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THE EFFECTIVENESS OF COGNITIVE BEHAVIOR THERAPY FOR BORDERLINE PERSONALITY DISORDER: RESULTS FROM THE BORDERLINE PERSONALITY DISORDER STUDY OF COGNITIVE THERAPY (BOSCOT) TRIAL

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Abstract

The outcome of a randomized controlled trial of cognitive behavior therapy in addition to treatment as usual (CBT plus TAU) compared with TAU alone (TAU) in one hundred and six participants meeting diagnostic criteria for borderline personality disorder is described. We anticipated that CBT plus TAU would decrease the number of participants with in-patient psychiatric hospitalizations or accident and emergency room contact or suicidal acts over twelve months treatment and twelve months follow-up, compared with TAU. We also anticipated that CBT plus TAU would lead to improvement in a range of secondary outcomes of mental health and social functioning compared to TAU. Of the 106 participants randomized, follow-up data on 102 (96%) was obtained at two years. Those randomized to CBT were offered an average of 27 sessions over 12 months and attended on average 16 (range 0 to 35). We found that the global odds ratio of a participant in the CBT plus TAU group compared with the TAU alone group having any of the outcomes of a suicidal act, in-patient hospitalization, or accident and emergency contact in the 24 months following randomization was 0.86 (95% confidence interval [*CI*] 0.45 to 1.66, $p = 0.66$). The corresponding global odds ratio, excluding accident and emergency room contact, was 0.75 (95% *CI* 0.37 to 1.54, $p = 0.44$). In terms of the number of suicidal acts, there was a significant reduction over the two years in favor of CBT plus TAU over TAU, with a mean difference of −0.91 (95% *CI* −1.67 to −0.15, $p = 0.020$). Across both treatment arms there was gradual and sustained improvement in both primary and secondary outcomes, with evidence of benefit for the addition of CBT on the positive symptom distress index at one year, and on state anxiety, dysfunctional beliefs and the quantity of suicidal acts at two year follow-up. CBT can deliver clinically important changes in relatively few clinical sessions in real clinical settings.

There is evidence of benefit from psychotherapeutic approaches in the treatment of borderline personality disorder but caution is required in the interpretation of results due to methodological weaknesses (Davidson et al., 2006). We have previously described the rationale for the BOSCOT randomized controlled trial, along with the trial methodology and

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description of patients (Davidson et al., 2006). In brief, one hundred and six patients with borderline personality disorder were randomized to two treatment conditions, either treatment as usual (TAU) or cognitive behavior therapy in addition to their usual treatment (CBT plus TAU). In this paper, we present the primary and secondary outcomes of the trial.

We anticipated that CBT plus TAU would decrease the number of participants with in-patient psychiatric hospitalizations or accident and emergency room contact or suicidal acts over twelve months treatment and twelve months follow-up, compared with TAU. The primary outcome is the joint occurrence of any of these constituent outcomes. These three components of the primary outcome were chosen, a priori, because they represent both a personal and health burden. We also compare the two randomized groups for the time to the first occurrence of any of these three components of the primary outcome, and also the number of occurrences of each of these component events. We anticipated that CBT plus TAU would increase the length of time to the first occurrence of any of the three outcomes. We also hypothesized that CBT plus TAU would lead to superior improvement in quality of life, social, cognitive and mental health functioning compared to TAU alone.

METHOD

Full details of recruitment and randomization, baseline and outcome assessments, the experimental intervention and treatment as usual, therapists, and statistical considerations are given in Davidson et al. (2006). In brief, the study was conducted between January 2002 and February 2005 at three United Kingdom sites, namely Glasgow, London, and Ayrshire/Arran. Patients were eligible if they satisfied the following criteria: aged between 18 and 65 years, met criteria for at least 5 items of the borderline personality disorder using the Structured Clinical Interview for DSM IV Axis II Personality Disorders (SCID-II; First, Gibbon, Spitzer, Williams, & Benjamin, 1997), had received either in-patient psychiatric services or an assessment at accident and emergency services or an episode of deliberate self-harm (either suicidal act or self-mutilation) in the previous 12 months and were able to give informed consent.

We excluded patients who were currently receiving in-patient treatment for a mental state disorder or were currently receiving a systematic psychological therapy or specialist service, such as psychodynamic psychotherapy. We also excluded those who had insufficient knowledge of English to enable them to be assessed adequately and to understand the treatment approach, those who were temporarily resident in the area, and those who had evidence of an organic illness, mental impairment, alcohol or drug dependence, schizophrenia or bipolar affective disorder, as assessed by SCID I,/P (W/ Psychotic Screen; version 2; First, Spitzer, Gibbon, & Williams, 1996). We did not exclude those who were abusing drugs or alcohol providing they did not meet criteria for dependence.

