

Clinical effectiveness of online computerised cognitive–behavioural therapy without support for depression in primary care: randomised trial

L. E. de Graaf, S. A. H. Gerhards, A. Arntz, H. Riper, J. F. M. Metsemakers, S. M. A. A. Evers, J. L. Severens, G. Widdershoven and M. J. H. Huibers

Background

Computerised cognitive–behavioural therapy (CCBT) might offer a solution to the current undertreatment of depression.

Aims

To determine the clinical effectiveness of online, unsupported CCBT for depression in primary care.

Method

Three hundred and three people with depression were randomly allocated to one of three groups: Colour Your Life; treatment as usual (TAU) by a general practitioner; or Colour Your Life and TAU combined. Colour Your Life is an online, multimedia, interactive CCBT programme. No assistance was offered. We had a 6-month follow-up period.

Results

No significant differences in outcome between the three interventions were found in the intention-to-treat and per protocol analyses.

Conclusions

Online, unsupported CCBT did not outperform usual care, and the combination of both did not have additional effects. Decrease in depressive symptoms in people with moderate to severe depression was moderate in all three interventions. Online CCBT without support is not beneficial for all individuals with depression.

Declaration of interest

None.

Although cognitive–behavioural therapy (CBT) is an effective treatment for depression^{1,2} many people with depression in primary care remain untreated.³ An effective, acceptable and feasible solution might be computerised CBT (CCBT).⁴ Computerised cognitive–behavioural therapy can vary greatly in terms of technologies used and amount of additional support. To our knowledge, only one study so far investigated the efficacy of CCBT for depression in primary care.⁵ It was shown that CCBT (delivered on a computer in the general practice) is more effective than usual general practitioner (GP) care. Nevertheless, the effectiveness of CCBT via the internet in primary care remains to be evaluated as well as the effects of CCBT combined with usual GP care. In a randomised trial, we addressed these issues by examining the effectiveness of online, unsupported CCBT (the Colour Your Life programme) for depression in primary care. In another study, this intervention was equally effective as group CBT in people over 50 years old with subthreshold depression.⁶ We hypothesised that CCBT would be superior to usual GP care, and that the combination of CCBT and usual GP care would be more effective than CCBT alone. The Medical and Ethical Committee of Maastricht University approved the study protocol. The study is registered at The Netherlands Trial Register, part of the Dutch Cochrane Centre (ISRCTN47481236).

Method

Study population and recruitment

Participants were recruited from the general population by means of a large-scale internet-based screening in the south of The Netherlands. A random selection of individuals was sent an invitation letter to complete an online screening questionnaire. Potentially eligible participants were invited to visit the research centre to assess final eligibility. Participants were eligible if they met the following criteria: age 18 to 65; access to the internet at home; at least mild to moderate depressive complaints (Beck

Depression Inventory II (BDI-II)⁷ score ≥ 16); duration of depressive complaints 3 months or more; no current psychological treatment for depression; no continuous antidepressant treatment for at least 3 months prior to entry; fluent in Dutch language; no alcohol and/or drug dependence; and no severe psychiatric comorbidity. To determine DSM–III–R⁸ Axis I diagnoses the computerised Composite International Diagnostic Interview (CIDI–auto)⁹ was used. Full details of the study method have been described elsewhere.¹⁰

Procedure

After informed consent was obtained, participants were randomly allocated to one of three groups: online CCBT without support (the Colour Your Life programme); treatment as usual (TAU) by a GP; or online, unsupported CCBT and TAU combined. Baseline assessment took place at the research centre before randomisation on a computer. All follow-up assessments took place at home via the internet. Preceding an upcoming assessment point participants received an email alert. Individuals received financial compensation for internet use (€25).

Interventions

The CCBT programme, named Colour Your Life,¹¹ is an online, multimedia, interactive computer program for depression. Colour Your Life is based on the principles of CBT and on the Dutch version of ‘The Coping with Depression Course’ of Lewinsohn.^{12,13} It consists of eight 30-min sessions and a ninth booster session, although the duration of sessions can vary among users. At the end of each session homework assignments are given. Participants were advised to complete one session per week. Participants were given log-in codes by the researchers and they accessed CCBT at home. No assistance was offered. Colour Your Life was originally developed for people over 50 years old⁶ and

was adapted for an adult population (18 to 65 years) for the current study.

Treatment as usual was delivered by the participant's own GP who was advised to follow guidelines from the Dutch College of General Practitioners.¹⁴ Treatment as usual can include 4 to 5 consultations, held every second week, and antidepressant treatment if indicated.

For each person, it was assessed whether the interventions received were according to 'protocol'. Adherence to CCBT was defined as being exposed to all essential steps of the intervention, which was operationalised as having completed five or more sessions. Treatment as usual adherence was defined as receiving at least four consultations or antidepressant medication. Computerised cognitive-behavioural therapy plus TAU adherence was defined as a combination of both.

Outcomes

The primary outcome measure was the severity of depression as measured with the BDI-II, high scores indicating severe depression (range 0–63).^{7,15,16}

Secondary outcomes included the following measures. General psychological distress was measured with the Symptom Checklist 90 (SCL-90). Scores range from 90 (no distress) to 450 (very severe distress).^{17,18} The Work and Social Adjustment Scale was used to assess impairment in social functioning attributable to depression.¹⁹ A high score is indicative of severe impairment (score range 0–40). The 36-item short-form Health Survey (SF-36) was used to assess specific features of quality of life.^{20–22} We used the two most relevant subscales: role limitations caused by emotional problems and general mental health. High scores indicate high levels of quality of life (score range 0–100). The intensity of dysfunctional beliefs was assessed with the Dysfunctional Attitude Scale form A.²³ We used a 17-item version,²⁴ with a score range of 17 to 119. The higher the score, the more dysfunctional attitudes an individual reports.

Additional measures included a healthcare use questionnaire that we developed for the study, which measured self-reported use of GP care, antidepressant medication and specialist care.

All outcomes were assessed at baseline and at 3-month follow-up. In addition, the BDI-II and the Dysfunctional Attitude Scale form A-17 were also assessed at 2 months and 6 months. The healthcare use questionnaire was assessed monthly.

