ORIGINAL ARTICLE

Clinical Effectiveness of Individual Cognitive Behavioral Therapy for Depressed Older People in Primary Care

A Randomized Controlled Trial

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Context: In older people, depressive symptoms are common, psychological adjustment to aging is complex, and associated chronic physical illness limits the use of antidepressants. Despite this, older people are rarely offered psychological interventions, and only 3 randomized controlled trials of individual cognitive behavioral therapy (CBT) in a primary care setting have been published.

Objective: To determine the clinical effectiveness of CBT delivered in primary care for older people with depression.

Design: A single-blind, randomized, controlled trial with 4- and 10-month follow-up visits.

Patients: A total of 204 people aged 65 years or older (mean [SD] age, 74.1 [7.0] years; 79.4% female; 20.6% male) with a Geriatric Mental State diagnosis of depression were recruited from primary care.

Interventions: Treatment as usual (TAU), TAU plus a talking control (TC), or TAU plus CBT. The TC and CBT were offered over 4 months.

Outcome Measures: Beck Depression Inventory-II (BDI-II) scores collected at baseline, end of therapy (4 months), and 10 months after the baseline visit. Subsidiary measures were the Beck Anxiety Inventory, Social Functioning Questionnaire, and Euroqol. Intent to treat using Generalized Estimating Equation and Compliance Average Causal Effect analyses were used.

Results: Eighty percent of participants were followed up. The mean number of sessions of TC or CBT was just greater than 7. Intent-to-treat analysis found improvements of −3.07 (95% confidence interval [CI], −5.73 to −0.42) and −3.65 (95% CI, −6.18 to −1.12) in BDI-II scores in favor of CBT vs TAU and TC, respectively. Compliance Average Causal Effect analysis compared CBT with TC. A significant benefit of CBT of 0.4 points (95% CI, 0.01 to 0.72) on the BDI-II per therapy session was observed. The cognitive therapy scale showed no difference for nonspecific, but significant differences for specific factors in therapy. Ratings for CBT were high (mean [SD], 54.2 [4.1]).

Conclusion: Cognitive behavioral therapy is an effective treatment for older people with depressive disorder and appears to be associated with its specific effects.

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MAJOR DEPRESSION OFten becomes a chronic disorder in older people, with up to 74% of people in the community remaining depressed 1 year after detection.[1] Physical ill health may make conventional pharmacotherapy less desirable, and factors such as bereavement and social isolation make psychological interventions more relevant. Despite the acceptability of psychological treatments in older people, they are used in only 5% of cases,[1,2] possibly owing to the assumption that they are less responsive than their younger counterparts.

Cognitive behavioral therapy (CBT) is an effective treatment that is recommended for depressive disorder in adults of all ages[3] and is associated with continued improvement over time[4]; it is one of the most systematically researched psychosocial treatments for depression in later life.[5,6] Although meta-analyses[7-9] and a systematic review by Wilson et al[10] support the use of CBT in older people, many published studies have methodological limitations such as relatively low sample sizes, the absence of suitable con-

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trol groups, unspecified treatment techniques, and high dropout rates. Furthermore, there is a dearth of randomized controlled trials for depressed older people in a primary care setting. Of the randomized controlled trials demonstrating the benefit of CBT, none has controlled for nonspecific therapeutic effects, and only 3 randomized controlled trials of individual CBTs have been done in primary care,[11-13] 2 of which were inconclusive.[11,12] In the trial by Wilson et al[11] 50% of participants dropped out; this makes results difficult to interpret. In the trial by Floyd et al,[12] only 4 people who had received individual CBT were followed up. The pilot trial by Laidlaw at al[13] was more positive, demonstrating a significant benefit of CBT for treating mild to moderate depression.

It has been suggested that depression in old age may be a consequence of social and emotional isolation and that simply spending time with the patient may be of benefit[14] and potentially more cost-effective than therapy in the short term. However, no trial has specifically addressed this issue compared with CBT.

We present a single-blind, randomized, controlled trial of individual CBT in primary care for older people with depression. A talking control (TC) arm was used to assess the effects of attention, and a treatment as usual (TAU) arm was also included. Our trial tests the hypothesis that CBT is clinically more effective than TAU and the subsidiary hypothesis that CBT is more clinically effective than TC.

METHODS

This was a single-blind, randomized, controlled trial in which the researchers were blind to group allocation until all data entry had been completed. The trial was conducted with the approval of relevant ethics committees. The study took place between April 2004 and September 2007. Measures were collected at baseline (time 1), 4 months (time 2), and 10 months (time 3) after entry into the study. The Beck Depression Inventory-II (BDI-II) score at time 2 was recorded as our primary endpoint.

