

Psychosocial and Pharmacological Treatment of Patients Following Deliberate Self-Harm: The Methodological Issues Involved in Evaluating Effectiveness

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Development of effective treatments for patients following deliberate self-harm (self-poisoning or self-injury) is a very important element in suicide prevention. The randomized controlled trial (RCT) is the mainstay of evaluation of treatments. In a systematic review of the literature, the effectiveness of treatments based on RCTs was examined and the quality of the RCTs was assessed. Twenty trials were identified, and where possible, these were grouped on the basis of similarities among the types of treatment. In this paper, we examine the methodological aspects of the trials and consider what may be learned that will assist in the design of future studies in this field. The methodological quality of the trials was reasonable, but most trials included too few participants to detect clinically important differences in rates of repeated self-harm. In planning future trials, the following major issues should be addressed: investigators should perform power

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calculations to determine the number of subjects necessary to detect clinically important effects, provide information on method of randomization and interventions, use standard measures of outcome, and focus on homogeneous subgroups of patients. Improving the methodology of future studies in this field will be essential if sound evidence is to be obtained which can inform effective service provision for deliberate self-harm patients.

During the past decade the issue of treatment and prevention of deliberate self-harm (i.e., attempted suicide) has received increased attention among clinicians, researchers, and policy makers. Although several treatment and prevention programs have been developed and evaluated, there is a lack of firmly established approaches substantiated by evidence from randomized controlled trials (RCTs). Several descriptive reviews have been performed concerning treatment studies of deliberate self-harm, but most of them have not used a systematic procedure to search the literature (Dew, Bromet, Bent, & Greenhouse, 1987; Goldney & Burvill, 1980; Hawton, 1997; Hirsch, Walsh, & Draper, 1982; Linehan, 1998; Van der Sande, Buskens, Allart, Van der Graaf, & Van Engeland, 1997). Therefore, it is unlikely that they have covered all available reports. Also, differences between studies with regard to research design and methodology were not taken into account, except by Linehan (1998). Therefore, it seemed important to assimilate all the existing knowledge about the results of treatments in such a way that the overall effectiveness of different approaches could be established (Gunnell & Frankel, 1994).

We have conducted a systematic review of the available literature concerning treatment studies of patients following deliberate self-harm according to criteria developed by the Cochrane Collaboration (Chalmers & Altman, 1995). The Cochrane Collaboration is an international organization, which was founded with the purpose of establishing the best evidence for treatments across all domains of health care (Chalmers, Dickersin, & Chalmers, 1992; "Cochrane's Legacy;" 1992). One of the aims of the Cochrane Collaboration is to identify all RCTs,

published and unpublished, which may not have been indexed as such on electronic, bibliographic databases. This is achieved through hand searches of relevant biomedical journals. The results of our systematic review, including the meta-analyses with regard to repetition of deliberate self-harm, have been reported elsewhere, both in a journal form (Hawton et al., 1998) and electronically in the Cochrane Library (Hawton et al., 1999). In the present paper we review the procedure used, the general characteristics of the studies we have identified and, in particular, the methodological issues highlighted by this research. We conclude by providing guidance for future research in this field.

METHOD

Search Strategy

A literature search was carried out using the electronic databases Medline, PsycLit, Embase, and the Cochrane Controlled Trials Register (see also Hawton et al., 1998). In the Medline search, a wide range of keywords was used to indicate deliberate self-harm in combination with a standard search strategy, developed for the Medline database by the Cochrane Collaboration, to identify RCTs (see Appendix). The term *self-mutilation* was included in the search criteria because of the considerable overlap between self-cutters and the broader group of deliberate self-harm patients. A shorter version of this search strategy was used for the other databases.

In addition, ten journals in the fields of psychiatry and psychology which had not been previously hand-searched for the Cochrane Collaboration database were carefully

searched. These included all English language specialist journals in the field of suicidology. We checked the reference lists of all the papers we identified. We also had access to the knowledge of the reviewers, all of whom are experts or have a special interest in the field. The Cochrane Collaboration strategy is that all trials of *any* disorder identified through this overall procedure (596 trials in our search) are notified to the Cochrane Controlled Trials Register.

