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Project title: Support for computerised therapy for patients with depression/anxiety: a factorial randomised controlled comparison of brief vs. enhanced support given by clinicians vs. assistants

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Plain language summary

BACKGROUND

Research has demonstrated that computerised Cognitive Behaviour Therapy (cCBT) can reduce symptoms of depression as much as face-to-face therapy, and more so than waiting lists or treatment as usual. cCBT's clinical outcomes, cost-effectiveness and acceptability may be influenced by the "human" support offered as an adjunct to it, which can vary in duration and can be offered by people with different levels of training and expertise. We do not know whether a clinician may be more effective but also more costly than an assistant, or whether offering extended support to patients using cCBT may lead to greater symptom improvement or satisfaction than brief support.

METHODS

In this two-by-two factorial randomised controlled trial, patients with depression had access to an 8-session cCBT programme called Beating the Blues (BtB) and were randomised to one of four types of scheduled phone support: brief-assistant, enhanced-assistant, brief-clinician, or enhanced-clinician. Brief support was 5 to 10 minutes per call whereas enhanced support was 20 to 30 minutes per call (up to 12 phone calls weekly or fortnightly). The clinician offering support was a PhD nurse with CBT qualifications and 20 years clinical experience and the assistant was a graduate psychologist with no clinical qualifications. We measured depression, anxiety and functioning at 12 weeks post-randomisation and we collected healthcare utilisation and patient experience data.

RESULTS

This study provides no evidence that an experienced specialist clinician offering support as an adjunct to cCBT for depression may confer different outcomes compared to an assistant, except for patient satisfaction. Likewise, the study provides no evidence that enhanced support may yield different outcomes than brief support, except for patient satisfaction. For those patients supported by the clinician, enhanced support led to a better patient experience than brief support. Patient experience by the clinician was not as good as that with the assistant but it improved with longer support and was no different to that with the assistant for patients who received enhanced support. The study's economic evaluation suggests that enhanced support costs more than brief support and that brief-clinician

support may offer better value for money than brief-assistant support but there is a high level of uncertainty associated with this conclusion.

Keywords

Depression, self-management, primary care, online interventions, improving access to psychological therapies (IAPT)

Summary of research findings

A. CLINICAL OUTCOMES (all results are at 12-weeks follow-up adjusted for baseline differences)

1. Attrition was high from referral (n=337) to randomisation (n=204, 61%). The majority of the referrals who were lost pre-randomisation (n=95, 28%) did not respond to an invite for an assessment. Of those assessed (n= 242), only a small proportion were ineligible (n=13/242, 5%) whereas the rest (n= 25/242, 11%) were eligible but chose not to participate in the study (n=17 did not return their consent form for unknown reasons and n=8 had a change in their circumstances). Just under half of those patients who were randomised completed their allocated intervention (n=89/204, 44%, completed at least 5 modules) and for a similar proportion of patients we had available follow-up data at the primary end-point (n=85/204, 42%, returned their postal questionnaires).

2. CONSORT reporting guidelines for a factorial RCT recommend that the results should be reported as comparisons between two groups for the main effects of each factor at the "control" level of the other factor, and NOT as comparisons between all four groups. In this trial, the planned analysis comparisons were for the main effect of clinician vs. assistant (at the brief-support level) and for the main effect of brief vs. extended support (at the assistant-support level). For WSA (and for BAI, GAD & PHQ) neither the main effect of clinician vs. assistant at the brief support level nor the main effect of brief vs. enhanced support at the assistant level were significant (For WSA: clin. vs. assist =1.9, 95%CI=-2.8, to 6.6, p=0.4; brief vs. enh.=-0.2, 95%CI=-5.7 to 5.4, p=0.9). For the BDI, the main effect of extended vs. brief support (at the assistant level) was almost significant (-7.4, 95%CI= -14.8 to 0.07, p = 0.05) and of clinician vs. assistant support (at the brief level) was not significant (-2.69, 95%CI= -9.03 to 3.65, p = 0.4). The means and standard deviations on the BDI and WSA for each comparison were:

a) Enhanced vs. Brief support: BDI: enhanced: pre=24.4 (11.3) post=12.4 (10.5) vs. brief: pre=28.3 (10.5) post=18.1 (13.4); WSA: enhanced: pre= 15.7 (9.4) post=11.9 (9.1) vs. brief: pre=18.6 (7.38) post=12.9 (9.7).

b) Clinician vs. Assistant support: BDI: clinician: pre=28.1 (11.2) post=17.3 (12.4) vs. assistant: pre=24.6 (10.6) post=14.0 (12.6); WSA: clinician: pre=18.5 (8.4) post=14.1 (8.7) vs. assistant: pre=16.2 (8.3) post=10.6 (9.9).

