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Psychosocial interventions for people who self-harm:

Methodological issues involved in trials to evaluate effectiveness

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ABSTRACT

Objective: We have assessed the methodological quality of randomized controlled trials (RCTs) of interventions to prevent self-harm repetition and suicide.

Methods: Trials were identified in two systematic reviews of RCTs of psychosocial treatments following a recent (within six months) episode of self-harm indexed in any of five electronic databases (CCDANCTR-Studies and References, CENTRAL, Medline, Embase, and PsycINFO) between 1 January, 1998 and 29 April, 2015.

Results: A total of 66 trials were included, 55 in adults and 11 in children and adolescents. While evidence for efficacy of some approaches has grown, there were few trials from low-to-middle income countries, little information on interventions for males, information on the control condition was often limited, data on suicides were often not reported, and, while trials have increased in size in recent years, most have included too few participants to detect clinically significant results.

Conclusions: There are major limitations in many trials of interventions for individuals who self-harm. Improved methodology, especially with regard to study size, provision of details of control therapy, and evaluation of key outcomes, would enhance the evidence base for clinicians and service users.

Keywords: self-harm; attempted suicide; suicide; methodology; outcome.

BACKGROUND

Self-harm [defined as intentional self-injury or self-poisoning irrespective of type of motivation or degree of suicidal intent; (Hawton, Zahl, & Weatherall, 2003)] represents a significant public health burden worldwide (Haagsma et al., 2016). The term self-harm as used in the United Kingdom (UK) and several other countries includes behavior that in the United States of America (USA) would be categorized as non-suicidal self-injury (NSSI) and suicidal behavior disorder (attempted suicide), but also non-suicidal (as well as suicidal) self-poisoning. Self-harm, and particularly self-poisoning, is an extremely common reason for presentation to healthcare facilities. In the UK alone, for example, there are now more than 200,000 hospital presentations for self-harm each year (Hawton et al., 2007). Self-harm is associated with numerous adverse outcomes. For example, between 16.3% (Carroll, Metcalfe, & Gunnell, 2014) and 30% (Perry et al., 2012) of those who present to hospital for self-harm will re-present to hospital following a repeat episode within one year. There will also be further episodes of self-harm which do not result in hospital representation (Guthrie et al., 2001). The risk of suicide is also elevated; over a one year period following an episode of self-harm between 1.0% (Beckman et al., 2016) and 1.6% (Carroll et al., 2014) of those presenting to hospital will die by suicide.

Given the prevalence of self-harm, the frequency with which it is repeated, and its association with completed suicide it is important that effective treatment interventions are developed and rigorously evaluated for their effectiveness. This has led in recent decades to a proliferation of therapeutic interventions to reduce self-harm repetition and suicide. A Cochrane Collaboration systematic review and meta-analysis, published in 1998, for example, identified 19 randomized controlled trials (RCTs) of psychosocial interventions to reduce repetition of self-harm in adults, and only one for children and adolescents specifically (Hawton et al., 1998), whereas a

recent update of this review identified 66 RCTs of psychosocial interventions; 55 for adults and 11 for children and adolescents (Hawton et al., 2016b; Hawton, Witt, Taylor Salisbury, Arensman, Gunnell, Townsend, et al., 2015).

Emerging evidence from meta-analysis of these RCTs suggests cognitive-behavioral therapy (CBT) based psychotherapy shows promise in reducing the proportion of adults repeating self-harm and that dialectical behavior therapy may reduce frequency of repetition of self-harm in both adults and adolescents (Hawton et al., 2016a, 2016b). However, there remains limited evidence about the effectiveness of other psychosocial interventions for self-harm repetition (Hetrick, Robinson, Spittal, & Carter, 2016). This is partly because most RCTs are underpowered to detect clinically significant effects (Arensman et al., 2001).

