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chapter 4



Outcomes of a Randomized Controlled Trial of a Cognitive Behavioural Intervention for Deliberate Self-Harm Patients

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Abstract

This study investigated the efficacy of a short cognitive-behavioural therapy (CBT) intervention with 90 adolescents and adults (aged 15-35) who had recently engaged in Deliberate Self-Harm (DSH). Participants were randomly assigned to treatment as usual plus CBT or treatment as usual only. Assessments were completed at baseline and 3, 6 and 9 months follow-up. DSH patients who received CBT in addition to treatment as usual were found to have significantly greater reductions in DSH, suicidal cognitions, symptoms of depression and anxiety, and significantly greater improvements in self-esteem and problem solving ability than controls. These findings extend the evidence that a time-limited CBT intervention is effective for patients with recurrent and chronic DSH.

Introduction

In recent years, there has been a marked rise in the frequency of young people engaging in Deliberate Self-Harm (DSH) (Evans, Hawton, Rodham, & Deeks, 2005). Identifying those who are at risk for DSH is important because every episode of DSH increases the risk of future episodes and (Colman, Newman, Schopflocher, Bland, & Dyck, 2004), eventually, of suicide (Zahl & Hawton, 2004). In this article, the term DSH refers to self-harm as well as self-poisoning, with or without suicidal intent (Hawton, Zahl, & Weatherall, 2003).

The risk of DSH increases when multiple risk factors are present (Colman et al., 2004). The presence of a severe psychiatric disorder such as major depression is among the strongest predictors of DSH (Fawcett, Clark, & Busch, 1993). Anxiety, especially if acute and intense, also has an important role (Busch, Clark, Fawcett, & Kravitz, 1993). In addition to anxiety, DSH patients describe feelings of chronic emptiness, alienation and isolation (Orbach, Mikulincer, Gilboa-Schechtman, & Sirota, 2003). In the context of these unpleasant experiences, they report thoughts of hopelessness (e.g. Glanz, Haas, & Sweeney, 1995), helplessness (e.g. D'Zurilla, Chang, Nottingham, & Faccini, 1998), of being a burden to loved ones (Brown & Vinokur, 2003), of unlovability and poor distress tolerance (Rudd, Joiner, & Rajab, 2001) and of low self-esteem (McAuliffe et al., 2006). Poor problem solving ability is assumed to interact with suicidal cognitions, increasing the risk of DSH (Townsend et al., 2001).

Although inpatient treatment is the standard of care for DSH patients, it has never been found efficacious in a controlled clinical trial (Comtois & Linehan, 2006). Furthermore, controlled Cognitive-Behavioural Therapy (CBT) intervention studies for DSH are limited and their results are inconsistent. Tyrer et al. (2003) reported that brief CBT is no more effective than usual care when it comes to preventing repetition of DSH, whereas Brown

et al. (2005) reported positive effects of Cognitive Therapy (CT) on suicide attempts, depression and hopelessness. In addition, several controlled studies have established the efficacy of Dialectical Behavioural Therapy in reducing self-injury in (female) patients with borderline personality disorder (Linehan et al., 2006). Schema-Focused Therapy has also been found to reduce DSH effectively in patients with borderline personality disorder (Giesen-Bloo et al., 2006). Furthermore, CBT interventions with a problem solving component seem to have positive effects on DSH (Hawton et al., 1998). These findings are important, given the strong association between acts of DSH and the risk of suicide described above. In addition, given the association between negative emotions, suicidal cognitions, problem solving deficits and DSH, it is important to assess in more detail the impact of treatment on these correlates of DSH.

In the study reported here the efficacy of a short, manualised CBT intervention for DSH was investigated. This intervention was based on a cognitive-behavioural model of maintenance factors of DSH (Slee, Arensman, Garnefski, & Spinhoven, 2007). The model assumed that vulnerability to DSH can be changed by changing suicidal and negative thinking and problem solving deficits. The intervention aimed to develop cognitive and behavioural skills for coping with situations that trigger DSH. Considering the wide range of psychiatric, psychological and social problems that patients present with, the intervention was intended to give therapists a clear framework to orient themselves within the therapy. At the same time, the intervention needed to be flexible enough to be of help to a broad range of patients, including those with high risk of repetition of DSH and high levels of psychiatric co-morbidity.

This study was designed to determine the short and long-term efficacy of the intervention with respect to the rate of repetition of DSH as well as emotional problems, suicidal cognitions and problem solving deficits. It was predicted that the rate of DSH of those participants who received Cognitive-Behavioural Therapy (CBT) in addition to treatment as usual (TAU) would be lower than in patients who received TAU only, and also that participants from the CBT condition would have significantly lower scores for emotional problems (depression and anxiety) and suicidal cognitions, and significantly higher scores for functional cognitions (self-esteem) and behavioural skills (problem solving ability) following treatment, than participants from the TAU condition.

Method

Participants

Patients aged 15-35 years were included in the study if they had recently engaged in Deliberate Self-Harm (DSH), defined as both self-poisoning (overdose) and self-injury

(Hawton, et al., 2003). Patients were excluded if they reported a severe psychiatric disorder (e.g. schizophrenia) requiring intensive inpatient treatment (as assessed during the baseline interview with a structured diagnostic interview: MINI., Sheehan & Lecrubier, 1992, 1994, 1998), were unable to converse in Dutch, had cognitive impairments, or lived outside the region of Leiden.

The study was conducted at the Leiden University Medical Centre and the Rivierduinen mental health centre from March 2003 till April 2006. The initial sample consisted of 222 individuals who had visited the Leiden University Medical Centre or the local mental health centre because of DSH. Of these 222 people, 32% (n=72) could not be reached, because the name, address or phone number they had left were incorrect. Of the 68% (n=150) that were contacted, 12% (n=26) declined to participate and 11% (n=24) were excluded from the study. Reasons for exclusion were the index episode not being an act of DSH (n=3), being under 15 years old (n=1), being hospitalized for an extended period because of schizophrenia or alcohol or drug misuse (n=11), being unable to converse in Dutch (n=3), having cognitive impairments (n=2) or living abroad (n=4). As a result, 100 individuals (45% of the initial sample) were invited for the baseline interview. The flow of these participants through the study is illustrated in Figure 1. It shows that 10 people failed to meet the inclusion criteria. They were unable to converse in Dutch (n=2), had cognitive impairments (n=1) or were living outside the region of Leiden (n=5). Two more persons did not want to complete the baseline interview. The 90 individuals who entered the study were randomly assigned to 12 CBT sessions in addition to TAU (n=48) or to TAU only (n=42).

