SHADE for adults with depression and drug or alcohol misuse

27 March 2018

- The **technology** described in this briefing is SHADE. It is designed to treat depression comorbid with drug or alcohol misuse.
- The **scope** for this briefing is to consider the use of SHADE in a therapist-guided model of care, in adult IAPT services.
- The **intended place in therapy** would be as an alternative to face-to-face treatments for people with mild to moderate depression with drug or alcohol misuse.
- The **main points from the evidence** summarised in this briefing are from 2 low-quality randomised controlled trials including a total of 371 adults in Australia. The studies report that SHADE is at least as effective as face-to-face therapy in reducing depression symptoms and drug or alcohol misuse.
- **Key uncertainties** around the evidence are that the trials may not have been adequately powered to detect the reported differences between the groups. Moreover, outcomes are not fully reported in 1 of the trials and it is not clear whether the same patients were reported in both studies.
- The **cost** of SHADE is expected to be around £24 per licence per year (including VAT) for an average service. The total average cost will be around £70 per patient, including staff time. The **resource impact** would be less expensive than 1-to-1 or group-based CBT and antidepressant treatment, but more expensive than guided self-help or workshop-based CBT.
- The IAPT expert panel **did not recommend** SHADE for the NHS England evaluation in practice programme.

The technology

SHADE (CCBT) is an online cognitive behavioural therapy (CBT) based programme designed to treat mild to moderate depression in people with drug or alcohol misuse. It is designed for people with a reading age of 14 years, with a voiceover available to read out all of the text sections. It comprises 10 modules that include video case studies, handouts and worksheets.

- Module 1 Introduction: learning about depression and substance abuse, introduction to exercises used in the programme.
- Module 2 Costs of substance abuse and mood monitoring: the financial costs of drinking and drug use, learning and using techniques.
- Module 3 ABC and interpreting situations: learning the ABC technique, learning how to interpret situations.
- Module 4 Control cravings: how to identify triggers for cravings and learning effective coping strategies.
- Module 5 Learning to let go: learning to identify helpful and harmful thoughts, practicing letting go of harmful thoughts.
- Module 6 Learning problem-solving techniques for withdrawal: developing a strategy for withdrawal, problem-solving techniques.
- Module 7 Core beliefs: how core beliefs shape addiction and depression, how to alter core beliefs.
- Module 8 'Let it be': refusal skills to help sustain recovery, creating an emergency plan to help sustain recovery.
- Module 9 Rule breaking: the negative aspect of breaking rules, good and bad decision making.
- Module 10 Relapse prevention: developing a relapse management plan.

Each module is intended to take 20 to 50 minutes. The full programme is designed to be completed in 10 weeks, although the user can work at their own pace. SHADE can be accessed on Windows or Mac computers and mobile devices using Android or iOS operating systems. The technology owner has stated that it plans to produce a SHADE app before 2020.

Regulatory status

The technology owner has stated that SHADE complies with the clinical safety standards SCCI0129 and SCCI0160, which are required by NHS Digital. SHADE does not have a CE mark.

Current usage and reach

SHADE has been available for use in the UK since 2005 and is currently used in 4 IAPT services in the NHS. People can also buy SHADE directly online for use with or without therapist guidance (provided by CCBT), depending on the level of service purchased.

Current care pathway

SHADE is aligned to the NHS England [Adult Improving Access to Psychological Therapies (IAPT)](#) programme. IAPT services provide evidence-based treatments for common psychological conditions such as depression and anxiety. IAPT services offer evidence-based psychological therapies given by accredited practitioners, with routine monitoring and regular outcomes focused supervision. The [IAPT positive practice guide for working with people who use drugs and alcohol](#) gives advice and support to IAPT services in identifying drug and alcohol misuse, deciding whether a person is suitable for treatment in IAPT services, and working effectively with alcohol and drug misuse services.

The Department of Health and Social Care [UK guideline on clinical management of drug misuse and dependence](#) states that co-occurring mental health problems are common among people who misuse drugs, and that the coexistence of a drug problem should not be a barrier to a person accessing treatment for their mental health condition. The guideline recommends that for depression, 1 or 2 sessions of CBT-based guided self-help can be helpful and should be part of routine clinical care.

The NICE guideline on the [diagnosis, assessment and management of harmful drinking and alcohol dependence](#) recommends that for people who

misuse alcohol and have comorbid depression or anxiety disorders, the alcohol misuse should be treated first because this may improve symptoms of depression and anxiety. If depression or anxiety continues after 3 to 4 weeks of not drinking alcohol, treatment of the mental health condition should be considered in line with NICE guidance.

In practice, there is sometimes a lack of clarity about whether people with depression comorbid with alcohol or drug misuse should be referred to mental health or alcohol and drug misuse services.