We previously undertook a review of the methodological quality of randomized controlled trials of psychosocial and pharmacological interventions for the prevention of self-harm repetition, finding that, in general, most trials included too few participants to detect clinically important differences in rates of repeated self-harm (Arensman et al., 2001). We also found that information on the method of randomization, content of the intervention and control arms, and information on the representativeness of patients in these RCTs was typically lacking (Arensman et al., 2001). We therefore recommended that investigators should include power calculations to justify their sample size, that specific subgroups of patients, in particular those engaging in self-cutting or with alcohol and other drug use comorbidity, should be included to provide greater sample representativeness, and that authors should provide more details on the experimental intervention and control conditions (Arensman et al., 2001).

We have investigated the methodological quality of RCTs of psychosocial interventions for people who self-harm based on our recent update of the treatment literature on the effectiveness of psychosocial interventions for self-harm in adults and children and adolescents (Hawton et al., 2016a, 2016b). The aim of the current study was to provide updated guidance for investigators conducting trials in this area.

METHODS

Search strategy

We searched for randomized controlled trials (RCTs) of psychosocial treatments following a recent (within six months) episode of SH indexed in any of five electronic databases (CCDANCTR-Studies and References, CENTRAL, Medline, Embase, and PsycINFO) between 1 January, 1998 and 29 April, 2015 using the electronic search strategy outlined in Appendix 1. Further hand searches were made of the reference lists of 44 major review papers, ten English language specialist suicidology and more general psychiatric journal. We also contacted researchers active in the field to identify unpublished literature.

Inclusion Criteria

Trials were eligible for inclusion provided they met the following criteria: (1) used random allocation to assign participants to the intervention and control groups; (2) all participants had engaged in self-harm no more than six months prior to randomization; and (3) the trial evaluated the effectiveness of any psychosocial therapy relative to treatment as usual (TAU), enhanced usual care (EUC), treatment by expert, or other standard forms of psychotherapy. Non-English language trials were eligible for inclusion and were translated by native speakers.

Trials were screened independently for inclusion by KW and one of either TTS, EA, DG, PH, ET, or KvH. Disagreements were resolved following discussion with KH. Where insufficient information was recorded in the study report to determine eligibility, study authors were contacted to provide additional clarification.

Apprising methodological quality

Given the focus of this paper, we rated the quality of the included studies with regards to our previous recommendations for improving the quality of RCTs of interventions for self-harm (Arensman et al., 2001). Specifically, KW and one of TTS, EA, DG, PH, ET, and KvH rated each included trial with regards to: (1) how representative the sample was of people who present to clinical services following self-harm; (2) clear definition of the intervention, including use of clearly specified and manualized interventions; (3) clear definition of the treatment(s) received by participants allocated to the control condition; (4) use of standardized outcome measures both for the primary outcome measure as well as any secondary outcomes reported; (5) whether hypothesized mechanisms of change were investigated, and; (6) adequacy of the sample size and use of power calculations to justify the sample size.)

Risk of bias assessment

For each study, we also assessed risk of bias using the approach favored by the Cochrane Collaboration (Higgins, Deeks, & Altman, 2008). Specifically, this tool assesses bias according to seven domains, including: (7) adequacy of the random sequence generation; (8) allocation concealment; (9) blinding of participants, clinical personnel and outcome assessors; (10) incomplete data bias as well as the adequacy of information on the proportion of participants who withdrew from the trial together with reasons for withdrawing; (11) selective outcome reporting bias, and; (12) other biases including details on the use of intention-to-treat analyses

for all measured outcomes. Each study was rated as at high, unclear, or low risk of bias across each of these seven domains.

RESULTS

The systematic search outlined in Appendix 1 retrieved a total of 23,830 citations. An additional 10 trials ongoing at the time of the systematic search were identified through hand searching. This figure was reduced to 16,799 following de-duplication. A total of 16,538 were excluded following screening, whilst a further 245 were excluded after reviewing the full text, including seven trials were excluded from the present review as they evaluated the effectiveness of a pharmacological intervention (Hawton, Witt, Taylor Salisbury, Arensman, Gunnell, Hazell, et al., 2015).