Sample size

Power calculations were based on elementary head-to-head comparisons of CCBT *v.* usual care and CCBT *v.* combination treatment (*t*-test). We calculated that a sample size of 84 participants per group was needed to detect a change score of 5 (s.d. = 5.25) on the BDI-II (power 90%, $\alpha = 0.05$). Adjusting for potential withdrawal from the study (20%), we estimated that 100 participants per group were needed.

Data analysis

Preliminary tests for distribution and outliers were performed. Skewness and kurtosis did not indicate substantial deviations from normality for all outcomes. The analyses were based on the intention-to-treat principle (i.e. those who provided follow-up data irrespective of treatment adherence). Only intermittent missing data were imputed ($n = 5$) by calculating the mean of the values of a previous and a subsequent time point. Missing data as a result of loss to follow-up were not replaced by imputed values. We tested all effects at the $P < 0.05$ level (two-tailed). All analyses were carried out using SPSS (version 15.0.1 for Windows).

First, to test the main hypotheses, repeated-measures analyses of variance (ANOVAs) were performed. In case of significant time \times group interactions, contrasts were conducted comparing changes from baseline to each subsequent time point for each pair of groups separately. Then, we computed improvement effect sizes for BDI-II scores for each time point according to Cohen's *d* statistic,²⁵ defined as $(M_{t_0} - M_{t_k}) / \text{sd}_{(M_{t_0} - M_{t_k})}$. Between-group effect sizes were determined by calculating the difference in improvement effect sizes between two groups. Next, we determined the proportion of participants who made clinically meaningful changes on the BDI-II using the methodology of Jacobson and Truax.²⁶ This approach is based on two components: reliable change, i.e. a decrease of 9 points; and clinically significant change, i.e. a score below 12. Chi-squared tests were used to test the frequency differences in reliable change, in clinically significant change, and in reliable change plus clinically significant change between the three groups. Based on the reliable change plus clinically significant change proportions, the number needed to treat was calculated.²⁷ Finally, we conducted per protocol analyses for treatment adherers only, using repeated-measures ANOVAs for the BDI-II scores.

Results

Participants

Figure 1 presents the flow of the participants. Recruitment took place from December 2005 to June 2007. Follow-up ended in December 2007. Three hundred and three people with depression were enrolled in the study. At 6-month follow-up, data were available for 275 participants (attrition rate 9.2%). Reasons for loss to follow-up were: too time-consuming ($n = 8$), personal circumstances or medical illness other than a mental disorder ($n = 5$) and no reason was given ($n = 15$). There seemed to be no baseline differences between participants who completed all assessments and those who were lost to follow-up (lowest $P = 0.10$). Baseline characteristics of all participants are shown in Table 1, stratified according to intervention group. Randomisation was successful; the characteristics are fairly similar in all three groups, although gender is not equally distributed across the groups.

Outcome of the interventions

Table 2 depicts the means and standard deviations of the clinical outcomes at follow-up. There were no significant group \times time

Table 1 Baseline characteristics of the total sample

Variable	CCBT ($n = 100$)	TAU ($n = 103$)	CCBT+TAU ($n = 100$)
Gender, male: n (%)	48 (48.0)	46 (44.7)	37 (37.0)
Age (18–65), years: mean (s.d.)	44.3 (11.8)	45.1 (12.2)	45.2 (10.9)
Education, ^a n (%)			
Low	18 (18.6)	16 (16.2)	17 (17.5)
Medium	55 (56.7)	55 (55.6)	52 (53.6)
High	24 (24.7)	28 (28.3)	28 (28.9)
Partner, n (%) ^b	72 (73.5)	73 (72.3)	71 (73.2)
Employed, n (%) ^c	67 (72.0)	64 (76.2)	69 (73.4)
Major depressive episode, ^d n (%)			
No	22 (22.0)	18 (17.5)	21 (21.0)
First	48 (48.0)	45 (43.7)	39 (39.0)
Recurrent	30 (30.0)	40 (38.8)	40 (40.0)

CCBT, computerised cognitive-behavioural therapy (Colour Your Life); TAU, treatment as usual.

a. Data unavailable: CCBT ($n = 3$), TAU ($n = 4$), and CCBT+TAU ($n = 3$).

b. Data unavailable: CCBT ($n = 2$), TAU ($n = 2$), and CCBT+TAU ($n = 3$).

c. Data unavailable: CCBT ($n = 7$), TAU ($n = 17$), and CCBT+TAU ($n = 6$).

d. Assessed using the Composite International Diagnostic Interview.

