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Computerised cognitive behaviour therapy for depression and anxiety

Review of Technology Appraisal 51

Technology Appraisal 97

Computerised cognitive behaviour therapy for depression and anxiety (review)

Ordering information

You can download the following documents from www.nice.org.uk/TA097

- The full guidance for this technology appraisal (this document).
- A quick reference guide, which has been distributed to healthcare professionals working in the NHS in England.
- Information for people with depression and anxiety, their families and carers, and the public.
- The assessment report – details of all the studies that were looked at.

For printed copies of the quick reference guide or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0979 (quick reference guide)
- N0980 (information for the public).

This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, 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.

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NOTE: This guidance replaces Technology Appraisal Guidance No. 51 issued in October 2002.

The Institute reviews each piece of guidance it issues.

The review and re-appraisal of the use of computerised cognitive behaviour therapy (CCBT) for depression and anxiety has resulted in a change in the guidance. In 2002, CCBT was not recommended. In this new guidance two CCBT packages have been recommended: Beating the Blues for the management of mild and moderate depression and FearFighter for the management of panic and phobia.

1 Guidance

This review concerns five specific packages for the delivery of computerised cognitive behaviour therapy (CCBT) accessed via a referral from a general practitioner (GP): three for depression (Beating the Blues, COPE and Overcoming Depression), one for panic/phobia (FearFighter) and one for obsessive-compulsive disorder (OCD) (OCFighter, previously known as BTSteps).

This guidance should be read in the context of the Clinical Guidelines on depression, anxiety and OCD*).

- 1.1 Beating the Blues is recommended as an option for delivering cognitive behaviour therapy (CBT) in the management of mild and moderate depression.
- 1.2 There is insufficient evidence to recommend the use of COPE and Overcoming Depression as a clinically or cost-effective option for the

* Available from www.nice.org.uk

management of depression, except as part of ongoing or new clinical trials that are designed to generate robust and relevant data on the clinical effectiveness of these specific CCBT packages.

- 1.3 FearFighter is recommended as an option for delivering CBT in the management of panic and phobia.
- 1.4 OCFighter (previously known as BTSteps) is not recommended as an option for delivering CBT in the management of OCD.
- 1.5 People currently using OCFighter, whether as routine therapy or as part of a clinical trial, should have the option to continue on therapy until the person, or the GP and/or specialist, consider it appropriate to stop.

2 Clinical need and practice

- 2.1 Mental disorders such as depression and anxiety are characterised by a number of symptoms. Diagnosis is made using the International Statistical Classification of Diseases and Related Health Problems – 10th Revision (ICD-10) or the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) (World Health Organization 1992 and American Psychiatric Association 1994, respectively).
- 2.2 Depression refers to a wide range of mental health problems characterised by the absence of positive affect (a loss of interest and enjoyment in ordinary things and experiences), low mood and a range of associated emotional, cognitive, physical and behavioural symptoms. Depression varies in severity, and individuals with major depression can be differentiated into those with mild, moderate and severe disease on the basis of symptom severity and impairment of functioning.
- 2.3 There are several anxiety disorders including generalised anxiety disorder (GAD), panic disorder, phobias (agoraphobia without panic disorder, agoraphobia with panic disorder, social phobias and specific [isolated] phobias) and OCD. Symptoms of depression and anxiety more often than not

co-exist. There is also often overlap between panic and phobias, with many people having both.

- 2.4 OCD is clinically distinct from the other anxiety disorders. Obsessions are defined as being recurrent persistent thoughts, impulses or images that are intrusive and inappropriate and that cause marked anxiety or distress. Compulsions are repetitive, purposeful and ritualistic behaviours or mental acts, performed in response to obsessional intrusion, to a set of rigidly prescribed rules.
- 2.5 Depression and anxiety have a broad impact and are associated with poor quality of life, occupational disadvantage, impairment in interpersonal and family relationships, and suicide. Diagnosable depressive disorders are implicated in 40–60% of suicide attempts, with 10–15% of people with major depressive disorders eventually committing suicide. ICD-10 uses an agreed list of ten depressive symptoms and divides the common form of major depressive episode into four groups: not depressed, mildly depressed, moderately depressed and severely depressed.
- 2.6 In 2000, the Psychiatric Morbidity Survey conducted by the Office of Population Censuses and Surveys found prevalences, per 1000 people aged 16–74 years in England and Wales, of 187 for mixed anxiety and depression, 95 for GAD and 62 for depressive episode. Corresponding figures for phobia, panic disorder and OCD were 38, 13 and 38, respectively. In 1995, 9 in every 100 people with mental health problems who consulted their GP were referred to specialist services for assessment, advice and treatment.
- 2.7 There is wide variation in the recorded prevalence and incidence of anxiety and depression. However, many individuals do not seek treatment, and both anxiety and depression are often undiagnosed. Recognition of anxiety disorders by GPs is often poor, and only a small minority of people who experience anxiety disorders actually undergo treatment.

- 2.8 Anxiety and depression are currently managed by drug therapy or a range of 'psychotherapies' (a generic term to cover the predominantly talk-based psychological therapies in their various forms), or both. There is, however, wide variation in care practices among individual GPs. In addition to prescribed medication, support can include access to self-help material, exercise and referral for occupational therapy, vocational rehabilitation and counselling. Primary care counselling services are now being established in many primary care trusts (PCTs) in England. After an appropriate assessment, the counsellor can offer short-term therapeutic interventions for people with mild and moderate anxiety or depression or refer individuals with severe depression and anxiety to more specialised services. In 'stepped-care' approaches, the individual is given basic interventions at the start of therapy and is stepped up to more complex interventions as and when necessary. Although careful risk assessment is required, such approaches can theoretically minimise the need for more specialised services.
- 2.9 A broad range of psychotherapies is provided by a number of different health professionals in the NHS. The range includes CBT, behaviour therapy, interpersonal therapy, problem-solving therapy, non-directive counselling and short-term psychodynamic psychotherapy.
- 2.10 CBT is a generic term that refers to the pragmatic combination of concepts and techniques from cognitive therapy and behavioural therapy. Both of these use structured approaches based on the assumption that prior learning is currently having maladaptive consequences. The purpose of therapy is to reduce distress or unwanted behaviour by undoing this learning or by providing new, more adaptive learning experiences. The way in which CBT is delivered varies, depending on the individual's needs.
- 2.11 The effectiveness of CBT is supported by evidence from randomised controlled trials (RCTs). For many diagnostic groups, controlled trials indicate that approximately 50% of individuals with depression experience clinically

important improvement, which is similar to outcomes achieved with antidepressant drugs.