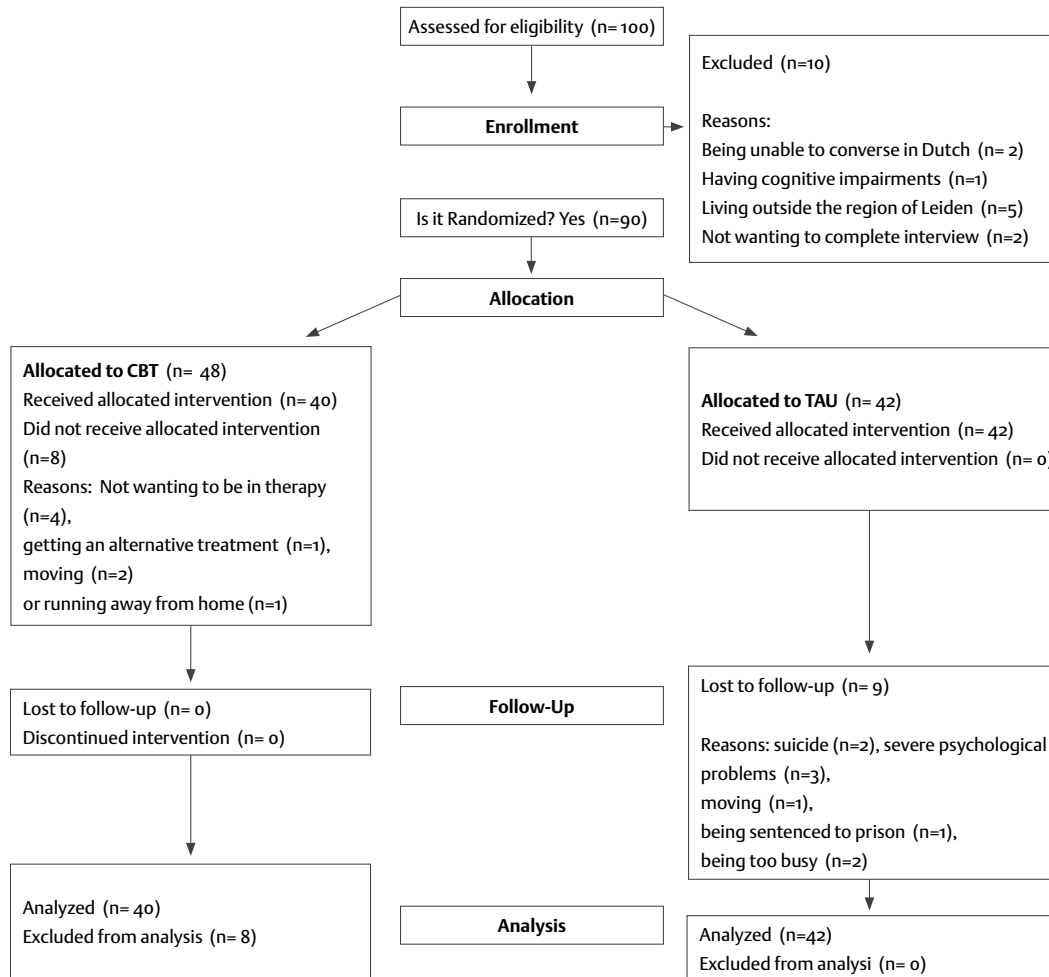
Of the 48 people who were randomly assigned to the CBT condition, 8 (17%) left the study prior to the first session (just after the baseline interview), leaving 40 clients to enter treatment. All 40 clients who entered CBT completed the 12 sessions of CBT, as well as the assessments 3, 6 and 9 months after the baseline interview. Reasons for leaving the study just after the baseline interview were: not wanting to be in therapy (n=4), having started an alternative treatment (n=1), having moved (n=2) or having run away from home (n=1).

Of the 42 clients who were randomly assigned to the TAU condition, 5 clients (12%) did not complete the 3-month follow-up interview, owing to severe psychiatric disorder (n=2), having moved out of region (n=1), being sentenced to prison (n=1) or reportedly being too busy (n=1). Three more persons did not complete the 6-month follow-up interview, owing to severe psychiatric disorder (n=1), no longer wishing to participate in the project (n=1) or having died by suicide (n=1). One person did not complete the 9-month follow-up interview because she had died by suicide, bringing the total leaving the study to 9 persons (21%).

Participants completing and leaving the study did not differ demographically, on history of DSH or on any of the outcome variables at baseline.

Outcomes of a Randomized Controlled Trial of a Cognitive Behavioural Intervention for Deliberate Self-Harm Patients

Figure 1. Flow of participants through the study



Procedure

On visiting one of the participating centres, individuals who had recently engaged in DSH received a brochure with a complete description of the study. In this brochure it was announced that the person would be contacted by a member of the research team, who would provide further information on the study and would ask if the person were interested in participating. Informed consent was obtained from all participants, and from parents of adolescents below the age of 16 years. After participants had given written consent they were interviewed in their home or at the medical centre. We allowed a week to pass between a person's index episode of DSH and entering the study, 2 weeks to pass between the index episode and the initial interview, and 3 weeks to pass between the index episode and the first session of CBT. Those who agreed to participate and were found to be eligible for the study were randomly assigned to 12 sessions of CBT in addition to TAU, or to TAU only. All participants were invited for subsequent assessments 3 months, 6 months and 9 months following the baseline interview. Like the baseline interviews, these interviews were conducted in the participant's home or at the medical centre. The medical ethics committee of the Leiden University Medical Centre approved all procedures.

Design

Participants were randomly assigned to 12 sessions of CBT in addition to TAU (n=48) or TAU only (n=42). Randomisation to treatment was accomplished using a computer program and a random number generator provided by an independent investigator. Stratification was not used. Although masked assessments were conducted at baseline, masking the follow-up assessments was not possible, because participants were asked about their use of health care services at each assessment. In addition, information regarding treatment assignment was essential to provide care for individuals who were in crisis. The assessments were conducted by an independent member of the research team who was not the participant's therapist.

Outcome measures

The primary outcome measure of the study was the number of episodes of DSH in the past 3 months, which was assessed using a structured clinical interview. DSH was defined as including both deliberate self-poisoning (overdose) and self-injury (Hawton, et al., 2003). An overdose was defined as the deliberate ingestion of more than the prescribed or recommended amount of chemical substances with the intention of self-harm. Patients were also asked about incidents of deliberate self-injury, which was defined as intentional self-injury, irrespective of the apparent purpose of the act, and included cutting, scratching, punching, kicking and head-banging. In this definition, both the original parasuicide definition of the WHO/Euro study and the study's current nomenclature of

fatal and nonfatal suicidal behaviour are included, as well as habitual behaviours and self-injuries with no intent to die. In line with the definition of the WHO/Euro study, DSH associated with mental retardation is excluded (De Leo et al., 2004; Schmidtke et al., 2004). Thus, all behaviour that was self-initiated with the intent to harm the body (regardless of intent to die) was included.

At each of the four assessments participants were asked about the number of episodes of DSH in the past 3 months. Other aspects of DSH were also recorded: suicide intent, motives, the antecedent events and consequences. However, only the number of episodes of DSH was selected as primary outcome measure. To investigate the reliability of the assessment of the number of episodes of DSH, the retrospective self-reports were compared with hospital records, as well as with information coming from the treatment sessions. The correlations between the three measures were high, with correlations ranging from .88 to .90. Scores of the number of episodes of DSH in the past 3 months range from 0-25.

