Therapist-delivered internet psychotherapy for depression in primary care: a randomised controlled trial

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Summary

Background Despite strong evidence for its effectiveness, cognitive-behavioural therapy (CBT) remains difficult to access. Computerised programs have been developed to improve accessibility, but whether these interventions are responsive to individual needs is unknown. We investigated the effectiveness of CBT delivered online in real time by a therapist for patients with depression in primary care.

Methods In this multicentre, randomised controlled trial, 297 individuals with a score of 14 or more on the Beck depression inventory (BDI) and a confirmed diagnosis of depression were recruited from 55 general practices in Bristol, London, and Warwickshire, UK. Participants were randomly assigned, by a computer-generated code, to online CBT in addition to usual care (intervention; n=149) or to usual care from their general practitioner while on an 8-month waiting list for online CBT (control; n=148). Participants, researchers involved in recruitment, and therapists were masked in advance to allocation. The primary outcome was recovery from depression (BDI score <10) at 4 months. Analysis was by intention to treat. This trial is registered, number ISRCTN 45444578.

Findings 113 participants in the intervention group and 97 in the control group completed 4-month follow-up. 43 (38%) patients recovered from depression (BDI score <10) in the intervention group versus 23 (24%) in the control group at 4 months (odds ratio 2·39, 95% CI 1·23–4·67; p=0·011), and 46 (42%) versus 26 (26%) at 8 months (2·07, 1·11–3·87; p=0·023).

Interpretation CBT seems to be effective when delivered online in real time by a therapist, with benefits maintained over 8 months. This method of delivery could broaden access to CBT.

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Introduction

Psychological therapies should be more widely accessible for depression in primary care than they are at present. There is an increased awareness of the health-care burden of depression[1] and a growing unease about the amounts of antidepressant prescribing compared with the resources made available for psychological therapies.[2] Questions are being asked about the efficacy of antidepressant drugs,[3] and some are concerned about the risk–benefit balance of selective serotonin re-uptake inhibitor antidepressants in specific groups of patients.[4]

The UK Government is committed to improving access to psychological therapies for people with depression. The plans include training a new workforce of 3600 therapists to deliver such therapies.[5] Cognitive-behavioural therapy (CBT) is a large part of these plans. Despite a strong evidence base,[6] CBT remains difficult to access, especially in primary care. CBT is adaptable to self-help materials, including interactive computerised programs.[7,8] Telephone-administered CBT is more effective than is usual care for patients with depression.[9] Information technology has the potential to increase access to psychological therapy, and CBT does not have to be delivered face-to-face.

Computerised CBT programs, although effective, are inflexible, can be difficult to tailor to individual patient needs, and are associated with low rates of adherence.[10] However, individual CBT can be offered by a therapist online, with instant messaging in which client and therapist communicate in real time with typewritten responses. Possible benefits from this approach include flexibility and optimum use of patient and therapist time, reaching client groups for whom travel to treatment centres is difficult for reasons of geography or disability, and access to foreign language therapists. Some evidence suggests that writing about traumatic events can lead to improvements in health.[11] This approach is acceptable to patients with depression, and therapy without face-to-face contact could encourage greater disclosure.[12] We investigated the effectiveness of online CBT for patients with depression in primary care.

Methods

Study design and participants

We undertook a randomised controlled trial, with recruitment taking place between Oct 1, 2005, and Feb 29, 2008. The sample comprised patients aged 18–75 years from primary care with a new episode of depression, which was defined as being diagnosed within the 4 weeks preceding referral. We excluded patients treated for depression in the 3 months before the present episode. Depression was defined as a score of 14 or more with the Beck depression inventory (BDI)[13] and a diagnosis of depression with the International

Statistical Classification of Diseases 10th revision (ICD-10)[14] with the revised clinical interview schedule.[15] We excluded patients with a history of bipolar disorder, psychotic disorder, alcohol or substance misuse, and those already receiving psychotherapy.