SETTING

Forty-seven general practices were selected through the North Central Thames General Practice Research Network, each with a mean (SD) of 6.8 (3.0) practitioners per practice and covering an area in North London (boroughs of Camden, Islington, Barnet, Enfield, and Haringey). The population of people older than 65 years in this area is just greater than 140 000.[15] People aged 65 years or older were recruited by methods developed from our previous feasibility work,[16] namely self referral, general practice referral (either from a direct approach by researchers or via the general practitioner [GP]), and by database searches.

RECRUITMENT

The 15-item Geriatric Depression Scale, a self-rated questionnaire for depression in the elderly,[17] was used for screening. Participants who scored 5 or higher were offered a further interview to see whether they satisfied the entry criteria.

Inclusion Criteria

The inclusion criteria were (1) a primary diagnosis of depressive disorder made by the researcher who administered the Geriatric Mental State and History and Etiology Schedule[18] using the computerized diagnostic program AGECAT (Automated Geriatric Examination for Computer Assisted Taxonomy), which has been validated in the community and used in international comparisons of depression; (2) a score of 14 or higher on the BDI-II[19] to include people with less severe mixed anxiety and depression, who are frequently seen in primary care and who may respond to CBT[20]; (3) sufficient command of English to use CBT techniques; and (4) if taking an antidepressant, a stable dose of medication for at least 8 weeks prior to randomization.

Exclusion Criteria

The exclusion criteria were (1) intense suicidal intent requiring inpatient admission; (2) a history suggestive of alcohol misuse or drug dependence; (3) a history of bipolar affective disorder; (4) the presence of hallucinations or delusions; (5) cognitive deficits, as judged by a score of less than 24 on the Mini-Mental State Examination[21]; (6) having received CBT in the last year; and (7) having received electroconvulsive therapy within the previous 6 months, because of possible residual effects on cognition.

Randomization

People were given 24 hours to consider the study before providing informed consent. Participants' treatment preference was recorded before they were randomized to 1 of 3 groups using computer-generated random numbers. Numbers were placed in opaque envelopes, and group allocation was managed by an independent administrator. The randomization was stratified according to severity of depression (BDI-II score of 14-19 indicated mild; 20-63, moderate/severe) and general practice size. Prior analysis of our feasibility data indicated that there were few differences between participants recruited from the 3 sources described above and, therefore, stratification on this basis was not conducted. Research staff were kept blind to trial arm allocation. All therapists provided the treatments in both intervention arms.

INTERVENTIONS

Although all 3 groups received TAU, for convenience we will refer to them as the TAU, TC, and CBT groups. (1) For the CBT group, up to twelve 50-minute sessions were offered to each patient; (2) for the TC group, up to twelve 50-minute sessions, to match the time spent face to face with a therapist in the CBT arm; and (3) for the TAU group, GPs were asked to provide usual treatment.

Cognitive Behavior Therapy

Cognitive behavioral therapy techniques were modified for use in older people,[22] with increased structure of the sessions and techniques to facilitate recall.[23,24] Where relevant, specific issues associated with old age were addressed with exploration of patients' beliefs about the negative effects of physical ill health and their perceptions of themselves in the context of their age.[23] We used a manualized treatment based on a study by Beck et al,[25] developed by Thompson et al,[26] and modified by Laidlaw to reflect an English perspective. A checklist was used to ensure that, where appropriate, all components of the manual were covered. *The Feeling Good Handbook*, by Burns,[27] originally developed for use with older people, was given to all participants as an adjunct to therapy, with selected chapters recommended for reading. The National Institute of Clinical Excellence guidelines recommend that 6 to 8 sessions of CBT be given

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to depressed adults in a primary care setting.[3] Up to 12 sessions were offered because older people may take longer to learn CBT techniques. For those unable to travel, home visits were offered for both interventions. At the end of the intervention period, participants were transferred back to their GPs to continue with TAU.

Talking Control

Clearly defined criteria for the TC group were used to prevent CBT from being delivered. Talking control therapy was developed during our feasibility work, and details are available from the authors. The therapists practiced delivering the TC in role plays with the supervisor so that difficult questions could be addressed. Dysfunctional beliefs were not challenged; however, the therapists were asked to show interest and warmth, encouraging participants to discuss neutral topics such as hobbies, sports, and current affairs. No advice or problem solving was given, and there was little focus on emotional issues. No suggestions for behavioral tasks were offered. So for example, if the patient said, "My daughter does not like me as she never comes to visit me," the therapist would ask, "How many children do you have?"

Treatment as Usual

Treatment as usual allowed for whatever medication, routine support, or referral to other services was felt appropriate by the GP. The only constraint was to refrain from referring patients for CBT or other brief talking therapies unless absolutely necessary. Participants could discuss their problems and their physical health, and pain management could be reviewed, medication prescribed, and referrals made to luncheon clubs or day centers. Antidepressant medication as a routine part of TAU was not constrained. We envisaged that the number of participants who began taking antidepressant medication during the course of the trial would likely be small.[20,28] General practitioners were notified about patients allocated to the trial for ethical reasons and to ensure that provision of therapy from other sources was limited.