A total of 66 independent RCTs were therefore included in the present article, comprising 55 trials of psychosocial interventions for self-harm in adults (aged 18 years of age and older) and 11 in children and adolescents (up to 18 years of age) (Figure 1).

Study characteristics

Full methodological details of these 66 trials are provided in Table 1. Briefly, the included trials comprised a total of 18,256 participants (17,117 in trials in adults and 1,139 in trials of children and adolescents). All participants had engaged in at least one episode of self-harm in the six months prior to randomization.

The largest number of trials had been conducted in the United Kingdom (UK; 23 trials; 34.9%), followed by the United States of America (USA; 13 trials; 19.7%). Fewer studies were conducted in New Zealand (5 trials; 7.6%), Australia (3 trials; 4.6), Canada (2 trials; 3.0%),

Denmark (2 trials; 3.0%), France (2 trials; 3.0%), Germany (2 trials; 3.0%), The Netherlands (2 trials; 3.0%), and the Republic of Ireland (2 trials; 3.0%). One trial was conducted in each of the following countries: Belgium, China, Finland, the Islamic Republic of Iran, Japan, Norway, Pakistan, Sri Lanka, and Sweden. One study was a multicenter study set in a number of different countries.

Study representativeness

Since the publication of our original commentary in 2001 (Arensman et al., 2001), an increasing number of trials have been conducted in low-to-middle income countries, including: Brazil, China, India, the Islamic Republic of Iran, Pakistan, and Sri Lanka. However, in line with previous research (Gholamrezaei, De Stefano, & Heath, 2015), we found that most trials to date, including more recent ones, have been conducted in high income Western countries; particularly the UK and USA.

Sample representativeness

In all trials at least one exclusion criterion was specified (Table 1). Age was the commonest reason for participant exclusion, reported in 55 (83.3%) trials, followed by intellectual disability and/or diagnosis of organic cognitive disorders (38 trials; 57.6%), residing outside of the study catchment area and/or homelessness (29 trials; 43.9%), and insufficient language ability (19 trials; 28.8%).

A number of trials also excluded potential participants on the basis of a diagnosis for any major mental illness (35 trials; 53.0%). Most commonly, this was for a diagnosis of psychosis and/or psychotic symptoms (35 trials; 53.0%), followed by bipolar disorder (12 trials; 18.2%). Potential participants with alcohol and other drug dependence and/or intoxication were also

excluded from a number of these trials (21 trials; 31.8%). In several trials participants were also excluded because they were currently receiving or had been referred for psychiatric treatment (24 trials; 36.7 %), including where treatment had been legally mandated (2 trials; 3.0%).

With regards to gender, males were specifically excluded from six trials whilst, in a seventh, although males were eligible for participation, no males were ultimately included (Table 1). Moreover, in the remaining 52 trials where information was provided on gender, in all but one over one-half of participants were female (range 48.5% to 94.1%; Table 1). We found no evidence of a significant increase in the proportion of male participants included in these trials by year of publication (β=-0.34, *se*=0.21, *p*=0.12; Appendix 2).

Types of intervention conditions

The trials included in this review were characterized by a diversity of interventions (Table 1). For adults, the most frequently evaluated intervention (18 trials; 32.7%) was cognitive-behavioral therapy (CBT). There were five trials of dialectical behavior therapy (DBT), four trials of case management, four trials of postcards, three trials of telephone contact, two each of 'green' (emergency) cards, emotion-regulation skills training, intensive outpatient follow-up, mixed multimodal interventions, and treatment adherence enhancement approaches. There was one trial each of a brief alcohol-related intervention, behavior therapy, brief information and support, general hospital admission, general practitioner letters, home-based problem-solving therapy, mentalization, mobile telephone-based psychotherapy, interpersonal problem-solving skills training, intensive inpatient treatment and aftercare and prolonged, long-term aftercare.

For children and adolescents, there were three trials evaluating the effectiveness of group-based psychotherapy, two trials of DBT adapted for adolescents (DBT-A), and one trial each of a CBT-based approach, 'green' (emergency) cards, home-based family therapy, mentalization, therapeutic assessment, and treatment adherence enhancement approaches (Table 1).