Secondary outcome measures assessed by patient self-report at the baseline, 3-month, 6-month and 9-month assessments included depression, anxiety, self-esteem, suicidal cognitions and problem solving ability:

(i) Depression was measured with the Beck Depression Inventory II (BDI-II) (Beck, Steer, & Brown, 1996; van der Does, 2002): a 21-question depression scale with each answer rated 0-3. Scores range from 0-63. The test has high internal consistency with an alpha reliability of .91 (Beck, Steer, & Brown, 1996; Beck, Steer, Ball, & Ranieri, 1996). In this study, we found an alpha reliability of .93.

(ii) Anxiety was measured using a sub-scale of the Symptom Checklist-90 (Derogatis, Lipman, & Covi, 1973; Arindell & Ettema, 1986), which is a self-report clinical rating scale of psychiatric symptomatology. The anxiety subscale consists of 10 items total, assessing whether and to what extent participants reported symptoms of anxiety. Items are measured on a 5-point Likert scale, ranging from "not at all distressing" (0) to "extremely distressing" (4). Individual subscale scores are obtained by summing the 10 items (range from 0-40). Previous studies have reported alpha-coefficients ranging from .71 to .91 for the anxiety subscale. In addition, test-retest reliabilities are found to be good and the subscale has been found to show strong convergent validity with other conceptually related scales (Arrindell & Ettema, 1986). In this study we found an alpha reliability of .93 for the anxiety subscale.

(iii) Self-esteem was measured with the Robson Self-Concept Questionnaire, Short version (Robson, 1989, developed for the CASE Study, see De Wilde, 2005, for CASE NL): an 8-item questionnaire dealing with attitudes and beliefs that people have about themselves ("I'm glad I am who I am"). All items are self-rated from 1-4 (strongly disagree-strongly agree). Scores range from 8-32. The original scale has good validity and reliability (Robson, 1989).

In this study we found an alpha reliability of .82.

(iv) Suicidal cognitions were measured using the Suicide Cognition Scale (Rudd et al., 2001): 20 questions about core beliefs of Perceived Burdensomeness (“I am a burden to my family”), Helplessness (“No one can help solve my problems”), Unlovability (“I am completely unworthy of love”) and Poor Distress Tolerance (“When I get this upset, it is unbearable”), with each answer rated 1 (strongly disagree) to 5 (strongly agree). Scores on the total scale range from 20-100. Scores on the subscale Perceived Burdensomeness (2 items) range from 2-10, scores on the subscale Helplessness (5 items) range from 5-25, scores on the subscale Unlovability (6 items) range from 6-30 and scores on the subscale Poor Distress Tolerance (7 items) range from 7-35. In this study we found an alpha reliability of .96 for the total scale, of .74 for Perceived Burdensomeness, of .88 for Helplessness, of .90 for Poor Distress Tolerance and of .89 for Unlovability.

(v) Problem Solving Ability was measured with the Coping Inventory for Stressful Situations (CISS, subscale task oriented coping; Endler & Parker, 1990). This subscale consists of 16 items scored on a 5-point Likert scale, referring to the extent to which people make use of problem solving techniques in the face of stress (“Make an extra effort”) with answers ranging from 1 (not at all) to 5 (very strongly). Scores range from 16-80. Across studies, the CISS has proved reliable. The internal consistency of the subscales is excellent ($\alpha > .85$) (Endler & Parker, 1990; Endler & Parker, 1994). In this study we found an alpha reliability of .93.

In addition, demographic information was obtained, as well as information about the use of health care services. Baseline characteristics also included suicide intent and motives of the index episode of DSH. Suicide intent was assessed with the Suicide Intent Scale (SIS; Beck, Schuyler, & Herman, 1974), an instrument with sound psychometric properties. The SIS has 20 items, but only the first 15 items are used for calculating the score. Scoring for each item ranges from 0 to 2. Items 1 to 9 are concerned with the act itself, 10 to 15 with the thoughts and feelings associated with the act, and 16 to 20 with the subject’s thoughts and feelings about suicide in the present. To assess motives for DSH, the Reasons for Overdose Scale was used (Hawton et al., 1982). The 10 motives presented were a subset of those originally developed by Bancroft, Skrimshire and Simkin (1976), including wanting to die, wanting to get relief and wanting to escape. Participants were asked to indicate the extent to which these motives were important to them at the time of the index episode.

For screening purposes, psychiatric diagnosis was assessed using a short structured diagnostic interview with an administration time of approximately 20-30 min, the Mini-International Neuropsychiatric Interview (MINI, Sheehan & Lecrubier, 1992, 1994, 1998). In this study the Dutch translation of the clinician rated (CR) version of the MINI (van Vliet, Leroy, & Van Megen, 2000) was used. Validation of the MINI-CR against the Structured

Clinical Interview DSM-III-R- patient version (SCID-P) and the Composite International Diagnostic Interview for ICD-10 (CIDI) showed good to very good kappa values (Sheehan & Lecrubier, 1998).

Intervention

Cognitive-Behavioural Therapy

In addition to usual care (e.g. prescribed psychotropic medication, psychotherapy, psychiatric hospitalisations), participants in the CBT condition received 12 out-patient CBT sessions specifically developed for preventing DSH. The sessions were provided on a weekly basis or as needed in case of crisis. Ten of the 12 sessions were given weekly; the last two were follow-up sessions. All together, the intervention lasted approximately 5.5 months. The central feature of this intervention was the identification and modification of the mechanisms that maintained DSH. Thus, the treatment started with the assessment of the most recent episode of DSH (e.g. circumstances at the time of the episode, motives and reasons for DSH, cognitions, emotions and behaviour prior to and at the time of the episode). The therapist and patient then investigated how emotional, cognitive and behavioural factors played a part in the maintenance of DSH. Specific maintenance factors that were addressed included dysfunctional cognitions, emotion regulation difficulties and poor problem solving. Near the end of therapy relapse prevention was addressed as well. The treatment is first and foremost an individual one. However, the involvement of the partner or the (non-abusive) parent(s) in the therapeutic process is of great importance, since DSH patients need the support of others to overcome DSH. A manual was written to standardise the intervention (available on request). To improve treatment compliance, therapists played an active part in keeping patients in treatment (e.g. calling patients to remind them of appointments).

All therapists were experienced practitioners of CBT and accustomed to working with patients who engage in DSH. Before they took part in the research project, they received two days of training in the standardised protocol. To maintain the integrity of treatment, the therapists followed this treatment protocol. In addition, checklists and outlines were used in every session to foster correct execution of the treatment. At monthly meetings, the treatment sessions were reviewed and therapists could share their experiences with their colleagues. Issues that were discussed were reactions in the therapist elicited by episodes of DSH (e.g. sadness, worry, aversion) or problems with treatment compliance. The average number of patients treated by each of the therapists was 8 (range 7-9).