- 2.12 The behavioural component of CBT aims to reduce dysfunctional emotions and behaviour by altering the individual's behaviour and the factors that control it. Methods used may involve behavioural experiments to test irrational thoughts, graded exposure to feared situations, target setting and activity scheduling. The cognitive component attempts to reduce dysfunctional emotions and behaviour by altering individual appraisals and thinking patterns. Methods used include discussion of the cognitive model, diary keeping (developing awareness of thoughts, affect, behaviour and physical symptoms), examination of evidence for and against dysfunctional beliefs, cognitive rehearsal and the development of skills to challenge negative thoughts and dysfunctional assumptions.
- 2.13 Anxiety disorders are commonly treated by the CBT technique of 'self-exposure' in which individuals expose themselves to situations of increasing difficulty. Individuals are asked to record their thoughts and beliefs about the exposure situation before, during and after exposure. Behavioural treatment for OCD involves exposure to whatever evokes obsessions and prevents avoidance or neutralisation of the resulting anxiety. Cognitive methods aim to challenge the obsessive thoughts.
- 2.14 In comparison with other psychotherapies, CBT is brief, highly structured, problem-orientated and prescriptive, and individuals are active collaborators. The optimal length of therapy will vary among individuals. For mild and moderate depression, brief CBT of six to eight sessions over 10 to 12 weeks is usual. For moderate to severe depression, the duration is typically in the range of 16 to 20 sessions over 6 to 9 months. For anxiety the optimal range of duration of CBT is between 7 and 14 hours. For people with OCD in whom the degree of functional impairment is mild, up to 10 hours of CBT including exposure and response prevention (ERP) may be offered; for those with a higher degree of functional impairment more than 10 hours of CBT that

includes ERP should be offered. CBT-trained therapists can be from a number of disciplines and may include clinical psychologists, mental health nurse specialists and psychiatrists.

- 2.15 There is evidence that some people prefer ‘talking therapies’ involving face-to-face contact with the therapist rather than drug treatment. However, access to counselling and psychotherapy services is restricted by the high level of demand, the limited availability of therapists – especially in some geographical areas – and a lack of clear referral criteria and pathways.
- 2.16 Computerised CBT (CCBT) is included as an option in the stepped-care model presented in the NICE clinical guideline for the management of depression in primary and secondary care and in the NICE clinical guideline for the management of anxiety (panic disorder, with or without agoraphobia, and GAD) in adults in primary, secondary and community care. A guideline for OCD has been published (see Section 8 – Related guidance).
- 2.17 Within step 2 of the NICE clinical guideline for the management of depression in primary and secondary care, CCBT is included as a more structured treatment alternative (together with problem solving, brief CBT or counselling) to initial interventions such as exercise or guided self-help.

3 The technology

- 3.1 CCBT is a generic term that is used to refer to a number of methods of delivering CBT via an interactive computer interface. It can be delivered on a personal computer, over the Internet or via the telephone using interactive voice response (IVR) systems. As with CBT, pre-therapy assessment is recommended to ensure that people are suitable for therapy, and individuals require ongoing monitoring and support. It is suggested that a wide range of health or social care personnel could be used to facilitate the sessions. Several CCBT packages are currently available. Each has been developed for a specific target group or groups and uses different CBT algorithms. The personnel required to implement CCBT can vary from psychiatrist to practice

nurse and the length of therapist's time will also vary depending on the programme.

- 3.2 Beating the Blues (Ultrasys plc) is a CBT-based package for people with anxiety and/or depression. It consists of a 15-minute introductory video and eight 1-hour interactive computer sessions. The sessions are usually at weekly intervals and are completed in the routine care setting (that is, GP practice). Homework projects are completed between sessions and weekly progress reports are delivered to the GP or other healthcare professional at the end of each session. These progress reports include anxiety and depression ratings and reported suicidality. No minimum reading age is specified.
- 3.3 COPE (ST Solutions Ltd) is a CBT-based system designed to help people with non-severe depression. COPE was developed as an IVR plus workbook-based system. It is also available as a network version (netCOPE). It assumes a minimum reading age of 11 years. People can phone as and when they wish. COPE is a 3-month programme with five main treatment modules. Suicide assessment questions are included and people are urged to contact their doctor if suicidal ideation or plans are experienced.
- 3.4 Overcoming Depression: a Five Areas Approach (a Calipso product from Media Innovations Ltd) is a CD-ROM-based CBT system for people with depression. The system consists of six sessions of about 45–60 minutes each. The sessions are delivered in a mixture of text, cartoon illustrations, animation, interactive text, sound and video. It assumes a minimum reading age of 9–12 years for all but one module. The CD-ROM training materials suggest that a practitioner reviews the person's use of the disc on three occasions over the course. Sessions are completed on a weekly basis.
- 3.5 FearFighter (ST Solutions Ltd) is a CBT-based package for phobic, panic and anxiety disorders. FearFighter was originally developed for a stand-alone personal computer (standaloneFF) but was later developed for use on the Internet (netFF). It is also available in a short version for educational purposes

(FFeducation). FearFighter assumes a minimum reading age of 11 years. FearFighter is divided into nine steps. Therapist contact for FearFighter is brief, with 5 minutes before the session and up to 15 minutes after each session. For netFF, therapist contact is by telephone or e-mail.

