The second Randomised Evaluation of the Effectiveness, cost-effectiveness and Acceptability of Computerised Therapy (REEACT-2) trial: does the provision of telephone support enhance the effectiveness of computer-delivered cognitive behaviour therapy? A randomised controlled trial

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Scientific summary

The REEACT-2 trial

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Scientific summary

Background

Depression is one of the most common reasons for consulting a general practitioner (GP) and its associated personal and economic burden is considerable. Although antidepressants remain an important treatment option, many patients and health-care professionals would like access to psychological therapy as an alternative or adjunct to drug therapy. Cognitive behaviour therapy (CBT) is the leading evidence-supported form of brief psychological therapy for people with depression, but the demand for CBT cannot be met with existing therapist resources. One promising alternative to therapist-delivered CBT that has the potential to increase access to psychological therapy is the provision of therapy via computers. The National Institute for Health and Care Excellence (NICE) guidelines recommend the provision of computerised CBT (cCBT) as an initial lower-intensity treatment for depression as part of a 'stepped care' approach in primary care. Much of the existing evidence for the short-term clinical effectiveness of cCBT for depression comes from research conducted by the developers of the cCBT programs. National Institute for Health Research-funded research [the Randomised Evaluation of the Effectiveness and Acceptability of Computerised Therapy (REEACT) trial] has recently shown that cCBT is no more effective than usual GP care and is not cost-effective. A possible explanation for the lack of effect is the low level of engagement with computer technology. Indirect evidence suggests that increasing the level of support that is offered beyond that which is routinely offered in NHS primary care psychological therapy services might increase uptake and, in turn, make the technology more effective. However, this has not been tested in a large-scale pragmatic trial conducted in primary care. The provision of a facilitated self-help program will increase the costs of cCBT, and the cost-effectiveness of a more intensively facilitated form of cCBT is not known. If psychological services were to begin routinely to offer cCBT with a higher level of support than is currently made available, then this should be on the basis of robust evidence of clinical effectiveness and cost-effectiveness. The REEACT-2 trial examines the potential of guided telephone facilitation to enhance the uptake and benefit of computer-delivered CBT.

Objectives

This was a fully randomised patient trial to examine the additional benefits of telephone facilitation and structured guidance alongside a free-to-use computer-delivered CBT package [MoodGYM (National Institute for Mental Health Research, Australian National University, Canberra, ACT, Australia)]. The comparator was a minimally supported mode of delivery of the same cCBT package that replicated the mode of delivery of cCBT, as offered in primary care in the NHS. The REEACT-2 study included a concurrent economic evaluation to meet the following specific aims:

- to establish the clinical effectiveness of a telephone-facilitated cCBT package compared with minimally supported cCBT over a 1-year trial follow-up period
- to establish the cost-effectiveness of a telephone-facilitated cCBT package compared with minimally supported cCBT over a 1-year trial follow-up period.

Methods

Design

This study was a multisite, pragmatic, open, two-arm, parallel-group randomised controlled trial with a concurrent economic evaluation. The design was a fully randomised comparative trial. Participants were

randomised using simple randomisation with allocation concealed. Treatment allocation and outcome measurement were not concealed.

Setting

Participants were recruited from UK-based GP practices in Bristol, Manchester, Sheffield, Hull and the north-east of England.

Participants

Potential participants were identified by (1) direct referral by a GP or health professional attached to a GP practice or (2) following a written approach by the GP after identification via GP practice database screening. Potential participants were eligible to participate in the trial if they were aged ≥ 18 years, scored ≥ 10 on a validated depression severity instrument [Patient Health Questionnaire-9 (PHQ-9)] and were not currently in receipt of cCBT or specialist psychological therapy.

Interventions

Participants were randomised to receive either minimally supported cCBT (MoodGYM alone) or telephone-facilitated cCBT. Each participant randomised to the telephone-facilitated cCBT arm was allocated a telephone support worker, who provided weekly telephone calls to (1) facilitate the use of a cCBT package (MoodGYM) and (2) engage in between-session exercises with problem formulation and adherence to CBT principles. All participants were also offered usual GP care.

Given the pragmatic design of the trial, no restrictions were imposed on the range of treatments that could be offered by a GP in either arm. The intervention programme was based on CBT and had been endorsed at the time of design of REEACT-2 by NICE in the initial treatment of depression in primary care. The cCBT program involved internet-based, interactive therapy sessions that could be accessed at the participant's home, in a central location close to the participant's home or at the GP practice, depending on patient preference and availability. All participants were given access to a free telephone helpline, in addition to which participants allocated to the telephone-facilitated cCBT arm were called on a weekly basis by a telephone support worker, who delivered structured guidance on the use of the cCBT program.

Main outcome measures

The primary outcome was depression at 4 months as indicated by a score of ≥ 10 on the PHQ-9. Secondary outcomes were depression severity at 4 and 12 months (PHQ-9) and anxiety [as assessed by the Generalised Anxiety Disorder Scale-7 items (GAD-7)], somatoform complaints (as assessed by the PHQ-15), health state utility (as assessed by the European Quality of Life-5 Dimensions questionnaire) and resource use at 4 and 12 months.