Treatment as Usual

For ethical reasons, participants of both conditions were free to pursue any form of usual care they deemed warranted. We recorded three forms of TAU: "psychotropic

medication”, “psychotherapy” and “psychiatric hospitalisations”. In addition, we recorded whether psychotherapy in TAU had a focus on DSH. However, we did not systematically record the specific types of psychotherapy or psychotropic medication the comparison condition received, nor did we record the specific types of psychotherapy or psychotropic medication those in the experimental condition received in addition to the DSH-focused CBT. As a result, we do not know whether the comparison group and experimental group were equivalent in this respect.

Although we did not systematically record specific types of psychotherapy in TAU, most of the interventions involved a limited number (2-30) of sessions of individual psychotherapy such as CBT and interpersonal psychotherapy. Social skills training was also common, especially among adolescents and young adults. No treatment specific to DSH was reported. These treatments focused, instead, on specific psychiatric problems (e.g. depression) or on specific needs of the patient (e.g. problems with housing, finances, social isolation).

Statistical Procedure

The study design was constrained to a maximum of four measurements per participant. Given this restriction, a power analysis was performed to determine the sample size needed to detect between-group differences on the primary outcome measure: the number of episodes of DSH. Results obtained with the program PINT (Snijders & Bosker, 1993) indicated that a sample size of approximately 45 participants in each group would be sufficient to detect a difference in average time slope between the groups of .40 (corresponding with a small effect size) with adequate power (.80) and an alpha of .05.

Sociodemographic characteristics and outcome measures of the groups were examined using *t*-tests or chi-square tests, as appropriate.

Multilevel analysis (MLA) was used to analyze the development of each outcome measure over time. MLA is especially suitable to analyze repeated measure data because it takes into account the dependencies among observations nested within individuals. Another advantage to the methodology is its ability to handle missing data, which is also common to the type of longitudinal research discussed in this paper. Random coefficient models¹ were fitted for all outcome measures, allowing for individual variation of intercepts and regression slopes. Fixed effects of Time, Condition and the interaction between Time and Condition were tested using two-tailed *z*-tests. Effects of baseline differences with regard to suicidal acts during the past 3 months on the development of all outcome measures over time were controlled for (Suicidal Acts X Condition X Time). Effects of baseline use of psychotropic medication and psychotherapy on the development of all outcome measures over time were also controlled for; Medication Use X Condition X Time and Psychotherapy X Condition X Time. Models were fitted using MLwiN (version 2.02; Rasbash, Steele, Browne, & Prosser, 2004).

In addition, effect sizes were calculated to facilitate comparison of improvement in the CBT condition with improvement in the TAU condition. Effect sizes were derived by calculating the difference of the means on the outcome variables in CBT and TAU at 3-month, 6-month or 9-month assessment, divided by the pooled standard deviation (see Thalheimer & Cook, 2002 for the program to calculate effect sizes). Furthermore, to give an indication of the differences between the conditions for a given variable at baseline, 3-month, 6-month and 9-month assessment, significance levels were calculated using t-tests or chi-square tests.

Results

Sample description and baseline characteristics

Demographic characteristics, psychiatric diagnosis and history of DSH for participants from the two conditions are reported in Table 1 and Table 2. There were no significant differences between individuals in the CBT condition (n=40) and TAU condition (n=42) on any of the demographic characteristics including gender, age, living situation, marital status, educational level, job status or nationality (see Table 1). In addition, no significant differences were found with regard to psychiatric co-morbidity, history of previous episodes of DSH, self mutilation in the past 3 months, or rate of leaving the study (see Table 2). However, there was a trend towards more suicidal acts in the past 3 months in TAU at baseline ($t=-1.90$, $df = 80$, $p = .06$), which variable was included in the MLA models. The baseline table also includes information on the nature of the index episode of DSH in both groups. The majority of the patients reported self-poisoning at index (87% in CBT and 91% in TAU, which is a non-significant difference). Suicide intent and motives at index did not differ significantly between the groups (see Table 2). We also investigated whether the groups differed significantly on use of health care services. There were no significant baseline differences, except for trends towards more medication use in TAU at baseline [$\chi^2(1, n = 82) = 3.12$, $p = .08$] and trends towards more psychotherapy in TAU at baseline [$\chi^2(1, n = 82) = 4.74$, $p = .09$]. Both medication use and psychotherapy at baseline were included in the MLA models. Psychiatric hospitalisation was not included as a covariate in the MLA models, because psychiatric hospitalisations had not been reported at baseline (see Table 3). In addition, we used MLA to determine whether there were any baseline differences between the groups on the primary and secondary outcome measures (see Condition Effects in Table 4, 5 and 6). No significant group differences were found on any of these outcome measures (see Table 4, 5 and 6). The mean number of episodes of DSH during the last three months as reported at baseline was 14.42 (SD=10.51) in CBT and 11.62 (SD =11.42) in TAU; score range 0-25 (see Table 3).

Table 1. *Characteristics of the study sample for CBT (n=40) and TAU (n=42)*

			t/[chi] ²	p
Gender (chi ²)	CBT	97% female (n=39)	1.77	.18
	TAU	91% female (n=38)		
Mean age (t-test)	CBT	23.9 years (SD=6.4)	-1.18	.24
	TAU	25.4 years (SD=4.5)		
Living situation (chi ²)	CBT	73% (n=29) lived alone, 27% (n=11) lived together with someone else	1.07	.59
	TAU	74% (n=31) lived alone, 26% (n=11) lived together with someone else		
Marital status (chi ²)	CBT	73% (n=29) unmarried, 8% (n=3) married, 17% (n=7) widowed, 2% (n=1) divorced	4.35	.36
	TAU	78% (n=33) unmarried, 5% (n=2) married, 10% (n=3) widowed, 7% (n=4) divorced		
Educational level (chi ²)	CBT	primary school (27%, n=11), secondary school (34%, n=14), lower education, (13%, n=5), higher education/university (25%, n=10)	12.41	.13
	TAU	primary school (19%, n=8), secondary school (35%, n=15), lower education, (25%, n=10), higher education/university (21%, n=9)		
Job status (chi ²)	CBT	38% (n=15) went to school/studies, 25% (n=10) had a full-time or part-time job, 37% (n=15) lived on social security	11.84	.34
	TAU	19% (n=8) went to school/studies, 27% (n=11) had a full-time or part-time job, 36% (n=15) lived on social security		
Nationality (chi ²)	CBT	90% (n=36) Dutch, 5% (n=2) other European, 5% (n=2) Turkish/Moroccan	7.08	.42
	TAU	93% (n=39) Dutch, 5% (n=2) other European, 2% (n=1) Turkish		

Description of the primary and secondary outcome measures

Table 3 shows the means and standard deviation of scores on the primary and secondary outcome measures at baseline, 3-month, 6-month and 9-month assessment, including significant group differences based on t-tests. In addition, it shows that during the study period, two persons in TAU died because of suicide. It also describes the use of health care services by patients in CBT and TAU and group differences based on chi-square tests.