EVALUATION OF THERAPY

Therapist Training and Supervision

Both interventions were delivered by therapists who were accredited by the British Association for Behavioral and Cognitive Psychotherapies (http://www.babcp.com), with at least 5 years practice in CBT. Our protocol demanded that therapists kept a checklist to ensure that the core components of the CBT treatment manual[26] were delivered and, if not, the reason for this recorded. Both CBT and TC sessions were audiotaped. Supervision of therapy sessions, supplemented by the audiotapes, was undertaken by an author (M.S.). Audiotapes were identifiable by a random number, but in all other respects were identical in appearance; this was to ensure that blindness was maintained with respect to the selection process and that no visual cues were given to an independent rater concerning treatment allocation. A random sample of 1 in 10 tapes was made. Audiotapes (CBT and TC) were rated by a British Association for Behavioural and Cognitive Psychotherapies–accredited therapist using the Cognitive Therapy Scale,[29] a reliable measure of adherence to the CBT model.[30]

Measures

Baseline information was collected on age, sex, ethnicity, marital status, occupation of the main salaried person in the household before retirement, education, number of previous episodes of depression, and diagnosis. The BDI-II[19] score was the main outcome measure. This is a 21-item self report measure with a maximum score of 63, indicating severe depressive symptoms.

Secondary outcome measures were (1) the Beck Anxiety Inventory as a measure of anxiety[31]; (2) the Euroqol[32] to measure health-related quality of life; (3) the Social Functioning Questionnaire[33] as a measure of social function; (4) patient satisfaction with treatment, determined by asking participants to rate on a 3-point scale (yes, no, unsure) whether they found CBT or the TC sessions useful and whether they found their therapist easy to talk to; and (5) the number of therapy sessions and "did not attend" rate, used as a proxy measure of engagement.

Measures of bias used were (1) expected outcome[34] (prior to the study, all therapists were asked to predict the degree to which they thought either treatment would do harm or good to each patient on a 7-point Likert scale ranging from –3 to +3); (2) patients' preferences for treatment, recorded on a 4-point Likert scale (scores, 0-3); and (3) assessment of blindness (the researcher undertaking assessment was asked to guess the trial group [yes, no, don't know]).

STATISTICAL ANALYSIS

Our principal hypothesis concerns CBT vs TAU. A 3.5-point difference in means (SD, 8.0) for the BDI[35] was assumed a priori as a clinically important change.[20] The BDI-II,[19] an updated version of the BDI,[35] has similar psychometric properties. Using normative data for the BDI-II for depression at 80% power, 5% significance, and an approximate intraclass correlation coefficient of 0.6 for the repeated BDI-II responses during the 2 follow-up periods, 67 participants were required in each treatment group.[36]

The analysis was performed using the CONSORT (Consolidated Standards of Reporting Trials) guidelines. Descriptive results (mean [SD]) for demographic, pretreatment, and posttreatment total outcome scores (with 95% confidence intervals) during the follow-up period are presented for each treatment group. We used intent to treat and compliers' average causal effect (CACE)[37] as sensitivity checks. Analyses with data imputed for missing observations using multiple imputation[38,39] were used to test the hypothesis. We used the Generalized Estimating Equation,[40] assuming an equal within-group correlation structure for intent to treat. We observed significant mean posttreatment BDI-II score differences at both of the time points for baseline BDI-II strata and at period 1 for GP number strata. We have included both factors in the analysis.

For CACE, we assumed that participants belonged to 1 of 2 potentially latent classes, compliers and noncompliers. Compliance in the treatment group is determined by the number of sessions attended, while an estimate is made for attendance in the usual care group if they were offered it. We observe compliance status in a treatment group while it is latent in a control group. Randomization ensures that, on average, the proportions of compliers in the treatment and control groups are equal. Thus, we estimate the proportion of unobserved compliers in the control group from the proportion observed in the treatment group. A random effects instrumental variable model[41] with Gaussian family and identity link was used for CACE to model the average BDI-II score during the follow-up period and the number of sessions of psychotherapy attended as response variables. Both models were adjusted for severity of depression (BDI-II score) at baseline.