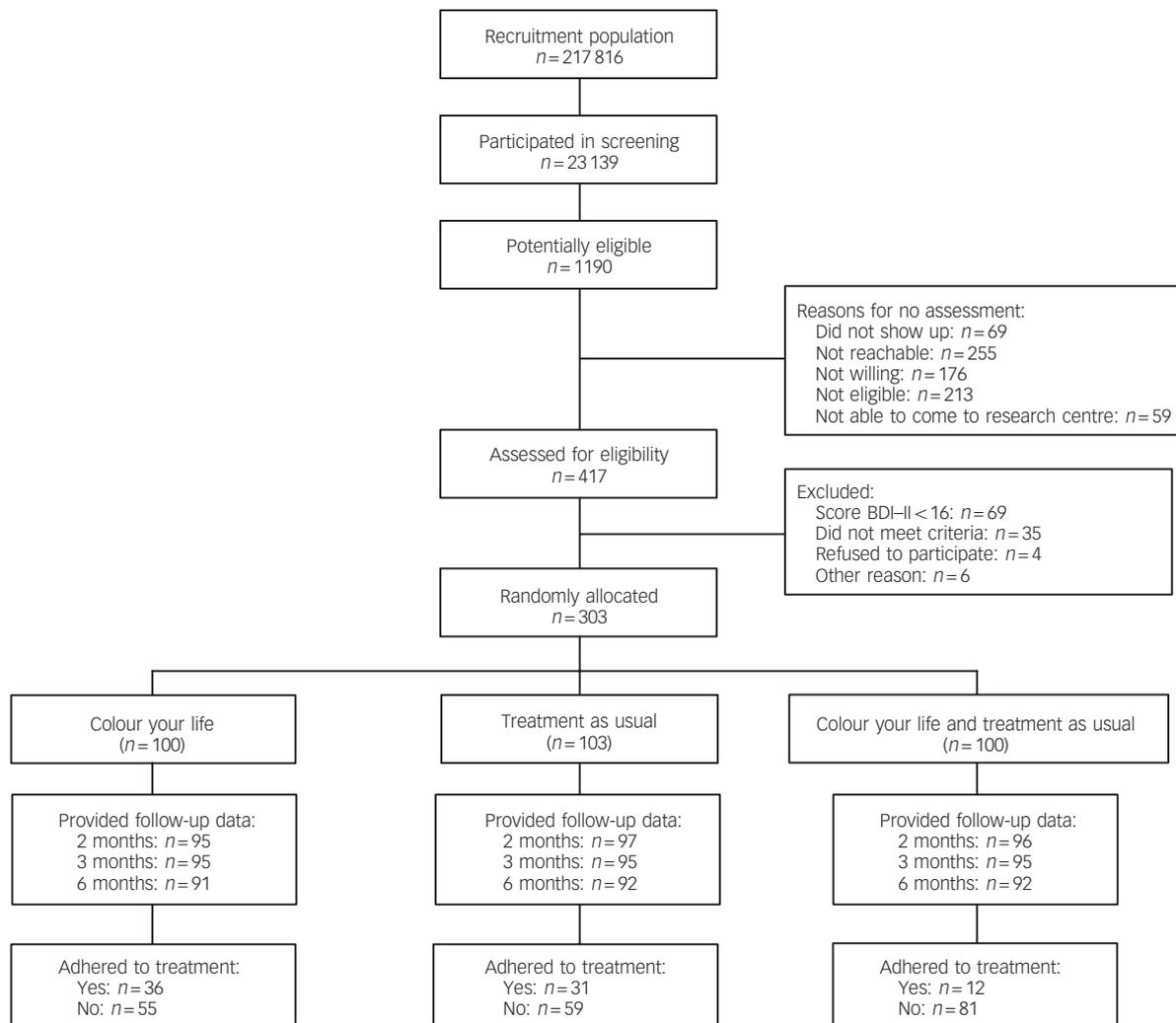


Fig. 1 Flow of the participants. BDI-II, Beck Depression Inventory-II.

Table 2 Mean scores (s.d.) for all outcome measures in the intention-to-treat population: results from repeated-measures ANOVA

Outcome	CCBT	TAU	CCBT+TAU	Time	Group	Time × group
BDI-II						
Baseline	28.2 (7.7)	27.9 (7.5)	27.4 (8.2)	$F_{3,271} = 71.13^{**}$	$F_{2,273} = 0.75$	$F_{6,542} = 1.22$
2 months	20.6 (10.4)	22.1 (10.2)	21.7 (10.1)			
3 months	20.4 (11.2)	21.4 (11.0)	19.1 (10.9)			
6 months	17.8 (10.6)	18.9 (11.8)	17.5 (12.2)			
DAS-A-17						
Baseline	62.2 (16.8)	62.6 (17.6)	61.9 (17.4)	$F_{3,270} = 17.17^{**}$	$F_{2,272} = 0.30$	$F_{6,540} = 0.52$
2 months	61.5 (16.7)	63.9 (16.3)	62.2 (18.7)			
3 months	59.0 (17.5)	60.4 (17.0)	57.9 (20.0)			
6 months	56.6 (15.2)	59.0 (18.3)	58.3 (19.6)			
SCL-90						
Baseline	182.9 (43.4)	179.9 (41.9)	180.0 (40.0)	$F_{1,282} = 1.14$	$F_{2,282} = 0.32$	$F_{2,282} = 0.33$
3 months	181.5 (53.8)	178.06 (46.6)	174.7 (50.7)			
SF-6 RL						
Baseline	29.7 (36.4)	34.0 (35.8)	33.7 (36.8)	$F_{1,278} = 6.41^*$	$F_{2,278} = 1.12$	$F_{2,278} = 0.71$
3 months	35.1 (37.2)	40.1 (38.9)	45.3 (41.8)			
SF-36 GMH						
Baseline	44.7 (13.7)	44.5 (13.9)	45.1 (14.3)	$F_{1,278} = 46.20^{**}$	$F_{2,278} = 0.19$	$F_{2,278} = 0.67$
3 months	50.4 (16.5)	51.9 (15.7)	52.8 (17.5)			
WSAS						
Baseline	19.3 (7.2)	18.4 (6.7)	19.1 (7.7)	$F_{1,282} = 11.26^{**}$	$F_{2,282} = 1.11$	$F_{2,282} = 3.61^*$
3 months	18.6 (8.7)	17.7 (7.8)	15.8 (7.5)			

CCBT, computerised cognitive-behavioural therapy (Colour Your Life); TAU, treatment as usual; BDI-II, Beck Depression Inventory II; DAS-A-17, 17-item Dysfunctional Attitude Scale form A; SCL-90, Symptom Checklist 90; SF-36, 36-item short-form Health Survey; RL, role limitations due to emotional problem subscale; GMH, general mental health subscale; WSAS, Work and Social Adjustment Scale.
* $P < 0.05$; ** $P < 0.001$.

interactions on the primary outcome measure as well as most secondary outcomes (all $P > 0.29$). A significant interaction effect was only found for the Work and Social Adjustment Scale ($P = 0.03$). Contrasts revealed that CCBT plus TAU resulted in a significantly greater reduction on the Work and Social Adjustment Scale compared with CCBT alone ($F_{1,188} = 5.63, P = 0.02$) and TAU alone ($F_{1,188} = 4.35, P = 0.04$). Since gender could have confounded the outcomes, we corrected for this in ancillary analyses by adding gender to the model as a between-group factor. This did not result in a significant outcome for the BDI-II (group \times time: $F_{6,536} = 0.94, P = 0.47$) nor was there a significant interaction between group and gender ($F_{2,270} = 0.47, P = 0.63$). We therefore omitted this correction from all further analyses.

Effect sizes

Regarding the magnitude of the effects, all three groups had medium to large improvement effect sizes, whereas between-group effect sizes were trivial (Table 3). Small negative between-group effect sizes were also found, indicating an effect in the opposite direction to that hypothesised.