- 3.6 BTSteps (ST Solutions Ltd) (now called OCFighter) is designed to help people with OCD by helping them plan and carry out CBT on a day-to-day basis. BTSteps was developed as an IVR system plus workbook. It assumes a minimum reading age of 11 years. An Internet version is under development and will obviate the need for IVR and workbook. Helpline support is provided. BTSteps is divided into nine steps.
- 3.7 The availability of CCBT programmes permits increased treatment flexibility, especially for individuals who do not want, or who are not suitable for, drug therapy or who do not wish to interact with a therapist. Computerised delivery of CBT can also be used to support therapist sessions. CCBT may also be of benefit to individuals with, for example, agoraphobia and social phobias because it can be delivered at home. Minimal therapist appointment time is necessary for the types of CCBT that can be conducted at home, and the therapy has 24-hour availability for the individual to access at his or her convenience. CCBT systems can also make it possible for users to repeat sessions if they wish.
- 3.8 The total annual operating costs depend on whether the purchase price includes a dedicated computer system, technical support, training and clinical support. The cost per completed treatment episode is primarily dependent on the amount of facilitator input required, the level of qualification and training of the facilitator, and the number of individuals who could use the programmes in a given time period.

4 Evidence and interpretation

The Appraisal Committee (Appendix A) considered evidence from a number of sources (Appendix B).

4.1 Clinical effectiveness

- 4.1.1 The Assessment Report reports effect sizes (ESs) for the trials. An effect size (ES) quantifies the size of the difference within or between groups by relating it to the corresponding standard deviation. A positive ES indicates a favourable effect in the direction of the intervention against the comparator within or between groups. The ESs were not weighted. The literature on ESs suggests that an ES can be thought of as 'small' when ES = 0.2, 'medium' when ES = 0.5 and 'large' when ES = 0.8. The importance of these ESs will also depend on the clinical effectiveness of the comparator therapy in each comparison.
- 4.1.2 Fourteen studies (six RCTs, two non-RCTs and six non-comparative studies) were identified for the five packages included in the review. Some of trials had considerably more female than male participants, particularly in the case of depression. In most studies, the mean age of patients was in the range 30–45 years. In the majority of trials, patients were included who were also taking medications for their particular disorder. Multiple outcomes using multiple measures were collected in the trials.

Depression

Beating the Blues

- 4.1.3 Two RCTs (one unpublished) and one non-comparator trial (unpublished) were used in the assessment of Beating the Blues. However, the unpublished RCT was marked 'academic in confidence'; hence the results are not reported in this review. The published RCT contained 274 patients at baseline assessment but pre-treatment values were recorded in only 241 patients, and only around two-thirds of patients were assessed at the end of the follow-up period of 6 months. Randomisation was stratified according to whether drug treatment was also being received. All of the trials were conducted in a primary care setting in the UK and all trials recruited patients through GP referral or screening with the General Health Questionnaire (GHQ).

- 4.1.4 The published RCT compared Beating the Blues (n = 146) with treatment as usual (TAU) (n = 128), which was defined as 'whatever treatment their GP prescribed'. Beating the Blues statistically significantly improved scores for depression (Beck Depression Inventory [BDI] – the primary outcome in the trial on which power calculations were based), negative and positive attributional style (Attributional Style Questionnaire [ASQCoNeg/Co Pos]), and work and social adjustment (WSA) compared with TAU. It was found, from an informal investigation of interaction, that treatment interacted with severity for anxiety (Beck Anxiety Inventory [BAI]) and positive attributional style. ESs, calculated between Beating the Blues and TAU for the BDI, BAI and WSA, were 0.65, 0.25 and 0.31, respectively.
- 4.1.5 With regard to patient satisfaction for Beating the Blues, the published RCT found that Beating the Blues patients were significantly more satisfied (as measured on a single item) with treatment than TAU patients, although values were not reported. In the submission from the manufacturer of Beating the Blues, an unpublished paper discussing the credibility and satisfaction of the programme was included. This open trial reported that nine out of ten patients stated that they would recommend the programme to others and over half stated that it was better than any other treatment that they had received.

COPE

- 4.1.6 Two non-comparator trials were used in the assessment of COPE (n = 39 and n = 41 patients), and the follow-up period for both was a maximum of 12 weeks. One trial was conducted in the UK and the other in both the USA and the UK, over the telephone. Recruitment for one of the studies was through self-referral and the other was through self- and healthcare professional-referral. Both trials reported information on patient history, such as duration of symptoms and previous therapy or medication. Only one of the trials gave reasons for loss to follow-up. In one of the trials, it was reported that patients felt comfortable with the system, found it easy to use and found

the booklets helpful, while 75% of the 28 completers said that COPE had improved the quality of their lives.

Overcoming Depression: a Five Areas Approach

4.1.7 One non-comparator trial was used in the assessment of Overcoming Depression (n = 20), with a follow-up period of 3 months. The trial was conducted in the UK. Recruitment in this trial was through consecutive referrals to a clinical psychology service. The trial did not report information on patient history or reasons for loss to follow-up. Of those who gave an opinion, all (n = 15) stated they would recommend the programme to others. At 6 weeks, 60% rated treatment usefulness as 'a lot' and 40% as 'a little'. At the end of treatment, 80% said they would prefer a CD-ROM over book treatment.

Panic/phobia

FearFighter

4.1.8 Two RCTs and two non-RCTs were used in the assessment of FearFighter. The total numbers of patients in the trials ranged from 27 to 93, with follow-up periods ranging from 1 to 4 months. Two of the trials were conducted in a secondary care setting in the UK, and two were conducted in non-healthcare settings in the UK. Three of the trials used a mixture of self- and healthcare professional-referral, whereas one used self-referral only. All the trials reported information on patient history, such as duration of symptoms and previous therapy or medication, but only the two RCTs reported reasons for loss to follow-up.

4.1.9 When FearFighter was compared with therapist-led cognitive behaviour therapy (TCBT), the results of the non-RCT showed that both groups (FearFighter n = 54; TCBT n = 31) improved statistically significantly from pre-treatment scores, although the TCBT group scores were more severe at baseline. An ES, calculated between FearFighter and TCBT for Fear

Questionnaire (FQ) total, was -0.12 . For the RCT (FearFighter $n = 37$; TCBT $n = 39$), there was a large number of drop-outs, with 30 patients lost to follow-up at 1 month. Both the FearFighter and TCBT groups improved statistically significantly at 3 months compared with baseline. ESs, calculated between FearFighter and TCBT for Main Problems (MP), Goals, Global Phobia and WSA, were -0.22 , 0.26 , -0.89 and -0.04 , respectively. A relaxation group ($n = 17$) was also included in this RCT. The relaxation group had no statistically significant improvement compared with the CCBT and TCBT groups. Almost twice as many patients dropped out of the FearFighter group than TCBT, although an intention-to-treat (ITT) analysis was carried out.

