GAD (Borkovec model).

The content assessors reported that Velibra uses a transdiagnostic approach, addressing the needs of people with panic disorder, social anxiety disorder and GAD. It achieves this through a brief screening at the start of the programme that asks individuals to indicate which of these 3 primary areas causes them most discomfort or difficulty; in response users follow different pathways. In line with its transdiagnostic approach, most of the units are common to each other whichever disorder is identified as primary. Specific sections address core issues for each disorder (worry exposure for GAD). The content assessors highlighted that this approach is not routinely used in IAPT services and is not NICE recommended.

The assessors noted the following points about using Velibra:

- There are several theoretical models included in the programme. Each 'track' includes behavioural and cognitive methods, as well as ideas derived from mindfulness and a values-based approach (based on Acceptance and Commitment Therapy). This is supplemented extensively by cognitive bias modification and an emphasis on relaxation techniques. Using these different models is not always appropriate or in line with approaches used in IAPT services.
- Because of the number of strategies used, the programme is lengthy, particularly time spent on cognitive bias modification, which users may find challenging. Breaks are encouraged, but it is not clear when these should be taken.
- There is some tailoring of content to the user's needs, but this is limited. To progress through the programme, users must choose from a list of pre-determined options that may not precisely fit their own feelings.
- The severity range of the intended user's condition is not clear.

- There are no triggers to identify when patient safety becomes a concern. When entering outcome scores that indicate a patient in crisis, only contact telephone numbers are provided. The content assessors felt therapists should be able to track patient progress and contact them directly if needed.
- The language used is broadly appropriate but some of the content is over-complex and may be difficult to follow. The programme provides signposting to academic references for users who wish to learn more. It would be more useful to signpost to specifically written texts.
- Detailed information is provided on other available treatment options. However, the content assessors felt that there was no indication of likely outcomes for users of Velibra. They thought it would be useful to inform users that they may not benefit from using the programme at the point that other options are mentioned.
- When discussing potential treatments for depression, the programme advises that day hospital visits and inpatient stays are options. This would only apply to very severe depression in the NHS.
- The relaxation techniques used in the programme focus on progressive rather than applied relaxation. Only applied relaxation is NICE recommended.

Scalability

The technology owner has stated that any additional increase in users following evaluation through this programme could be managed within its current capacity.

Technical standards

Technical assessment

Velibra has had a technical evaluation using relevant sections from version 2.1 of the Digital Assessment Questions (DAQ). This is a tool developed by NHS Digital and is 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.

Velibra met the digital standards set out in the DAQ. The technology assessors noted that Velibra and its technology owner appear to be relatively well aligned with NHS standards. The assessors noted that there was room for improvement in the domains of security, usability and accessibility, interoperability and technical stability. However, they concluded that, overall, the standards were acceptable.

Clinical evidence

A literature search was carried out for this briefing in accordance with the process and methods statement on the IAPT page of the NICE website. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology.

This briefing summarises 1 study (Berger et al. 2017), involving 139 adults with anxiety disorders.

Overall assessment of the evidence

One randomised controlled trial has looked at the effectiveness of Velibra compared with a waiting-list control group (Berger et al. 2017). Velibra was used as a standalone therapy, without therapist guidance, which does not directly reflect how Velibra would be used in IAPT services.

This study recruited people with primary diagnoses of panic disorder with or without agoraphobia, social anxiety disorder or GAD. Recruitment to the study fell short of the target but was still powered sufficiently to detect medium (but not small) effect sizes between people having treatment with Velibra and people in the control group.

The primary outcomes of the study measured general anxiety and depression but were not specific to the 3 anxiety conditions in the study. The secondary outcomes were GAD specific and were reported for each subgroup.

The diagnostic subgroups reported included people with a primary diagnosis of each condition, pooled with people who had a comorbid diagnosis of that condition. This means that, when the outcomes for people with GAD were reported, they included people whose primary diagnosis was not GAD. It is unclear whether this may have affected the study outcomes.

People in the study were randomised to either Velibra or the waiting-list control group. Both groups had access to usual care. The level and nature of this care in the study was not recorded, so it is unclear whether this could have affected the study outcomes.

People who had immediate treatment with Velibra were contacted at 6 months post-treatment to record follow-up data. This extended time point is useful to help understand the longer-term outcomes from Velibra use.

