A randomised controlled trial of computerised cognitive behaviour therapy for the treatment of depression in primary care: the Randomised Evaluation of the Effectiveness and Acceptability of Computerised Therapy (REEACT) trial

Elizabeth Littlewood,[1] Ana Duarte,[2] Catherine Hewitt,[3] Sarah Knowles,[4,5] Stephen Palmer,[2] Simon Walker,[2] Phil Andersen,[1] Ricardo Araya,[6,7] Michael Barkham,[8] Peter Bower,[5] Sally Brabyn,[1] Gwen Brierley,[1,9] Cindy Cooper,[10] Linda Gask,[5] David Kessler,[11] Helen Lester,[5,12†] Karina Lovell,[13] Usman Muhammad,[3] Glenys Parry,[10] David A Richards,[1,14] Rachel Richardson,[1] Debbie Tallon,[15] Puvan Tharmanathan,[3] David White[10] and Simon Gilbody[1*] on behalf of the REEACT Team

[1]Department of Health Sciences, University of York, York, UK
[2]Centre for Health Economics, University of York, York, UK
[3]York Trials Unit, Department of Health Sciences, University of York, York, UK
[4]Centre for Primary Care, Institute of Population Health, University of Manchester, Manchester, UK
[5]National Institute for Health Research (NIHR) School for Primary Care Research, Manchester Academic Health Science Centre, University of Manchester, Manchester, UK (previously National Primary Care Research and Development Centre, University of Manchester, Manchester, UK)
[6]Academic Unit of Psychiatry, University of Bristol, Bristol, UK
[7]Department of Population Health, London School of Hygiene and Tropical Medicine, London, UK
[8]Centre for Psychological Services Research, University of Sheffield, Sheffield, UK
[9]Medical Research Council (MRC) Epidemiology Unit, University of Cambridge School of Clinical Medicine, Cambridge, UK
[10]Clinical Trials Research Unit, School of Health and Related Research, University of Sheffield, Sheffield, UK
[11]Academic Unit of Primary Health Care, University of Bristol, Bristol, UK
[12]Primary Care Clinical Sciences, University of Birmingham, Birmingham, UK
[13]School of Nursing, Midwifery and Social Work, University of Manchester, Manchester, UK
[14]University of Exeter Medical School, University of Exeter, Exeter, UK
[15]School of Social & Community Medicine, University of Bristol, Bristol, UK

*Corresponding author
†In memoriam

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Scientific summary

A RCT of cCBT for the treatment of depression in primary care

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Scientific summary

Background

Depression is the most common mental health disorder in community settings and is estimated to become the second largest cause of global disability by 2020. It is one of the most common reasons for consulting a general practitioner (GP) and is associated with significant personal and economic burden. Antidepressant medication is an important treatment option for depression; however, many patients and health-care professionals would like to access psychological therapy as an alternative or adjunct to medication. A leading evidence-supported form of brief psychological therapy for people with depression is cognitive behaviour therapy (CBT), but unfortunately patient demand for CBT cannot be met from existing therapist resources. There is a need to increase patient access to psychological therapy and one potential way of achieving this might be the provision of CBT delivered via computer. The provision of computerised CBT (cCBT) is recommended in the National Institute for Health and Care Excellence (NICE) guidelines 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. Research conducted by independent researchers is needed to establish both the clinical effectiveness and the cost-effectiveness of cCBT in the short term and over the longer term. Whether or not free-to-use cCBT programs are as effective as commercial pay-to-use cCBT programs also needs to be determined. There is also a lack of research examining the acceptability of cCBT, both to patients and health professionals, as well as the issue of patient preference and its relationship to treatment uptake and effectiveness.

Objectives

The REEACT (Randomised Evaluation of the Effectiveness and Acceptability of Computerised Therapy) trial was a randomised controlled trial (RCT) of usual GP care versus the addition of one of two cCBT programs for the treatment of depression in adults. This included concurrent qualitative and economic evaluations.

The specific objectives of the REEACT trial were:

1. to establish the clinical effectiveness and cost-effectiveness of cCBT in addition to usual GP care compared with usual GP care alone over a 2-year trial follow-up period
2. to establish the acceptability (to patients and health professionals) of cCBT
3. to establish the differential clinical effectiveness and cost-effectiveness of a free-to-use cCBT program (MoodGYM; National Institute for Mental Health Research, Australian National University, Canberra, Australia) in comparison with a commercial pay-to-use cCBT program (Beating the Blues®; Ultrasis, London, UK) over a 2-year and longer-term time horizon.

Method

Design

A pragmatic, multicentre, three-armed RCT with concurrent economic and qualitative evaluations. The design included a fully randomised patient preference approach. Participants were randomised using simple randomisation (1 : 1 : 1) with allocation concealed. Treatment allocation and outcome measurement were not concealed.

Setting

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

Participants

Potential participants were identified (1) by 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 and over, scored 10 or above on a validated depression severity instrument [Patient Health Questionnaire-9 (PHQ-9)] and were not in receipt of cCBT or specialist psychological therapy.