- 4.1.10 For the RCT that compared FearFighter ($n = 45$) with another computer programme ($n = 23$) (also delivered by the Internet) with cognitive components but no exposure (Managing Anxiety), both groups improved statistically significantly from baseline. An ES, calculated between FearFighter and Managing Anxiety for Total Phobia, was -0.19 . At the 1-month follow-up, FearFighter was statistically significantly more effective than the other computer programme on some measures.
- 4.1.11 One non-RCT compared the two delivery methods of FearFighter. Delivery of FearFighter in a clinical setting comprised seven sessions ($n = 17$), whereas the Internet group had unlimited access at home over a 12-week period ($n = 10$). Both groups improved statistically significantly on all measures. An ES, calculated between groups for FQ total, was -0.11 .
- 4.1.12 With regard to patient satisfaction, only one RCT reported ratings of treatment helpfulness and found no statistically significant differences between FearFighter, TCBT and relaxation. Satisfaction ratings in the other RCT did not differ statistically significantly between FearFighter and the Managing Anxiety programme. In one of the non-RCTs, Internet users were said to be generally satisfied, although no data were reported. Three of ten Internet users said they would have preferred face-to-face guided self-help to Internet-guided self-help.

Obsessive-compulsive disorder

BTSteps (now OCFighter)

- 4.1.13 Two RCTs and two non-comparator trials were used in the assessment of BTSteps. The total numbers of patients in the trials ranged from 21 to 218, with follow-up periods ranging from 14 to 22 weeks. Patient history and socio-economic information were reported in three of the studies, but none of the trials reported reasons for loss to follow-up. Two of the trials were conducted in the UK, one in the US and Canada, and one was conducted at two centres in the US and UK. Three of the four studies used DSM-III-R criteria for diagnosis, and one used ICD-10. Both of the RCTs had methodological problems; one did not use blind assessment or did not report reasons for loss to follow-up and the other did not report the method of randomisation, use blind assessment (except for a subgroup of 41% that was rated blind at the two main time periods) and did not report reasons for loss to follow-up.
- 4.1.14 One RCT compared BTSteps (n = 74) with TCBT (n = 69) and relaxation (n = 75). TCBT was found to be statistically significantly more effective than BTSteps at 14 weeks post treatment. ESs, calculated between BTSteps and TCBT for the Yale-Brown Obsessive Compulsive Scale (Y-BOCS), the Hamilton Rating Scale for Depression (HAM-D) and the Work and Social Adjustment Scale (WSA), were -0.45, -0.25 and -0.23, respectively. Relaxation was shown to be ineffective compared with BTSteps and TCBT.
- 4.1.15 The other RCT compared BTSteps plus scheduled support (n = 22) with BTSteps plus on-demand support (n = 22). Statistically significant greater improvement was reported in the scheduled support group at 17 weeks. An ES of 0.77 was calculated between the groups for the Y-BOCS.
- 4.1.16 With regard to patient satisfaction, one of the RCTs reported that patients who received TCBT or BTSteps were significantly more satisfied than patients who received relaxation, and patients treated with TCBT tended to be more satisfied than patients who used BTSteps. Another separate report also found

that when patients who had received BTSteps went on to clinician-guided care (n = 9), patients were statistically significantly more satisfied with TCBT than BTSteps.

4.2 Cost effectiveness

4.2.1 The Assessment Group identified one published economic evaluation. No formal analyses of cost effectiveness were included in the manufacturer submissions. The Assessment Group developed its own economic models for the three disease areas: depression, panic/phobia and OCD.

Depression

4.2.2 One published economic study detailed a cost-effectiveness analysis of Beating the Blues versus TAU. Data on resource use were collected prospectively alongside the clinical effectiveness trial. The costs of Beating the Blues were supplied by the manufacturer. The study covered a wide range of NHS resource usage, and estimates were also made of the indirect costs of lost production (costs were reported separately with and without indirect costs). Resource use data were collected for the period 6 months prior to study entry and for the 8 months' duration of the study. Comparisons were made between the mean costs of Beating the Blues and TAU using a bootstrapping technique to generate 95% confidence intervals (CIs). The analyses were conducted on an ITT basis and revealed that the mean service cost for CCBT was £397 compared with £357 for TAU, resulting in a mean incremental service cost of £40 (90% CI, -£28 to £148). Total costs including lost employment were less for the Beating the Blues group at £533 compared with £900 for TAU. Data on reported clinical outcomes were combined with cost data to produce a cost per point reduction in the BDI and a cost per symptom-free day. A cost-utility analysis was undertaken by applying a utility value to days with and without symptoms. The mean number of depression-free days was 89.7 (standard deviation [SD] 74.2) for Beating the Blues compared with 61 (SD 67.1) for TAU. From a published review of utilities studies of patients, figures of 0.59 and 1.0 for depression days and

depression-free days, respectively, were taken, resulting in an estimated quality-adjusted life year (QALY) gain of 0.032, or a cost per QALY gained (CQG) of £1250. Valuing a one-unit improvement in the BDI at £40 was associated with an 81% chance of Beating the Blues being cost effective.

- 4.2.3 The Assessment Group developed a decision analytic model, which was used to assess the cost effectiveness of the three products (Beating the Blues, COPE and Overcoming Depression). The model compared CCBT with TAU over an 18-month period. The main model results were based on the initial distribution over the three severity classes from the Beating the Blues trial. A subgroup analysis was performed to examine the variation in cost effectiveness by severity of depression. The Assessment Group presented two scenarios in the model: one assumed patients received one cycle of CCBT, and the second assumed 70% of patients relapsed and received a second cycle of CCBT; this relapse rate equals the relapse rate for traditional CBT. A sensitivity analysis was carried out for the one cycle of CCBT.
- 4.2.4 The Assessment Group reported the costs resulting from the following: licence fees, computer hardware, screening of patients for suitability, clinical support, capital overheads and training of staff. The basic principles of costing were very similar for all three products; however, the Assessment Group assumed a lower screening time for COPE. CCBT also had an impact on reducing the level of depression compared with TAU, which has consequences for use of other services.
- 4.2.5 The Assessment Group used utility values obtained from a study that provided data on 62 patients with BDI total scores and Euroqol EQ-5D. Mean scores for three depression categories were estimated: mild to moderate 0.78 (SD 0.20), moderate to severe 0.58 (SD 0.31) and severe 0.38 (SD 0.32). For the minimal category, it was assumed that the mean score was 0.88 (SD 0.22).