Participants were recruited from 55 general practices in three centres in England: Bristol (n=26), London (17), and Warwickshire (12). Patients were invited to give consent to be contacted by the study team, either by their general practitioner (GP) in the consultation or by post after a search of the practice records for a diagnosis of depression. The pretrial assessment consisted of a preliminary telephone screen to confirm the referral eligibility criteria. If eligible, the individual was invited to attend an appointment with a researcher to complete a computerised assessment with the revised clinical interview schedule and BDI to confirm the remaining eligibility criteria. As part of this assessment, potential participants were also asked whether in the preceding 6 months they had had any of the following life events: bereavement; divorce or separation; serious illness or injury; mugging, burglary, or serious assault; problems with the police; difficulties with debt; a serious dispute with a relative, friend, or neighbour; or dismissal from employment.

We obtained full written informed consent from participants at interview. Ethics approval was given by the Royal Free and Hampstead Research Ethics Committee, reference number 05/Q0501/18.

Procedures

After administering the baseline questionnaires and obtaining consent, we randomly assigned participants to online CBT (with a therapist online in real time) in addition to usual care or to usual care from their GP while on an 8-month waiting list for online CBT. Allocation was stratified by centre, with minimisation for present antidepressant treatment (yes *vs* no), sex, whether or not their GP practice had a counsellor, and severity of depression (BDI score 14–19 [mild]), 20–28 [moderate], or >28 [severe]). Randomisation was by means of a computer-generated code, implemented by an individual who was not involved in the recruitment process, and communicated to the participant within 48 h of the baseline interview. The allocation was concealed in advance from participants, researchers involved in recruitment, and therapists.

The intervention comprised up to ten sessions, each of 55 min of CBT delivered online, to be completed within 16 weeks of randomisation when possible. The expectation was that at least five sessions would be delivered by the time of the primary outcome at 4-month follow-up, with scheduling left to the discretion of the therapist and participant. Every participant was assigned to one therapist for the duration of the study. All the psychologists worked for the organisation PsychologyOnline, were CBT-trained, and had experience of providing psychotherapy in this setting. Participants were allocated on a rota basis to the next available therapist, and made their own appointments online. The sessions were secured by individual passwords. Participants and therapists typed free text into the computer, with messages sent instantaneously; no other media or means of communication were used. All participants were reassessed after 8 months, and those on the waiting list who still had an eligible BDI score were offered the intervention at that time. The integrity of the psychological therapy was assessed with the cognitive therapy rating scale[16] to score transcripts of 40 online sessions for patients who had completed at least five sessions of therapy. With use of computer-generated random numbers, at least one such patient was selected for each therapist. For these patients, either session 6 or the penultimate session was rated by two independent CBT-trained psychologists, who gave mean ratings of 31 (SD between therapists 9) and 32 (13) of 72. Participants on the waiting list were not to receive psychotherapy during the study follow-up period.

The primary outcome was the BDI score 4 months after randomisation, analysed as a binary variable for which a score of less than 10 represented recovery.[17] Secondary outcomes were continuous 4-month BDI score; 8-month BDI score, analysed in both binary and continuous form; and health status (the short-form [SF-12] mental subscore)[18] and quality of life (the EuroQol [EQ-5D])[19] analysed as continuous variables at 4 and 8 months.

Statistical analysis

The study was powered to detect differences in the proportion of participants who recovered from depression, rather than the extent of improvement, because we thought recovery was most relevant to clinicians and patients. The original target sample size was 200 in each group to detect a difference between 50% and 65% recovery, with 83% power and 5% two-sided significance level. After recruitment difficulties, a revised power calculation indicated that 290 participants would (assuming 30% attrition) provide 80% power and 5% significance level to detect a difference between 50% and 70% recovery. This corresponded to an odds ratio (OR) of 2·3, which was still smaller than the pooled OR for recovery of 3·01 in a systematic review of the effectiveness of psychological treatments.[6] For the continuous outcome, a difference of 0·39 SDs was detectable; we considered differences smaller than this not worthwhile detecting. Initially, we planned to recruit from 51 practices equally divided between the three centres. In view of the slower than anticipated recruitment we increased this number to 66; potential participants were referred to the study from 55 of these practices. There were non-referring practices in each of the three centres, but fewest in Bristol.