We included papers in the review if they met the following criteria:

- All the study participants had to have been engaged in an act of deliberate self-harm shortly before entry into the trial;
- The study compared a specific type of intervention (psychosocial or pharmacological) for the treatment of deliberate self-harm with another type of treatment, including standard or routine aftercare, a different specific therapy, or, in the case of drug trials, placebo;
- The study participants were randomized to treatment and control groups; and
- Repetition of deliberate self-harm was an outcome measure.

Quality Assessment

For each trial, reviewers from our group independently performed quality assessments of the papers. A 7-item instrument and three additional questions to assess the likelihood of bias in the reports were used. The methodological quality of the papers was rated according to the standard Cochrane criteria for assessment of the quality of randomization (Clarke & Oxman, 1999), plus additional criteria: number of withdrawals after randomization, blinding with regard to treatment group of those who assess patient outcome, reporting of compliance with treatment, use of test statistics in order to verify significance or major end points, and quoting

of confidence limits (Moher, Jadad, & Tugwell, 1995, 1996). Pharmacological trials were also screened for the quality of blinding of patients to treatment conditions.

RESULTS

Number of Reports and Trials

A total of 31 reports concerning treatment of deliberate self-harm were identified, 25 of which described RCTs and 6 nonrandomized controlled clinical trials. In accordance with common Cochrane Collaboration practice, our systematic review used only data from RCTs, and the rest of the paper is therefore concerned only with results of the RCTs. The number of trials included was 20, all of which were presented in English language reports. One further RCT, by Patsiokas and Clum (1985), was excluded as we were unable to obtain data on repeated episodes of deliberate self-harm during follow-up. Four of the included trials were reported in more than one publication. The included trials are summarized in Table 1. Overall, considerable agreement was found in terms of the number of trials identified by searching the different databases.

General Aspects of the Trials

The duration of treatments in the trials varied from 10 days to 12 months, with an average of 4 months. The time to follow-up assessment varied from 3 months to 24 months, with an average of 1 year. The acquisition of informed consent from the patients was mentioned in eight reports. In the majority of the trials the experimental and control or placebo groups comprised relatively small numbers of patients. However, power calculations, detailing the number of participants required to minimize the chance of missing clinically relevant effects, were included in only two reports (Allard, Marshall, & Planet, 1992; van Heeringen et al.,

TABLE 1
Randomized Controlled Trials (RCTs) Concerning Treatment of Deliberate Self-Harm Patients

Author(s)	Publication year	Place	Duration of follow-up	Number of participants and % repeaters				Type of intervention (experimental vs. control group)
				Exp. N	Rep. %	Con. N	Rep. %	
1. Chowdhury et al.	1973	Edinburgh, Scotland	6 months	71	23.9	84	22.6	Special aftercare (regular outpatient appointments, home visits to patients that missed appointments, emergency 24-hour telephone access) vs. standard aftercare
2. Welu	1977	Texas, USA	4 months	62	4.8	57	15.8	Special outreach program (home visits, weekly/bi-weekly contact with therapist) vs. standard aftercare
3. Gibbons et al.	1978	Southampton, UK	12 months	200	13.5	200	14.5	Task-centered social work service (crisis orientated, time limited task-centered social work at home) vs. standard aftercare
4. Montgomery et al.	1979	London, UK	6 months	14	21.4	16	75.0	Flupenthixol (20 mg. intramuscular flupenthixol decanoate for 6 months) vs. placebo for 6 months
5. Liberman & Eckman	1981	Los Angeles, USA	24 months	12	16.7	12	25.0	Behavior therapy vs. insight-orientated therapy (inpatient)
6. Hawton et al.	1981	Oxford, UK	12 months	48	10.4	48	14.6	Domiciliary therapy (brief problem-orientated) vs. outpatient therapy
7. Hirsch et al.*	1982	London, UK	3 months	76	21.1	38	13.2	Antidepressants: either 30-60 mg mianserin for 6 weeks or 75-150 mg nomifensine for 6 weeks vs. placebo for 6 weeks
8. Montgomery et al.*	1983	London, UK	6 months	17	47.1	21	57.1	Mianserin (30 mg. For 6 months) vs. placebo for 6 months
9. Hawton et al.	1987	Oxford, UK	12 months	41	7.3	39	15.4	Outpatient problem-orientated therapy vs. GP care
10. Torhorst et al.	1987	Munich, Germany	12 months	64	17.6	69	5.5	Same therapist (continuity of care) vs. different therapist
11. Torhorst et al.	1988	Munich, Germany	12 months	40	22.5	40	22.5	Long-term therapy (one therapy session per month over a period of 12 months) vs. short-term therapy (12 weekly therapy sessions over a period of 3 months)
12. Salkovskis et al.	1990	Leeds, UK	12 months	12	25.0	8	50.0	Domiciliary cognitive-behavioral problem solving treatment vs. treatment as usual