Beating the Blues

- 4.2.6 Mean package costs (cost per patient) for Beating the Blues were estimated at £219.30 for a single-copy licence and £104.62 for a 20-copy licence. These estimates come with large ranges, reflecting the uncertainties around the unit costs and the expected numbers of treated patients at practice level. The transition probabilities for Beating the Blues were estimated from changes on the BDI in the pivotal trial.
- 4.2.7 The CQG of Beating the Blues over TAU was reported as £1801 for the single-copy licence (assumed mean number of patients treated 37.5). If the licence was to be offered to PCTs for 20 copies (assumed mean number of patients treated 750) the CQG would fall to £415. Running the model for one cycle increased the CQG to £4961. For the subgroup analysis, the results showed that the mild to moderate group had the lowest mean CQG of £1802, but there was little difference among groups.

COPE

- 4.2.8 Two costings were undertaken for practice level licences, one assuming that the practice would provide computer access and the other assuming that patients could access the Internet from home or some other location (cost-free to the NHS). Both options included the cost for a telephone support line. The estimated mean cost per patient was £171.30 for no practice computer access and £195.86 with practice computer access. At PCT level, the cost fell to £110.53. These estimates come with large ranges, reflecting the uncertainties around the unit costs and the expected numbers of treated patients at practice level. For COPE, the transition probabilities were estimated from one of the non-comparative trials and no individual level data were available.
- 4.2.9 The CQG of COPE over TAU was reported as £7139 when modelled using a GP practice licence (assumed mean number of patients treated 37.5). If the licence were to be offered to PCTs (assumed mean number of patients

treated 750), the CQG would fall to £3915. Limiting the model to one cycle increased the CQG to £16,469.

Overcoming Depression: a Five Areas Approach

4.2.10 Costs were estimated for a single licence with one and two copies and a PCT licence of 20 copies at £72.64 and £66.64 per treated patient, respectively. These estimates come with large ranges, reflecting the uncertainties around the unit costs and the expected numbers of treated patients at practice level. For Overcoming Depression, the transition probabilities were estimated from individual level data provided by the non-comparative trial.

4.2.11 The incremental CQG of Overcoming Depression over TAU was £5391 when modelled using a GP practice licence (assumed mean number of patients treated 37.5). If the licence was to be offered to PCTs (assumed mean number of patients treated 750), the CQG would fall to £4856. Limiting the model to one cycle increased the CQG to £26,087.

Panic/phobia

FearFighter

4.2.12 The Assessment Group developed a discrete-state Markov model in which patients were assumed to be either well or having panic/phobia. The model runs for four cycles, each lasting 3 months. The costs associated with the product in terms of licence fees, computer hardware, screening of patients for suitability, clinical support, capital overheads and the training of staff were the same as those for netCOPE. Utilities data were obtained from the European Study of the Epidemiology of Mental Disorders (ESEMED) survey.

4.2.13 The estimated mean cost of FearFighter was £171.30 per patient if patients could access the Internet from home or some other location, and this increased to £195.86 if the practice had to provide computer access. At PCT level, the cost fell to £110.53 per patient. These estimates come with large ranges, reflecting the uncertainties around the unit costs and the expected

numbers of treated patients at practice level. If the disorder resulted in a lower throughput than for depression, then the average costs would be higher than for netCOPE.

4.2.14 No clear dominance between interventions was reported. FearFighter achieved a CQG of £2380 over relaxation when modelled using a GP practice licence (assumed mean number of patients treated 37.5). TCBT, in the same GP practice licence scenario, resulted in a CQG over FearFighter of £17,608. A sensitivity analysis using costs at PCT level (assumed mean number of patients treated 750) resulted in the CQG of FearFighter over relaxation being reduced to £901 and the CQG of TCBT over FearFighter being increased to £25,432.

4.2.15 As part of the response to the Appraisal Consultation Document (ACD) the manufacturer of FearFighter submitted an economic analysis by the same author as that of the published analysis for Beating the Blues. Costs for FearFighter and TCBT used in this model were similar to those used by the Assessment Group. Outcomes analysed in the model were self-rating of (i) the patient's main problem and (ii) global phobia. Cost effectiveness was presented as cost per unit improvement in either one of these two scales. A 'net-benefit' approach was used to present cost-effectiveness acceptability curves based on a range of hypothetical values that society would place on a unit improvement on the two scales. Valuing a one-unit improvement in the main problem score at £60 was associated with a 50% chance of FearFighter being cost effective over relaxation. No incremental analysis of TCBT versus CCBT was presented, nor was a CQG estimate.

Obsessive-compulsive disorder

BTSteps (now OCFighter)

4.2.16 The Assessment Group developed a decision-tree model for OCD with two cycles. The model runs for 18 months. The costs associated with the product in terms of licence fees, computer hardware, screening of patients for

suitability, clinical support, capital overheads and the training of staff were the same as for netCOPE. The only difference was that the number of patients with OCD was significantly lower. The lower throughput of BTSteps compared with COPE resulted in a lower level of helpline support required per copy of the programme used. Otherwise, the total costs were the same as for COPE. This resulted in costs per treated patient that were substantially higher than the other CCBT products. For BTSteps, the model drew heavily on one of the RCTs. The Assessment Group found little evidence on the health state utility values of people with OCD but used the outcomes of the ESEMeD survey in which changes in scores on the obsessive scale of the Y-BOCS were correlated with changes mapped on the EQ-5D. They found that a one-point reduction in the obsessive scale was equivalent to a 0.04 reduction in the EQ-5D preference scale. The Assessment Group subsequently used changes on the Y-BOCS from the pivotal trial to define a group of responders and non-responders and calculated relevant EQ-5D values: 0.92 (SD 0.07) for responders (that is, they have a Y-BOCS value equivalent to a post-treatment score of 16) and 0.80 (SD 0.15) for non-responders (that is, they have a Y-BOCS value equivalent to the mean treatment score assumed to be 25).