The care pathway for depression is described in the 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.

In IAPT services, SHADE could be used in a therapist-guided care model as a step 2 therapy for depression, in adults with depression who misuse alcohol or drugs.

Population, setting and intended user

SHADE could be used in any setting where the user has access to the internet, including in the home or in outpatient clinics. It would be used by adults with mild to moderate depression and alcohol or drug misuse, with support from an appropriately trained therapist. In IAPT services this would likely be a psychological wellness practitioner (PWP).

The technology owner has stated that most service users do not need any training to use SHADE. Therapists need to have some training to learn how to use the therapist portal and review the users' reports. CCBT provides training and handouts to IAPT services, and has a therapist helpdesk service that can be accessed through email, phone or online chat, to answer questions.

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 SHADE may be unsuitable for people with visual impairments or learning disabilities. Disability is a protected characteristic under the Equality Act.

The content

Care model

The user accesses SHADE by logging into a secure patient 'bookshelf' called Jupiter. The therapist can view the user's activity by accessing the therapist portal, Helix. The therapist provides weekly support to the user as they proceed through the SHADE programme. In addition, the therapist and user and send each other secure online messages.

The therapist monitors progress, provides feedback, ensures the user understands the modules, reviews homework, and plans future homework. This is intended to increase engagement, improve motivation, provide positive reinforcement and encourage continued progress.

In Helix, the therapist can see when the user has logged into the programme, for how long and which modules and exercises they have done. The therapist can view symptom scores over time to see if symptoms are improving. An alarm message is sent to the therapist if the user's score on a 1-item suicidal score reaches a preset threshold.

Some materials (such as psychoeducation sheets and module summary sheets) are in PDF format for users to download and print, so these can't be reviewed by the therapist. The technology owner has stated that it aims to change this, so that in future releases of Helix the therapist can see more of the user's work (where appropriate and only if consent is given).

Outcome measures

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

Content assessment

The therapeutic content of SHADE was assessed using a framework designed to measure how closely its content maps to the standard principles of CBT.

The content assessor reported that SHADE is generally consistent with the principles of CBT. The assessor noted that as SHADE is intended to treat depression comorbid with drug and alcohol misuse, there is no established competence framework against which to assess the treatment offered by SHADE.

The assessor noted that SHADE covers relevant issues thoroughly. It employs many different cognitive behavioural techniques directed at different aspects of depression and drug and alcohol misuse. Each of these has face validity, but it is not clear whether all of these strategies are needed. This means that SHADE includes a lot of possibly unnecessary content for the user to work through.

The therapeutic content of SHADE is presented in a form of slow-scrolling text with an American-accented voiceover reading the text at the same pace. The technology owner has stated that this voiceover was a panel's preferred voice out of a range of differently-accented male and female voices. The user cannot change the pace of the text, nor skip ahead through content. This is designed to make sure that the user does not miss relevant information, but it

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could challenge the concentration and motivation of some users. Within each module there are 'save points' where the user can stop and save the module to complete later.

The assessor made the following comments on SHADE:

- The fixed speed at which the scrolling text and voiceover deliver the content is aimed at people with a reading age of 14 years. This means that the pace of the information is slow and may be frustrating.
- The level of therapist guidance and interaction between the therapist and user appeared to be appropriate.
- The therapist's manual was useful and contained sensible guidance for therapists.

Scalability

The technology owner expects that any additional increase in users from the NHS could be managed using the current systems.

Technical standards

Technical assessment

SHADE has had a technical evaluation using sections of the [Digital Assessment Questions (DAQ)](#), a pilot tool currently available to developers in beta form. The evaluation included 6 domains of the DAQ: clinical safety, privacy and confidentiality, security, usability and accessibility, interoperability, and technical stability.

Acceptable scores were achieved in the DAQ domains of clinical safety, privacy and confidentiality, and technical stability. The DAQ assessment identified concerns in the domains of security, usability and accessibility, interoperability and technical stability, for all of which the technology owner provided acceptable remediation plans. The technical assessors noted that the technology owner is planning to change the platform of SHADE to a web-

based app in the next year, and this app would need a separate DAQ assessment.

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 2 randomised controlled trials (described in 3 publications) including a total of 371 people. Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

Both trials had useful and informative comparators, comparing the use of SHADE with identical therapeutic content delivered face-to-face. The Kay-Lambkin et al. (2009) study reported relatively long-term outcomes, up to 12 months after treatment.

However, the trials are associated with some uncertainties. Kay-Lambkin et al. (2011) is described as a 'large-scale replication' of the 2009 study, but the 2 studies were done by the same research group in the same geographical area in Australia, with overlapping recruitment periods, so it is not clear whether there is overlap in the cohorts. Neither study included a power calculation, so it is not clear whether they were adequately powered to detect the changes reported between groups.