13. Waterhouse & Platt	1990	York, UK	4 months	38	7.9	39	10.3	General hospital admission vs. discharge from hospital
14. Linehan et al.**	1991	Seattle, USA	12 months	19	26.3	20	60.0	Dialectical behavior therapy (individual and group work for 1 year, telephone access) vs. treatment as usual
15. Allard et al.	1992	Montréal, Canada	12 months	63	34.9	63	30.2	Intensive intervention (at least 1 home visit, therapy provided where needed) vs. treatment by another staff team in the same hospital
16. Morgan et al.	1993	Bristol, UK	12 months	101	5.0	111	10.8	Standard care plus green card (emergency card indicating that a doctor was available and how to contact them) vs. standard care
17. McLeavey et al.	1994	Cork, Ireland	12 months	19	10.5	20	25.0	Interpersonal problem-solving skills training vs. brief problem-solving therapy
18. Cotgrove et al.	1995	London, UK	12 months	47	6.4	58	12.1	Standard care plus green card (emergency card; green card acted as a passport to re-admission into a pediatric ward in the local hospital) vs. standard follow-up or treatment
19. Van Heeringen et al.	1995	Gent, Belgium	12 months	196	10.7	195	17.4	Special care (home visits to patients who did not keep outpatient appointments) vs. standard aftercare
20. Van der Sande et al.	1997	Utrecht, The Netherlands	12 months	140	17.1	134	14.9	Intensive inpatient and community intervention (brief psychiatric unit admission, 24-hour emergency access to unit) vs. standard aftercare
Total				1,280		1,272		

*RCT reported in 2 papers; ** RCT reported in 3 papers.

1995), and these were two of the three largest trials identified.

Types of Interventions

The trials were characterized by a diversity of interventions, which prevents an overall comparison. Therefore, trials were grouped on the basis of the similarity of types of interventions evaluated by consensus of our research team. The resultant categories (n = number of trials) are: (1) Intensive intervention plus outreach versus standard aftercare (n = 6); (2) problem-solving therapy versus standard aftercare (n = 4); (3) emergency care versus standard aftercare (n = 2); and (4) antidepressant medication versus placebo (n = 2). The remainder of the studies reported diverse interventions, none of which could be sensibly grouped (see Hawton et al., 1998, for further details).

Where the comparison treatment was "standard aftercare" or "treatment as usual," the authors did not usually provide details of what standard treatment consisted of in the trial locality. Standard aftercare may vary from country to country, and between clinical services within a country, which can affect the relative efficacy observed for experimental treatments in different settings.

In several trials of psychosocial interventions, there was no indication that the experimental treatment had been described in a manual that would enable other researchers and clinicians to replicate it. Thus, rarely was there evidence of evaluation of process measures, such as whether problem-solving ability improves in those experiencing problem-solving treatment compared to the controls.

Types of Outcome Measures

There was also lack of consistency among the trials in the types of outcome measures used. Where similar outcome measures were assessed they were often recorded in different ways or using different instruments. Thus, while repetition of self-harm was the outcome that defined inclusion in the review, information concerning repeated acts

of self-harm was obtained in different ways; for example, from hospital records, from general practitioners, or patients' self-report. In the problem-solving trials alone (n = 4), 15 different outcomes were measured. The occurrence of suicides during the follow-up period (even if there were none) was reported in only six trials.