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We used descriptive statistics to assess the individuals recruited in relation to those eligible and the comparability of the randomised groups at baseline. Logistic regression was used in the primary (intention-to-treat) analysis to compare the (binary) primary outcome at 4 months between the groups as randomised, with adjustment for baseline BDI score, study centre, and the four minimisation variables. Similar regression models were used for secondary analyses with additional adjustment for any variables showing baseline imbalance and any differences in the actual time to follow-up. Clustering by practice was accounted for with random-effects logistic regression. All these analyses were repeated for the continuous version of the 4-month BDI. For all other secondary outcomes, only the primary analysis and adjustment for baseline imbalance were done.

For the binary and continuous versions of the BDI, we undertook several additional analyses. First, repeated-measures regression models were obtained for the two follow-up points with adjustment for baseline BDI and stratification and minimisation variables. Second, the primary analyses at every timepoint were repeated after adjustment for antidepressant use up to the relevant follow-up, to investigate possible mediating effects. Third, we did preplanned subgroup analyses involving interactions between randomisation group and the following baseline variables: severity (mild or moderate *vs* severe according to BDI score) and whether or not the participant was being prescribed antidepressants. Fourth, a sensitivity analysis investigated the effect of missing data with multiple imputation by chained equation methods in Stata (ice program: April 25, 2008, version 1.4.6; 25 datasets were generated and ten switching procedures were undertaken). The imputation model included potential confounders with any suggestion of an interaction with missing BDI scores at either 4 or 8 months.

Further secondary analyses compared participants according to the treatment actually received (on the basis of records of sessions of online CBT), accounting for any selection effects after random allocation. These analyses of complier-average causal effect used instrumental variables linear regression for BDI at each follow-up, both as a continuous score and as a binary variable (with and without a probit transformation).[20,21] Finally, we used generalised linear and latent mixed models to obtain a fully heteroscedastic model to ascertain whether the primary analyses at 4 months were affected by incorporating any clustering effects according to therapist.[22]