Reliable and clinical change

Table 4 shows the proportion of participants in each group who showed a reliable change, a clinically significant change and both for each time point. There were no significant differences between the three groups (all $P > 0.12$). In Fig. 2 the percentage of participants with both a reliable change and a clinically significant change are graphically shown. We calculated the number needed to treat (NNT) with TAU as the reference group. At 6 months

the NNT were 72 and 25 respectively for CCBT and CCBT plus TAU.

Treatment received

In Table 5, treatment adherence and the use of healthcare services are shown for each group during the 6 months after baseline. As was expected, there were some significant differences between the three groups ($P < 0.05$). More participants in TAU and CCBT plus TAU visited their GP for depressive complaints compared with those in the CCBT alone group. Concerning the use of CCBT, more participants in the CCBT plus TAU group completed the last session compared with the CCBT alone group. Furthermore, more individuals in the TAU group received specialist mental healthcare than in the other groups, and they received it earlier. Finally, only a small proportion of participants in each group received an adequate dosage of treatment (TAU: at least four consultations or prescribed antidepressants; CCBT: at least five sessions).

Per protocol analyses

First, we compared the outcomes on the BDI-II only for those who adhered to the treatment. Group \times time interaction was not statistically significant ($F_{6,148} = 0.85, P = 0.53$). We repeated these analyses using a less strict definition of adherence in the CCBT plus TAU group, i.e. adherence was defined as either an adequate dosage of CCBT or an adequate dosage of TAU ($n = 59$). Again no significant interaction effect was obtained ($F_{6,242} = 1.67, P = 0.13$).

Next, we compared the BDI-II scores between those who adhered to the treatment protocol and those who did not within each intervention group. None of these within-group tests revealed statistically significant adherence \times time interaction effects

Table 3 Improvement and between-group effect sizes based on the Beck Depression Inventory II in the intention-to-treat population

Time point	Improvement effect size ^a			Between-group effect size ^b		
	1. CCBT	2. TAU	3. CCBT+TAU	1 v. 2	3 v. 2	3 v. 1
2 months	0.71	0.63	0.57	0.08	-0.06	-0.14
3 months	0.71	0.69	0.74	0.02	0.05	0.03
6 months	0.86	0.81	0.89	0.05	0.08	0.03

CCBT, computerised cognitive-behavioural therapy (Colour Your Life); TAU, treatment as usual.
 a. Improvement effect size = $(M_{i0} - M_{it}) / sd_{(M_{i0} - M_{it})}$.
 b. Between group effect sizes = difference in improvement effect sizes between two groups.

Table 4 Proportion of participants in the intention-to-treat population showing reliable and/or clinically significant change based on the Beck Depression Inventory II

Outcome	CCBT <i>n</i> (%)	TAU <i>n</i> (%)	CCBT+TAU <i>n</i> (%)	χ^2 (<i>d.f.</i> = 2)
Reliable change ^a				
2 months	36 (37.1)	30 (30.9)	30 (31.3)	1.06
3 months	35 (36.8)	33 (34.7)	43 (45.3)	2.48
6 months	45 (49.5)	44 (47.8)	54 (58.1)	2.25
Clinically significant change ^b				
2 months	24 (24.7)	16 (16.5)	16 (16.7)	2.76
3 months	22 (23.2)	18 (18.8)	28 (29.5)	3.06
6 months	26 (28.6)	29 (31.5)	33 (35.5)	1.02
Reliable change+clinically significant change				
2 months	23 (23.7)	13 (13.4)	14 (14.6)	4.32
3 months	21 (22.1)	16 (16.7)	24 (25.3)	2.15
6 months	26 (28.6)	25 (27.2)	29 (31.2)	0.37

CCBT, computerised cognitive-behavioural therapy (Colour Your Life); TAU, treatment as usual.
 a. Decrease of 9 points.
 b. A score below 12.

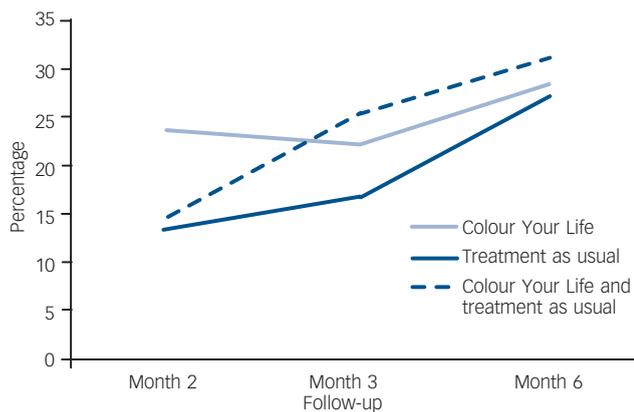


Fig. 2 Percentage of participants in the intention-to-treat population with reliable and clinically significant change.

(CCBT: $F_{3,87} = 0.59$, $P = 0.62$; TAU: $F_{3,86} = 2.03$, $P = 0.12$; CCBT+TAU: $F_{3,89} = 0.76$, $P = 0.52$). When we used the less strict definition of adherence in the CCBT plus TAU group, a small effect, albeit clinically negligible, for adherence \times time interaction was obtained ($F_{3,88} = 2.70$, $P = 0.05$). Contrasts revealed no differences between those who adhered to the treatment and those who did not for each change score ($P > 0.30$).

Subgroup analyses

Since initial depressive severity was high (as can be concluded from the baseline BDI-II scores in Table 2), we conducted ancillary subgroup analyses. First, subgroups were formed according to the initial median score on the BDI-II for the total group; low scores = $BDI < 27$, and high scores = $BDI \geq 27$. No statistically significant group \times time interaction effects were found in each subgroup ($BDI < 27$: $F_{6,262} = 1.27$, $P = 0.27$; $BDI \geq 27$: $F_{6,270} = 1.15$, $P = 0.34$). Second, subgroups were formed based on the presence or absence of a major depressive episode. In the no

major depressive episode subgroup, the group \times time interaction was not statistically significant ($F_{6,84} = 1.02$, $P = 0.42$), whereas a significant interaction was obtained in the major depressive episode group ($F_{6,448} = 2.25$, $P = 0.04$). Contrasts revealed a significant effect only for change from baseline to 3-month follow-up in favour of the CCBT plus TAU group compared with the TAU alone group ($F_{1,161} = 6.03$, $P = 0.02$).