Types of control conditions

The experimental interventions were compared against a diversity of control conditions (Table 1). Most trials (52 trials; 78.9%) compared the intervention to treatment as usual (TAU). The remaining 14 trials compared the intervention to either a different form of active psychotherapy (10 trials; 15.1%), enhanced usual care (two trials; 3.0%), waitlist (one trial; 1.5%), or no treatment (one trial; 1.5%).

However, although in most trials (53 trials; 80.3%) some information was provided on the treatment(s) that were available to control participants, information was provided on the therapies actually received by these participants in only six trials (9.1%). Elsewhere we have shown previously that effects in favor of CBT-based psychotherapy vary by quality of TAU and TAU content (Witt et al., 2018). For this reason, data on TAU content and amount received should wherever possible be included in future trials in this area.

Outcomes related to suicidal thoughts and behavior

Data on the primary outcome measure, repetition of self-harm, were reported for all but one of the included trials (65 trials; 98.5%; Table 1). Most commonly, information about repetition of self-harm was obtained through self-report only (with or without the use of a standardized interview schedule) (27 trials; 41.5%), followed by hospital and/or medical records (18 trials; 27.7%). This information was less commonly obtained from collateral informant and/or

hospital and/or medical records supplemented by self-reported information (13 trials; 20.0%) and, in single trials, through collateral informant report only or using mixed methods, namely, self-reported information at the post-intervention assessment and hospital records at follow-up. No information was provided on how the primary outcome measure was ascertained in four (6.1%) trials.

Information on suicide deaths was recorded for the majority of trials (53 trials; 78.8%; Table 1); although we as reviewers often had to request these data from the study authors. In a few studies suicides were ascertained from official sources, including mortality data or Coroner's records (14 trials; 26.4%), collateral informant report only (five trials; 9.4%), or collateral informant report supplemented by data from official sources (four trials; 7.5%). In general, however, no information was provided on how suicides were ascertained (30 trials; 56.7%).

Data on suicidal ideation were reported in 27 trials (40.9%; Table 1). Most commonly this was assessed using the self-report Beck Scale for Suicidal Ideation [BSSI; (Beck, Kovacs, & Weissman, 1979); 15 trials; 55.6%], followed by the Suicidal Ideation Questionnaire [SIQ; (Reynolds, 1988); six trials; 22.2%], the Suicidal Behaviors Questionnaire [SBQ; (Linehan, 1981); two trials; 7.4%], the Suicidal Cognition Scale [SCS; (Rudd, Joiner, & Rajab, 2001); one trial; 3.7%], the Schotte Scale for Suicidal Ideators [SSI; (Schotte & Clum, 1982); one trial; 3.7%], from an idiosyncratic scale (one trial; 3.7%), and from self-report (one trial; 3.7%).

Outcomes related to other measures

Data on other non-suicidal secondary outcomes were also reported in a number of trials (Table 1). In line with the NICE guidelines on the short-term assessment of self-harm (National Institute for Clinical Excellence 2004), many trials reported data on depression (37 trials;

56.1%), hopelessness (19 trials; 28.8%) and, to a lesser extent, problem-solving ability (16 trials; 24.2%). Mostly, this was using self-reported scales such as the Beck Depression Inventory [BDI; (Beck, Ward, Mendelsohn, Mock, & Erbaugh, 1961)], the Beck Hopelessness Scale [BHS; (Beck & Steer, 1988)], and various self-report scales for problem solving.

Given the role of anxiety in the etiology of self-harm (Hawton, Saunders, Topiwala, & Haw, 2013) data on anxiety were also reported in 17 trials (25.7%). However, despite recent work implicating alcohol as an important proximal risk factor for suicidal behavior (Borges, Bagge, Cherpitel, & Conner, 2017), only six trials (9.1%) evaluated the effect of treatment for self-harm on alcohol and/or drug use.