The treatment effect under intent-to-treat analysis is the average causal effect of treatment, which is the difference between the pretreatment and posttreatment average BDI-ll scores for the treatment and control groups, regardless of compli-

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ance status. The CACE is the difference between pretreatment and posttreatment average BDI-ll scores for the compliers in the treatment group and estimated compliers in the control group. All analyses used Stata release 9 SE (StataCorp, College Station, Texas)

RESULTS

Source of referral, response rates to recruitment, and dropouts are shown in the trial flowchart (**Figure 1**). A total of 376 people were referred for assessment. Forty five percent (n=170) were self referrals, 27% (n=101) GP referrals, and 28% (n=105) recruited from general practice database searches. Of these, 54% (n=204) met the inclusion criteria; 41% (n=83) were self referrals, 31% (n=63) were GP referrals, and 28% (n=58) were referrals from database searches.

There were no major differences between participants in the 3 trial arms (**Table 1**). All (n=204) patients taking part had a Geriatric Mental State and History and Etiology Schedule AGECAT diagnosis of depression. One hundred eighty (88%) had a *DSM-IV* diagnosis of major depression; the remaining 24 had a diagnosis of minor depression (Table 1).

Follow-up data are shown in **Table 2**. There were differences in response rates for the different questionnaires, as some participants were reluctant to complete them all (BDI-II, Beck Anxiety Inventory-II, Euroqol, and Social Functioning Questionnaire) because of the time required. Emphasis was, therefore, placed on collecting data for the main outcome measure. It was not possible to collect any data from 37 people at the 10-month follow-up because 8 (6 in the TAU and 2 in the TC group) were dissatisfied with their group allocation, 8 were too physically or mentally ill, 7 had moved or were not contactable, 6 refused for no reason, 5 died, 2 developed cognitive problems, and 1 was angry with the therapist. Although numbers were small, there was no difference in demographic variables at baseline between those who dropped out and those who did not.

Table 3 shows the intent-to-treat comparisons in a Generalized Estimating Equation model. The change in BDI-II score was adjusted for baseline BDI-II scores and time. Between-group comparisons found a reduction in BDI-II score of 3.07 for CBT compared with TAU and a reduction of 3.65 when CBT was compared with TC. There was also a 0.35 improvement in BDI-II score per session with CBT compared with TC. We did not observe any significant further changes after the end of the intervention (period effect, 0.09 ; 95% confidence interval, −1.49 to 1.66). Mean BDI-II scores are plotted for each trial arm in **Figure 2**. These findings were confirmed with CACE analysis, adjusted for baseline BDI-II, which showed the benefit of CBT as 0.40 of a BDI-II point (95% confidence interval, 0.01-0.72) per therapy session. Although caution is required when interpreting unadjusted BDI-II scores, we found that 33% of participants in the CBT group experienced a 50% or greater reduction in BDI-II after intervention compared with 21% and 23% in the TC and TAU groups, respectively. We used Generalized Estimating Equation models for the main and secondary analyses. As the Generalized Estimating

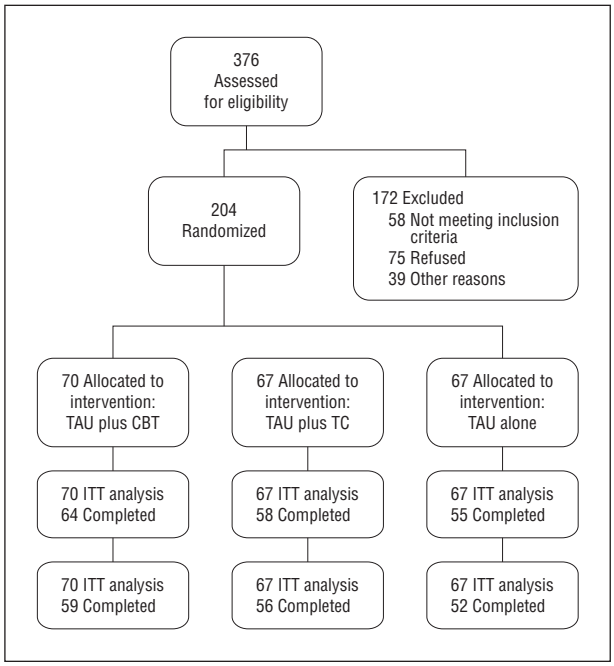

Figure 1. Flow diagram of participants recruited to trial. CBT indicates cognitive behavioral therapy; ITT, intent-to-treat; TAU, treatment as usual; TC, talking control.

Equation does not provide an estimate of effect size (η^2 and partial-η^2), we have derived the effect size using ordinary linear regression, which accounted for repeated measure clustering; this, however, underestimates treatment effect. The estimated η^2 and partial-η^2 for the main treatment effect were 0.03 and 0.04, respectively. The estimate of intraclass correlation was 0.53, using a similar multilevel model.

No significant changes in Beck Anxiety Inventory-II, Euroqol, or Social Functioning Questionnaire scores were observed with time or by intervention group.