Interventions

Participants were randomised to receive: (1) a free-to-use cCBT program (MoodGYM) plus usual GP care; (2) a commercial pay-to-use cCBT program (Beating the Blues) plus usual GP care; or (3) usual GP care alone. Given the pragmatic design of the trial, no restrictions were imposed on the range of treatments that could be offered by a GP as part of usual care. Both intervention programs were based on CBT and both have been endorsed by NICE in the initial treatment of depression in primary care. The cCBT programs involved internet-based interactive therapy sessions, which 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. Intervention participants received technical support and encouragement to complete the cCBT program via weekly telephone calls.

Main outcome measures

The primary outcome was self-reported symptoms of depression, assessed by the PHQ-9 at 4 months post randomisation. Secondary outcomes were: self-reported symptoms of depression (PHQ-9) at 12 and 24 months; global and generic measures of mental health, health-related quality of life and patient-level resource use, each at 4, 12 and 24 months; treatment preference; and participants' and health professionals' experiences of cCBT and perceptions of its acceptability.

Results

Clinical effectiveness: a total of 691 patients, aged 18–76 years, were recruited to the trial between August 2009 and March 2011, with 210 participants randomised to receive pay-to-use cCBT (Beating the Blues) plus usual GP care, 242 participants randomised to receive free-to-use cCBT (MoodGYM) plus usual GP care and 239 participants randomised to receive usual GP care alone. Analyses used intention-to-treat. There was no significant difference in depression at the primary outcome measured at 4 months for either Beating the Blues versus usual GP care alone [odds ratio (OR) 1.19, 95% confidence interval (CI) 0.75 to 1.88] or MoodGYM versus usual GP care alone (OR 0.98, 95% CI 0.62 to 1.56). There was no overall difference across all time points for either intervention compared with usual GP care alone in a mixed model (Beating the Blues vs. usual GP care alone, $p = 0.96$; and MoodGYM vs. usual GP care alone, $p = 0.11$). However, a small, but statistically significant, difference between MoodGYM and usual GP care alone at 12 months was found (OR 0.56, 95% CI 0.34 to 0.93). In a non-inferiority analysis, free-to-use cCBT (MoodGYM) was not shown to be inferior to pay-to-use cCBT (Beating the Blues) (OR 0.91, 90% CI 0.62 to 1.34; $p = 0.69$). There were no consistent benefits for either intervention when secondary outcomes were examined. Participants showed a preference for cCBT prior to randomisation; however, cCBT was equally ineffective for those with and without a strong preference. Despite the provision of regular telephone calls for technical support and encouragement, there was low uptake of the cCBT programs. There were no serious adverse events thought likely to be related to the trial intervention.

Cost-effectiveness: the trial-based cost-effectiveness analyses suggest that neither Beating the Blues nor MoodGYM was cost-effective compared with usual GP care alone. Beating the Blues was more expensive and resulted in fewer quality-adjusted life-years (QALYs) than usual GP care (dominated), and MoodGYM

resulted in fewer QALYs but at lower cost. Usual GP care alone compared with either cCBT intervention was also the cost-effective intervention in the majority of scenario analyses and was the intervention most likely to be cost-effective at a £20,000 per QALY threshold (probabilities ranging across scenarios from 0.545 to 0.619).

Qualitative evaluation: when exploring the reasons for poor engagement of the cCBT programs, it was found that depression often demotivated participants to access the computer programs in their own time and when left to their own devices. Some said that a greater level of therapeutic input would be needed to promote engagement. GPs did not believe that cCBT could be offered within primary care premises.

Conclusions

The benefits that have previously been observed in developer-led trials were not found in this large pragmatic RCT conducted in routine UK primary care services. The benefits of cCBT when added to routine primary care were minimal and there was relatively low uptake of this mode of therapy.

Implications for health care

- In this trial for patients with moderate or severe depression powered to detect non-inferiority, technically supported cCBT in addition to usual GP care was no more effective than usual GP care alone. Practice recommendations such as those offered by NICE and Improving Access to Psychological Therapies stepped models of care might usefully be re-examined in the light of these findings.
- We consider that, where cCBT continues to be offered within the portfolio of low-intensity psychological treatment, there should be early follow-up in primary care to identify patients for whom the intervention may be unsuitable.
- Commissioners of services should take note of our findings that commercially produced products may add little benefit to usual GP care.
- We found no substantial difference in outcomes between the commercially produced product (Beating the Blues), when offered in addition to usual GP care, and the free-to-use product (MoodGYM), which is clearly less costly for the NHS.
- Free-to-use products such as MoodGYM could be offered in response to patient choice. However, our overall finding of the relative lack of benefit of these programs in addition to usual GP care should also be taken into account in this context.

Recommendations for future research

There remains a clinical and economic need for effective low-intensity psychological treatments for depression. Trials of alternative low-intensity treatments such as telephone-guided bibliotherapy, telephone-guided self-help or more intensively guided cCBT are needed. All such studies should be framed in primary care and conducted by researchers other than product developers. In the longer term, if computers are to be used to deliver psychological treatment with minimal therapist input, then there needs to be improved patient experience and engagement through greater personalisation of treatment packages. This requires further research and innovation at the human–computer interface.

Trial registration

This trial is registered as ISRCTN91947481.

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Editorial contact: nihredit@southampton.ac.uk

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