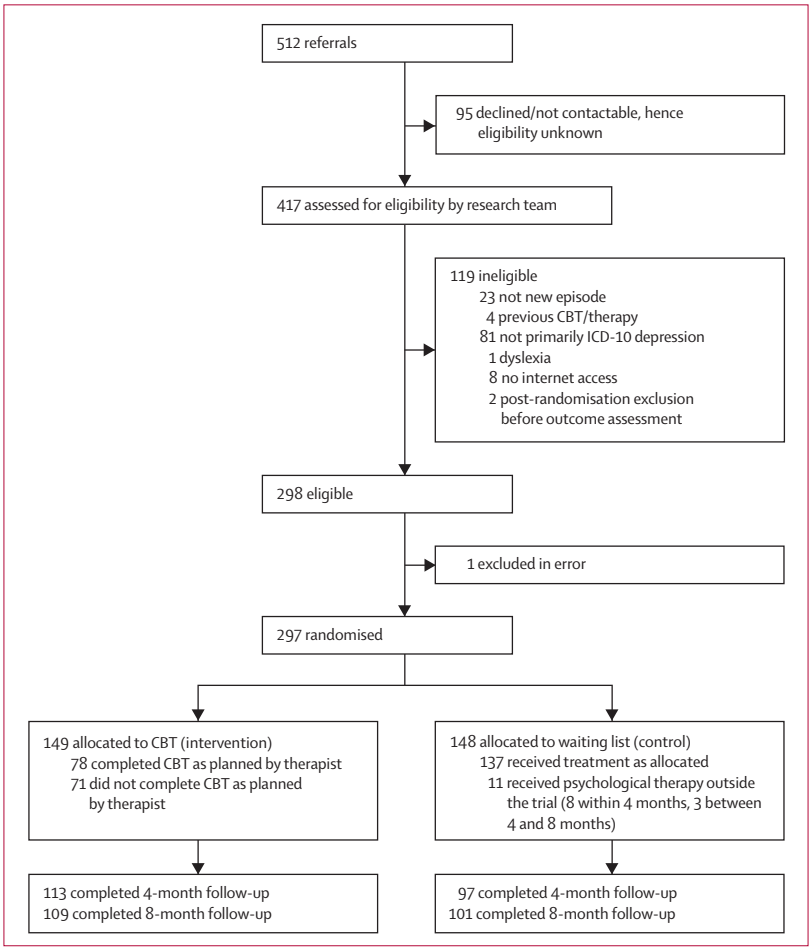

Figure: **Trial profile**
CBT=cognitive-behavioural therapy. ICD-10=International Statistical Classification of Diseases 10th revision.

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, interpretation of data, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Of the 512 people invited to participate, 119 were ineligible, 95 declined or were not contactable, and one was excluded in error (figure). The proportion of those eligible who were randomly assigned was 297 of 393 (76%). We recorded no differences between people randomly assigned and the remainder in terms of age and deprivation score, although randomised participants were slightly more likely to be women and less likely to be from a practice that had its own counsellor (data not shown).

Of the 297 participants randomly assigned, more than two-thirds were women and the mean age was 34·9 (SD 11·6) years. The median number of participants per practice was two (IQR 1–5). As well as a primary diagnosis of depression, all but four participants had a secondary psychiatric diagnosis according to the revised clinical interview schedule: generalised anxiety disorder (n=174), mixed anxiety and depression (81), phobia (22), and panic disorder (16).

The randomisation groups were similar at baseline (table 1). In both control (waiting list) and intervention

	Intervention (n=149)	Control (n=148)
Women	103 (69%)	99 (67%)
Age (years)	35·6 (11·9)	34·3 (11·3)
Centre		
Bristol	119 (80%)	121 (82%)
London	21 (14%)	20 (14%)
Warwickshire	9 (6%)	7 (5%)
Antidepressant treatment	80 (54%)	73 (49%)
Practice has a counsellor	86 (58%)	83 (57%)
Preference for treatment		
CBT	122 (82%)	134 (91%)
Other	27 (18%)	14 (9%)
BDI score	32·8 (8·3)	33·5 (9·3)
Mild (14–19)	8 (5%)	7 (5%)
Moderate (20–28)	40 (27%)	38 (26%)
Severe (>28)	101 (68%)	103 (70%)
SF-12 mental subscore*	23·8 (7·6)	23·9 (8·2)
SF-12 physical subscore*	52·0 (10·1)	50·7 (9·3)
EQ-5D score†	0·66 (0·23)	0·63 (0·23)
Marital status		
Married	51 (34%)	57 (39%)
Single	74 (50%)	69 (47%)
Separated/divorced/widowed	24 (16%)	22 (15%)
Employment status		
Employed	97 (65%)	83 (56%)
Student	23 (15%)	35 (24%)
Not in employment	29 (20%)	30 (20%)
Housing tenure		
Home owner	69 (46%)	51 (35%)
Tenant	56 (38%)	70 (47%)
Other‡	24 (16%)	27 (18%)
Highest educational level		
A-level or above	97 (65%)	93 (63%)
Other	47 (32%)	49 (33%)
No educational qualifications	5 (3%)	6 (4%)
History of depression		
No history of depression	33 (21%)	38 (26%)
History of depression no previous treatment	32 (22%)	31 (21%)
History of depression treated with antidepressants	84 (56%)	79 (53%)
(Continues on next column)		
(Continued from previous column)		
Alcohol use score (0–18)	4·8 (4·2)	5·2 (4·2)
Median (IQR)	4 (2–7)	4 (2–7)
0–4	87 (59%)	92 (62%)
≥5	61 (41%)	57 (38%)
Social support score (1–16)	11·7 (4·0)	12·2 (3·8)
Number of life events in past 6 months		
0	45 (30%)	35 (24%)
1	44 (30%)	43 (29%)
2	42 (28%)	39 (26%)
≥3	18 (12%)	31 (21%)