EXPERIENCE OF THERAPY

There was no significant difference in reported experience of therapy between those who received the CBT or TC intervention. Of those who provided feedback, 72% of patients (37 of 51) found CBT useful, 20% (10 of 51) did not, and 8% were unsure. Sixty three percent of patients (29 of 46) found TC useful, 20% (9 of 46) did not, and 17% (9 of 46) were unsure. Most older people found their therapist easy to talk to (86% of patients [44 of 51] in the CBT and 91% [2 of 46] in TC group). Only 8% of patients (4 of 51) in the CBT group and 9% (4 of 46) in the TC group found the therapist hard to talk to. Six percent (3 of 51) of those receiving CBT were neutral about whether the therapist was easy to talk to.

ENGAGEMENT WITH THERAPY

There was no significant difference between the mean number of sessions attended for CBT (mean [SD], 7.09 [4.41] sessions) or TC (mean [SD], 7.58 [4.56] sessions). We aimed to have 1 therapist deliver most sessions to control for therapist factors. Allowing for

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Table 1. Characteristics of Participants in Each Arm of Study

Baseline Variables	Patients, No. (%)			
	Total (N=204)	CBT (n=70)	TC (n=67)	TAU (n=67)
Source of referral				
Self	83 (40.7)	31 (44.3)	29 (43.3)	23 (34.3)
GP	72 (35.3)	21 (30.0)	23 (34.3)	28 (41.8)
Database	49 (24.0)	18 (36.7)	15 (22.4)	16 (23.8)
Mean (SD) age, y	74.1 (7.0)	74.4 (7.6)	75.0 (7.1)	72.8 (5.9)
Sex				
Male	42 (20.6)	11 (15.7)	17 (25.4)	4 (20.9)
Female	162 (79.4)	59 (84.3)	50 (74.6)	53 (79.1)
Ethnicity				
White	154 (75.5)	50 (71.4)	51 (76.1)	53 (79.1)
White other	38 (18.6)	14 (20.0)	13 (19.4)	11 (16.4)
African Caribbean	6 (2.9)	2 (2.9)	1 (1.5)	3 (4.5)
Asian	2 (1.0)	1 (1.4)	1 (1.5)	0 (0)
Other	4 (2.0)	3 (4.3)	1 (1.5)	0 (0)
Living situation				
Alone	128 (62.8)	42 (60.0)	42 (62.7)	44 (65.7)
With spouse or partner	49 (24.0)	16 (22.9)	19 (28.4)	14 (20.9)
With family	20 (9.8)	8 (11.4)	5 (7.5)	7 (10.4)
Other	7 (3.4)	4 (5.7)	1 (1.4)	2 (3.0)
Marital status				
Widowed	75 (36.8)	25 (35.7)	26 (38.8)	24 (35.8)
Married or cohabitating	57 (27.9)	19 (27.1)	21 (31.3)	17 (25.4)
Single	26 (12.8)	6 (8.6)	8 (11.9)	12 (17.9)
Separated or divorced	46 (22.5)	20 (28.6)	12 (17.9)	14 (20.9)
Working				
Yes	14 (6.9)	6 (8.6)	3 (4.5)	5 (7.5)
No/retired	190 (92.1)	64 (91.4)	64 (95.5)	62 (92.5)
DSM-IV diagnosis				
Major depression	180	62	57	61
Minor depression	24	8	10	6
Previous episode of depression				
Yes	159 (77.0)	50 (71.4)	54 (80.6)	55 (82.1)
No	47 (23.0)	20 (28.6)	13 (19.4)	12 (17.9)
Previous treatment for depression				
Medication in past	39 (19.1)	13 (18.6)	10 (14.9)	16 (23.9)
Talking therapy	50 (24.5)	12 (17.1)	20 (29.8)	18 (26.9)
Medication and talking treatment	51 (25.0)	22 (31.4)	13 (19.4)	16 (23.9)
Hospitalization	17 (8.3)	4 (5.7)	10 (14.9)	3 (4.5)
None recorded	47 (23.0)	19 (27.1)	14 (20.9)	14 (20.9)
Medication at baseline				
Antidepressants	54 (26.5)	18 (25.7)	16 (23.8)	21 (37.3)
Hypnotic or anxiolytic or combined	20 (9.8)	7 (10.0)	4 (6.0)	9 (13.4)
No antidepressant or hypnotic	130 (63.7)	48 (68.6)	46 (48.6)	36 (53.7)
Antidepressants[a]				
SSRI total	32	12	7	13
Citalopram	11	4	2	5
Fluoxetine	10	5	2	3
Paroxetine	9	3	2	4
Sertraline	2	0	1	1
Tricyclic total	16	3	6	7
Amitriptyline	9	2	2	5
Dothiepin	5	0	4	1
Trimipramine	1	0	0	1
Clomipramine	1	1	0	0
Other total	4	2	1	1
Lofepramine	2	1	1	1
Trazodone	1	1	0	0
Mirtazapine	1	0	0	0
SNRI total	4	0	2	2
Venlafaxine	4	0	2	2
Imipramine	55 (27.0)	17 (24.2)	16 (23.8)	23 (34.3)
Mean (SD) equivalent baseline dose	84.8 (50.5)	81.9 (53.6)	88.2 (51.0)	87.6 (49.2)

Abbreviations: CBT, cognitive behavioral therapy; GP, general practitioner; SNRI, serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor; TAU, treatment as usual; TC, talking control.