3. We have carried out a sub-group analysis of clinician vs. assistant for those patients receiving extended support only, and for brief. vs. extended support for those patients supported by the clinician only because of the loss of fidelity in the delivery of brief support by the assistant (it was longer than that originally specified in the protocol and longer than the corresponding brief support by the clinician); therefore, we did not compare brief vs.

extended support for those patients supported only by the assistant (because the gap between brief and extended support by the assistant was not wide enough) and we did not compare clinician vs. assistant for brief support only (because the brief support for the assistant and the brief support for the clinician were very different). For patients receiving enhanced support only, we found no differences between clinician and assistant on all outcome measures (for BDI: 6.7, -0.4 to 13.7, 0.06; for WSA: 4.2, -1.8 to 10.1, 0.2). For patients receiving clinician support only, we found no differences between brief and enhanced support on all outcome measures (BDI: 1.1, -5.7, 7.8, 0.7; WSA: 0.8, -4.3, 5.9, 0.8).

4. Therapeutic alliance scores were used as an indicator of patients' experience/satisfaction (the higher the scores the better the experience). We found no significant main effect on therapeutic alliance scores between extended and brief support at the assistant level whereas we found that the main effect of clinician vs. assistant was significant in favour of the assistant (-29.4, -47.4 to -11.4, $p=0.00$). In view of the fact that the assistant's brief support was longer than that originally specified in the protocol and longer than the corresponding brief support by the clinician, the main effects of the factorial design on patient experience are difficult to interpret. Descriptive statistics of therapeutic alliance scores per randomised group were: Brief-Clinician: $n=21$, $m=65.2$, $sd=36.1$; Extended-Clinician: $n=18$, $m=91.7$, $sd=33.2$; Brief-Assistant: $n=22$, $m=94.6$, $sd=24.8$; Extended-Assistant: $n=12$, $m=103.6$, $sd=15.4$. For patients supported by the clinician only, enhanced support led to a better patient experience than brief support (26.5, 3.83, to 49.14, 0.02).

After adjusting for duration of support and for differences in patient baseline characteristics and other therapy variables (e.g. number of computer sessions completed), therapeutic alliance scores remained significantly higher for the assistant than the clinician (mean difference, 95%CI, $p: -20.8, -38.6$ to $-3.1, 0.02$); however, the difference between clinician and assistant on patient experience was diluted to non-significant for the sub-group of patients who only received extended support. Longer support (expressed in minutes) was associated with a better patient experience in general (coeff=0.1, 0.1 to 0.2, 0.001) but this effect was modified by the person offering support and was more pronounced for the clinician.

B. ECONOMIC EVALUATION

1. The mean estimated cost of the intervention, based on the cost of staff time associated with phone calls, associated staff supervision and the BtB licence fee and training, was estimated to be lower for those who received brief support (clinician: £179; assistant: £165) compared to those who received enhanced support (clinician: £242; assistant: £203). Other NHS and PSS costs were similar across the 4 groups.

2. The total time spent on the phone by participants was 59.22 minutes for the brief assistant (BA), compared to 70.00 minutes for the extended assistant (EA), 46.26 minutes for the brief clinician (BC) and 90.80 minutes for the extended clinician (EC). It is estimated that completion of a BtB session takes an average of 50 minutes. When the minimum wage cost (£6.80 in 2011) (as an estimate of the value of forgone leisure time) was assigned to both

time associated with phone calls and BtB sessions the estimated cost of patient time equates to £30.57 (BA), £30.71 (EA), £29.78 (BC) and £32.84 (EC).