Data are number (%) or mean (SD), unless otherwise stated. CBT=cognitive-behavioural therapy. BDI=Beck depression inventory. SF-12=short-form 12. EQ-5D=EuroQol score. *n=140 per group. †n=146 in intervention group and n=147 in control group. ‡Living with relative or friend, in hostel or care home, homeless, or other.

Table 1: **Baseline characteristics of participants in intervention (online CBT) and control (waiting list) groups**

(online CBT) groups, more than two-thirds of participants scored more than 28 on the BDI (severe depression). Baseline scores on the SF-12 and the EQ-5D showed little difference between the groups (table 1). More people in the control group showed a preference for allocation to CBT before randomisation than did those allocated to intervention. More people in the intervention group were in employment and owned their own homes, whereas a higher proportion of those in the control group were students, tenants, and had had three or more life events in the preceding 6 months (table 1).

Primary outcome data at 4 months were obtained for 210 (71%) participants; the BDI score was also obtained for 210 individuals at 8 months (figure), and at least one follow-up was achieved for 237 (80%) participants: 123 (80%) in the intervention group and 114 (77%) in the control group. The follow-up rate at 4 months was higher in the intervention group than in the control group, although this difference had diminished at 8 months (figure).

Although a higher proportion in the intervention group than in the control group reported taking antidepressants, the differences were small and neither was greater than could occur by chance. At 4 months, 53 of 104 (51%) patients in the intervention group and 43 of 92 (47%) in the control group reported antidepressant use; at 8 months the figures were 40 of 98 (41%) and 29 of 90 (32%), respectively.

In an intention-to-treat analysis, participants allocated to the intervention group were more likely to have recovered from depression at 4 months than were those in the control group (table 2). Additional adjustment for variables displaying imbalances at baseline (housing tenure, employment status, and number of life events in the preceding 6 months) had no material effect on these results (data not shown), and neither did adjustments for time to follow-up, antidepressant use at 4 months, or clustering by practice, for which the primary outcome intracluster correlation coefficient was 0·012 (data not shown). The difference in the proportions recovered yielded a number needed to treat of 7 (95% CI 4–50) for each additional recovering participant.

The intention-to-treat analyses for the secondary outcomes at 4 months confirmed the findings for the primary outcome (table 2). The benefit from the intervention in terms of BDI score was 7 points—an effect

	Intervention		Control		Adjusted OR/adjusted difference in means (95% CI)†	p value
	N	n (%)/mean (SD)*	N	n (%)/mean (SD)*		
Recovery (BDI <10)	113	43 (38%)	97	23 (24%)	2·39 (1·23 to 4·67)	0·011
BDI score	113	14·5 (11·2)	97	22·0 (13·5)	–7·1 (–10·0 to –4·2)	<0·0001
SF-12 mental subscore	96	41·5 (12·6)	89	35·4 (12·5)	6·0 (2·5 to 9·5)	0·001
EQ-5D score	103	0·82 (0·19)	91	0·75 (0·23)	0·06 (0·01 to 0·12)	0·028

Intention-to-treat analysis adjusted for baseline BDI score and stratification (centre) and other minimisation variables (sex, use of antidepressant, practice counsellor). OR=odds ratio. BDI=Beck depression inventory. SF-12=short-form 12. EQ-5D=EuroQol score. *Data are n (%) for recovery, and mean (SD) for BDI score, SF-12 mental subscore, and EQ-5D score. †Data are adjusted OR (95% CI) for recovery, and adjusted difference in means (95% CI) for BDI score, SF-12 mental subscore, and EQ-5D score.