Results

Clinical effectiveness

One hundred and eighty-two participants were randomised to minimally supported cCBT and 187 participants were randomised to telephone-facilitated cCBT (MoodGYM). There was a difference in the severity of depression at 4 months and at 12 months, with lower levels of depression in the telephone-facilitated group. The odds of no longer being depressed (defined as a PHQ-9 score of < 10) at 4 months were twice as high in the facilitated cCBT group than in the minimally supported cCBT group [odds ratio (OR) 2.05, 95% confidence interval (CI) 1.23 to 3.42]. The benefit of telephone-facilitated cCBT was no longer significant at 12 months (OR 1.63, 95% CI 0.98 to 2.71). At 4 months the between-group difference in PHQ-9 scores was 1.9 (95% CI 0.5 to 3.3), with a standardised effect size (Cohen's *d*) of 0.32 ($p = 0.009$). At 12 months, there was no longer evidence of a between-group difference in PHQ-9 scores (0.9, 95% CI –0.5 to 2.3). Over the whole trial period, the between-group difference in PHQ-9 scores was 1.4 (95% CI 0.2 to 2.6).

There was a significant improvement in anxiety scores (GAD-7) when all time points were considered (between-group difference 1.1, 95% CI 0.1 to 2.3; $p = 0.037$). In the case of somatic complaints there was a borderline significant difference when all time points were considered (between-group difference 1.1, 95% CI 0.0 to 1.8; $p = 0.051$).

Scrutiny of computer records revealed that few participants completed all five sessions of either minimally supported or telephone-facilitated cCBT, but use was substantially higher among participants offered telephone facilitation.

Cost-effectiveness

Trial-based cost-effectiveness analyses showed gains in quality-adjusted life-years (QALYs) at a reduced cost when telephone facilitation was added to MoodGYM, suggesting that this was a dominant enhancement. In a more conservative sensitivity analysis, telephone facilitation was no longer cost saving but was likely to be cost-effective at £6933 per additional QALY gained. The addition of telephone facilitation was likely to be cost-effective at a £20,000 per QALY threshold (probability of cost-effectiveness of 0.55).

Conclusions

Our previous research (REEACT) has demonstrated that minimally supported cCBT is largely ineffective. Based on the results of REEACT-2, the provision of telephone facilitation appears to offer statistically significant benefits. Telephone facilitation of a free-to-use cCBT program (MoodGYM) resulted in reduced depression severity, and reduced the chances of being depressed in the short and medium term. Additional benefits were seen across secondary outcomes, including anxiety and somatoform complaints. The magnitude of effect was small to moderate and was comparable with that of other primary care-delivered psychological interventions. Telephone facilitation represented good value for money (i.e. was well within conventional thresholds used to determine value for money in the NHS). cCBT is one of a range of effective low-intensity psychological treatments that can be offered to patients, but only with telephone support.

Minimally supported cCBT (which is routinely offered in the NHS in many services) is likely to be ineffective. NHS services that currently offer cCBT should consider how best to support this technology, and this will require sufficient staff being available to offer guidance and facilitation by telephone. The results of the REEACT-2 study provide a template for telephone facilitation, which the NHS could adopt to deliver low-intensity psychological therapy at a higher volume.

The magnitude of benefits was modest, but was achieved using a low-cost low-intensity intervention.

Implications for health care

- In this trial for primary care patients with moderate depression, telephone-facilitated cCBT was clinically effective compared with minimally supported cCBT. Practice recommendations, such as those offered by NICE, and IAPT (Improving Access to Psychological Therapies) stepped models of care might usefully be re-examined in the light of these findings with due consideration of the level of support that should be offered alongside cCBT.
- Minimally supported cCBT (which is routinely offered in the NHS in many services) is ineffective and our research suggests that it should be offered only when there is sufficient staff in place to support this technology with guidance and facilitation by telephone. This can be offered by telephone according to structured delivery manuals, and allows support to be offered at low intensity and higher volume.
- Telephone-facilitated cCBT is likely to be cost saving or cost-effective to the NHS.

Recommendations for research

- The uptake and use of cCBT was not as high as expected. More research is needed to understand the reasons for lower uptake and more development is needed for cCBT products to evolve further, such that they are more acceptable to people with depression. This requires further research and innovation at the human–computer interface.
- People with depression commonly have coexisting anxiety and somatoform complaints. Although some benefits were observed in these symptoms, the cCBT materials did not specifically address these problems. Further research and development is needed to ensure that cCBT products are able to address coexisting common mental disorders within a single-treatment programme.
- cCBT is a form of self-help. It would be useful to know how cCBT compares with other forms of guided self-help, since computer-delivered therapy is not acceptable to a significant portion of patients. Large-scale pragmatic trials of treatments such as bibliotherapy or telephone-based psychological interventions are therefore needed.
- There is a need to examine the comparative effectiveness of cCBT and traditional face-to-face therapy in head-to-head trials.
- All effectiveness studies should be framed in primary care and conducted by researchers other than product developers.

Trial registration

This trial is registered as ISRCTN55310481.

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