[a]Total numbers of prescribed antidepressants given by class (SSRI, tricyclic, etc) and name.

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Table 2. Unadjusted Mean Scores and Standard Deviations for Outcome Measures

Completer Data	Score					
	CBT		TC		TAU	
Measure by Time Point	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	No.
BDI-II						
Baseline	27.3 (8.7)	70	26.4 (6.9)	67	27.7 (7.7)	67
Postintervention 1	18.4 (10.8)	64	20.2 (9.0)	58	20.3 (11.3)	55
Postintervention 2	18.3 (10.6)	59	20.3 (9.0)	56	20.8 (10.5)	52
BAI-II						
Baseline	16.7 (9.8)	70	16.3 (8.2)	67	19.3 (10.2)	67
Postintervention 1	13.2 (8.8)	60	15.3 (9.3)	53	16.2 (9.7)	55
Postintervention 2	15.1 (9.7)	55	16.1 (8.2)	50	15.7 (8.3)	49
Euroqol						
Baseline	0.50 (0.32)	70	0.52 (0.31)	67	0.46 (0.29)	67
Postintervention 1	0.53 (0.34)	61	0.55 (0.39)	57	0.47 (0.38)	55
Postintervention 2	0.54 (0.33)	56	0.52 (0.32)	53	0.52 (0.31)	50
SFQ						
Baseline	14.5 (6.1)	50	15.6 (5.5)	57	14.7 (5.6)	54
Postintervention 1	12.0 (5.9)	51	13.4 (6.2)	47	13.8 (6.0)	46
Postintervention 2	13.5 (6.6)	47	14.2 (6.3)	43	13.3 (6.1)	40

Abbreviations: BAI-II, Beck Anxiety Inventory-II; BDI-II, Beck Depression Inventory-II; CBT, cognitive behavioral therapy; SFQ, Social Functioning Questionnaire; TAU, treatment as usual; TC, talking control.

Table 3. Multivariable Analysis of Outcomes[a]

Postintervention Outcome	β (95% CI)		
	CBT vs TAU	TC vs TAU	CBT vs TC
BDI-II			
Treatment	−3.07 (−5.73 to −0.42)	0.14 (−2.74 to 3.02)	−3.65 (−6.18 to −1.12)
Sessions, No.	NA	NA	−0.35 (−0.66 to −0.05)
BAI-II			
Treatment	−1.62 (−3.95 to 0.71)	0.58 (−1.91 to 3.08)	−2.15 (−4.45 to 0.16)
Sessions, No.	NA	NA	−0.19 (−0.47 to 0.09)
Euroqol			
Treatment	0.05 (−0.04 to 0.14)	0.22 (−0.06 to 1.06)	0.04 (−0.05 to 0.12)
Sessions, No.	NA	NA	0.01 (0.002 to 0.02)
SFQ			
Treatment	−1.65 (−3.57 to 0.26)	−1.20 (−3.14 to 0.72)	−1.14 (−3.12 to 0.84)
Sessions, No.	NA	NA	−0.13 (−0.37 to 0.10)

Abbreviations: BAI-II, Beck Anxiety Inventory-II; BDI-II, Beck Depression Inventory-II; CBT, cognitive behavioral therapy; CI, confidence interval; NA, not applicable; SFQ, Social Functioning Questionnaire; TAU, treatment as usual; TC, talking control.
[a] Adjusted for baseline BDI-II, general practitioner numbers, baseline outcome value, time period, and number of sessions, as appropriate.

sickness and holidays, 799 of the 1003 sessions (80%) were delivered by 1 therapist, of which 46% (364 of 799) were in the CBT and 54% (435 of 799) in the TC group. The remaining 204 sessions were approximately equally distributed between 5 other therapists, with 42% (119 of 204) in the CBT and 58% (85 of 204) in the TC group. Sixty per cent of therapy sessions (600 of 1003) took place in the family practice clinics, and 40% in the patient's home.

BIASES

Treatment Preference

Although more people wanted CBT, there was no significant difference in this preference between trial arms (**Table 4**).