COGNITIVE BEHAVIOR THERAPY PLUS TREATMENT AS USUAL (CBT PLUS TAU) FOR BORDERLINE PERSONALITY DISORDER

This was a pragmatic trial that investigated if CBT could deliver worthwhile benefit in real clinical settings. It therefore differs from an explanatory trial that would investigate if CBT could work under optimal conditions. CBT was developed to treat those with Cluster B personality disorder and delivered according to the trial protocol (Davidson, 2000). All therapists received training in the protocol at the beginning of the trial and regular meetings of all therapists were held to ensure consistency of approach across the sites. In addition, all therapists received weekly supervision from CBT experts at each site (P. Tata, K. Davidson, & A. Gumley). CBT focuses on the patient's core beliefs and overdeveloped behavioral patterns that impair adaptive functioning. We aimed to deliver up to thirty sessions of CBT over one year, each session lasting an hour. Providing that a patient was not immediately

suicidal at entry into the trial, therapists first developed an agreed formulation of the patient's problems, then, priority was given to the goals agreed between therapist and patient to improve adaptive functioning. In CBT, patients develop new, more adaptive beliefs about self and others and work on developing underdeveloped behavioral strategies to promote improved levels of social and emotional functioning. All trial participants randomized to CBT also received the treatment they would have received if the trial had not been in place (see below for further information).

TREATMENT AS USUAL (TAU)

All participants received the standard treatment (TAU) they would have received if the trial had not been in place. All treatment, including CBT, took place within the National Health Service in the U.K. Treatment is free to the patient at the point of delivery. We believed that a patient's usual treatment would involve general practitioner care and contact with community mental health teams, at a minimum. Patients were unlikely to be receiving CBT for personality disorder as this is a new treatment though it is possible that after randomization, they may have received psychological help from community mental health teams to manage a crisis. Although we expected standard treatment might vary within and across the three sites and depend on the specific problems of the individual participant, we found reasonable consistency across sites. Over 90% of participants were in contact with mental health services, including psychiatric nurses, and around half had contact with accident and emergency services for repeated self-harm episodes. Information related to health and social services and to other personal or societal costs incurred by patients (e.g., criminal justice contacts, state benefits, over the counter medications etc.) was obtained directly from the Client Service Receipt Inventory (CSRI). Full details are described in the companion paper (Palmer et al., 2006).

PRIMARY OUTCOME

There were three components of the primary outcome: 1. suicidal acts, 2. in-patient psychiatric hospitalization, and 3. accident and emergency attendance. A suicidal act was recorded using the Acts of Deliberate Self-Harm Inventory (Davidson, 2000) and needed to fulfill all three of the following criteria: 1. deliberate, 2. life threatening, and 3. the act resulted in medical intervention or intervention would have been warranted. We distinguished between suicidal acts and acts of self-mutilation (see secondary outcomes below). Where a research assistant had uncertainty about whether a participant's past history of suicidal act placed them in one or other category, this was resolved by a panel consisting of a psychiatrist (P. Tyrer) and two clinical psychologists (A. Gumley, K. Davidson, or P. Tata) who each rated the act independently and then agreed a rating. In-patient psychiatric hospitalization was defined as any in-patient psychiatric hospitalization reported by a study participant or noted in hospital records. A&E attendance was defined as any A&E contact reported by the study participant or noted in hospital records. These primary outcomes are described in more detail elsewhere (Davidson et al., 2006).

Inter-rater reliability for the Acts of Deliberate Self Harm Inventory was established on the basis of twelve clinical interviews with study participants: two assessors independently rated acts reported by patients being interviewed by one of the assessors. Kappa coefficients were calculated for occurrence of any suicidal act ($\kappa = 1.0$), number of suicidal acts ($\kappa = 1.0$), and occurrence of self-mutilation ($\kappa = 1.0$) indicating perfect agreement.

SECONDARY OUTCOMES

Acts of self-mutilation needed to satisfy the following criteria: 1. not a suicidal act as defined above, 2. deliberate (i.e., the act could not be construed as an accident and that the individual accepts ownership of the act, and 3. results in potential or actual tissue damage. If

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a patient reports self-harm events that occur within hours of each other (for example, scratching wrists or cigarette burning), these are to be considered as one event. Other secondary outcomes were as follows: Beck Depression Inventory—II (BDI-II; Beck, Steer, & Brown, 1996), the Spielberger State-Trait Anxiety Inventory for Adults (STAI; Spielberger, Gorsuch, & Lushene, 1970), the Brief Symptom Inventory (BSI; Derogatis, 1993), the Inventory of Interpersonal Problems—Short form (IIP-32; Horowitz, Alden, Wiggins, & Pincus, 2000), Social Functioning Questionnaire (SFQ; Tyrer et al., 2005), Young Schema Questionnaire (YSQ; Young, 1998), and the EuroQol (EQ-5D; The EuroQol group, 1990). The Working Alliance Inventory (Tracey & Kokotovic, 1989) was completed by those receiving CBT and their therapists between sessions three and five of treatment.

STATISTICAL ISSUES

Full details of all statistical issues relating to the study—in particular, randomization, blinding and analysis—appear in the companion article (Davidson et al., 2006).

In brief, randomization was stratified by center, and, high or low self harm in the 12 months prior to randomization (more than 13 episodes of self harm, including suicidal acts, being high). The outcomes assessors remained blind to treatment allocation throughout the study, whereas participants and their therapists were aware if CBT was given. The analyses were according to the intention-to-treat principle. Baseline characteristics were tabulated by randomized group, including the analogues of outcomes measured in the 12 months prior to randomization.