Discussion

Main results

In contrast to our hypotheses, the findings suggest that there are no meaningful differences between CCBT, TAU, and CCBT plus TAU combined during 6 months of follow-up in terms of depressive severity, quality of life, dysfunctional beliefs and general psychological distress. Although we found medium improvement effect sizes in depressive severity for all interventions, the between-group effect sizes were rather small or even negative. Moreover, per protocol analysis between and within groups revealed no differences between the interventions either. Finally, we found that treatment adherence was low in all interventions. It should be noted that at 3 months, a significant effect was found for social functioning in favour of the combined treatment. We are reluctant to interpret this effect given the high number of statistical tests we performed.

Previous studies

To be able to compare the effects of CCBT in our study with previous ones, we calculated the usual Cohen's d (i.e. dividing the pre-post difference by the pooled standard deviation) for the 2-month follow-up period. Our improvement effect size for Colour Your Life ($d = 0.84$) was smaller than in the previous study on Colour Your Life ($d = 1.00$)⁶ and than in the previous primary care study⁵ ($d = 1.27$). The between-group effect size for Colour Your Life relative to TAU was smaller ($d = 0.20$) than found for Colour Your Life in a previous study⁶ ($d = 0.55$), CCBT in primary care⁵ ($d = 0.65$), online CCBT with support ($d = 1.05$),²⁸ and

Table 5 Treatment adherence and use of mental healthcare services during 6 months of follow-up in the intention-to-treat population

Variable	CCBT	TAU	CCBT+TAU
<i>Use of GP care^a</i>			
Depression related GP contact, n (%)	25 (28.7)	66 (73.3)	67 (73.3)***
Details of those who visited the GP, mean (s.d.)			
Number of contacts	4.7 (4.5)	3.7 (3.4)	2.9 (3.3)
Prescription of antidepressants	8 (32.0)	25 (37.9)	17 (25.4)
<i>Use of other mental healthcare^a</i>			
Use of antidepressants, n (%)	12 (13.8)	24 (26.7)	23 (25.0)
Specialist mental healthcare, n (%)	17 (23.6)	33 (36.7)	22 (23.9)*
Details of those who received specialist mental healthcare, mean (s.d.)			
Month of first contact	3.4 (1.7)	2.0 (1.1)	2.5 (1.5)*
Number of contacts	7.8 (6.2)	7.5 (6.3)	7.3 (5.2)
<i>Use of the CCBT programme</i>			
Completed first session, n (%)	72 (72.0)	–	76 (76.0)
Completed last session, n (%)	14 (14.0)	–	26 (26.0)*
Number of sessions, mean (s.d.)	3.4 (3.0)	–	4.0 (3.4)
<i>Protocol adherence, n (%)</i>			
Adequate dosage of TAU	–	31 (34.4)	26 (28.3)
Adequate dosage of CCBT	36 (36.0)	–	47 (47.0)
Overall treatment adherence	36 (36.0)	31 (34.4)	12 (12.9)***

CCBT, computerised cognitive-behavioural therapy (Colour Your Life); TAU, treatment as usual; GP, general practitioner. Adequate dosage of TAU = at least four consultations or antidepressant prescription; adequate dosage of CCBT = at least five sessions. Chi-squared tests for categorical variables and t -tests/ANOVAs for continuous variables were used.
 a. Data unavailable: CCBT ($n = 13$), TAU ($n = 13$), and CCBT+TAU ($n = 8$).
 * $P < 0.05$; *** $P < 0.001$.

CCBT with shortened face-to-face therapy ($d=1.14$).²⁹ Comparable effect sizes were found for bibliotherapy with minimal contact in primary care ($d=0.18$),³⁰ and online CCBT without support ($d=0.22$).³¹ It should be noted here that most of these studies used other comparison groups, making it difficult to directly compare the effects.

There are several reasons that may explain the small effects in our study. First of all, one might argue that Colour Your Life itself was less effective than other CCBT programmes. Results from the previous study using Colour Your Life seemed very promising for subthreshold depression in people over 50 years old.^{6,52} However, in that study, baseline assessment of the primary outcome was conducted after randomisation, which could have violated the results.

Second, the way CCBT was offered might explain the different outcomes. Various technologies can be used, ranging from the telephone to CD-ROMs, hi-tech computers, palmtops and the internet.^{33–36} The latest interventions use highly sophisticated computer systems, which might stimulate and improve engagement and motivation.³⁷ Although Colour Your Life makes full use of the current technologies, this might not have been enough to stimulate treatment adherence. We think that the lack of clinician support might account for the poor adherence and response to online, unsupported CCBT that we observed. Similar studies also showed a lack of response,^{31,38,39} whereas studies that offered some form of support reported more treatment adherence and larger effects with online CCBT for several psychological disorders.^{28,33,40–42} Poor treatment adherence in our study might thus have masked potential effects of the interventions, but our ancillary per protocol analyses did not reveal differences between the treatment groups either. We did observe a small trend in favour of the group receiving CCBT plus TAU as opposed to both single therapies for reliable change and clinically significant change, and in favour of the subgroup with a major depressive episode. However, our combined group cannot be seen as supported self-help, since the GP was not directly involved in the CCBT intervention.

Third, the low effect sizes in all three interventions might be attributable to our study sample, which was more severely depressed than in previous studies.^{5,28} The mean starting levels on the BDI-II were even higher than generally seen in primary care patients with depression.⁴³ Chronicity might also have negatively influenced the outcome.⁴⁴ Unfortunately, we do not have details of the exact duration of each current depressive episode. Moreover, because of our recruitment strategy our sample did not consist of active help-seekers, despite the high severity of their depression. This might have resulted in less-motivated participants.