Mechanisms of change

Few trials (3 trials; 4.5%) explicitly included data on hypothesized mechanisms of change. In two trials of emotion-focused regulation training, for example, the authors hypothesized that the intervention would improve emotion regulation and experiential avoidance which, in turn, would lead to a reduction in repetitive self-harming behavior (Gratz & Gunderson, 2006; Gratz, Tull, & Levy, 2013). In a separate report the authors found that reductions in emotion regulation indirectly led to reductions in self-harm through their effect on borderline personality disorder-related cognition and affective functioning, suggesting that the ability to regulate emotion is an important treatment target for women with borderline personality disorder who engage in frequent, repeated self-harm (Gratz, Bardeen, Levy, Dixon-Gordon, & Tull, 2015).

In a study of mentalization-based therapy for adolescents (MBT-A), the authors not only included measures of mentalization ability and avoidance, which they hypothesized would be related to mechanisms of change (Rossouw & Fonagy, 2012), but also used mediation analyses

to determine whether changes in these outcomes were related to reductions in self-harming behavior. These authors found that once improvements in these measures were statistically controlled, the effect of MBT-A on repetition of self-harm at the post-intervention assessment was no longer significant, suggesting that the ability to mentalize is an appropriate treatment target for the prevention of self-harming behavior in this age group.

In some other trials, variables which could be related to such mechanisms were assessed but without explicit mention that they were hypothesized to be mechanisms of change. For example, in a number of trials of CBT-based psychotherapy, effects of the intervention on problem-solving ability were also assessed. In two other trials of problem-solving based approaches, the authors also reported information on whether the intervention actually produced changes in ability to solve interpersonal or other problems. A number of trials of DBT also included information on whether the intervention led to an improved ability to tolerate emotional arousal.

Selective outcome reporting

Selective outcome reporting occurs when outcomes within an RCT are selectively reported on the basis of their significance (Dwan, Gamble, Williamson, & Kirkham, 2013). To investigate this, we searched international trial registries to obtain the study protocols for all trials published subsequent to the International Committee of Medical Journal Editors' (ICMJE) mandatory trial registration guidelines in 2005 (De Angelis et al., 2004). Of the 34 trials published after 2005, just under one-half (15 trials; 44.1%) had been registered with an international trial registry. Just over half of the registered trials had been prospectively registered. However, for six (40%) they had been registered retrospectively after the trial had been completed. The clinical trial registry record was no longer available for one trial (Ougrin et al., 2011). For one further trial, additional information on the intervention was available

online; however, details on participant inclusion and exclusion criteria and details on the primary and secondary outcomes to be assessed were not available (Fleischmann et al., 2008).

Sample size and power analysis

Although the sample size for included trials has increased over time (β=23.6, *se*=11.9, *p*=0.05; Figure 2), most trials are still underpowered to detect significant effects for self-harm repetition and suicide. Using rates of self-harm and suicide for cognitive behavioral-based therapy in adults, the approach we found to be associated with the greatest reduction in self-harm repetition and suicide in our recent Cochrane review (Hawton et al., 2016b), we estimate that a minimum of 1,862 participants would be needed in each trial arm to detect a significant effect for repetition of self-harm with 80% power at the conventional *p*=0.05 level (Table 2). For suicide, moreover, a minimum of 8,757 participants would be required in each trial arm to detect a significant treatment effect (Table 2).

Adequacy of random sequence generation

We found that for most trials (49 trials; 74.2%) the random sequence generation was adequate. We did not find that outcome estimates were exaggerated in trials with inadequate or unclear random sequence generation as compared to those with adequate sequence generation. For CBT-based interventions in adults, for example, adequacy of the random sequence generation made no material difference to overall findings regarding the intervention for self-harm repetition at the final follow-up assessment, although only two such trials were rated as having inadequate/unclear random sequence generation (Inadequate/unclear random sequence generation: OR 0.63, 95% CI 0.27 to 1.49, 2 trials, *p*=0.29, I^2=0.0%; Adequate random sequence generation: OR 0.68, 95% CI 0.52 to 0.89, 15 trials, *p*=0.005, I^2=23.0%; Test for

subgroup differences: χ^2=0.03, *df*=1, *p*=0.87). For all other categories of intervention there were too few included studies to meaningfully undertake such analyses.