Table 1 Summary of evidence

Kay-Lambkin et al. 2009	
Study size, design and location	Randomised controlled trial, n=97. Australia.
Intervention and comparator(s)	All people in the trial had a 2-hour face-to-face brief intervention for depression and were then randomised to receive either:

	- no further treatment after the brief intervention (BI group; n=30) - 9 sessions of face-to-face motivational interviewing and CBT (F2F group, n=35) - or the same therapy delivered through the SHADE computer programme (SHADE group; n=32) with brief weekly input from a therapist.
Population	People referred from mental health, alcohol or drug misuse services, and primary care, and people who self-referred in response to local media advertisements. Eligibility criteria included: BDI-II score of 17 or more, confirmed diagnosis of depressive disorder, current alcohol or drug misuse.
Key outcomes	The primary outcomes were depression measured using the BDI-II score, and alcohol and cannabis use. Depression scores decreased statistically significantly in all 3 groups. The F2F group showed the greatest reduction at 3 months but this was not maintained to 12 months. The SHADE group had the greatest decrease at 12 months. Alcohol consumption decreased in all 3 groups with no statistically significant difference between groups. There was a significant reduction in cannabis use. The SHADE group had a statistically significantly greater reduction compared with the BI group. Depression: BI group: Baseline BDI-II (SD) **32.86** (9.59); 3 months **22.95** (10.46); 6 months **28.29** (13.19); 12 months **24.76** (12.55). F2F group: Baseline BDI-II **34.91** (9.7); 3 months **13.04** (10.51); 6 months **15.46** (11.11); 12 months **20.35** (14.49). SHADE group: Baseline BDI-II **28.57** (9.89); 3 months **17.09** (12.14); 6 months **16.65** (10.63); 12 months **13.65** (9.55). Alcohol use (occasions per day over past month): BI group: baseline **8.18** (5.17); 3 months **4.79** (4.95); 6 months **6.41** (5.91); 12 months **5.97** (4.03). F2F group: baseline **9.6** (5.45); 3 months **3.58** (4.6); 6 months **3.62** (5.31); 12 months **2.49** (3.47). SHADE group: baseline **7.34** (4.48); 3 months **3.81** (4.92); 6 months **6.39** (9.57); 12 months **4.13** (5.78). Cannabis use (occasions per day over past month): BI group: baseline **9.22** (8.57); 3 months **7.24** (7.77); 6 months **8.0** (9.7); 12 months **8.61** (10.16).

	F2F group: baseline **15.03** (13.87); 3 months **8.9** (11.25); 6 months **7.1** (9.51); 12 months **5.72** (6.22).
	SHADE group: baseline **11.94** (9.14); 3 months **5.77** (6.56); 6 months **4.97** (6.93); 12 months **3.34** (5.52).
	The secondary outcome of the study was hazardous alcohol or drug use index scores. There was a statistically significant reduction in hazardous drug and alcohol use over 12 months, with the SHADE group reporting a statistically significant reduction compared to the BI group.
	Hazardous alcohol or drug use (occasions per day over past month):
	BI group: baseline **39.67** (15.4); 3 months **31.11** (13.54); 6 months **38.78** (17.14); 12 months **34.11** (16.01).
	F2F group: baseline **43.11** (17.04); 3 months **39.84** (50.27); 6 months **27.0** (22.8); 12 months **24.21** (18.71).
	SHADE group: baseline **42.1** (20.17); 3 months **23.43** (16.92); 6 months **25.76** (14.58); 12 months **21.05** (11.75).
Strengths and limitations	The study was not sufficiently powered to detect differences between groups.
	47% (15 of 32) of people randomised to receive SHADE completed all 9 sessions. 54% (19 of 35) of people in the F2F group completed all sessions.
Kay-Lambkin et al. 2011	
Study size, design and location	Randomised controlled trial, n= 274. Australia.
	This is described as a large-scale replication of the Kay-Lambkin et al. 2009 study. It is not clear if there was any overlap between the 2 cohorts.
Intervention and comparator(s)	All people in the trial had 1 face-to-face session with a therapist and were then randomised to have either:
	• 9 sessions of face-to-face CBT and motivational interviewing with a therapist (F2F group, n=87)
	• Treatment with SHADE and minimal therapist assistance (SHADE group, n=97)
	• 9 sessions of person centred therapy with a therapist (PCT group, n=88)
Population	As for Kay-Lambkin et al. 2009.
Key outcomes	The primary outcomes were changes in depression, alcohol use and drug use at 3 months after treatment.
	People in the SHADE and F2F groups had significantly reduced PHQ-9 scores compared with the PCT group at 3 months (6.87 point reduction compared with 3.84 point reduction). There were no