Table 2: **Intention-to-treat analyses of primary and secondary outcomes at 4-month follow-up**

	Intervention		Control		Adjusted OR/adjusted difference in means (95% CI)†	p value
	N	n (%)/mean (SD)*	N	n (%)/mean (SD)*		
Recovery (BDI <10)	109	46 (42%)	101	26 (26%)	2·07 (1·11 to 3·87)	0·023
BDI score	109	14·7 (11·6)	101	22·2 (15·2)	–6·2 (–9·3 to –3·0)	0·0002
SF-12 mental subscore	95	41·0 (13·4)	84	37·1 (14·2)	3·2 (–0·6 to 7·0)	0·10
EQ-5D score	99	0·83 (0·19)	91	0·75 (0·26)	0·07 (0·01 to 0·13)	0·024

Intention-to-treat analysis adjusted for baseline BDI score and stratification (centre) and other minimisation variables (sex, use of antidepressant, practice counsellor). OR=odds ratio. BDI=Beck depression inventory. SF-12=short-form 12. EQ-5D=EuroQol score. *Data are n (%) for recovery, and mean (SD) for BDI score, SF-12 mental subscore, and EQ-5D score. †Data are adjusted OR (95% CI) for recovery, and adjusted difference in means (95% CI) for BDI score, SF-12 mental subscore, and EQ-5D score.

Table 3: **Intention-to-treat analyses of primary and secondary outcomes at 8-month follow-up**

size of 0·81 SDs with use of the baseline SD for BDI score. This result was unaffected by adjustments for clustering by practice, time to follow-up, and treatment with antidepressants. Similarly, the findings for the secondary outcomes at 8 months favoured the intervention (effect size of 0·70), with similar magnitudes of effect and levels of evidence apart from for the SF-12 mental subscore (table 3). Adjustment for baseline imbalance increased the comparisons (eg, for the SF-12 outcome the difference was then 4·0, 95% CI 0·1–8·0; p=0·045).

From the repeated-measures regression models we noted no evidence that the effect of the intervention changed through time (for intervention by time interaction p=0·65 for the binary version and p=0·35 for the continuous version of the BDI). Exclusion of the interaction terms from these models led to average effects (ie, the main effects of the intervention in repeated-measures regression models) of the intervention over the 8 months of the trial, represented by OR 2·12 (95% CI 1·26–3·55; p=0·004) and –6·4 points (–9·0 to –3·8; p<0·0001).

We noted no evidence at either follow-up of differential effects of the intervention according to prescription of antidepressants at baseline (interaction p values >0·25). At 4 months the intervention effect was greater for severe depression at baseline than for mild depression (interaction p=0·025 for binary BDI and interaction p=0·021 for continuous BDI). At 8 months the p value was similar for the continuous outcome (interaction p=0·040) but not for the binary outcome (interaction p=0·70). For participants with baseline BDI score greater than 28, the intervention benefit increased to about 10 points (from 6 to 7 overall and compared with about 2 for BDI score ≤28). For the binary outcome at 4 months, we noted the intervention effect only in those with BDI score greater than 28 (data not shown). We recorded no such differential effect for the 8-month binary outcome because the intervention effect was present in both severity subgroups (data not shown). Regression models, including imputed values for missing BDI outcome data at 4 and 8 months, gave very similar results to the primary analyses (table 4).

None of the 148 participants allocated to the control group had any sessions of online CBT before their 8-month follow-up. Eight reported having received non-CBT-based psychotherapy at the 4-month follow-up, and a further three at 8 months (figure). Of the 149 participants allocated to receive the intervention, 92 (62%) had had therapy as intended by 4 months (90 had at least five sessions of CBT; two had four sessions and were described by their therapist as having completed therapy). By 8 months, 99 (66%) participants had had therapy as intended. For the primary analysis, 81 of 113 (72%) had had therapy as intended. The median number of sessions was six (IQR 2–10). Only 19 (13%) received no sessions of therapy, nearly half (70/149) had had at least eight sessions, and one had had 11 sessions.