The components of the primary outcome (suicidal act, in patient psychiatric hospitalization, and A&E contacts) were compared between the randomized groups using logistic regression models for the number of subjects with an event (reporting an odds ratio and 95% confidence interval and associated *P*-value). These models adjusted for baseline covariates and the stratification factor of high or low pre-randomization self-harm. For the composite outcomes such as the primary outcome a global odds ratio was used (Tilley et al., 1999). The global odds ratio combines the treatment effects across several outcomes. It was developed in the context of stroke trials, in which no single outcome adequately measures the effect of an intervention may have had over an extended period on the outcomes of mortality, morbidity and disability. The number of events was compared with normal linear models (adjusting for baseline covariates), reporting a difference in means between the two randomized groups (and 95% *CI* and *P*-value). For the time-to-event data Kaplan Meier curves were plotted, and the two randomized groups compared using log rank statistics and using Cox proportional hazards regression models to adjust for baseline covariates. For the secondary outcomes normal linear models (adjusting for baseline covariates) were used to estimate the mean difference between the two groups (with 95% *CI* and *P*-value). For both the primary and secondary outcomes, repeated measures mixed models were used to investigate any time development in the treatment effects. All analyses were conducted in SAS 9.1 for Windows to an agreed Statistical Analysis Plan, finalized before database lock and unblinding. No adjustment has been made for any multiple comparisons.

RESULTS

Figure 1 shows the Consort diagram of flow of patients through the trial. Out of the 106 patients recruited, follow-up data (from face-to-face interview and case note) was obtained for 102 (96%) patients. The lowest percentage of patients interviewed face-to-face at follow-up was 85% at 24 months follow up.

UPTAKE OF CBT SESSIONS

We offered on average 27 (standard deviation [*SD*] 13) sessions of CBT to the patients in the trial (median 31; range 1 to 49). An average of 16 (*SD* 12) sessions was attended (median 15; range 0 to 35). An average of 8 (*SD* 8) sessions was refused (median 5; range 0–30) and an average of 3 (*SD* 3) sessions was cancelled (median 5; range 0–30). Fifty-one percent of participants randomized to CBT plus TAU had 15 or more sessions of CBT. Table 1 gives details of the number of patients seen by therapist and the range of sessions delivered by each therapist.

TREATMENT AS USUAL

Usual treatment consisted of a wide variety of resources such as inpatient and outpatient hospital services, including A&E services, community based services such as drop in centers, and primary and community care services (GP, practice nurse, Community Psychiatric Nurse, etc.). Full details of treatment as usual are described in the companion paper on the cost-effectiveness analysis of this study (Palmer et al., 2006).

COMPETENCE OF THERAPISTS

All five therapists in the trial submitted audiotapes of CBT sessions from 38 (73%) out of a potential of 52 patients randomized to CBT who consented to audiotaping of sessions. Therapist competence was assessed using the Cognitive Therapy Rating Scale and, as CBT for personality disorders differs from traditional CBT, a specific rating scale for CBT for personality disorder was developed for the trial (the BOSCOT Rating Scale; available on request from K. Davidson). The therapists saw different numbers of patients, varying from three to eighteen patients (see Table 1). Not all patients consented to have their CBT sessions recorded. Two of the therapists saw and recorded small numbers of patients (one recorded 2 patients and one therapist, 4 patients). In this case, a sample of tape recordings from all patients seen by these two therapists was rated. For the remainder of study therapists ($N = 3$) who saw greater numbers of patients randomized to CBT and for whom we had taped sessions, we rated a sample of patient tapes from individual therapists in 10 out 18 patients, three out of seven patients, and five out of seven patients. One patient refused to see one of our therapists and was treated by a mental health professional not trained in CBT for personality disorder (therapist 6) and another patient saw a different therapist due to practical reasons (therapist 7). One of these latter therapists was also rated in terms of competence but as only one tape was available and the patient attended very few sessions, we do not report on this therapist. A sample of audiotapes from 24 out of 38 patients (63%) was rated by two raters, (K. Davidson and A. Gumley), both blind to final treatment outcome. A correlation of $r_S = 0.75$ ($n = 11$) indicated an acceptable magnitude of inter-rater agreement on therapist competence.

Both the CTRS and the BOSCOT Rating Scale (BRS) have total scores of 84. The average scores on the BRS Scale for individual therapists were 69.4, 64.2, 54.2, 55.2, and 43.3, and, in the same order of therapist, average scores on the CTRS were 67.7, 61, 50, 48.1, and 37.9. The therapists therefore varied in their degree of competence in delivering the CBT and all, bar one, could be considered competent. The BRS and CTRS were highly correlated at $r_S = 0.94$ ($n = 44$).

WORKING ALLIANCE INVENTORY

For 37 of the 52 participants randomized to CBT plus TAU, the Working Alliance Inventory Short Form-T (therapist) and C (client) was completed around the fifth or sixth session of therapy. Of the 12 questions, 2 were ‘negatively’ phrased (questions 4 and 10) and so were re-scored for analysis. Mean task, goals and bond scores were calculated, with a minimum

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of 0 and a maximum of 28 (Andrusyna, Tang, DeRubeis, & Luborsky, 2001). The mean task score for (therapist, client) was (18.7, 22.0); for goal (20.0, 22.1), and for bond (21.2, 21.2), with the total (60.0, 65.0) indicating that the clients scored the interaction slightly higher than the therapists, but that both seemed to have thought the process worthwhile.