4.2.17 Two costings were carried out for a practice level licence, one assuming that practices would provide computer access and the other assuming that the patients could access the Internet from home or some other location. The estimated mean cost per patient was £837.23 and £714.49, respectively. At PCT level, assuming the recruitment of 249 patients, the cost fell to £248.83 per patient. These estimates come with large ranges, reflecting the uncertainties around the unit costs and the expected numbers of treated patients at practice level.

4.2.18 In the base-case analysis, when modelled using a GP practice licence (assumed mean number of patients treated 7.5), BTSteps was dominated by TCBT and had an incremental CQG of £52,000 versus relaxation. A sensitivity analysis using costs at PCT level (assumed mean number of patients treated 249) resulted in a CQG for TCBT over BTSteps of £22,484,

and of BTSteps over relaxation of £15,581. An additional, intermediate, scenario was also reviewed that included a maximum licence fee of £200 per patient for the GP practice licence. This intermediate scenario resulted in BTSteps being dominated by a scenario in which a proportion of patients receive TCBT and a proportion of patients receive relaxation.

4.2.19 As part of the response to the ACD the manufacturer of BTSteps submitted an economic analysis by the same author as that of the published analysis for Beating the Blues. BTSteps was assumed to cost £200 per person (the price charged by the manufacturer for a minimum of 30 users). Ten 1-hour sessions of therapist time were provided to the TCBT group costed at £69 per hour. As outcome measure the model used incremental changes in scores on the Y-BOCS from baseline. Cost effectiveness was presented as cost per unit improvement on the Y-BOCS. A 'net-benefit' approach was used to present cost-effectiveness acceptability curves based on a range of hypothetical values that society would place on a unit improvement on the Y-BOCS. Valuing a one-unit improvement in the Y-BOCS score at £50 was associated with a 50% chance of BTSteps being cost effective over relaxation. No incremental analysis of TCBT versus CCBT was presented; nor was a CQG estimate.

4.3 Consideration of the evidence

4.3.1 The Committee reviewed the data available on the clinical and cost effectiveness of CCBT for the management of depression and anxiety, having considered evidence on the nature of the condition and the value placed on the benefits of CCBT by people with depression and anxiety, those who represent them, and clinical experts. It was also mindful of the need to take account of the effective use of NHS resources.

4.3.2 The Committee noted that NICE guidelines have been published for the management of depression in primary and secondary care and for the management of anxiety (panic disorder, with or without agoraphobia, and GAD) in adults in primary, secondary and community care. Both guidelines

place CCBT as an option only within step 2 of a stepped-care approach. The Committee also heard testimony from the patient and clinical experts that there are several methods available for delivering CBT in the NHS and that the comparators used in the studies reviewed had excluded some important ones such as group CBT and bibliotherapy. The Committee appreciated that CCBT would not necessarily be the best delivery method for CBT for all patients. However, the Committee heard that enabling patient choice between various methods of delivery of CBT was likely to increase the motivation to comply with treatment. The Committee was also informed by the experts that, in general, the CCBT packages being appraised could be considered as being as 'safe' as CBT in that the information and guidance delivered by these packages were similar to that given in a standard CBT approach. The experts also stated that CCBT would not be appropriate for the management of severe depression.

- 4.3.3 The Committee carefully considered all the comparators that had been used in the trials. The Committee heard testimony from the clinical experts that TAU was an appropriate comparator for CCBT for patients with mild and moderate depression, but that relaxation was considered an imperfect comparator for the management of panic and phobia and OCD. The Committee also noted that TCBT could be considered as an appropriate comparator for all three disease areas but took on board the issue of the lack of availability of trained therapists and consequently the long waiting times for treatment.

Depression

- 4.3.4 The Committee noted that the evidence base for Beating the Blues had improved since the previous appraisal. In particular, more data relating to the single RCT had become available. The results from this RCT showed that Beating the Blues was more effective than TAU on a number of outcome measures, and the ES for the Beck Depression Inventory was particularly notable. The Committee noted some limitations in the evidence base which

were only partially reflected in the uncertainty around the cost-effectiveness estimates. However, the Committee was persuaded that the evidence base was sufficient for the CQG estimate for Beating the Blues to be acceptable.

- 4.3.5 The Committee noted that there is no RCT evidence for COPE or Overcoming Depression for the management of depression. Therefore, the Committee could not establish with a reasonable degree of certainty that either of these packages is a clinically or cost-effective method of treating people with depression over and above other management options such as TAU. Furthermore, it was not able to conclude that the CCBT packages for depression could be considered to be equivalent as in a 'class', because of the differences between the packages' presentation, style and complexity.
- 4.3.6 Therefore, on the basis of currently available data, the Committee concluded that, of the three CCBT packages for depression, only Beating the Blues could currently be recommended as an option for delivering CBT in the management of mild and moderate depression as outlined in the current NICE clinical guideline for the stepped-care management of depression in primary and secondary care (see Section 8 – Related guidance).

Panic/phobia

- 4.3.7 The Committee considered the evidence base for FearFighter for the management of panic and phobia, and noted that there was one relevant RCT that established that FearFighter was more effective than TCBT on one outcome measure, but less effective on others.
- 4.3.8 The Committee noted that the use of FearFighter could be considered to be cost effective versus relaxation. It was mindful, however, of the fact that the comparison of TCBT versus CCBT resulted in a CQG of £18,000 (with a sensitivity analysis increasing this to £25,000 depending on the purchasing scenario). On this basis, TCBT would be the preferred option for the management of panic/phobia. However, the Committee considered that, not only were both TCBT and CCBT to some extent effective, but also that there

was substantial uncertainty in the greater effectiveness of TCBT implied by the economic model.

- 4.3.9 The Committee concluded that it was acceptable to consider FearFighter as an option for delivering CBT in the management of panic/phobia as outlined in the current NICE clinical guideline for the stepped-care management of anxiety (panic disorder, with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care (see Section 8 – Related guidance).