Adequacy of allocation concealment

For the majority of trials (38 trials; 57.6%), allocation concealment was adequate, having been conducted using opaque, sealed envelopes (16 trials), by an offsite researcher (10 trials), or a third-party researcher working independently of the research team (10 trials). In the two remaining trials, correspondence with study authors indicated that allocation had been adequately concealed.

We did not find that intervention estimates were exaggerated in trials with inadequate or unclear allocation concealment. For CBT-based interventions in adults, for example, adequacy of the allocation concealment procedure made no material difference to overall findings regarding the intervention for self-harm repetition (Test for subgroup differences: χ^2=2.35, *df*=1, *p*=0.12; Figure 3). Similarly, for suicide, there was no evidence to suggest that trials with inadequate or unclear allocation concealment were associated with exaggerated treatment effects, although there were only seven trials in which the sequence generation procedure was either inadequate or unclear (Inadequate/unclear allocation concealment: OR 0.81, 95% CI 0.23 to 2.88, 7 trials, *p*=0.75, I^2=0.0%; Adequate allocation concealment: OR 0.57, 95% CI 0.19 to 1.69, 8 trials, *p*=0.31, I^2=0.0%; Test for subgroup differences: χ^2=0.17, *df*=1, *p*=0.68). For all other categories of intervention, there were too few included studies to meaningfully undertake these analyses.

Blinding

Adequately blinding participants, clinical personnel, and outcome assessors to treatment allocation minimizes the role of performance and detection bias as neither party is then likely to provide biased assessments as to the effectiveness of the intervention. Psychosocial treatment trials present unique challenges to blinding, however, as it is generally not possible to blind participants to the treatment they are actively receiving, or clinical personnel to the treatment they are delivering (Shean, 2014). As a consequence, participant and clinical personnel blinding could not convincingly be achieved in any of the included trials.

Perhaps most surprisingly, in well under one-half of all the trials (28 trials; 42.4%) outcome assessors were either not blind to treatment allocation or there was insufficient information to confirm whether outcome assessors were blind. Whilst there was some suggestion that outcome estimates for repetition of self-harm may have been greater in trials with inadequate or unclear outcome assessor blinding, this was not significant for CBT-based trials for either repetition of self-harm at the final follow-up assessment (χ^2=3.61, *df*=1, *p*=0.06; Figure 4) or for suicide (χ^2=2.17, *df*=1, *p*=0.14; Figure 5). For all other categories of intervention, there were too few included studies to meaningfully undertake these analyses.

Zelen's post-consent design

Four trials (6.1%) included in this review used Zelen's post-consent randomization design (Carter, Clover, Whyte, Dawson, & D'este, 2005; Hatcher, Coupe, Wikirwhi, Durie, & Pillai, 2016; Hatcher et al., 2015; Hatcher, Sharon, Parag, & Collins, 2011), in which eligible participants are both identified and randomly allocated to the intervention or control group prior to seeking their consent to take part in the trial. Allocation status is then revealed to participants, who can then either consent to participate, decline, or consent to participate only

if they can change groups (Adamson, Cockayne, Puffer, & Torgerson, 2006). In three of these trials, participants who refused to provide consent following treatment allocation were excluded from further analysis for all non-suicidal secondary outcome measures (Hatcher et al., 2016; Hatcher et al., 2015; Hatcher et al., 2011).

DISCUSSION

Recent years have seen a substantial increase in the number of RCTs of psychosocial treatments for adults who self-harm. Thus the number of trials has nearly trebled as of 29 April, 2015 since we previously reviewed trial methodology (Arensman et al., 2001). In children and adolescents, however, the number of trials remains relatively small, especially given the extent of self-harm in this population (Hawton, Saunders, & O'Connor, 2012), with one trial in our earlier review and just 11 in the current review.