BASELINE CHARACTERISTICS

Full details of the baseline characteristics are given in the companion paper (Davidson et al., 2006). As one would expect, there was reasonable balance between the two randomized groups, with some indication that by chance there were slightly more participants living alone in the CBT plus TAU group than in the TAU group (44% vs. 27%) and that the TAU plus CBT group scored slightly higher on some of the secondary outcomes at baseline in the 12 months prior to randomization. All analyses reported adjusted for baseline covariates, so allowing for any slight imbalance between the two groups, and in addition, in the case of the linear models (Ford, Norrie, & Ahmadi, 1995) allowing a more precise estimate of the treatment effect.

PRIMARY OUTCOME

For the primary outcome of the occurrence of any of suicide attempt, in-patient psychiatric hospitalization, or A&E contact, Table 2 shows that at both 12 months (the end of the treatment period) and 24 months (the end of the follow-up period), the global odds ratio was 1.04 (95% confidence interval [*CI*] 0.52 to 2.00, $P = 0.96$) and 0.86 (95% *CI* 0.45 to 1.66, $P = 0.66$) respectively. There were no significant differences for CBT plus TAU compared with TAU alone in both the occurrence and the number of events for both in-patient psychiatric hospitalization and A&E contacts.

There was a significant reduction over the two years in the mean number of suicidal acts in favor of CBT plus TAU over TAU, with a mean difference of −0.91 (95% *CI* −1.67 to −0.15, $p = 0.020$).

Figure 2 shows the Kaplan Meier curves for the primary outcome and its components, confirming the results above, with some suggestion of a lagged treatment effect in the suicide attempt and in-patient psychiatric hospitalization components.

SECONDARY OUTCOMES

There were some significant differences between CBT plus TAU compared with TAU alone in several of the measures (see Table 3). At 24 months: State Anxiety, mean difference CBT plus TAU—TAU alone −7.96 (95% *CI* −14.2 to −1.73, $P = 0.013$), Young's Schema Questionnaire −0.58 (95% *CI* −1.00 to −0.17, $P = 0.0064$), and at 12 months, differences on the Brief Symptom Positive Symptom Distress Index −0.39 (95% *CI* −0.66 to −0.12, $P = 0.0047$).

Table 4 gives a summary of the significant findings, abstracted from Tables 2 and 3, for ease of reading.

DISCUSSION

Two other randomized controlled trials, investigating the effectiveness of dialectical behavior therapy, have presented intention to treat analysis of main outcomes (Turner, 2000; Verheul et al., 2003). Also Bateman and Fonagy (2001) presented intention to treat analysis for data on follow-up of patients treated by partial hospitalization. We analyzed the data from the BOSCOT trial according to an intention to treat principle and declared our primary and secondary outcomes before having sight of the data. These factors, in combination with

the numbers of participants included, blindness of assessors at follow-up, the high follow-up rate, and the use of case note and interview data sources, add emphasis to the provenance of the study findings.

On average patients in the CBT plus TAU, and TAU alone treatment groups had reduced suicidal behavior, attendance at A&E services and in-patient psychiatric days over the study period of two years. No significant differences between the randomized groups were noted in the components of the primary outcome though the odds ratios for suicidal acts indicate a 23% reduction in the odds of having at least one suicide attempt in favor of CBT compared with TAU and a 37% reduction in in—patient psychiatric hospitalization. Attendance at accident and emergency services reversed this trend with the CBT plus TAU group showing an increase in the odds of having an A&E attendance over the two years. However, while the number of participants in the CBT plus TAU group with at least one A&E attendance was larger (non-significantly), overall the average number of contacts with A&E was lower for the CBT plus TAU group. This pattern of result is repeated for the composite outcome, a combination of A&E service use, in-patient hospitalization, and suicidal behavior. Both groups show a decline in the composite outcome over the two years period with no significant advantage of one treatment condition over the other.

The use of accident and emergency attendance as one of the components of the primary outcome is problematic as individuals use A&E services for a variety of reasons, some of which were likely to be unrelated to the current study. We were unable to examine A&E contacts to determine if they were related to borderline psychopathology and behavior. Future studies, may wish to consider the utility of A&E contact as an outcome measure despite it being considered as one of the core features of borderline pathology (Linehan, 1993).

Exploring the primary outcomes in terms of the overall quantity over the two-year period of the study, those who had the addition of CBT showed a significant reduction in the mean number of suicidal acts over the course of the study. In terms of secondary outcomes, significant differences between the treatment conditions were noted after one year by the Brief Symptom Inventory positive symptom distress index and, at two-year follow-up, on dysfunctional core beliefs and state anxiety. There were no differences at either 12 months or 24 months follow up in the outcome of scores on depression, trait anxiety, other psychiatric symptom indexes, interpersonal functioning, or on quality of life. Again all patients showed sustained and gradual improvement over the course of treatment and follow-up.

Although the addition of CBT to usual treatment did not result in significant differences on measures such as depression, social functioning, quality of life, psychiatric symptoms, other than PDSI, and interpersonal problems, all participants did show a general improvement on these measures. The addition of CBT to usual treatment was expected to produce enhanced cognitive change and a reduction in mood based symptoms and this was confirmed for change in beliefs but not for depression. The level of distress and dysfunction experienced by all trial participants remained relatively high, even at two years. This suggests that treatment, even if relatively brief, may be helpful to patients with borderline personality disorder but that the degree of benefit should not be overstated.