Table 1 Summary of evidence Berger et al. (2017)

Study size, design and location	Randomised controlled trial, n=139 people with anxiety disorders: 36 had a primary diagnosis of GAD (63 had a primary diagnosis of panic disorder and 40 had a primary diagnosis of social anxiety disorder). People recruited to the study were from Germany, Austria and Switzerland.
Intervention and comparator	People were randomised to treatment with the German language version of Velibra (as a standalone treatment without therapist guidance) or to waiting-list control. Both groups had access to usual care in addition to the randomised treatment.
Population	People were recruited to the study through a website, in response to newspaper adverts or through information from their GP.
Key outcomes	**Primary outcome measures:** non-condition-specific measures were DASS-21, BAI, BDI-II, BSI, SF-12 MH and SF-12 PH. These were reported for the whole Velibra group (n=70) versus the whole control group (n=69) irrespective of GAD, panic disorder or social anxiety disorder diagnosis. The results showed that, from pre- to post-treatment, people in the Velibra group had improvements across all primary outcome measures. These improvements were all

	statistically significant compared with those in the control group, except for SF-12 PH, which was not statistically significant. Improvements were maintained at 6-month follow up. Effect sizes comparing pre- and post-treatment results were medium to large. The control group did not show statistically significant improvements in any primary outcome measure. Selected primary outcomes included: **Mean DASS-21 scores (SD):** Velibra group pre-treatment 58.2 (24.4); post-treatment 40.9 (25.7); 6-month follow up 41.9 (30.0). Control group pre-treatment 55.8 (21.3); post-treatment 52.7 (24.7); 6-month follow up not reported. **Mean BAI scores (SD):** Velibra group pre-treatment 34.9 (9.1); post-treatment 27.8 (9.1); 6-month follow up 26.6 (9.4). Control group pre-treatment 33.3 (10.3); post-treatment 31.4 (10.0); 6-month follow up not reported. **Mean BDI-II scores (SD):** Velibra group pre-treatment 22.6 (10.6); post-treatment 15.8 (12.4); 6-month follow up 16.3 (13.7). Control group pre-treatment 22.0 (11.0); post-treatment 22.9 (12.6); 6-month follow up not reported. **Secondary outcome measures** were condition specific and were reported for condition-specific subgroups (which included people with a primary diagnosis of each condition as well as those with a comorbid diagnosis of that condition), as well as for the whole treatment groups. For people with GAD, the condition-specific secondary outcome measures were PSWQ and BDI-II. People with GAD in the Velibra group (n=29) reported statistically significant improvements in BDI-II compared with people with GAD in the control group (n=29) post-treatment.

	Improvements in PSWQ were, however, not statistically significant (p=0.06). The improvements were maintained at 6-month follow up. **Mean BDI-II (SD) in people whose diagnosis included GAD:** Velibra GAD subgroup pre-treatment 27.0 (10.3); post-treatment 19.1 (13.6); 6-month follow up 18.6 (15.8). Control GAD subgroup pre-treatment 24.4 (10.0); post-treatment 25.4 (12.8); 6-month follow up not reported. **Mean PSWQ (SD) in people whose diagnosis included GAD:** Velibra GAD subgroup pre-treatment 67.6 (7.0); post-treatment 63.0 (11.2); 6-month follow up 61.7 (10.4). Control GAD subgroup pre-treatment 66.7 (9.2); post-treatment 66.3 (9.1); 6-month follow up not reported. When comparing the whole Velibra group with the whole control group (including people with panic disorder, social anxiety disorder and GAD), BAI, BDI-II and PSWQ were all statistically significantly improved post-treatment. Thirteen of 29 people with an initial diagnosis of GAD in the Velibra group no longer met the diagnosis for GAD post-treatment. None of the 29 people in the control group met the diagnosis for GAD.
Declarations of interest	One study author is an employee of Gaia, the developer of Velibra.
Strengths and limitations	Subgroup analysis showing results specific to people with GAD included people with a primary diagnosis and a comorbid diagnosis of GAD. The study was not adequately powered to report small effect sizes. Of 139 people randomised, 120 completed the post-treatment questionnaires; 45.7% of people completed the whole Velibra programme and 11.4% did not start the programme at all. Recruitment was partially via the internet, so people in the study may have had stronger IT skills than the general population.