Obsessive-compulsive disorder

- 4.3.10 The Committee considered the RCT evidence for BTSteps for the management of OCD in which BTSteps was compared with TCBT and relaxation. The Committee was concerned with the methodology reported for the RCT with regard to aspects of the study design. The Committee noted that in the randomised clinical trials BTSteps was never more effective than TCBT. It also noted that patients were more satisfied with TCBT than with BTSteps.
- 4.3.11 Regarding the cost effectiveness the Committee noted that there were a number of scenarios modelled for purchasing BTSteps in the NHS. In all these scenarios TCBT was more cost effective than BTSteps and relaxation. Only in the scenario in which an average PCT has to purchase a bulk licence is BTSteps more cost effective than relaxation. However, the Committee did not consider that an average PCT should reasonably seek to treat a mean number of 250 patients with BTSteps when TCBT is the most cost-effective option for that PCT to deliver CBT.
- 4.3.12 The Committee considering both the clinical and cost-effective evidence concluded that BTSteps should not be recommended as an option for delivering CBT in the management of OCD.

5 Recommendations for further research

5.1 Future studies of CCBT should be RCTs that include an ITT analysis, to take account of drop-outs, and record and report any adverse effects, including major self-harm or suicide. They should also collect appropriate information on costs and health-related quality of life – that is, data should be collected using generic preference-based measures (in conjunction with condition-specific instruments) because they facilitate the calculation of QALY. They should also attempt to identify the type of individual within any one treatment group (that is, depression, panic/phobia or OCD) most likely to benefit from CCBT. Consideration should be given to undertaking these RCTs within a GP setting, because most patients with depression and anxiety are currently treated in this setting and patients recruited to the trials should not be self-referrers. Consideration should also be given to whether the packages can be used effectively by patients of all ages and from all ethnic groups. The majority of consultees thought that specific RCTs that would be useful include:

- pragmatic RCTs for CCBT packages in a stepped-care programme
- comparisons of CCBT with other self-help comparators that are currently used by this patient group, such as bibliotherapy and exercise
- comparisons of CCBT with placebo
- comparisons of CCBT with brief and longer duration TCBT as well as group TCBT
- head-to-head trials between the packages for depression.

6 Implications for the NHS

6.1 Since the final appraisal determination was issued, NICE has carried out more detailed costing analysis to support implementation of the guidance. The following costing tools are available from the NICE website (www.nice.org.uk/TA097).

- A national costing report, which estimates the overall resource impact associated with implementation.
- A local costing template: a simple spreadsheet that can be used to estimate the local cost of implementation.

7 Implementation and audit

7.1 NHS organisations that offer treatment for people with depression and anxiety and general practitioners should review their current practice and policies to take account of the guidance set out in Section 1.

7.2 Local guidelines, protocols or care pathways that refer to the care of people with depression or anxiety should incorporate the guidance.

7.3 To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C.

7.3.1 A person with mild or moderate depression is offered Beating the Blues as an option for the management of the condition as outlined in the current NICE clinical guideline for the stepped-care management of depression in primary and secondary care.

7.3.2 A person with depression is offered CCBT with COPE or Overcoming Depression only as part of an ongoing or new clinical trial that is designed to generate robust and relevant data on the clinical effectiveness of these specific CCBT packages.

- 7.3.3 A person with panic or phobia is offered the option of FearFighter as an option for the management of the condition as outlined in the current NICE clinical guideline for the stepped-care management of anxiety (panic disorder, with or without agoraphobia, and generalised anxiety disorder) in primary, secondary and community care.
- 7.3.4 A person with OCD is not offered CCBT with OCFighter. A person who is currently using OCFighter as routine therapy or as part of a clinical trial should have the option to continue on therapy until the person, or the GP and/or specialist, consider it appropriate to stop.

8 Related guidance

- 8.1 This guidance replaces the following guidance issued by the Institute:

Guidance on the use of computerised cognitive behavioural therapy for anxiety and depression. *NICE Technology Appraisal Guidance* No. 51 (2002).

- 8.2 The Institute has issued the following related technology appraisal guidance:

Depression: management of depression in primary and secondary care. *NICE Clinical Guideline* No. 23 (2004). Available from: www.nice.org.uk/CG023

Anxiety: management of anxiety (panic disorder, with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care. *NICE Clinical Guideline* No. 22 (2004). Available from: www.nice.org.uk/CG022

Obsessive-compulsive disorder: core interventions in the treatment of obsessive-compulsive disorder and body dysmorphic disorder. *NICE Clinical Guideline* No. 31 (2005). Available from: www.nice.org.uk/CG031

Depression in children and young people: identification and management in primary, community and secondary care. *NICE Clinical Guideline* No. 28 (2005). Available from: www.nice.org.uk/CG028

9 Review of guidance

- 9.1 The review date for a technology appraisal refers to the month and year in which the Guidance Executive will consider whether the technology should be reviewed. This decision will be taken in the light of information gathered by the Institute, and in consultation with consultees and commentators.
- 9.2 The guidance on this technology will be considered for review in September 2008.

Andrew Dillon
Chief Executive
February 2006

Appendix A. Appraisal Committee members and NICE project team

A. Appraisal Committee members

NOTE The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets regularly and the Committee membership is split into two branches, with the chair, vice-chair and a number of other members between them attending meetings of all branches. Each branch considers its own list of technologies and ongoing topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Tony Ades

MRC Senior Scientist, MRC Health Services Research Collaboration, Department of Social Medicine, University of Bristol

Professor David Barnett (Chair)

Professor of Clinical Pharmacology, University of Leicester

Dr Richard Cookson

Senior Lecturer in Health Economics, School of Medicine Health Policy and Practice, University of East Anglia

Professor Christopher Eccleston

Director Pain Management Unit, University of Bath

Professor Terry Feest

Professor of Clinical Nephrology, Southmead Hospital

Ms Alison Forbes

Lay Representative, Health Consultant Associate, Eden Insight

Mr Adrian Griffin

Health Outcomes Manager, Johnson & Johnson Medical Ltd

Dr Elizabeth Haxby

Lead Clinician in Clinical Risk Management, Royal Brompton Hospital

Dr Rowan Hillson

Consultant Physician, Diabeticare, The Hillingdon Hospital

Dr Catherine Jackson

Clinical Lecturer in Primary Care Medicine, Alyth Health Centre, Angus, Scotland

Dr Katherine Payne

Health Economist, The North West Genetics Knowledge Park, The University of Manchester