Methodological Quality of the Trials

The methodological quality for both psychosocial and pharmacological trials was reasonable, with more than half of the trials using adequate concealment procedures (method of randomization: adequate n = 13, inadequate n = 4, unclear method n = 3, see Hawton et al., 1998, for further details). However, the adequacy of concealment in some studies was only verified after personal communication with the authors.

In only three trials were there no withdrawals from the study. Seven trials listed the number of participants who withdrew from the trial and provided reasons for the withdrawals.

Seven of the 20 trials reported that the observers in the trial were blind to treatment condition, but only two of these had fully reported the techniques of blinding used. In the remaining 13 trials it was unclear whether the observers were blind to treatment condition. Of the three pharmacological trials, one fully reported the techniques used to blind patients to the type of medication received, while the other two merely stated that the trial was "double-blind."

Power Analysis

Altogether, in the 20 trials considered, a total of 2,741 patients were randomized. Outcome data regarding repetition of deliberate self-harm during follow-up were available for 2,552 patients (n = 1,280 in the experimental groups, n = 1,272 in the control groups) (see Table 1).

Most of the trials included too few participants to have the statistical power to detect clinically meaningful differences in the

rates of repeated deliberate self-harm between the experimental and control treatments. The sample size is a function of both the expected rate of repetition (repetition rate in the control group), and the size of the difference in repetition rate and decisions concerning acceptable Type I and Type II error rates (Pocock, 1983). As a guide for further research in this area we have produced sample size estimates for the number of patients needed in order to detect statistically significant differences in rates of repetition of deliberate self-harm (Table 2). These were calculated using STATA (StataCorp, 1999). The table illustrates that to detect small treatment effects, relatively large samples are required. It is clear that in most trials in our review there was a considerable discrepancy between the actual number of patients included and the numbers needed.

DISCUSSION

In spite of the massive worldwide problem of suicidal behavior, especially in young people, our systematic approach to identify RCTs of specific types of treatment following deliberate self-harm revealed that relatively few trials have been conducted over the past 30 years. This is in marked contrast

to the situation for many disorders in psychiatry and psychology; for example, depression. More trials are surely required given the extent of deliberate self-harm, the frequency of repetition, and its strong link with suicide.

Methodological Issues

Our meta-analysis of the published trials has highlighted several important methodological issues. The grouping of the trials into several categories and the fact that some trials could not be grouped indicates the range of interventions that have been attempted in this population.

Apart from the diversity of interventions, the wide range of outcome measures makes comparisons among trials in terms of measures other than repetition difficult. Even if similar outcome measures were used, sometimes these were assessed in different ways. An additional problem with several outcome measures was that data (e.g., standard deviations associated with means) were often missing, preventing synthesis of the results in a meta-analysis. This is one reason why we have so far restricted our analysis to repetition of deliberate self-harm.

Quality of Studies

Differences in methodological quality of studies, in particular the quality of the ran-

TABLE 2
Examples of Power Calculations

Control group % repetition	Experimental group % repetition	% difference	Number of patients needed in each trial arm to detect such a relation
20	18	10	6139
	16	20	1497
	14	30	647
	10	50	219
40	36	10	2361
	32	20	589
	28	30	260
	20	50	91

Note. Based on predicted rates of repetition of deliberate self-harm of 20% and 40% in the control group and variable rates of repetition in the experimental group, with significance set at 5% and power set at 80%.

domization procedure, may affect the outcome of a meta-analysis (Schulz, Chalmers, Hayes, & Altman, 1995) and should be taken into account when comparing the trials. While in general the methodological quality of trials in this field in terms of randomization of participants was acceptable, for some trials it was not possible to determine the methodological quality on the basis of information obtained from the reports. Contact with authors to clarify the procedure used for concealment often resulted in higher quality scores. Researchers conducting future trials are strongly encouraged to report details of the randomization procedure they use. The recently produced CONSORT statement (Altman, 1996) is a comprehensive set of guidelines for the reporting of RCTs in biomedical journals. If these guidelines are followed, this should result in improvements in the methodology and reporting of trials.