Anticipated Treatment Effect

Following the initial meeting with the patient, therapists were asked to make a subjective prediction of improvement on a 7-point Likert scale, ranging from −3 (very much worse) to +3 (very much better). There was no significant difference in the mean (SD) predicted degree of improvement of 0.84 (0.70) with CBT (n=64) and 0.63 (0.61) with TC (n=60).

Site of Delivery of Intervention

A post hoc analysis was conducted to see whether site of therapy influenced outcome. None was found; nor was there a significant difference in the number of sessions completed between the interventions delivered at home or in a community setting.

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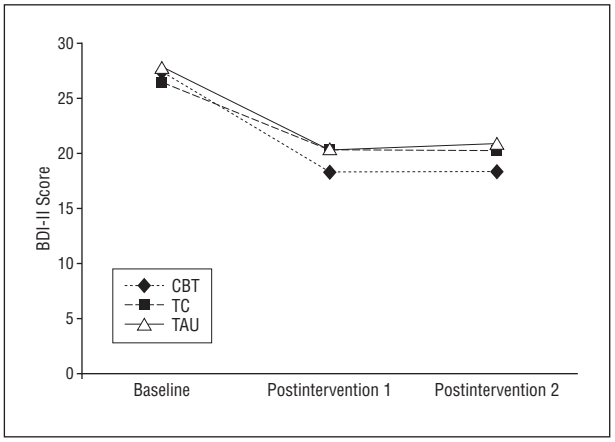

Figure 2. Plot of mean Beck Depression Inventory-II (BDI-II) scores in each trial arm. CBT indicates cognitive behavioral therapy; postintervention 1, 4 months after baseline visit; postintervention 2, 10 months after baseline visit; TAU, treatment as usual; TC, talking control.

Table 4. Measures of Patients' Treatment Preference and the Masking of Research Assessments at Follow-up

	No.			
Measure of Biases	**CBT**	**TC**	**TAU**	**Total**
Treatment preference				
CBT	37	36	31	104
TC	10	11	20	41
TAU	1	0	0	1
No preference	22	20	16	58
Total	**70**	**67**	**67**	**204**
Masking correctly guessed				
No	18	12	11	41
Yes	36	24	35	95
Don't know	10	22	9	41
Total	**64**	**58**	**55**	**177**

Abbreviations: CBT, cognitive behavioral therapy; TAU, treatment as usual; TC, talking control.

Blindness

The researcher conducting the follow-up interviews was asked to guess the treatment allocation group each patient was allocated to (CBT, TAU, TC, or unsure). Data were available for 177 participants at the 4-month postbaseline follow-up (Table 4). As shown in Table 4, though participants were asked not to disclose their allocated treatment group to the researcher, it proved impossible, and the researcher guessed the correct treatment allocation group more often than not (χ^2_4=11.9; P=.01).

Prescribed Antidepressants

Data for mean equivalent doses of antidepressants in older people are limited, and maximum recommended doses are lower than in younger people.[42] Mean equivalent doses of imipramine were calculated for the selective serotonin reuptake inhibitors venlafaxine[43] and trazadone.[44] Doses of 30 mg of mirtazapine and 140 mg of lofepramine were taken as equivalents to 50 mg of imipramine using the British National Formulary (2008).[45] Mean (SD) equivalent doses of imipramine at baseline were provided (Table 1). Of 204 participants, 40 (19.6%) were taking an equivalent of 50 mg of imipramine or more at baseline, with no significant difference in mean dose across the 3 intervention groups. There was no significant change in prescribing pattern at times 2 and 3; GPs had discontinued giving antidepressants in 6 and 10 participants by times 2 and 3, respectively. At time 3, only 4 participants had begun taking antidepressants. No significant differences in prescriptions by treatment condition were observed, nor did antidepressants moderate outcome.

RATINGS OF INTERVENTIONS

A total of 1005 sessions were delivered (508 in the TC and 497 in the CBT group). Because of problems with audibility, of the 100 tapes selected, 50 of the 53 in the CBT and 43 of the 47 tapes in the TC group were rated. The mean (SD) total Cognitive Therapy Scale score was 54.2 (4.1) for the CBT and 23.2 (1.2) for the TC group. Subanalysis showed that the therapy in both intervention arms was rated highly for nonspecific factors in therapy (empathy, warmth, professionalism, etc). However the CBT group showed a significant difference (t_{91}=24.3; P=.001) for specific CBT techniques; of a maximum score of 36, CBT had a mean (SD) score of 23.7 (3.0) compared with 0.79 (2.5) for the TC group.

COMMENT

This is the largest randomized trial of individual CBT for older people with depression in primary care. The results, strengthened by CACE analysis, show that CBT is an effective treatment when compared with usual GP care or a TC intervention. Adjusted BDI-II scores are significantly reduced with CBT compared with either TAU or TC. Most participants reported that treatments were helpful and the therapist easy to talk to. Inclusion of a TC arm is a strength of the study, as this suggests nonspecific factors such as warmth and attention are not the mediators of change. Cognitive behavioral therapy appeared to have little effect on anxiety symptoms or social functioning.