Table 2. *Characteristics of the study sample for CBT (n=40) and TAU (n=42)(continued)*

		t / [chi ²	p
Psychiatric co-morbidity (t-test)	CBT on average 3.6 diagnoses per person (SD=3.0) TAU on average 4.5 diagnoses per person (SD=4.1)	-1.15	.25
Range of diagnosis (chi ²)	CBT 88% (n=35) mood-; 65% (n=26) anxiety-; 10% (n=4) eating- and 5% (n=2) somatoform disorder; 10% (n=4) alcohol/drug abuse TAU 90% (n=16) mood-; 46% (n=19) anxiety-; 24% (n=10) eating- and 3%(n=1) somatoform disorder 24%(n=10) alcohol/drug abuse		
History of DSH (chi ²)	82% (n=33) in CBT and 70% (n=30) in TAU reported 10 or more previous episodes of DSH (self-poisoning and/or self-injury)	.73	.47
Self mutilation past 3 months (t-test) ¹	CBT (92%, n=37); TAU (57%, n=24)	1.54	.13
Suicidal acts past 3 months (t-test) ²	CBT (45%, n=18); TAU (81%, n=34)	-1.91	.06
Index episode of DSH (chi ²)	self-poisoning 83% (n=33) in CBT and 91% (n=38) in TAU; self-injury 17% (n=7) in CBT and 9% (n=4) in TAU	4.69	.70
Suicide Intent index episode (t-test) ³	range (0-30); CBT: 10.83 (6.65); TAU: 12.58 (6.84)	8.27	.94
Motives index episode (chi ²)	get relief from a terrible state of mind (92%), want to die (67%), escape impossible situation (64%); similar for CBT & TAU	19.80	.14
Psychotropic Medication at baseline (chi ²)	53% (n=21) of the patients in CBT and 71% (n=30) of the patients in TAU	3.12	.08
Psychotherapy at baseline (chi ²)	43% (n=17) of the patients in CBT and 55% (n=23) of the patients in TAU	4.74	.09

¹ Suicide Intent was measured with the Suicide Intent Scale; Motives were measured with the Reasons for Overdose Scale.
² Suicide Intent was measured with the Suicide Intent Scale; Motives were measured with the Reasons for Overdose Scale.
³ Suicide Intent was measured with the Suicide Intent Scale; Motives were measured with the Reasons for Overdose Scale.

9-month outcome of treatment

In Table 4 (MLA without the 8 early withdrawals, n=82), Table 5 (MLA with completers, n=73) and Table 6 (MLA with intent-to-treat/LOCF, n=90) fixed effects and corresponding standard errors are reported for the MLA models regarding the primary and secondary outcome measures². The effect of Time indicates the overall increase or decrease for each of the outcome measures. The effect of Condition indicates the difference between CBT and

Table 3. *Primary and secondary outcome measures: means and standard deviations at baseline and follow-up (n=82)*

		Baseline	3 months	6 months	9 months
N(CBT/TAU)		40/42 M (SD)	40/37 M(SD)	40/34 M(SD)	40/33 M(SD)
Primary outcome measure (t-tests)					
DSH in the past 3 months	CBT	14.42 (10.51)	5.63(9.04)	5.30(9.44)	1.18(4.22)*
	TAU	11.62 (11.42)	5.65(9.24)	4.03(7.16)	4.58(8.37)
Suicide in the past 3 months	CBT	-	-	-	-
	TAU	-	-	1	1
Secondary outcome measures ¹ (t-tests)					
Depression (BDI-II)	CBT	31.35 (12.85)	21.15 (13.48)*	16.58 (13.70)**	11.58 (12.12)**
	TAU	34.67 (14.01)	30.08(18.63)	28.56(18.62)	29.61 (17.51)
Anxiety (SCL-90)	CBT	30.60 (8.67)	24.95(9.02)	24.20(8.14)	19.78 (7.70)**
	TAU	28.05 (10.51)	28.78(12.00)	29.03(11.57)	27.36(11.08)
Self-Esteem (RSCQ)	CBT	16.38 (3.24)	18.13(4.35)	19.15(3.71)*	20.58(4.36)**
	TAU	15.38 (4.46)	16.11(5.65)	16.85(5.56)	16.70(5.10)
Suicide-Cognitions Scale (SCS)	CBT	58.33(14.86)	46.63(16.56)*	42.48(19.67)*	36.60(17.05)**
	TAU	63.29 (19.47)	59.70(24.48)	56.26(22.50)	54.88(19.05)
Perceived burdens. (SCS)	CBT	6.65(2.01)	4.98(2.41)	4.75(2.67)*	3.88(2.03)**
	TAU	6.88 (2.33)	6.24(2.82)	6.21(2.57)	5.76(2.35)
Helplessness (SCS)	CBT	15.85(4.97)	12.90(4.78)*	11.95(5.90)**	10.38(4.80)**
	TAU	17.55 (5.83)	17.11(7.36)	16.32(6.79)	15.97(5.25)
Poor distress tolerance (SCS)	CBT	19.38(5.33)	15.13(5.92)*	13.65(6.61)*	11.65(5.73)**
	TAU	20.88 (6.29)	19.24(7.84)	18.09(7.88)	17.52(6.77)
Unlovability (SCS)	CBT	16.45(5.21)	13.63(5.56)	12.13(6.14)*	10.70(5.56)**
	TAU	17.98 (6.14)	17.11(7.40)	15.64(6.50)	15.64(5.90)
Problem-solving (CISS)	CBT	27.00(10.42)	31.18(11.05)	32.55(11.66)	36.25(11.50)**
	TAU	25.76 (13.45)	26.97(13.19)	25.70 (13.99)	26.24(13.13)
Use of health care services/usual care (chi ² tests)					
Psychotropic Medication	CBT	53% (n=21)	38%* (n=15)	42%* (n=17)	46% (n=18)
	TAU	71% (n=30)	59% (n=25)	57% (n=24)	70% (n=29)
Psychotherapy	CBT	43% (n=17)	21% (n=8)	28% (n=11)	52% (n=21)
	TAU	55% (n=23)	83% (n=35)	72% (n=30)	72% (n=30)
Psychiatric Hospitalisations	CBT	none	2% (n=1)	6% (n=3)	2%* (n=1)
	TAU	none	14% (n=6)	16% (n=7)	21% (n=9)
* indicates significance at .05 level; ** indicates significance at .01 level					
¹ BDI-II is the Beck Depression Inventory II; SCL-90 is the Symptom Checklist-90; RSCQ is the Robson Self-Concept Questionnaire (short version); SCS is the Suicide Cognitions Scale; CISS is the Coping Inventory for Stressful Situations.					

TAU at baseline. The interaction effect (Time X Condition) indicates whether there is a significant difference between CBT and TAU upon the development of the outcome measures over time.