Jadad et al., (1996) demonstrated that the methodological quality of reports is related to whether or not participants who withdraw from trials are described. They found that whether or not withdrawals are described adequately is an important aspect on the basis of which trials of good methodological quality can be discriminated from those of poor methodological quality. Only half of the trials identified in our review included either adequate description of the withdrawals or stated that there were no withdrawals. In the future, authors reporting trials should provide details of the number of withdrawals, including reasons for withdrawal.

An additional source of bias that should be minimized is the allegiance effect, in that those who design a trial are likely to invest more in the design of the experimental treatment than the control condition. Furthermore, in planning and designing treatments to be examined in trials, the control treatment condition should be equally credible to patients compared to the experimental condition.

Blinding of Assessors

In the majority of studies identified it was unclear whether assessors were blind to

which treatment conditions patients were in. Trials that are not double-blind are more likely to yield positive results for experimental treatments (Colditz, Miller, & Mosteller, 1989), as well as yield larger effect estimates (Schulz et al., 1995). All three of the drug trials were reported as double-blind—yet only one trial described in full the procedures used for blinding. Blinding of assessors can be difficult in psychosocial treatments. Use of self-report and assessor-rated outcome measures can help to provide unbiased responses as well as determine whether assessor bias is present. Blinding of patients to treatment condition is of course not feasible in psychosocial treatment studies. In future trials the nature of blinding and the procedures used should be fully described.

Size of Trials

The most striking finding was that most trials included too few participants to detect clinically relevant differences in treatment effects. This is clearly an important factor to take into account in future trials. Indeed, it has even been argued that because of the constraints of these statistical limitations, randomized controlled trials may not be feasible in addressing this important clinical issue and alternative research methodologies should be utilized (Goldney, 1998). However, it must be emphasized that the RCT is the most powerful method of demonstrating the efficacy of any specific treatment, and therefore it is essential that larger trials be carried out with sufficient numbers of patients to allow statistical substantiation of clinically meaningful differences. This will probably necessitate multicenter trials. If trials are underpowered it means that clinically significant effects of treatments may not be detected and effective treatments may be erroneously abandoned, which can only be to the detriment of patients.

In trials focusing on repetition of suicidal behaviors as an outcome, the power of the studies and, therefore, the number of patients required will be influenced by the degree of risk of repetition. Such trials might

be focused on those patients known to be at particularly high risk of repeating (e.g., those with multiple previous episodes), although this will exclude a large proportion of deliberate self-harm patients, including, paradoxically, many (if not the majority) who actually repeat (Kapur et al., 1998).

Patient Samples

Not only were most of the study populations small, they were also often not representative of the total population of patients (e.g., only those admitted to hospital). There are no indications in most reports of how many patients were approached but refused to be included (e.g., because of awareness of the randomization procedure). Low recruitment rates influence the generalizability of findings.

The study populations included in the trials were often heterogeneous in terms of sex, age, method of self-harm, and psychological or psychiatric problems. In order to improve comparability across studies, it is important to include either well-defined homogeneous study populations or ensure that the study population is adequately described in terms of diagnoses, problems, nature of the deliberate self-harm episode, previous episodes, and so on. Treatment studies in this field might also be focused on meaningful subgroups among deliberate self-harm patients; for example, patients with particularly high risk of repetition, patients who cut themselves, patients with suicidal behavior in the context of substance abuse or other specific psychiatric diagnoses, and patients with comorbid psychiatric and personality disorders.

RECOMMENDATIONS FOR FUTURE TRIALS

On the basis of our systematic review we would like to make the following recommendations for future trials to evaluate the efficacy of specific treatments for patients following deliberate self-harm.