3. Missing cost and outcome data was imputed and regression analysis was subsequently performed, where the brief assistant arm was used as the comparator as this was considered to most closely resemble treatment as usual. The incremental costs (from the NHS and PSS viewpoint), compared to the brief assistant, were estimated to be –£37 (95%CI –£142 to £67) for the brief clinician, –£9 (95%CI –£115 to £92) for the extended clinician, and –£58 (95%CI –£168 to £56) for extended assistant. The incremental QALY gains, were similarly estimated to be 0.001 (95%CI –0.017 to 0.019) for the brief clinician, –0.024 (95%CI –0.043 to –0.006) for the extended Clinician, and –0.009 (95%CI –0.024 to 0.006) for extended assistant.

4. Based on the mean incremental cost and QALY gain values this suggests that the brief clinician dominates the brief assistant as it is estimated to have both a lower cost and greater QALY gain. It should however be noted that neither of these differences were significantly different at the $p < 0.05$ level. This suggests there is a large level of uncertainty associated with this decision. Similarly, the cost-effectiveness acceptability curve (CEAC) for the brief clinician estimates that the probability that the brief clinician arm is cost-effective is 55.4% at the threshold of £20,000 per QALY.

C. CONCLUSIONS

This study provides no evidence that an experienced specialist clinician offering support as an adjunct to cCBT for depression may confer different outcomes compared to an assistant, except for patient satisfaction. Likewise, the study provides no evidence that enhanced support may yield different outcomes than brief support, except for patient satisfaction.

Enhanced support led to a better patient experience than brief support when offered by a clinician; this was not observed for the assistant either because of the smaller sample size (less people returned outcome measures) or because of the narrow gap between brief and enhanced support in the assistant group (only a few minutes difference). The study also found that patients had a better experience with the assistant than the clinician even after adjusting for differences in support duration and demographic and clinical variables (such as severity of depression, education, gender, etc.); however, patient experience with the clinician improved with longer duration of support and was no different to patient experience with the assistant for patients who only received enhanced support.

Our non-significant findings do not mean that there are no differences between clinician and assistant or between brief and enhanced support, but that we were not able to capture any differences at our powered effect size (there might have been smaller and clinically important differences which a larger sample size would have been able to capture). Also, non-significant findings in our study do not mean that the compared modes of support are equal; this would have required a different trial design, an equivalence study, as opposed to a comparative study like ours which interprets its non-significant results to mean that one mode of support may be no better than the other.

The study's economic evaluation suggests that enhanced support costs more than brief support and that brief-clinician support may offer better value for money than brief-assistant support but there is a high level of uncertainty associated with this conclusion.

Patient and public involvement

A focus group involving public and service user representatives was set up with help from the Patient and Public Involvement in Research (PPIRes) at the local Primary Care trust (NHS Norfolk), to discuss cCBT implementation and patient recruitment. This focus group reviewed some of the study documents (such as the patient information sheet, screening questionnaire and invitation letter) and made recommendations as to how these could become more patient-friendly and less cumbersome. They have also made useful suggestions as to how to improve the return rates of the postal questionnaires by offering individualised feedback to each patient who returns their questionnaires and collecting data by phone and email as well as by post. The PPI focus group was not in favour of offering to participants the incentive of payment for return of outcome measures because this would not have captured a population representative of all socio-economic groups and it could bias the pragmatic nature of the study (given that paying patients to return outcome measures is not what happens in routine services).

One of the focus group members has been participating in the study trial management group and steering committee. They have also been actively involved in the analysis, interpretation and dissemination of the study's findings. They were a co-presenter with the chief investigator in a PPI conference and they were the co-author in one of the study's papers about patient experiences of the trial's interventions. The PPI conference was a useful platform to discuss the study and it gave the research team a perspective of which findings the public and service users are mostly interested in.

One of the areas highlighted by our PPI group is that the economic evaluation of self-management interventions does not usually consider the cost for patients in terms of demands on their time or other expenses (e.g. having internet, cost of printing). This is true given that NICE recommends that economic evaluations are carried out from the perspective of the NHS. Within the context of "self-management" interventions, patients bear the cost of therapy (which is different to when patients receive clinician-led interventions such as when they are in hospital). Taking into account our PPI feedback, our economic evaluation will also estimate the cost of the intervention for patients. This can be useful if personalised budgets are introduced for patients, or if a private insurance system needs to reimburse patient costs (including loss of earnings, travelling, use of computer etc.) for carrying out an intervention similar to the one in our trial.

Data sharing statement

See link

[\[https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253\]](https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253) for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

Disclaimer

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This project was carried out between March 2010 and December 2012. This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.