General practitioners were only aware of current depression in one-third of the sample, despite patients' histories of depression. Self-referral allowed recruitment of those who would otherwise be missed[16] and ensured the external validity of our findings. Poor mobility of older people, a recognized barrier to accessing psychological services,[46] was addressed by seeing 40% of people in their homes. The demographics of the trial arms were evenly balanced, with more women, characteristic of people in this age group in primary care.[47] Attrition was relatively low, with more than 80% of people followed up 10 months after the baseline visit, and there were no significant differences in baseline variables between participants who completed research assessments and those who dropped out.

The changes in BDI-II scores and the number of therapy sessions recorded are consistent with those reported by Laidlaw et al.[13] However, our sample population had more severe levels of depression at trial entry and were simi-

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lar to those studied by Ward et al[20] when evaluating CBT in depressed people of all ages in primary care.

Compliers' average causal effect analysis revealed a significant effect of CBT, with a change in BDI-II score of 0.4 points per therapy session, suggesting that if patients attend all 12 sessions, then a change in BDI-II score of 4.8 (or approximately 0.5 SD) may be expected. This treatment effect may also be underestimated because a number of items on the BDI-II are potentially less sensitive to change in older age such as sex life and energy levels.

Although depressive symptoms may be seen as a normal consequence of aging,[48] our results challenge the myth that older people are just lonely and in need of company and a listening ear. Consistent with previous studies,[16,49] older people can be recruited and engaged in talking therapies, welcome psychological interventions,[1,2] and benefit from a specific treatment such as CBT.[7-9,11] Consistent with Laidlaw et al,[13] in a UK primary care setting, more CBT sessions were attended by older than younger people[20] and improvements in anxiety and social functioning were not observed.[13] Although CBT may be helpful for anxiety symptoms in younger adults, anxiety in older people was often associated with physical problems, which may not improve with psychological interventions alone. Furthermore, many of the deficits of social functioning (eg, sex life, availability of close relationships) may also be less amenable to change.

Unlike CBT in younger populations (eg, Fava et al[4]), our data suggest that the treatment effects were maintained, but not enhanced, at the 10-month follow-up. Wilkinson[22] suggests that older people may take slightly longer to adjust to change. Although the number of sessions attended was similar to Laidlaw et al,[13] little is known about the optimal length and frequency of therapy sessions; it is possible that shorter and more frequent sessions would be more suitable.

A threshold for adequate therapy on the Cognitive Therapy Scale has not been established in older people, and a score of 39 is regarded as acceptable in people of all ages.[50] High scores for CBT and nonspecific factors in the TC group were achieved, suggesting that there was a clear difference between the 2 intervention types. Finally, the results of the intent-to-treat and CACE analyses were similar, lending support to our overall findings.

Despite the positive findings, potential biases (blindness, therapist's factors, intervention issues, antidepressant use) need to be considered when evaluating the study.

It was difficult for researchers to remain masked to group allocation. However, participants completed self-rating assessments of mood; therefore, the lack of blindness should not have affected our primary outcome to any great extent.

Although BDI-II scores had improved, *DSM-IV* criteria for depression were not reassessed after the interventions or at follow-up for practical reasons; however, this may have been valuable.

Therapist skills and their allegiance to treatment influence outcome. Multiple therapists delivering the intervention may be used to control for both known and unknown therapist factors, with some adjustments being made in sample size for a therapist cluster effect. Our alternative approach was to standardize the interventions (manualized CBT and a TC) and control for nonspecific therapist skills (eg, empathy and warmth). We acknowledge that therapists had a greater allegiance to CBT; however, patients' subjective belief in treatment is probably more relevant, and no difference in this was observed.

Cognitive bibliotherapy has received some support as a stand-alone intervention for depressed older adults.[51] It is likely that, in addition to our therapist-given CBT, some self-administered CBT may have taken place; these 2 components cannot clearly be separated and present an asymmetry in mediators of therapeutic change, especially because no homework was given to the TC group.

Despite the range of antidepressants prescribed, and consistent with findings by Bockting et al,[52] only one-fifth of patients were prescribed a therapeutic dose of antidepressant (50 mg or more of imipramine equivalent). As adherence is known to be poor in this population, the number of people actually taking a therapeutic dose is likely to be small; this is consistent with our finding that antidepressant prescription does not affect outcome.

Older people with depression in the primary care setting engage well with talking treatments and benefit from individual CBT. A specific treatment such as CBT is better than simply talking with a warm and empathic therapist. The optimum frequency and timing of CBT sessions in older people needs to be further investigated.

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