We previously stated that less than 15 sessions might be an inadequate amount of therapy and indicative of non-engagement (Davidson et al., 2006). Our data on uptake of CBT therapy suggested that this group of patients are hard to engage in therapy in spite of efforts by therapists to keep them in active treatment. We believe that our patients had only the bare minimum amount of therapy required to benefit but this is an opinion and we have not

examined this as a research question. Our trial participants were not overly selected—only four patients meeting inclusion criteria were not included in the trial because they either refused or lost contact before randomization—and unlike other studies, there was no attempt to screen out those who might be unsuitable or likely unwilling to comply with study requirements. We did not rule out comorbid problems such as depression or alcohol and drug abuse that are common in BPD.

Other studies have reported relatively high drop out rates from the experimental therapy, for example up to 37% (Verheul et al., 2003). Determining drop-out from active treatment can be problematic as it depends on the definition of drop-out. We have presented the quantity of sessions of CBT that participants received. We had intended to give CBT according to a weekly then fortnightly schedule of appointments. In practice, some patients did not attend therapy at regular intervals over the 12 month therapy period. On the whole, patients did not drop out but continued to attend irregularly. The participants offered CBT in this trial therefore varied in the degree to which they received the schedule of CBT we considered might be optimal, though at least half (51%) received more than 15 sessions with just over one quarter receiving over 28 sessions (26%) of CBT over the year.

It is possible that some patients did not engage because they did not find the therapy helpful but ratings from patients who had at least three to five sessions of CBT on the Working Alliance Inventory suggest that both the patients and therapists view the experience of therapy to have been positive. Nonetheless, some patients simply did not attend. It is therefore more likely that the group as a whole represent the pattern of attendance that is often found in mental health clinics in the National Health Service (UK) (NHS), with some patients never attending (in our case, $N = 3$), some attending in a rather chaotic fashion, and around half attending sessions regularly.

Therapists varied in their degree of competence in delivering CBT. Shaw et al., (1999) used a cut off score on the CTRS (of 39) below which therapists would not be considered as being competent enough to deliver CBT in a trial of CBT of depression. One out of the five therapists in this trial had a median score below this level (median rating of 37 on the CTRS), though individual scores from sessions of therapy rated varied with the session and the patient (range 27 to 49 on CTRS). This therapist had no previous formal training in CBT and may therefore have been significantly disadvantaged when trying to work with using a systematic structured therapy with patients with such complex problems. The variation in competence of therapists might be considered a limitation of the study. However, in this pragmatic trial we were unable to recruit volunteer “expert” doctoral level therapists and could only provide a minimum level of training, although regular and intensive supervision was provided throughout the trial. As such, the therapists in this trial are probably representative of qualified CBT therapists, though none would have considered themselves as particularly expert.

In conclusion, there is evidence that the addition of CBT to usual treatment has benefit in terms of reducing the volume of suicidal acts, reducing dysfunctional beliefs, state anxiety, and psychiatric symptom distress. The results of this study highlight the importance of measuring outcomes that are meaningful clinically, address the economic and health burden associated with this group of patients, and being able to assess outcome, even if the patient is lost to follow-up but not withdrawn consent. Commonly, longer-term follow-up of patients with borderline personality disorder indicate improvement over time, but again this is often not dramatic and psychosocial functioning often remains relatively poor (e.g., Zanarini, Frankenburg, Hennen, Reich, & Silk, 2005). Our patients also continued to experience relatively high levels of dysfunction though they had clearly improved over the two-year period of the study.

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It appears CBT can deliver worthwhile and clinically important changes in suicidal and self-harm behaviors, affective distress and dysfunctional thinking in representative samples of patients with borderline personality disorder. Therapists can be trained in CBT for personality disorders relatively easily particularly if they have previous experience and training in CBT, and, providing they are given appropriate levels of support and supervision. In this pragmatic trial, we investigated if CBT could deliver worthwhile benefit in real clinical settings and found that positive changes can be delivered in the community without recourse to intensive or lengthy treatment in highly specialized services. Future research may wish to carry out an explanatory trial that would investigate under what conditions CBT works more effectively, especially in terms of optimal therapist competence.

REFERENCES

Andrusyna P, Tang T, DeRubeis R, Luborsky L. The factor structure of the Working Alliance Inventory in cognitive-behavioral therapy. Journal of Psychotherapy Practice & Research. 2001; 10:173–178. [PubMed: 11402080]

Bateman AW, Fonagy P. Treatment of borderline personality disorder with psychoanalytically oriented partial hospitalization: An 18 month follow-up. American Journal of Psychiatry. 2001; 158:36–42. [PubMed: 11136631]

Beck, AT.; Steer, RA.; Brown, GK. Manual for the Beck Depression Inventory-II. San Antonio, Texas: Psychological Corporation; 1996.