To control for baseline differences in suicidal acts during the past 3 months, the interaction of Suicidal Acts X Condition X Time was included in the models as well. In addition, to control for baseline differences in psychotropic medication use and psychotherapy, the interaction of Medication Use X Condition X Time and the interaction of Psychotherapy X Condition X Time were included in the models. Fixed effects were tested by two-tailed z-tests. Variance components are omitted here because they are not the primary focus of our study. MLA results without the 8 participants who left the study (n=82, see Table 4) showed that overall DSH, depression and suicidal cognitions (total scale and the subscales perceived burdensomeness, poor distress tolerance and unlovability) significantly decreased over Time. Self-esteem was shown to significantly increase over time. No significant effects were found for Condition, indicating that on average, there were no significant baseline differences between the groups on all outcome measures. The fixed effects of Time X Condition showed that there was a significant effect of condition upon the development (increase or decrease) of all outcome measures over time. For instance, the estimated value of -.576 in the model for DSH indicates that the individuals in the CBT condition, on average, show a significant difference in decrease of DSH compared to individuals in the TAU condition (see Table 4). The significant Time X Condition effects remain with different ways of handling withdrawals. MLA results using the completers sample (n=73, see Table 5) and the Last Observation Carried Forward (LOCF) method (n=90, see Table 6) showed a slightly smaller effect for Time on average, but a similar significant effect for Time X Condition as MLA without the 8 early withdrawals (n=82, see Table 4). The most conservative analysis (LOCF) showed the strongest effect for CBT on DSH ($t = -2.843$), while the more optimistic analysis without the 8 early withdrawals showed the weakest effect for CBT on DSH ($t = -2.390$). However, each of the three analyses led to the same significant effect of Time X Condition. Moreover, none of the effects of Suicidal Acts during the past 3 months X Condition X Time were significant, indicating that there were no effects of suicidal acts at baseline on the development of the outcome measures over time in the two conditions. In addition, none of the effects of Medication Use X Condition X Time were significant, indicating that there were no effects of medication use at baseline on the development of the outcome measures over time in the two conditions. Furthermore, none of the effects of Psychotherapy X Condition X Time were significant, indicating that there were no effects of psychotherapy at baseline on the development of the outcome measures over time in the two conditions. These interaction effects are omitted from the models. Table 4 (MLA without the 8 early withdrawals; n=82), Table 5 (MLA with completers; n=73) and Table 6 (MLA with LOCF method; n=90) present the results of a simple model

with only three fixed effects, which is preferable because it is easier to understand.

In addition, effect sizes were calculated to facilitate comparison of improvement in the CBT condition with improvement in the TAU condition (see Table 4, 5 and 6). Effect sizes of .20 indicate small effects, effect sizes of .50 indicate medium effects, whereas values of .80 indicate large effects (Cohen, 1992). As can be derived from Table 4, 5 and 6, the effect sizes became larger during the follow-up period and at 9-months follow-up effect sizes were medium for the difference in DSH and large to very large for the differences on all other primary and secondary outcome measures between both treatment conditions. The use of parametric statistics with skewed data (the number of episodes of DSH) may have reduced the effect size estimates as presented in Table 4, 5 and 6.

Visual inspection of means in Table 3 and effect sizes in Table 4, 5 and 6 suggests a curvilinear time trend for DSH in TAU, but a linear trend for DSH in CBT. However, the curvilinear trend did not prove to be significant. Therefore, we used a linear model for DSH in CBT as well as TAU.

Table 4 *MLA Effects for Time, Condition and Time X Condition and Cohen's d effect sizes for differences on outcome measures between CBT and TAU for n=82*

Variables ¹	Time	Condition ²	Time X Condition	Cohen's d	Cohen's d	Cohen's d
	B(SE)	B(SE)	B(SE)	3 months (post-treatment) n=40/37	6 months (follow-up) n=40/34	9 months (follow-up) n=40/33
DSH	-.794(.177)*	2.892(2.089)	-.576(.241)*	.0	.06	.53
Depression (BDI-II)	-.515(.223)*	-4.047(2.956)	-1.617(.302)*	.56	.75	1.24
Anxiety (SCL-90)	-.065(.174)	-.748(2.018)	-1.038(.235)*	.37	.22	.82
Suicide Cognitions total (SCS)	-.835(.304)*	-6.339(3.661)	-1.497(.411)*	.64	.67	1.03
Perceived burdensomeness (SCS)	-.106(.039)*	-.489(.465)	-.175(.052)*	.49	.56	.88
Helplessness (SCS)	-.142(.089)	-1.987(1.120)	-.457(.132)*	.69	.70	1.13
Poor distress tolerance (SCS)	-.328(.106)*	-1.797(1.248)	-.514(.143)*	.60	.62	.96
Unlovability (SCS)	-.268(.097)*	-2.074(1.168)	-.349(.130)*	.54	.56	.88
Self-esteem (RSCQ)	.141(.066)*	.852(.810)	.309(.089)*	.41	.50	.83
Problem-solving (CISS)	-.072(.215)	.999(2.382)	1.068(.290)*	.35	.54	.83

* indicates significance at .05 level

¹ BDI-II is the Beck Depression Inventory II; SCL-90 is the Symptom Checklist-90; RSCQ is the Robson Self-Concept Questionnaire (short version); SCS is the Suicide Cognitions Scale; CISS is the Coping Inventory for Stressful Situations.

² "Condition" means baseline differences between CBT and TAU

Use of health care services during the study period

Chi-square tests were used to examine differences in the use of health care services during the study period. Table 3 shows that at baseline, 43% (n=17) of the patients in the CBT condition received psychotherapy. About half of these patients preferred to interrupt their regular psychotherapy schedule for a period of 3 months, which was the period in which 10 out of 12 CBT sessions took place. Between baseline and 3-month assessment, only 21% of the patients received CBT for DSH and regular psychotherapy at the same time. Between 3-month and 6-month assessment, 28% of the patients received CBT for DSH in addition to usual care (see Table 3). After the CBT intervention, 52% (n=25) of the patients continued or started with regular psychotherapy. Table 3 also shows that individuals in CBT used significantly less psychotropic medication from baseline to 3-month assessment [$\chi^2(1, n = 77) = 3.970, p = .046$ and from 3-month to 6-month assessment [$\chi^2(1, n = 74) = 4.270, p = .039$, but not from 6-month to 9-month assessment. From baseline to 6-month assessment, the number of psychiatric hospitalisations was lower in CBT (n=4) than in TAU (n=13), but this difference was not significant. However, between 6-month and 9-month

Table 5. *MLA Effects for Time, Condition and Time X Condition and Cohen's d effect sizes for differences on outcome measures between CBT and TAU for completers (n=73)*