There has been a notable increase in trials from low-to-middle income countries. However, guidance on treatments for self-harm is still dominated by research from high income countries, particularly the USA and UK. Although relatively few studies have investigated characteristics of persons who engage in self-harm in non-Western settings (Spears, Montgomery, Gunnell, & Araya, 2014), there would appear to be important differences both in the methods of self-harm used as well as the characteristics of those who engage in self-harm between lower-to-middle income countries as compared to higher-income countries (Gholamrezaei et al., 2015). Opportunities for intervention are also more limited in lower-to-middle income countries. Possible reasons include the fact that fewer persons in low-to-middle income countries have a history of repeated, non-fatal episodes of self-harm, perhaps as a consequence of ready availability of highly lethal means (Mohamed et al., 2011), and that resource limitations mean

that availability of mental health professionals trained to deliver complex multi-component and prolonged psychosocial interventions is very limited (Benson & Shakya, 2008).

The majority of participants in these trials have been female, reflecting the general characteristics of self-harm patients attending hospital-based services (Arensman, Griffin, & Corcoran, 2016; Geulayov et al., 2016). However, there appears to have been little effort to develop and evaluate interventions specifically focused on males. This is surprising, especially given the greater risk of suicide following self-harm in males than females (Carroll et al., 2014; Hawton, Bergen, et al., 2015). Clinically important subgroups of self-harm patients were also excluded from a number of these trials, including those with a diagnosis of a major mental illness (especially psychosis) and those with alcohol and/or other drug dependence. There were also no identified trials of participants older than 65 years at randomization, despite increasing risks of suicide in older age groups, particularly in males.

We found that in trials where an intervention was compared with TAU, while the potential range of interventions available in the TAU condition was often indicated, there was rarely any record of the treatments actually received and by how many patients. In future trials where TAU is used as a control treatment condition we suggest that not only should the potential types of interventions in this condition be pre-specified, but the actual treatments received by patients should, if possible, be recorded. We acknowledge that specific information on the treatment received by participants randomized to the TAU arm may have to be excluded from publications owing to space limitations. For this reason, we would recommend RCTs of psychosocial interventions for self-harm should consider submitting this information as supplementary documents, as was recently done in a trial of DBT (Priebe et al., 2012).

The main outcome measures in the trials in our reviews were related to repetition of self-harm. These were assessed in a variety of ways, with some studies relying on self-report, which may have led to the identification of more episodes, especially those not resulting in presentation to clinical facilities (Guthrie et al., 2001). Other trials relied on hospital and/or medical records, which will largely identify hospital-presenting episodes only. We would therefore suggest that a combination of both is ideal. We would also suggest future trials in this area report data on frequency of repetition of self-harm.

Given the strong association between self-harm and future suicide (Carroll et al., 2014; Hawton, Bergen, et al., 2015), it was surprising how infrequently deaths by suicide (including where there were no deaths), were reported, especially when requests to authors revealed that this information was available. However, whilst the majority of coronial investigations are closed within a year and a half from the date of death, we would acknowledge that at least a third of suicide cases remain open two years later, and a few of these remain open four years later based on Australian data (Studdert, Walker, Kemp, & Sutherland, 2016). We would therefore strongly recommend that deaths from any cause should be reported in addition to those attributable to suicide specifically, given the well-recognized misclassification of deaths likely to have been due to suicide (Gunnell et al., 2013), particularly suicides involving self-poisoning (Bohnert et al., 2013). To date, however, only three trials included such information (Fleischmann et al., 2008; Kawanishi et al., 2014; Morthorst, Krogh, Erlangsen, Alberdi, & Nordentoft, 2012).