Davidson, KM. Cognitive therapy for personality disorders: A guide for clinicians. 2nd Edition. London: Arnold (Hodder); 2000. (in press). Hove: Routledge

Davidson KM, Tyrer P, Gumley A, Tata P, Norrie J, Palmer S, et al. A randomised controlled trial of cognitive behavior therapy for borderline personality disorder: Rationale for trial, method and description of sample. Journal of Personality Disorders. 2006; 20(5):431–449. [PubMed: 17032157]

Davidson KM. Acts of deliberate self-harm inventory. 2000 Unpublished manuscript.

Derogatis, LR. Brief Symptom Inventory (BSI): Administration, Scoring and Procedures Manual. 4th ed.. Minneapolis, Minnesota: NCS Pearson Incorporated; 1993.

The EuroQol Group. Euro-Qol: A new facility for the measurement of health-related quality of life. Health Policy. 1990; 16:199–208. [PubMed: 10109801]

First, MB.; Gibbon, M.; Spitzer, RL.; Williams, JB.; Benjamin, LS. Structured Clinical Interview for DSM IV Axis II Personality Disorders (SCID-II). Washington, DC: American Psychiatric Press; 1997.

First, MB.; Spitzer, RL.; Gibbon, M.; Williams, JBW. Structured clinical interview for Axis I DSM-IV disorders—Patient Edition (with psychotic screening) SCID-I/P (W/ psychotic screen) (version 2). New York: Biometrics Research Department, New York State Psychiatric Institute; 1996.

Ford I, Norrie J, Ahmadi S. Model inconsistency, illustrated by the Cox Proportional Hazards Model. Statistics in Medicine. 1995; 14:735–746. [PubMed: 7644855]

Horowitz, LM.; Alden, LE.; Wiggins, JS.; Pincus, AL. Manual for Inventory of Interpersonal Problems. United States of America: Psychological Corporation; 2000.

Linehan, MM. Cognitive behavior therapy of borderline personality disorder. New York: Guilford Press; 1993.

Palmer S, Davidson K, Tyrer P, Gumley P, Tata P, Norrie J, et al. The cost-effectiveness of cognitive behaviour therapy for borderline personality disorder: Results from the BOSCOT trial. Journal of Personality Disorders. 2006; 20:466–480. [PubMed: 17032159]

Shaw BF, Elkin I, Yamaguchi J, Olmsted M, Vallis MT, Dobson K, et al. Therapist competence ratings in relation to clinical outcome in cognitive therapy of depression. Journal of Consulting & Clinical Psychology. 1999; 67:837–846. [PubMed: 10596506]

Spielberger, CD.; Gorsuch, RL.; Lushene, RE. Manual for the State-Trait Anxiety Inventory. Palo Alto, California: Consulting Psychologists Press; 1970.

Tracey TJ, Kokotovic AM. Factor Structure of the Working Alliance Inventory. Psychological Assessment. 1989; 1:207–210.

Tilley BC, Pillemer SR, Heyse SP, Li S, Clegg DO, Alarcon GS. Global statistical tests for comparing multiple outcomes in rheumatoid arthritis trials. Arthritis and Rheumatism. 1999; 42:1879–1888. [PubMed: 10513802]

Turner RM. Naturalistic evaluation of dialectical behaviour therapy-oriented treatment for borderline personality disorder. Cognitive and Behavioral Practice. 2000; 7:413–419.

Tyrer P, Nur U, Crawford M, Karlsen S, McLean C, Rao B, Johnson T. Social Functioning Questionnaire: A rapid and robust measure of perceived functioning. International Journal of Social Psychiatry. 2005; 51:265–275. [PubMed: 16252794]

Verheul R, van den Bosch LMC, Koeter WJ, de Ridder MA, Stijnen T, van den Brink W. Dialectical behaviour therapy with women with borderline personality disorder. 12-month, randomised clinical trial in the Netherlands. British Journal of Psychiatry. 2003; 182:135–140. [PubMed: 12562741]

Young, JE. Young Schema Questionnaire short form. New York: Cognitive Therapy Centre; 1998.

Zanarini MC, Frankenburg FR, Hennen J, Reich B, Silk KR. Psychosocial functioning of borderline patients and Axis II comparison subjects followed prospectively for six years. Journal of Personality Disorders. 2005; 19:19–29. [PubMed: 15899718]

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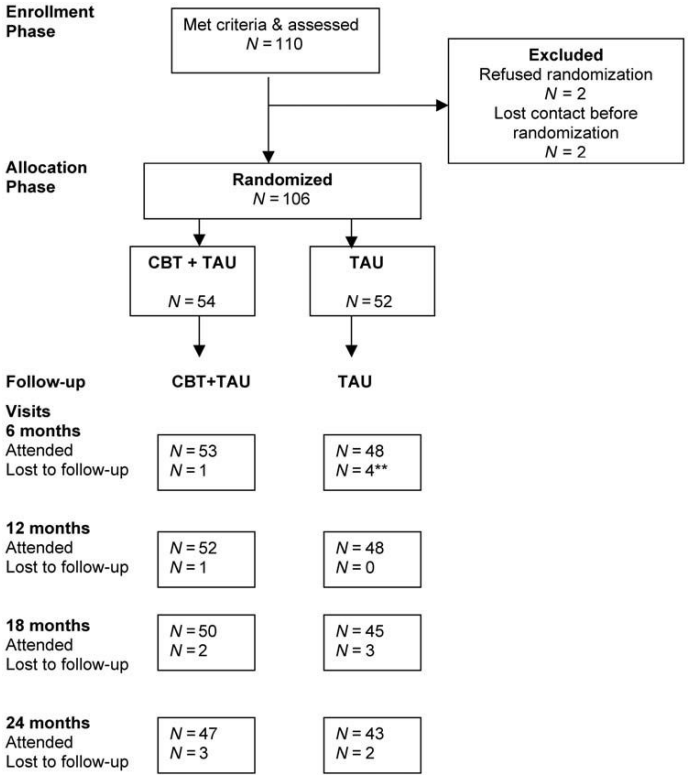

FIGURE 1.