Table 4 presents the results from the complier-average causal effect analyses for the continuous BDI at 4 and 8 months (adjusted for baseline BDI, study centre, and minimisation variables). This difference between intervention and control groups was larger than both the difference from the corresponding intention-to-treat analysis (table 2) and the crude difference of –6·2 (from –9·3 to –3·1) resulting from a comparison of the 81 who had had therapy as intended versus the remaining 129 participants. Regression models for the (primary) binary outcome also led to larger differences between the groups in the analysis of the complier-average causal effect than in the corresponding intention-to-treat analyses (data not shown).

Participants in the intervention group were allocated to 18 therapists. The median number per therapist was 5·5 (IQR 4–9) for the 113 participants for whom the primary outcome was known. We observed an intracluster correlation coefficient of 0·015 for the primary (binary) outcome in these 113 participants and of 0·061 in the 81 in this group who received therapy as intended. Of the 113 participants for whom the primary outcome was known, 109 had at least one session of therapy. When we compared these 113 participants with the 97 in the control

	N	Adjusted OR/adjusted difference in means (95% CI)*	p value
Imputation of missing data			
Recovery (BDI <10) at 4 months	297	2·72 (1·46 to 5·07)	0·002
Recovery (BDI <10) at 8 months	297	2·19 (1·20 to 4·01)	0·011
BDI score at 4 months	297	−7·9 (−10·6 to −5·1)	<0·0001
BDI score at 8 months	297	−6·4 (−9·6 to −3·1)	0·0002
CACE analyses			
BDI score at 4 months	210	−10·0 (−14·2 to −5·7)	<0·0001
BDI score at 8 months	210	−8·1 (−12·4 to −3·9)	0·0002
Therapist effects			
Recovery (BDI <10) at 4 months	210	2·41 (1·19 to 4·87)	0·015
BDI score at 4 months	210	−7·1 (−10·1 to −4·2)	0·0001

OR=odds ratio. BDI=Beck depression inventory. CACE=complier-average causal effect. *Data are adjusted OR (95% CI) for recovery, and adjusted difference in means (95% CI) for BDI score.

Table 4: **Secondary analyses of primary and secondary BDI outcomes at 4-month and 8-month follow-ups**

group in a fully heteroscedastic model (including baseline BDI score, centre, and minimisation variables), results were very close to those from the intention-to-treat analyses (table 4).

Discussion

CBT for depression seems to be effective when delivered online by a therapist in real time. The participants' BDI scores suggest that more than two-thirds were severely depressed. All were confirmed ICD-10 cases of depression. Participants in the intervention group were more likely to recover than were those on the waiting list receiving usual GP care. The gains recorded at the 4-month follow-up were maintained at 8 months. Quality of life and measures of functional health status showed improvement at both follow-up points.

CBT is helpful in depression compared with usual care,[6,23] but the feasibility and effectiveness of online CBT were unknown. The proportion of potentially eligible participants who were randomly assigned and the proportions followed up over 8 months were fairly high despite difficulties in recruitment and retention. This finding could be an indicator of the scarcity of psychological interventions in primary care, but could also indicate a genuine interest in this novel interface. We have no indication that the recruitment difficulties were specific to the intervention—indeed, the parallel qualitative research showed that it was reasonably acceptable to participants eligible for the trial.[12] Of the 66 practices originally recruited, 11 did not refer patients to the trial. However, any effect of variation in referrals across centres in terms of internal validity was removed by stratification.

Adjustment for baseline differences had no discernible effect on the results for the primary outcome and, if anything, increased the differences for secondary outcomes. Analyses imputing missing values suggested that differences in attrition between the groups did not introduce any noticeable bias.