Dr Ann Richardson

Lay Representative, Independent Research Consultant

Professor Philip Routledge

Professor of Clinical Pharmacology, College of Medicine, University of Wales, Cardiff

Dr Debbie Stephenson

Head of HTA Strategy, Eli Lilly and Company

Professor Andrew Stevens (Vice-Chair)

Professor of Public Health, University of Birmingham

Dr Cathryn Thomas

General Practitioner, and Senior Lecturer, Department of Primary Care & General Practice, University of Birmingham

Dr David Winfield

Consultant Haematologist, Royal Hallamshire Hospital, Sheffield

B. NICE Project Team

Each appraisal of a technology is assigned to a Health Technology Analyst and a Technology Appraisal Project Manager within the Institute.

Joanna Richardson and Meindert Boysen

Technical Leads, NICE project team

Alec Miners

Technical Advisor, NICE project team

Alana Miller

Project Manager, NICE project team

Appendix B. Sources of evidence considered by the Committee

- A The assessment report for this appraisal was prepared by School of Health & Related Research (SchARR).

Kaltenthaler E, Brazier J, De Nigris E, Tumur I, Ferriter M, Beverley C, Parry G, Rooney G, Sutcliffe P. *Computerised cognitive behaviour therapy for depression and anxiety update: a systematic review and economic evaluation*. December 2004

- B The following organisations accepted the invitation to participate in this appraisal. They were invited to make submissions and comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD). Consultee organisations are provided with the opportunity to appeal against the Final Appraisal Determination.

I Manufacturer/sponsors:

- Media Innovations Ltd
- Mental Health Foundation
- ST Solutions Ltd
- Ultrasis

II Professional/specialist and patient/carer groups:

- Association of British Healthcare Industries (ABHI)
- Anxiety Care
- British Association for Counselling and Psychotherapy
- British Association of Behavioural and Cognitive Psychotherapies
- British Psychological Society
- Counsellors and Psychotherapists in Primary Care
- Department of Health
- Mental Health Foundation

- National Phobics Society
- Royal College of Nursing
- Royal College of Psychiatrists
- South Cambridgeshire Primary Care Trust
- Triumph over Phobia

III Commentator organisations (without the right of appeal):

- Institute of Psychiatry
- National Primary Care Research & Development Centre
- National Public Health Service for Wales
- NHS Quality Improvement Scotland

C The following individuals were selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups. They participated in the Appraisal Committee discussions and provided evidence to inform the Appraisal Committee's deliberations. They gave their expert personal view on computerised cognitive behavioural therapy for depression and anxiety by attending the initial Committee discussion and/or providing written evidence to the Committee. They were invited to comment on the ACD.

- Dr Paul Blenkiron, Consultant in Adult and Community Psychiatry and Senior Lecturer, Bootham Park Hospital York nominated by the Royal College of Psychiatrists
- Professor Dave Peck, Professor of Health Research, University of Stirling nominated by the Institute of Psychiatry
- Miss Myrna Rollins, patient expert nominated by the National Phobics Society
- Mrs Celia J Scott Warren, patient expert nominated by Triumph over Phobia

Appendix C. Detail on criteria for audit of the use of CCBT for depression and anxiety

Possible objectives for an audit

An audit could be carried out to ensure the appropriateness of use of CCBT for depression and anxiety.

Possible patients to be included in the audit

An audit could be carried out on all people seen for depression or anxiety or OCD over a reasonable period for audit, for example 3 to 6 months. For this purpose, anxiety includes panic disorder, with or without agoraphobia, and generalised anxiety disorder.

Measures that could be used as a basis for an audit

The measures that could be used in an audit of CCBT are as follows.

Criterion	Standard	Exception	Definition of terms
1. A person with mild or moderate depression is offered Beating the Blues as an option for the management of the condition as outlined in the current NICE clinical guideline for the stepped-care management of depression in primary and secondary care	100% of people seen with mild or moderate depression	None	Clinicians will need to agree locally on how the offer of the option of management with CCBT is documented, for audit purposes. See the NICE clinical guideline for the management of depression for a description of the stepped-care approach.
2. A person with depression is offered the option of management	100% of people with depression who are	None	Clinicians will need to agree locally on how the offer of the option of

with CCBT with COPE or Overcoming Depression only as part of an ongoing or new clinical trial	offered CCBT with COPE or Overcoming Depression		management with CCBT is documented, for audit purposes. A clinical trial is designed to generate robust and relevant data on the clinical effectiveness of these specific CCBT packages.
3. An adult with panic or phobia is offered FearFighter as an option for the management of the condition as outlined in the current NICE clinical guideline for the stepped-care management of anxiety	100% of people seen with panic or phobia	None	Clinicians will need to agree locally on how the offer of the option of management with CCBT is documented, for audit purposes. See the NICE clinical guideline for the management of anxiety for a description of the stepped-care approach.
4. A person with OCD is offered CCBT with OCFighter	0% of people with OCD	The person is currently using OCFighter as routine therapy or as part of a clinical trial and such therapy should have the option to continue until the person, or the GP and/or specialist consider it appropriate to stop	'OCD' means obsessive-compulsive disorder. OCFighter was previously known as BTSteps. Clinicians will need to agree locally on how the decision to continue management with OCFighter is documented, for audit purposes. A clinical trial is designed to generate robust and relevant data on the clinical effectiveness of this specific CCBT package.

Calculation of compliance

Compliance (%) with each measure described in the table above is calculated as follows.

$$\frac{\text{Number of patients whose care is consistent with the **criteria** plus number of patients who meet any **exception** listed}{\text{Number of patients to whom the **measure** applies}} \times 100$$

Clinicians should review the findings of measurement, identify whether practice can be improved, agree on a plan to achieve any desired improvement and repeat the measurement of actual practice to confirm that the desired improvement is being achieved.