Finally, we should note that none of our interventions did particularly well. Clinical improvement was approximately 30% in all groups. Given the fact that the response rate with pill-placebo is generally high in depression (i.e. 30–40%),^{45,46} we might have observed the natural course of depression in the current study. Nevertheless, improvement in our study was somewhat greater than seen in patients with depression on waiting lists.⁴⁷

Implications

Our findings might have several implications for the primary care treatment of depression. First, treatment might only be indicated for those who ‘get stuck’ in their depression, since depressive symptoms seem to improve over time without adhering to treatment, as was shown in the current study. Second, for more severe depression online CCBT offered with some support might

be more helpful. Third, this group of people with more severe depression might also fare better in secondary mental healthcare, where they can receive psychotherapy or antidepressant medication, for which larger effect sizes have been found relative to our effect size.^{48,49} Fourth, careful implementation of unsupported online self-help is warranted. Stepped-care and collaborative care models might be viable options.^{50,51} Fifth, if large differences in costs between the interventions exist, this might be a reason to choose one primary care treatment over another. Only one study so far has conducted an economic evaluation of CCBT.⁵² It was shown that supported CCBT was both more effective and more costly compared with usual GP care. When willing to pay for an additional unit of effect, CCBT could be very cost-effective.⁵² In a further paper, we will report the economic evaluation of Colour Your Life without support in primary care. Finally, qualitative process evaluation and information on individuals’ experiences (e.g. treatment satisfaction) might also help to decide which treatment should be given to an individual. The acceptability of CCBT both before and after treatment (e.g. expectancy, credibility and satisfaction) has rarely been assessed in research.⁵³ Taken together, more work needs to be done to optimise treatment adherence in CCBT, to determine the best way of providing online and unsupported CCBT in actual practice and to determine for whom CCBT is best suited.

Methodological considerations

We feel that our results cannot be explained by clear methodological flaws. Our large sample size ($n=303$) provided us with sufficient power to detect significant differences between the interventions. Furthermore, we had a relatively low attrition rate, so we feel confident that no biases occurred as a result of missing data. Finally, we were able to recruit participants from the general population. Unlike in samples selected in general practices or clinics, no biases occurred as a result of help-seeking behaviour of individuals and illness recognition by physicians, which is often a problem in depression.⁵⁴

Some limitations of the present study should also be noted. All our outcomes were measured online and one might question the equality of computerised questionnaires and paper and pen versions. However, there are sufficient indications that computerised and paper and pen questionnaires show similar construct validity.^{55–57} Furthermore, we relied on self-report measures at follow-up and, as a result, we have no information on actual diagnoses of depressive episodes at follow-up. Finally, it should be noted that the number of participants included is merely a fraction of the original recruitment population (i.e. 0.14%), despite the high prevalence of depression in the community.^{58,59} Participants had to come to the research centre for an intake, which could have reduced the number of applicants, but could also have increased the adherence. Overall, the low response rate in the current study might be discouraging to the belief of many researchers that online CCBT can be disseminated to large parts of the general population.⁶⁰

In the current study we were unable to confirm the previously reported high effectiveness of CCBT using online, unsupported Colour Your Life. Moreover, adding Colour Your Life to treatment as usual had no extra beneficial effects. These findings cannot merely be explained by the lack of treatment adherence, since per protocol analyses showed no differences between the interventions either. It is entirely possible that we have observed natural, although not complete, recovery in a group of people with moderate and severe depression who showed a decrease in symptoms irrespective of the nature of the intervention they received. Computerised cognitive-behavioural therapy, offered

online without any support, is not beneficial for all people with depression (nor is any treatment of any kind). Adding therapist support to CCBT or treatment in secondary mental healthcare might have yielded better results in this group of people with depression.

L. E. de Graaf, MSc, **S. A. H. Gerhards**, MSc, **A. Arntz**, PhD, Department of Clinical Psychological Science, Faculty of Psychology, Maastricht University, The Netherlands; **H. Riper**, PhD, Trimbos-institute, Utrecht, The Netherlands; **J. F. M. Metsemakers**, Department of General Practice, Faculty of Health, Medicine and Life Sciences, Maastricht University, The Netherlands; **S. M. A. A. Evers**, PhD, Department of Health Organization, Policy and Economics, Faculty of Health, Medicine and Life Sciences, Maastricht University, The Netherlands; **J. L. Severens**, PhD, Department of Health Organization, Policy and Economics, Faculty of Health, Medicine and Life Sciences, Maastricht University, and the Department of Clinical Epidemiology and Medical Technology Assessment, University Hospital Maastricht, The Netherlands; **G. Widdershoven**, PhD, Department of Health, Ethics and Society/Metamedica, Faculty of Health, Medicine and Life Sciences, Maastricht University, The Netherlands; **M. J. H. Huibers**, PhD, Department of Clinical Psychological Science, Faculty of Psychology, Maastricht University, The Netherlands.

Correspondence: L. E. de Graaf, Erasmus Medical Centre, Department of Medical Psychology and Psychotherapy, P.O. Box 2040, 3000 CA Rotterdam, The Netherlands. Email: l.e.degraaf@erasmusme.nl

First received 8 May 2008, final revision 7 Oct 2008, accepted 11 Nov 2008

Funding

The trial was financed by ZonMw (Netherlands Organisation for Health Research and Development; project number 945-04-417), research institute EPP and research institute CAPHRI. Municipalities Eijsden, Meerssen, Sittard-Geleen, Valkenburg and Maastricht sponsored the study. The study sponsors had no role in the design of the study; in the collection, analysis, and interpretation of the data; in the writing of the report; and in the decision to submit the article for publication.

Acknowledgements

We thank Annie Hendriks and Greet Kellens for their assistance during the study and Rosanne Janssen for the development of the infrastructure for online data collection.