The results from the analyses for treatment received reinforce the conclusion from the primary analysis that the intervention is effective. In particular, reduction of the selection bias inherent in a crude comparison of participants who received therapy as intended against all controls by applying the complier-average causal effect method increased the magnitude of the intervention effect beyond that of the primary intention-to-treat analysis, because patients who were randomly assigned to CBT but who were non-adherent tended to improve anyway.

Therapeutic gains at 4 months were maintained at 8 months. We noted no change in the mean symptom score in the control group between 4 and 8 months. Although this finding lends support to the stability of the therapeutic gains over time, it also raises concerns about the chronic nature of the illness and its resistance to improvement with usual care alone. Participants in the intervention group were more likely to be taking antidepressants at follow-up than were those in the control group, especially at 8 months, but these differences were small and adjustment for them had no effect on the comparisons for recovery at either follow-up.

With respect to integrity of therapy, a similar study in primary care used a cut-off of 39 on the cognitive therapy rating scale to define adequate CBT.[24] Although the lower mean ratings for the therapists in our study could be an indicator of the smaller amount of material available for analysis in online sessions compared with transcripts of face-to-face sessions, they are indicative of substantial CBT content.

In a comparison of non-directive counselling, CBT, and usual GP care for patients with depression, CBT showed an advantage compared with usual GP care at 4 months (effect size 0·52), but this effect was not maintained at 12-month follow-up.[24] A comparison of the computerised CBT-based package *Beating the Blues* with treatment as usual reported benefits at 3 months (effect size 0·51) and at 6 months (effect size 0·62).[8] The effect sizes here (0·81 at 4 months and 0·70 at 8 months) compare favourably with these findings. The baseline symptom scores suggest that more participants had severe depression in our study than in either of these previous studies, and the benefits of the intervention are still present after 8 months. The numbers needed to treat and the improvement in depression scores produced by telephone CBT reported by Simon and colleagues[9] are similar to those in our study.

The effect sizes, achieved by a brief pragmatic intervention, are quite large compared with similar interventions in primary care. The method of delivery of online CBT could enhance its effect by encouraging reflection. Thoughts and feelings have to be put into written rather than spoken words, and the complete transcript of the session is immediately available to the participant for review. This approach could enhance metacognitive awareness, a term applied to changing the

patient's relationship with negative thoughts and feelings, rather than changing their belief in the content of the negative thoughts.[25] Metacognitive awareness has been suggested as a mechanism by which CBT and related therapies lead to improvement and reduce risk of relapse. Perhaps delivering a therapy that forces the patient to write about negative material helps to create a distance from feelings and thoughts, and reduces the emotional effect of negative thinking.

Concerns have arisen about the effectiveness of CBT in treatment of severe depression. Derubeis and colleagues[26] noted that antidepressant medication was more effective than was CBT in people with severe illness. In our trial no such comparison was possible. However, the effect of the intervention was greater in participants with severe symptoms at baseline than in those with mild depression; results from a planned subgroup analysis suggest that the intervention had its main effect in patients with severe depression at baseline.

The number of patients for whom online CBT is feasible and attractive will grow. It could be useful in areas where access to psychological treatment is scarce, and for patients whose first language is not English. It could make access to psychotherapies more equitable by providing a service to patients in areas or even countries where psychological treatment is not readily available. Real-time online CBT offers the flexibility and responsiveness of face-to-face CBT and is appropriate for people with severe symptoms. It affords an opportunity for reflection and review as part of the therapeutic process, which could enhance its effectiveness.

Contributors

DK, NW, GL, DJS, RA, and TJP wrote the proposal and designed the study with contributions from MK and SH. SK acted as trial coordinator. DK and TJP wrote the final report, with all authors contributing to the editing. TJP, NW, DK, and SK analysed data, with input from MK and GL.

Conflicts of interest

We declare that we have no conflicts of interest.

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