	statistically significant differences between the SHADE and F2F groups.
	17% of people in the PCT group showed a 50% reduction in alcohol consumption at 3 months. 45% of people in the SHADE group reported the same reduction, 2.5 times greater reduction than people in the F2F and PCT group combined (28%). This difference was statistically significant (p=0.002).
Strengths and limitations	No power calculation is stated for this study and so it is unclear if it is adequately powered to detect differences between the groups.
	There is limited reporting of outcome data, with results pooled rather than giving outcomes per treatment group.
	30 of the 88 people (34%) randomised to SHADE completed all modules of the programme.
Kay-Lambkin et al. 2012	
Study size, design and location	Further analysis of outcomes for the 163 of 274 people from Kay-Lambkin et al. 2011 who provided responses at 3-month follow-up.
Intervention and comparator(s)	As for Kay-Lambkin et al. 2011.
Key outcomes	User perceptions of SHADE compared with face-to-face therapy, as a function of urban or rural residence.
	No difference between urban and rural residing people was reported for treatment preference, depression outcomes, or reduction in alcohol or cannabis use.
Strengths and limitations	As for Kay-Lambkin et al. 2011.
Abbreviations: BDI-II, Beck depression inventory II; PHQ-9, patient health questionnaire-9.	

Recently completed and ongoing studies

No recent, ongoing or in-development trials on the use of SHADE were identified in the preparation of this briefing.

Cost and resource impact

Technology costs

The license fee for SHADE ranges from £12 to £119 per licence, depending on the number of licences purchased. An average service would be expected to pay around £24 per licence (prices including VAT). In addition to the licence

cost, about 144 minutes of clinician time is needed in total per person (Kay-Lambkin et al. 2011). 144 minutes of band 5 PWP time costs £46, giving a total cost for SHADE of £70.

Costs of standard care

Resource consequences compared with standard care

Table 2 Comparison of SHADE to current treatments for depression

Treatment	Per treatment course per person		
	Existing cost	Cost using SHADE	Cost/saving
1 or 2 sessions of CBT-based guided self-help	£23	£70	£47 cost
Guided self-help (3-6 sessions)	£59	£70	£11 cost
Group-based CBT	£97	£70	£27 saved
Workshop-based CBT	£8	£70	£62 cost
1-to-1 face-to-face CBT	£560	£70	£490 saved
Antidepressant medication for 6 months (weighted average cost based on minimum daily dose)	£110	£70	£40 saved

The following costing assumptions have been made for SHADE:

- The SHADE user subscription is expected to cost on average around £24 per person (including VAT).
- SHADE may be delivered by a PWP; costs include 144 minutes of their time per person.
- The cost for training therapists is included in the licence fee.

Overall impact

Using SHADE 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-to-face CBT would release therapist time.

Cost and resource impact statement from the developer

The developer stated that SHADE offers recovery rates above the standard care for step 2 treatment, at lower costs than face-to-face care.

IAPT expert panel considerations

The expert panel considered the assessments of the therapeutic content, digital technical factors, clinical evidence and resource impact. They concluded that SHADE should not proceed to the evaluation in practice phase of this programme.

Technical assessment

The panel noted that acceptable scores were achieved in the DAQ domains of clinical safety, privacy and confidentiality, and technical stability. Remediation plans provided by CCBT were acceptable for issues in the DAQ domains of security, usability and accessibility, and interoperability. However, the technical assessors noted caution regarding the remediation plans for the accessibility issues, because they involved the planned change of platform from web programme to an app. Before the app could be considered in this programme it would need to undergo its own DAQ assessment.

Content assessment

The panel noted the unusual format of SHADE. The programme is delivered entirely through scrolling text with a voiceover reading the text aloud. The delivery is slow and users cannot skip ahead through content. The panel regarded that this may be very frustrating for users and challenging to their concentration and commitment. The panel also noted that while the American accent of the voiceover was chosen by a panel, it may be distracting to users in the UK.

The panel were keen to emphasise that they felt that a well-designed digital therapy tool for people with depression comorbid with alcohol and drug misuse would be welcome in IAPT services. However, they were concerned that a poor user experience of SHADE could deter users, and observed that poor treatment experience may dissuade people from seeking any further treatment.

Clinical evidence

The panel examined the 2 randomised controlled trials using SHADE and noted that although the outcomes reported in the studies were favourable, there studies were of low quality. This was because of problems with the power of the studies, a lack of detailed reporting of some outcomes and questions about whether there was overlap between the cohorts.

Cost and resource impact

The panel noted that SHADE would be cheaper than 1-to-1 or group-based CBT and antidepressant medication, and slightly more expensive than guided self-help or workshop-based CBT.

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 SHADE 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, national clinical director for mental health, NHS England and NHS Improvement.
- Professor Steve Pilling, professor of clinical psychology and clinical effectiveness, University College London.
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