References

- Butler AC, Chapman JE, Forman EM, Beck AT. The empirical status of cognitive-behavioral therapy. A review of meta-analyses. *Clin Psychol Rev* 2006; **26**: 17–31.
- Hollon SD, Stewart MO, Strunk D. Enduring effects for cognitive behavior therapy in the treatment of depression and anxiety. *Annu Rev Psychol* 2006; **57**: 285–315.
- Hirschfeld RM, Keller MB, Panico S, Arons BS, Barlow D, Davidoff F, et al. The National Depressive and Manic-Depressive Association consensus statement on the undertreatment of depression. *JAMA* 1997; **277**: 333–40.
- Kaltenthaler E, Brazier J, De Nigris E, Tumur I, Ferriter M, Beverley C, et al. Computerised cognitive behaviour therapy for depression and anxiety update: a systematic review and economic evaluation. *Health Technol Assess* 2006; **10**: 1–186.
- Proudfoot J, Ryden C, Everitt B, Shapiro DA, Goldberg D, Mann A, et al. Clinical efficacy of computerised cognitive-behavioural therapy for anxiety and depression in primary care: randomised controlled trial. *Br J Psychiatry* 2004; **185**: 46–54.
- Spek V, Nyklíček I, Smits N, Cuijpers P, Riper H, Keyzer J, et al. Internet-based cognitive behavioural therapy for subthreshold depression in people over 50 years old: a randomized controlled clinical trial. *Psychol Med* 2007; **37**: 1797–806.
- Van der Does AJW. De Nederlandse versie van de Beck Depression Inventory – second edition (BDI-II-NL): Handleiding (in Dutch) [*The Dutch Version of the Beck Depression Inventory – Second Edition (BDI-II-NL): A Manual*]. The Psychological Corporation, 2002.
- American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (3rd edn, revised) (DSM-III-R)*. APA, 1987.
- Robins LN, Wing J, Wittchen HU, Babor TF, Burke J, Farmer A, et al. The Composite International Diagnostic Interview. *Arch Gen Psychiatry* 1988; **45**: 1069–77.
- De Graaf LE, Gerhards SAH, Evers SMAA, Arntz A, Riper H, Severens JL, et al. Clinical and cost-effectiveness of computerised cognitive behavioural therapy for depression in primary care: design of a randomised trial. *BMC Public Health* 2008; **8**: 224.
- Riper H, Kramer JJAM. Kleur je leven [Colour Your Life] (online self-help course in Dutch). Trimbos-institute, 2004 (<https://www.kleurjeleven.nl>).
- Cuijpers P, Bonarius M, van den Heuvel A. *De 'omgaan met depressie' cursus: een handreiking voor begeleiders en organisatoren [The Coping with Depression Course: A Manual]*. NcGv, 1995.
- Lewinsohn PM, Antonuccio DO, Steinmetz JL, Teri L. *The Coping with Depression Course: A Psychoeducational Intervention for Unipolar Depression*. Castalia Publishing, 1984.
- Van Marwijk HWJ, Grundmeijer HGLM, Bijl D, van Gelderen MG, de Haan M, van Weel-Baumgarten, et al. NHG-standaard depressieve stoornis (in Dutch) [*Depression guideline of the Dutch College of General Practitioners*]. Huisarts Wet 2003; **46**: 614–23.
- Beck AT, Steer RA, Ball R, Ranieri WF. Comparison of Beck Depression Inventories–IA and –II in psychiatric outpatients. *J Pers Assess* 1996; **67**: 588–97.
- Arnau RC, Meagher MW, Norris MP, Bramson R. Psychometric evaluation of the Beck Depression Inventory–II with primary care medical patients. *Health Psychol* 2001; **20**: 112–9.
- Arrindell WA, Eetema H. Dimensionele structuur, betrouwbaarheid en validiteit van de Nederlandse bewerking van de Symptom Checklist (SCL–90); gegevens gebaseerd op een fobische en een 'normale' populatie (in Dutch) [Dimensional structure, reliability and validity of the Dutch version of the Symptom Checklist (SCL–90): findings based on a phobic and a 'normal' population]. *Ned Tijdschr Psychol* 1981; **36**: 77–108.
- Derogatis LR, Rickels K, Rock AF. The SCL–90 and the MMPI: a step in the validation of a new self-report scale. *Br J Psychiatry* 1976; **128**: 280–9.
- Mundt JC, Marks IM, Shear MK, Greist JMH. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *Br J Psychiatry* 2002; **180**: 461–4.
- McHorney CA, Ware JE, Raczek AE. The MOS 36-item short form health survey (SF–36). II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med Care* 1993; **31**: 247–63.
- Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF–36). I. Conceptual framework and item selection. *Med Care* 1992; **30**: 473–83.
- Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R, et al. Translation, validation, and norming of the Dutch language version of the SF–36 Health Survey in community and chronic disease populations. *J Clin Epidemiol* 1998; **51**: 1055–68.
- Weissman A. The Dysfunctional Attitude Scale: a validation study. *Diss Abs Int* 1979; **40**: 1389–90.
- De Graaf LE, Roelofs J, Huibers MJH. Measuring dysfunctional attitudes in the general population: the DAS–A revised. *Cog Ther Res* 2009; in press.
- Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Erlbaum, 1988.
- Jacobson NS, Truax P. Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. *J Consult Clin Psychol* 1991; **59**: 12–9.
- Cook RJ, Sackett DL. The number needed to treat: a clinically useful measure of treatment effect. *BMJ* 1995; **310**: 452–4.
- Andersson G, Bergström J, Holländare F, Carlbring P, Kaldö V, Ekselius L. Internet-based self-help for depression: randomised controlled trial. *Br J Psychiatry* 2005; **187**: 456–61.
- Wright JH, Wright AS, Albano AM, Basco MR, Goldsmith LJ, Raffield T, et al. Computer-assisted cognitive therapy for depression: maintaining efficacy while reducing therapist time. *Am J Psychiatry* 2005; **162**: 1158–64.
- Willemsse GRWM, Smit F, Cuijpers P, Tiemens BG. Minimal-contact psychotherapy for sub-threshold depression in primary care. Randomised trial. *Br J Psychiatry* 2004; **185**: 416–21.
- Spek V, Cuijpers P, Nyklíček I, Riper H, Keyzer J, Pop V. Internet-based cognitive behaviour therapy for symptoms of depression and anxiety: a meta-analysis. *Psychol Med* 2007; **37**: 319–28.
- Spek V, Cuijpers P, Nyklíček I, Smits N, Riper H, Keyzer J, et al. One-year follow-up results of a randomized controlled clinical trial on internet-based cognitive behavioural therapy for subthreshold depression in people over 50 years. *Psychol Med* 2008; **38**: 635–9.
- Christensen H, Griffiths KM, Jorm AF. Delivering interventions for depression by using the internet: randomised controlled trial. *BMJ* 2004; **328**: 265.
- Newman MG, Consoli AJ, Barr Taylor C. A palmtop computer program for the treatment of generalized anxiety disorders. *Behav Modif* 1999; **23**: 597–619.
- Osgood-Hynes DJ, Greist JH, Marks IM, Baer L, Heneman SW, Wanzel KW, et al. Self-administered psychotherapy for depression using a telephone-accessed computer system plus booklets: an open US–UK study. *J Clin Psychiatry* 1998; **59**: 358–65.