Consort diagram of flow of patients through the trial.

*For the primary outcomes, casenote data was used in addition to the data collected at the visits and was unavailable for *N* = 3 TAU and *N* = 1 CBT plus TAU.

**Includes one death of natural causes before the first follow-up.

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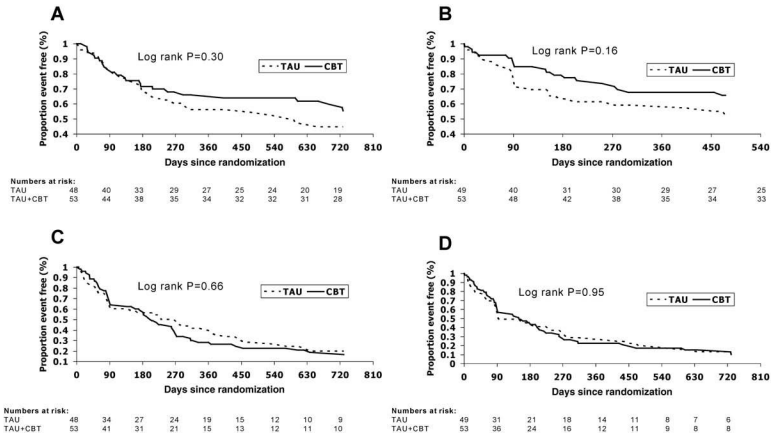

FIGURE 2.

Kaplan-Meier curves for primary endpoint and its composites.

A = Suicidal acts; B = Inpatient psychiatric hospitalization; C = A&E contact; D = Suicidal acts or Inpatient psychiatric hospitalization or A&E contact.

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Table 1

Patient Attendance at CBT by Therapist

Therapist	Patients Allocated (*n*)	Patients attending zero sessions (*n*)	Patients attending CBT sessions (*n*)	Range of CBT sessions taken up
1	13	0	13	4–35
2	11	1	10	1–35
3	20	2	18	2–35
4	3	0	3	19–21
5	5	0	5	2–35
6*	1	0	1	25
7*	1	0	1	8
Totals	54	3	51	

*Therapist 6 and 7 saw one patient each due to non-study related circumstances.

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Table 2

Primary Outcome and its Composites

	0–12 months			0–24 months		
Outcome	**TAU (*N* = 48)**	**CBT (*N* = 53)**	**CBT-TAU Treatment difference (95% confidence interval), and P-value**	**TAU (*N* = 49)**	**CBT (*N* = 53)**	**CBT-TAU Treatment difference 95% confidence interval, and P-value**
(a) Subjects *	***N*(%)**	***N*(%)**	**Odds Ratio**	***N*(%)**	***N*(%)**	**Odds Ratio**
1. Suicidal acts	21 (46)	18 (37)	0.77 (0.29, 2.01), *P* = 0.59	26 (54)	23 (43)	0.78 (0.30, 1.98), *P* = 0.59
2. Inpatient Psyc.Hosp	20 (41)	17 (33)	0.79 (0.30, 2.07), *P* = 0.63	23 (47)	18 (34)	0.63 (0.24, 1.64), *P* = 0.35
3. A&E Contacts	31 (66)	40 (75)	2.05 (0.76, 5.52), *P* = 0.16	38 (79)	44 (83)	1.81 (0.58, 5.68), *P* = 0.31
1. + 2.	28 (58)	24 (46)	0.83 ** (0.38, 1.79), *P* = 0.64	32 (65)	30 (57)	0.75 ** (0.37, 1.54), *P* = 0.44
1. + 2. + 3.	36 (75)	42 (79)	1.02 ** (0.52, 2.00), *P* = 0.96	42 (86)	47 (89)	0.86 ** (0.45, 1.66), *P* = 0.66
(b) Episodes *	**Mean (*SD*)**	**Mean (*SD*)**	**Mean Difference**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean Difference**
1. Suicidal acts	1.02 (2.14)	0.61 (0.95)	−0.36 (−0.83, 0.13), *P* = 0.15	1.73 (3.11)	0.87 (1.47)	−0.91 (−1.67, −0.15), *P* = 0.020
2. Inpatient Psyc.Hosp	1.21 (3.99)	0.77 (1.81)	−0.38 (−1.43, 0.68), *P* = 0.48	1.67 (3.93)	1.00 (2.59)	−0.63 (−1.89, 0.62), *P* = 0.32
3. A&E Contacts	2.64 (4.99)	2.40 (3.77)	0.25 (−1.54, 2.04), *P* = 0.78	5.04 (10.03)	4.89 (11.05)	1.12 (−3.25, 5.49), *P* = 0.61
1. + 2.	2.17 (4.13)	1.35 (2.20)	−0.72 (−1.94, 0.50), *P* = 0.24	3.37 (5.35)	1.87 (3.15)	−1.46 (−3.00, 0.09), *P* = 0.065
1. + 2. + 3.	4.75 (8.78)	3.72 (5.72)	−0.52 (−3.26, 2.22), *P* = 0.71	8.31 (14.54)	6.75 (13.66)	−0.53 (5.59, 4.54), *P* = 0.84

Notes. Data are shown on (a) number of subjects with at least one episode, and (b) episodes. The means and standard deviations are the raw data, the treatment difference and 95% confidence interval are adjusted for baseline covariates.