Variables ¹	Time	Condition ²	Time X Condition	Cohen's d	Cohen's d	Cohen's d
	B(SE)	B(SE)	B(SE)	3 months (post-treatment) n=40/33	6 months (follow-up) n=40/33	9 months (follow-up) n=40/33
DSH	-.728(.178)*	3.361(2.233)	-.604(.239)*	.02	.05	.39
Depression (BDI-II)	-.458(.246)	-2.613(3.189)	-1.694(.331)*	.50	.41	1.24
Anxiety (SCL-90)	-.025(.179)	-1.608(2.211)	-1.102(.241)*	.36	.46	.82
Suicide Cognitions total (SCS)	-.747(.306)*	-4.637(4.103)	-1.607(.412)*	.58	.64	1.03
Perceived burdensomeness (SCS)	-.093(.039)*	-.298(.529)	-.196(.052)*	.44	.56	.88
Helplessness (SCS)	-.116(.100)	-1.658(1.230)	-.470(.134)*	.66	.68	1.13
Poor distress tolerance (SCS)	-.308(.107)*	1.271(1.385)	-.534(.143)*	.53	.58	.96
Unlovability (SCS)	-.230(.096)*	-1.409(1.319)	-.407(.129)*	.49	.58	.88
Self-esteem (RSCQ)	.139(.067)*	.683(.904)	.326(.090)*	.36	.47	.83
Problem-solving (CISS)	-.163(.218)	-.434(2.541)	1.137(.293)*	.35	.47	.83

* indicates significance at .05 level

¹ BDI-II is the Beck Depression Inventory II; SCL-90 is the Symptom Checklist-90; RSCQ is the Robson Self-Concept Questionnaire (short version); SCS is the Suicide Cognitions Scale; CISS is the Coping Inventory for Stressful Situations.
² "Condition" means baseline differences between CBT and TAU

assessment, significantly less people had been hospitalized in CBT (n=1) compared to TAU (n=7) [$\chi^2(1, n = 73) = 6.488, p = .011$].

Table 6. *MLA Effects for Time, Condition and Time X Condition and Cohen's d effect sizes for differences on outcome measures between CBT and TAU in the intent-to-treat group/ LOCF method (n=90)*

Variables ¹	Time	Condition ²	Time X Condition	Cohen's d	Cohen's d	Cohen's d
	B(SE)	B(SE)	B(SE)	3 months (post-treatment) n=48/42	6 months (follow-up) n=48/42	9 months (follow-up) n=48/42
DSH	-.610(.163)*	2.225(2.069)	-.637(.224)*	.08	.15	.49
Depression (BDI-II)	-.438(.218)*	-3.996(2.809)	-1.434(.299)*	.56	.77	1.19
Anxiety (SCL-90)	-.033(.152)	.865(1.993)	-.945(.209)*	.38	.47	.77
Suicide Cognitions total (SCS)	-.678(.267)*	-6.077(3.633)	-1.373(.367)*	.61	.68	.98
Perceived burdensomeness (SCS)	-.095(.034)*	-.470(.462)	-.156(.047)*	.48	.56	.82
Helplessness (SCS)	-.110(.084)	-1.906(1.109)	-.403(.116)*	.64	.67	1.00
Poor distress tolerance (SCS)	-.247(.093)*	-1.643(1.233)	-.487(.127)*	.55	.61	.89
Unlovability (SCS)	-.226(.087)*	-2.049(1.168)	-.328(.120)*	.56	.64	.89
Self-esteem (RSCQ)	.106(.058)*	.742(.814)	.298(.079)*	.33	.48	.77
Problem-solving (CISS)	-.144(.180)	.917(2.412)	.996(.247)*	.38	.50	.77

* indicates significance at .05 level

¹ BDI-II is the Beck Depression Inventory II; SCL-90 is the Symptom Checklist-90; RSCQ is the Robson Self-Concept Questionnaire (short version); SCS is the Suicide Cognitions Scale; CISS is the Coping Inventory for Stressful Situations.

² "Condition" means baseline differences between CBT and TAU

Discussion

This short cognitive-behavioural intervention was designed to supplement usual care following an episode of DSH. Our main study hypothesis, that CBT in addition to TAU would be more effective in reducing repetition of DSH than TAU alone, was supported. Furthermore, those who received CBT in addition to TAU were shown to have significantly greater reductions in depression, anxiety and suicidal cognitions, and significantly

greater improvements in self-esteem and problem solving ability. It is reasonable to assume that these positive findings are attributable to the effect of the CBT, given the random assignment as well as the absence of between group differences with respect to demographics, the number of episode of DSH, history of DSH, psychopathology and use of health care services.

While this study confirms prior studies showing that DSH can be effectively treated by CBT (Giesen-Bloo et al., 2006; Linehan et al., 2006), the findings are among the first to suggest that these changes can occur with a brief intervention. Furthermore, this study's findings that time-limited CBT decreases DSH contrasts with the results reported by Tyrer et al. (2003). The difference in outcome could be attributed to the fact that all subjects who began CBT completed all sessions, a fact that probably contributed to its efficacy. The positive treatment effect on DSH is important given the high suicide risk following DSH (Zahl & Hawton, 2004). The suicidal process (Van Heeringen, 2001) appears to have been at least partially deflected by the CBT intervention. It is especially important that these results are found for people with recurrent and chronic DSH, with high risk of repetition, and high levels of psychiatric co-morbidity.

The theoretical model underlying the cognitive-behavioural intervention suggested that vulnerability to DSH was related to underlying suicidal cognitions and behavioural skills deficits (Slee et al., 2007). From this perspective, reduction in repetition of DSH following CBT might be seen as a consequence of the therapy reducing specific suicidal thoughts and problem solving deficits and increasing self-esteem. As expected, over the course of treatment, there were marked changes in suicidal cognitions as well as in self-esteem. The significant decrease in suicidal cognitions is especially important, since these are considered to be the main triggers of DSH, especially for individuals with recurrent and chronic DSH (Rudd et al., 2001). Given the central role of suicidal cognitions in repetition of DSH, the CBT aimed to increase the patient's hope by systematically targeting cognitions of perceived burdensomeness, helplessness, poor distress tolerance and unlovability. This occurred as the therapist, while validating the patient's emotions, modelled hopefulness and the ability to improve the current situation through the identification and modification of unhelpful thoughts as well through the use of effective problem solving skills.

Helping patients with their current problems was another important element of treatment, because previous research had shown that DSH patients display poor problem solving ability, which seems to be independent of mood (McAuliffe et al., 2006) and relatively stable unless intervened upon (Raj, Kumaraiah, & Bhide, 2001). At the start of therapy, patients commonly reported feeling overwhelmed by the problems they were facing, believing they were lacking effective problem solving strategies. By identifying effective strategies they already used, the idea that control was already part of their repertoire was introduced. In addition, patients were encouraged to develop and use

new strategies (Nezu, Nezu, & Perri, 1989). As expected, patient's problem solving skills significantly improved during treatment.

It is remarkable that effects on secondary measures -particularly depression, suicidal cognitions and problem solving- were stronger than on the target variable "DSH" (the number of episodes of DSH in the past 3 months). Moreover, changes in these factors seems to precede changes in DSH. This suggests that the CBT primarily targeted depression, suicidal cognitions and problem solving and that the specific DSH effect (which was only apparent at 9-month assessment) was a secondary effect. This would be consistent with the assumption that repetition of DSH could be reduced by revising its maintenance factors (Slee et al., 2007). Given the emphasis in cognitive-behavioural therapy on challenging suicidal thinking and increasing problem solving ability, either of these might be the mechanisms of change.