1. Adequate sample sizes are required. Investigators must perform power calculations to determine the number of participants necessary for adequate statistical evaluation of outcome. Multicenter trials may be needed to achieve adequate power.
2. Further trials are indicated for specific subgroups of deliberate self-harm patients; such as those who frequently repeat deliberate self-harm, patients with substance abuse, and adolescents. Subgroups should be defined in advance and not based on post hoc examination of the data.
3. Authors should provide more detailed information on the interventions that are evaluated, particularly for control interventions, such as "treatment as usual" or "routine aftercare." Experimental psychosocial treatments should be described clearly (preferably in a manual) in order to enable other investigators and clinicians to replicate the treatment. Researchers investigating psychosocial treatments should endeavor to evaluate whether the intervention results in changes in the psychological or social mechanisms which are the targets of treatment (e.g., improved problem solving, regulating emotions, changes in interpersonal skills).
4. Investigators should use certain standard measures of outcome and ensure that these data are reported adequately. Repetition (both nonfatal and fatal) is clearly a crucial measure. Other important outcomes are depression, hopelessness, suicidal ideation, hospitalization, and problem solving. With regard to data on repetition, authors should indicate how these data were obtained; for example, from hospital records, GP records, or self-report from patients. Standardization of outcome measures might be achieved through consensus agreement within and be-

tween international and national associations of suicide research.

5. Authors should provide more information regarding precise method of randomization, blinding procedures, and participants who withdraw from trials.
6. Information should be provided on the overall patient population from which the sample is drawn, and the included patients compared with excluded patients on sociodemographic and diagnostic characteristics.
7. The outcome data should be analyzed on the basis of an intention-to-treat analysis, so that all objects are included, with explicit statement

about how all missing values are dealt with.

CONCLUSIONS

It is extremely important that effective treatments for deliberate self-harm patients that can be widely utilized in clinical practice be identified. Systematic review of the published treatment studies in this area has shown that currently this is not the case. We have utilized the knowledge gained from reviewing this field to identify guidelines for the design of future treatment studies. If these guidelines are followed, it is likely that there will be substantial advances in our knowledge of how to treat patients most effectively.

APPENDIX

Search Strategy Used to Identify RCTS Concerning the Treatment of Patients Following Deliberate Self-Harm:

- #1 (ATTEMPT*) near (SUICID*)
- #2 (SUICID*) near (BEHAV*)
- #3 (SELF) near (HARM*)
- #4 (SELF) near (POIS*)
- #5 (SELF) near (INJUR*)
- #6 (SELF) near (MUTILAT*)
- #7 (SELF) near (CUTT*)
- #8 (WRIST) near (CUTT*)
- #9 #1 #2 or #3 or #4 or #5 or #6 or #7 or #8
- #10 RANDOMIZED-CONTROLLED-TRIAL in PT
- #11 CONTROLLED-CLINICAL-TRIAL in PT
- #12 RANDOMIZED-CONTROLLED-TRIALS
- #13 RANDOM-ALLOCATION
- #14 DOUBLE-BLIND-METHOD
- #15 SINGLE-BLIND-METHOD
- #16 #10 or #11 or #12 or #13 or #14 or #15

- #17 TG = ANIMAL not (TG = HUMAN and TG = ANIMAL)
- #18 #16 not #17
- #19 CLINICAL-TRIAL in PT
- #20 explode CLINICAL-TRIALS
- #21 (CLIN* near TRIAL*) in TI
- #22 (CLIN* near TRIAL*) in AB
- #23 (SINGL* or DOUBL* or TREBL* or TRIPL*) near (BLIND* or MASK*)
- #24 (#23 in TI) or (#23 in AB)
- #25 PLACEBOS
- #26 PLACEBO* in TI
- #27 PLACEBO* in AB
- #28 RANDOM in TI
- #29 RANDOM in AB
- #30 RESEARCH-DESIGN
- #31 #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30
- #32 TG = ANIMAL) not (TG = HUMAN and TG = ANIMAL)
- #33 #31 not #32
- #34 #33 not #18
- #35 TG = COMPARATIVE-STUDY
- #36 explode EVALUATION-STUDIES

#37 FOLLOW-UP-STUDIES
 #38 PROSPECTIVE-STUDIES
 #39 CONTROL* or PROSPECTIV*
 or VOLUNTEER*
 #40 (#39 in TI) or (#39 in AB)
 #41 #35 or #36 or #37 or #38 or #39

#42 TG = ANIMAL not (TG =
 HUMAN and TG = ANIMAL
 #43 #41 not #42
 #44 #43 not (#18 or #34)
 #45 #18 or #34 or #44
 #46 #9 and #45

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