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* *N* refers to the number of subjects with at least one episode.

** Global odds ratio. For the Episodes data, descriptive statistics on median and range, with Wilcoxon rank sum tests are available on request.

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Table 3

Secondary Outcomes at 12 and 24 Months

Outcome Class	Outcome Type	TAU Mean (*SD*)	CBT Mean (*SD*)	CBT-TAU Adjusted Mean Difference (95% *CI*)	*P*-value
(a) at 12 months (TAU *n* = 47, CBT *n* = 52)					
Acts of self-mutilation[†]		27 (64)	35 (91)	9 (−18, 36)	0.51
Mood	BDI-II total	31.3 (16.6)	29.6 (14.8)	−1.85 (−7.76, 4.07)	0.54
	STAI—state total	49.7 (15.5)	49.2 (14.8)	−2.68 (−8.53, 3.17)	0.36
	STAI—trait total	60.0 (11.2)	59.7 (10.3)	−1.73 (−6.16, 2.71)	0.44
Psychiatric Symptoms	BSI—GSI	2.00 (0.93)	1.97 (0.91)	−0.29 (−0.64, 0.06)	0.11
	BSI—PST	37.7 (12.0)	40.0 (9.5)	−0.38 (−4.76, 4.01)	0.86
	BSI—PSDI	2.63 (0.70)	2.46 (0.76)	−0.39 (−0.66, −0.12)	0.0047
Cognition	YSQ mean total	3.44 (0.91)	3.49 (0.84)	−0.22 (−0.61, 0.17)	0.27
Interpersonal & Social	IIP-32 total	55.0 (22.3)	60.4 (23.9)	0.57 (−9.40, 10.5)	0.91
Functioning	SFQ total	13.1 (4.6)	13.1 (4.4)	−0.39 (−2.19, 1.42)	0.67
EuroQoL-WHSV		0.62 (0.35)	0.51 (0.41)	−0.07 (−0.21, 0.07)	0.31
(b) at 24 months (TAU *n* = 48, CBT *n* = 53)					
Acts of self-mutilation[†]		38 (89)	50 (136)	16 (−24, 56)	0.44
Mood	BDI-II total	28.8 (15.7)	26.5 (15.3)	−3.16 (−9.75, 3.42)	0.34
	STAI—state	50.9 (15.7)	48.2 (14.4)	−7.96 (−14.2, −1.73)	0.013
	STAI—trait	58.0 (10.9)	56.4 (11.9)	−4.09 (−8.83, 0.64)	0.089
Psychiatric Symptoms	BSI—GSI	1.93 (1.00)	1.81 (1.00)	−0.34 (−0.74, 0.07)	0.10

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Outcome Class	Outcome Type	TAU Mean (*SD*)	CBT Mean (*SD*)	CBT-TAU Adjusted Mean Difference (95% *CI*)	*P*-value
	BSI—PST	38.0 (12.7)	38.1 (13.0)	−4.05 (−9.29, 1.18)	0.13
	BSI—mPSDI	2.49 (0.81)	2.32 (0.81)	−0.25 (−0.59, 0.10)	0.16
Cognition	YSQ mean total	3.48 (0.91)	3.46 (0.99)	−0.58 (−1.00, −0.17)	0.0064
Interpersonal & Social	IIP-32 total	53.7 (24.1)	54.0 (23.9)	−9.1 (−20.1, 1.8)	0.10
Functioning	SFQ total	12.3 (5.3)	13.0 (5.0)	0.07 (−1.94, 2.09)	0.94
EuroQoL-WHSV		0.66 (0.32)	0.58 (0.36)	−0.02 (−0.17, 0.13)	0.79

Notes. The means and standard deviations are for the raw data, the mean difference and 95% CI and P-value are adjusted for baseline covariates.

N is the maximum number. All available data used.

†Number of acts from baseline to 12 months or baseline to 24 months, respectively. GSI = Global Severity Index; PSS = Positive Symptom Total; PSDI = Positive Symptom Distress Index; WHSV = Weight Health Score Value. Data on medians and ranges, with Wilcoxon rank sum tests, are available on request.

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Table 4

Significant Findings

Outcome	Time	CBT-TAU Mean Adjusted Difference (95% *CI*)	*P*-value
Number of suicidal acts	0–24m	−0.91 (−1.67, −0.15)	0.020
Mood—State Anxiety total	24m	−7.96 (−14.2, −1.73)	0.013
Cognition—Youngs Schema mean total	24m	−0.58 (−1.00, −0.17)	0.0064
BSI—Positive Symptoms Distress Index	12m	−0.39 (−0.66, −0.12)	0.0047