- 36 Proudfoot J, Goldberg A, Mann A, Everitt B, Marks I, Gray JA. Computerized, interactive, multimedia cognitive behavioral program for anxiety and depression in general practice. *Psychol Med* 2003; **33**: 217–27.
- 37 Cavanagh K, Shapiro DA. Computer treatment for common mental health problems. *J Clin Psychol* 2004; **60**: 239–51.
- 38 Clarke G, Eubanks D, O'Connor E, DeBar LL, Kelleher C, Lynch F, et al. Overcoming Depression on the Internet (ODIN): a randomised controlled trial of an Internet depression skills intervention program. *J Med Internet Res* 2002; **4**: e14.
- 39 Patten SB. Prevention of depressive symptoms through the use of distance technologies. *Psychiatr Serv* 2003; **54**: 396–8.
- 40 Clarke G, Eubanks D, Reid E, Kelleher C, O'Connor E, DeBar LL, et al. Overcoming depression on the internet (ODIN) (2): a randomized trial of a self-help depression skills program with reminders. *J Med Internet Res* 2005; **7**: e16.
- 41 Carlbring P, Gunnarsdóttir M, Hedensjö L, Andersson G, Ekselius L, Furmark T. Treatment of social phobia: randomised trial of internet-delivered cognitive-behavioural therapy with telephone support. *Br J Psychiatry* 2007; **190**: 123–8.
- 42 Kenwright M, Marks I, Graham C, Franses A, Mataix-Cols D. Brief scheduled phone support from a clinician to enhance computer-aided self-help for obsessive-compulsive disorder: randomized controlled trial. *J Clin Psychol* 2005; **61**: 1499–508.
- 43 Vuorilehto M, Melartin TK, Rytälä HJ, Isometsä E. Do characteristics of patients with major depressive disorder differ between primary and psychiatric care? *Psychol Med* 2007; **37**: 893–904.
- 44 Hamilton KE, Dobson KS. Cognitive therapy of depression: pretreatment patient predictors of outcome. *Clin Psychol Rev* 2002; **22**: 875–93.
- 45 Walsh BT, Seidman SN, Sysko R, Gould M. Placebo response in studies of major depression: variable, substantial, and growing. *JAMA* 2002; **287**: 1840–7.
- 46 Bialik RJ, Ravindran AV, Bakish D, Lapierre YD. A comparison of placebo responders and nonresponders in subgroups of depressive disorder. *J Psychiatry Neurosci* 1995; **20**: 265–70.
- 47 Posternak MA, Miller I. Untreated short-term course of major depression: a meta-analysis of outcomes from studies using wait-list control groups. *J Affect Disord* 2001; **66**: 139–46.
- 48 DeRubeis RJ, Hollon SD, Amsterdam JD, Shelton RC, Young PR, Salomon RM, et al. Cognitive therapy vs medications in the treatment of moderate to severe depression. *Arch Gen Psychiatry* 2005; **62**: 409–16.
- 49 Dimidjian S, Hollon SD, Dobson KS, Schmaling KB, Kohlenberg RJ, Addis ME, et al. Randomized trial of behavioral activation, cognitive therapy, and antidepressant medication in the acute treatment of adults with major depression. *J Consult Clin Psychol* 2006; **74**: 658–70.
- 50 Katon W, Von Korff M, Lin E, Walker E, Simon GE, Bush T, et al. Collaborative management to achieve treatment guidelines. Impact on depression in primary care. *JAMA* 1995; **273**: 1026–31.
- 51 Scogin FR, Hanson A, Welsh D. Self-administered treatment in stepped-care models of depression treatment. *J Clin Psychol* 2003; **59**: 341–9.
- 52 McCrone P, Knapp M, Proudfoot J, Ryden C, Cavanagh K, Shapiro DA, et al. Cost-effectiveness of computerised cognitive-behavioural therapy for anxiety and depression in primary care: randomised controlled trial. *Br J Psychiatry* 2004; **185**: 55–62.
- 53 Kaltenthaler E, Sutcliffe P, Parry G, Beverly C, Rees A, Ferriter M. The acceptability to patients of computerized cognitive behaviour therapy for depression: a systematic review. *Psychol Med* 2008; **38**: 1521–30.
- 54 Paykel ES, Tylee A, Wright A, Priest RG. The Defeat Depression Campaign: psychiatry in the public arena. *Am J Psychiatry* 1997; **154**: 59–65.
- 55 Butcher JN, Perry J, Hahn J. Computers in clinical assessment: historical developments, present status, and future challenges. *J Clin Psychol* 2004; **60**: 331–45.
- 56 Butcher JN, Perry JN, Atlis MM. Validity and utility of computer-based test interpretation. *Psychol Assess* 2000; **12**: 6–18.
- 57 Schulenberg SE, Yutzenka BA. Equivalence of computerized and conventional versions of the Beck Depression Inventory-II (BDI-II). *Current Psychology* 2001; **20**: 216–30.
- 58 Bijl RV, Ravelli A, van Zessen G. Prevalence of psychiatric disorder in the general population: results of the Netherlands Mental Health Survey and Incidence Study (NEMESIS). *Soc Psychiatry Psychiatr Epidemiol* 1998; **33**: 587–95.
- 59 Kessler RC, Berglund P, Demler O, Jin R, Koretz D, Merikangas KR, et al. The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication (NCS-R). *JAMA* 2003; **289**: 3095–105.
- 60 Andersson G, Cuijpers P. Pros and cons of online cognitive-behavioural therapy. *Br J Psychiatry* 2008; **193**: 270–1.

100
words

Stigma

Peter Byrne

Stigma is a prejudice (negative attitude) based on stereotypes usually leading to discrimination. Familiar mental illness stereotypes (weak, violent, comic) drive prejudice in society. Discrimination ranges from simple avoidance through exit life events (relationship, employment and housing losses) and institutional discrimination (denial of health interventions, insurance, jury service, *visa inter alia*). Stigma-discrimination cannot occur without a power differential. When a person with mental health problems shares societal prejudices, their self-stigma contributes to further morbidity and status loss. Reducing stigma requires multiple interventions: a language of inclusion (no more 'schizophrenics'), legal and organisational reforms, and cultural changes based on empowerment.

The British Journal of Psychiatry (2009)
195, 80. doi: 10.1192/bjp.195.1.80