The trajectory for the average patient in the CBT group showed a relatively rapid reduction on many outcome measures early in therapy and this reduction continued as therapy progressed and during the follow-up period. However, this rapid reduction is also found in the TAU group, as indicated by the strong effect of time in the MLA. This effect might be explained by the fact that people were in crisis when they entered the study; at that time, their risk of DSH was elevated, their mood was particularly low, suicidal cognitions were persistent, and they had great difficulty solving the problems they were facing. It has been argued that crises are by themselves time-limited, even in those exhibiting recurrent and chronic DSH (Rudd et al., 2001). However, the magnitude of the interaction effects in the MLA clearly show the unique additional effect of CBT. Furthermore, cognitions of helplessness and problem solving ability did not seem to change significantly over time in the TAU condition. Therefore, it seems that CBT emphasises these important risk factors and possible mediators of treatment effect. Targeting both cognitions of helplessness and problem solving difficulties might have made the intervention especially effective.

Despite these generally positive findings, several limitations of this study deserve comment. A primary limitation is that the instrument used in the present study to assess the number of episodes of DSH during the last three months does not have well established psychometric properties. Validated instruments that cover the number of episodes of DSH as well as other aspects of DSH (e.g. circumstances of the act, motives, intent, consequences) were not available at the start of the project.

A second limitation is the absence of an extended follow-up period. A longer follow-up period could clarify whether the positive treatment effects persist or even further develop over time. A follow-up period of 12 months would be advisable, because the risk of repetition of DSH (and completed suicide) is at its greatest during the first 12 months following an episode of DSH (Harriss & Hawton, 2005).

A third limitation is the way in which usual treatment was specified. We recorded three

forms of such treatment: “psychotropic medication”, “psychotherapy” and “psychiatric hospitalisations”. We can conclude that both conditions received a comparable level of care within these *general* categories of treatment. However, we did not record *specific* types of psychotherapy or psychotropic medication in the TAU condition. Therefore, it is unclear if the conditions were equivalent in this respect. Future studies should record specific types of usual treatment received by people in the experimental and comparison condition. Furthermore, the effect of CBT was only demonstrated in relation to TAU. Therefore, it is unclear whether the treatment effects are attributable to specific ingredients of the CBT or to the total package of the CBT in addition to TAU. Moreover, since people in the TAU group did not always receive psychotherapy, it is conceivable that the treatment effects in the CBT group were non-specific. In addition, 52% of the patients in CBT continued with psychotherapy or started with psychotherapy after the DSH intervention had ended. Future research is necessary to identify variables that mediate treatment effects (e.g. specific cognitions) and to detect the active ingredients of the CBT (e.g. identifying and modifying suicidal cognitions) (Kraemer, Wilson, Fairburn, & Agras, 2002).

A fourth limitation is the low recruitment rate (45%) and the relatively high rate of withdrawal from the CBT condition (17%), in which 8 patients left prior to treatment. However, session attendance of those who began the CBT was high. Furthermore, other studies also report that adherence to treatment is a well known problem among DSH patients, because of the severity of their psychological distress and the wide range of problems they face (e.g. social, financial, housing) (Berk, Henriques, Warman, Brown, & Beck, 2004). Importantly, the recruitment and withdrawal rates in this study did not exceed rates reported in similar studies.

A fifth limitation concerns treatment integrity in the CBT condition. Treatment integrity could have been more systematically assessed by rating audio- or videotapes of the treatment sessions. Furthermore, the assessments were not carried out masked to treatment group, which might have influenced outcome.

A sixth limitation is the way study withdrawals were handled. MLA uses all available data, but assumes that withdrawals occur at random, which is questionable in this population. As the assumption of randomness is unlikely, we also executed and reported the results with missing data estimated with the LOCF method (n=90). Both that analysis (n=90) and the analysis without the 8 withdrawals (n=82) led to a significant effect of Time X Condition. A significant effect of CBT for DSH was also observed in the “completers” sample (n=73). The true effect of the CBT is probably somewhere between the conservative LOCF method (n=90) and the more optimistic analysis without the 8 withdrawals (n=82). Remarkably, the LOCF method showed the strongest effect of CBT for DSH, which is contrary to our expectations.

A further limitation is that the presence of personality disorders was not assessed

with a structured clinical interview. The presence of borderline personality disorder or a range of personality disorders is likely to have an impact on treatment outcome. A previous study showed that personality disturbance has an impact on repetition of DSH, patients with borderline personality disorder being most likely to repeat episodes quickly (Tyrer et al., 2004). Furthermore, with the absence of data on personality disorders, it remains unclear whether the study population has similar Axis II diagnoses as the patients described in the studies of Tyrer et al. (2003) and Linehan et al. (2006). However, patients in the present study strongly endorsed maladaptive beliefs associated with personality disorders, especially borderline and avoidant beliefs (Slee, Spinhoven, Garnefski, & Arensman, 2008), to a greater extent than patients with borderline personality disorder (Arntz, Dietzel, & Dreesen, 1999), which can be seen as an indication for the presence of personality disturbance. The high rate of repetition of DSH found in this study seems to confirm this. A last limitation is that this study primarily involved young females with Dutch nationality. This absence of diversity limits the generalisability of findings.

In sum, our findings extend the evidence that CBT is effective in patients with chronic and recurrent DSH (Brown et al., 2005; Linehan et al., 2006). The results of the study are strengthened by the consistency of the results across several outcomes. Adding this short cognitive-behavioural intervention to usual care may provide us with an important tool to prevent repetition of DSH in people who are at risk. It might, for instance, be the first intervention in a stepped-care program, in which DSH is addressed first, followed by a treatment focusing on underlying personality characteristics, such as Schema Focused Therapy (Young, 1994) or Mentalization Based Treatment (Bateman & Fonagy, 2004). Replication of these findings using a longer follow-up period and more insight into underlying mechanisms of change is necessary.

¹ In all models Time was included as a variable with values 0, 3, 6 and 9; Condition, Medication Use, Psychotherapy and Suicidal Acts were all included as dummy variables (condition: 0= TAU and 1=CBT; medication use: 0= no medication and 1= medication; psychotherapy: 0= no psychotherapy and 1=psychotherapy; 0=no suicidal acts and 1=suicidal acts).

² In MLA the most commonly used estimation method is maximum likelihood. For this method it is necessary to assume normality for the dependent variable. The distribution of DSH does not satisfy the normality assumption. However, all conclusions are based on the interpretation of fixed effects. Simulation results (Hox, 2002; Maas & Hox, 2004) show that with the sample size in this study estimates of fixed effects and their standard errors are not seriously affected by non-normality of the residuals. Moreover, a comparison between the maximum likelihood standard errors and the so called “robust standard errors”, used as a tool to assess model misspecifications, showed that results for DSH can be considered reliable and can be interpreted correctly.

Outcomes of a Randomized Controlled Trial of a Cognitive Behavioural Intervention for Deliberate Self-Harm Patients