Abbreviations: *BAI, Beck anxiety inventory; BDI-II, Beck depression inventory II; BSI, brief symptom inventory; DASS-21, depression anxiety stress scales-short form; GAD, generalised anxiety disorder; PSWQ, Penn State Worry Questionnaire; SD, standard deviation; SF-12 MH, short form health survey-12: mental health; SF-12 PH, short form health survey-12: physical health*

Recently completed and ongoing studies

The technology owner has stated that a pilot study using Velibra in a university-based mental health clinic in the US is currently underway. No other recent, ongoing or in-development trials on the use of Velibra for people with GAD were identified in the preparation of this briefing.

Cost and resource impact

There are currently no published economic studies on Velibra.

Technology costs

Velibra is not yet in use in the UK, but the technology owner estimates that the cost to the NHS of using this technology would be around £324 per user (including VAT). Around 1 hour of PWP time would be needed per patient, per course of treatment, bringing the total cost to £343 including 1 hour of PWP time.

Resource impact compared with standard care

Table 2 Comparison of Velibra with current treatments for GAD

Treatment	Cost per treatment course per person		
	Existing cost	**Cost using Velibra**	**Cost/saving**
Individual non-facilitated self-help	£10	£343	£333 cost
Individual facilitated self-help	£57	£343	£286 cost
Psychoeducational groups	£29	£343	£314 cost
Cognitive behavioural therapy	£733	£343	£390 saving
Applied relaxation	£733	£343	£390 saving
Course of selective serotonin reuptake inhibitors	£75	£343	£268 cost

Table 2 shows direct staff costs and licence fees only. Indirect and overhead costs have not been included.

The following costing assumptions have been made for Velibra:

- The licence is expected to cost around £324 (including VAT) per person per 90 days.
- There is no cost for training.
- It may be delivered using a lower grade of staff (PWP).
- The technology owner estimates that the therapist will spend 2 to 5 minutes on average per consultation to discuss the user's progress. A total of 1 hour of PWP time has been included in the cost of Velibra.

Overall impact

Use of the technology is unlikely to deliver cash releasing savings, but it may free staff time to deal with more dependent people. For example, a reduction in individual guided self-help is expected to release therapist time.

Early interventions and home treatment for mental health problems can reduce hospital admissions, shorten hospital stays and result in fewer high-

cost intensive interventions. This may create more capacity and access for people needing urgent mental health services.

Early treatment of people with mental health problems may help individuals to continue to work or return to work more quickly after a mental health problem.

Cost and resource impact statement from the technology owner

The technology owner has stated that Velibra will reduce the amount of therapist time needed to support people with GAD.

There will be an element of training needed for PWPs to support people using Velibra, but the technology owner has stated that this will be free.

The technology owner has stated that, because people with anxiety disorders frequently experience medically unexplained symptoms, better treatment for this condition could reduce healthcare costs through fewer GP consultations and diagnostic tests.

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 Velibra for GAD should not progress to the evaluation in practice phase of this programme.

Technical assessment

The panel noted the technical assessment and the technical assessors' conclusion that, overall, Velibra met the appropriate digital standards and no remediation was needed.

Content assessment

The panel discussed whether Velibra fits the eligibility criterion of being in line with NICE guidance. The panel noted that the content assessors highlighted the following issues with Velibra where it did not follow NICE guidance:

- a transdiagnostic approach, with limited tailoring of content to user needs
- several theoretical models
- cognitive behaviour bias extensively, which is not always appropriate or in line with approaches used in IAPT services.

They also highlighted that the technology is lengthy and may be difficult for some users to follow. The panel also considered the care model offered by Velibra, noting that there was no inbuilt secure messaging system, no regular schedule for contact between the therapist and user, and no risk-flagging capacity. They acknowledged that the technology owner had advised that this functionality could be added if Velibra was moved onto the same platform as another technology it owns, Deprexis. This would involve an 8-week implementation period.

The panel concluded that Velibra did not match the eligibility criterion needed to progress to evaluation in practice because the content was not in line with NICE's recommended psychological therapy for GAD.

Clinical evidence

The panel considered the main points from the evidence from 1 randomised controlled trial including 139 adults recruited in Germany, Austria and Switzerland. They noted its strengths and limitations particularly around the assessment of 3 subgroups in a single study.

Cost and resource impact

The panel noted that Velibra costs less than a course of face-to-face CBT. However, it is more expensive than other digital technologies being used in IAPT services.

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 Velibra for this assessment programme. The process and methods statement on the IAPT page of the

NICE website 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
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