There is also the question of what outcomes should be assessed in trials of therapies for self-harm patients and at what time points. Clearly this will depend partly on the characteristics of the patient population. Also, consideration must be paid to restricting the number of patient-

rated outcomes to a level that will not discourage their participation. However, where possible, we suggest that the following factors should be considered for inclusion in trials in this field. Depression is one, given the strong links with suicidal behavior. However, with increasing recognition of the contributory role of anxiety in the etiology of self-harm (Hawton et al., 2013), we suggest that this is another important factor that should be considered for inclusion. Finally, because of the key mediating roles of hopelessness, suicidal ideation, and problem-solving (Thompson, Mazza, Herting, Randell, & Eggert, 2005), consideration should also be given to inclusion of measures of these outcomes.

There may also be other outcomes which participants would view as being particularly important; investigating what these outcomes might be, and ensuring they are assessed in future trials in this area, is essential to ensure treatments are pertinent to this patient group (Owens, 2010). Qualitative evaluations of future interventions will also help to generate insight into how the intervention process is perceived by participants themselves; and may also help to improve participation and adherence rates (Whitehead, Crowe, Bugge, & Coppell, 2016).

One potential component of trials that is often neglected is assessment of likely mediators of treatment effect. However, it can reasonably be argued that the key initial aim in conducting trials should be to assess whether a treatment is effective, and then if it is, to investigate mediating factors, including through treatment dismantling procedures.

In our previous paper on methodological issues in trials of interventions for self-harm patients we highlighted the fact that all trials were too small to allow detection of differences between treatment conditions in terms of repetition of self-harm (Arensman et al., 2001). While we have shown that the size of trial has increased somewhat in recent years, most trials are still

underpowered. This is likely to represent a waste of resources since the results will not usually generate information that can inform clinical services as to the best options for treatment. Larger trials are therefore required to demonstrate whether interventions are effective (Ioannidis, 2005). To achieve the size of trials necessary to generate reliable evidence multicenter studies will usually be required to allow access to sufficiently large populations of patients. Multicenter trials, such as the World Health Organization's SUPRE-MISS trial (Fleischmann et al., 2008) and the Saving and Empowering Lives in Europe (SEYLE) Project (Wasserman et al., 2010). These types of trial can also provide access to diverse populations thereby improving the representativeness of trial participants and hence the generalizability of the results. However, it is recognized that trials of sufficient size to detect robust effects on suicide are probably not feasible.

Zelen's post-consent design was used in some recent trials, but, unlike in Zelen's original concept, data on participants who subsequently refused consent to participate were excluded from secondary analyses. This particularly affected non-suicidal outcome measures which mainly relied on self-reported information. Zelen originally envisaged keeping participants' data in the group to which they were randomized (Richter & Dewey, 2014). However, without participant consent, this does not seem feasible. The use of this trial design therefore presents some problems for the interpretation of results from trials.

In none of the trials we reviewed were participants blind to the treatment condition to which they had been allocated, but in reality this is virtually impossible in trials of psychosocial interventions. This limitation similarly applied to the clinicians delivering treatment. As a result, the quality of psychosocial trials for self-harm are typically downgraded, relative to pharmacological trials, when entered into reviews and meta-analyses, such as those conducted

for the Cochrane Collaboration (Higgins & Altman, 2008). This downgrading, in turn, implies that these trials indicate poorer quality evidence. We suggest that in future separate rating measures related to blinding should be developed and applied to trials of psychosocial interventions to avoid giving the impression that the quality of evidence for psychosocial interventions is of a poorer methodological quality relative to trials for pharmacological interventions.

In most trials that we have reviewed assessments have been conducted at certain time points (e.g. end of therapy and at follow up). With the advent of successful electronic methods of assessing changes in mood and other psychological parameters these might be incorporated in future trials (Miklowitz et al., 2012). These technologies have the advantage that they can be used to assess progress at relatively short time-intervals (e.g., weekly), thereby providing an analogue for real-time assessments through, for example, the use of ecological momentary assessment.

Finally, the end date of the systematic search which informed this paper is 29 April, 2015. Whilst several important trials in the field have been published in the interim, [e.g., (Asarnow, Hughes, Babeva, & Sugar, 2017; Cottrell et al., 2018; Furuno et al., 2018; McMain, Guimond, Barnhart, Habinski, & Streiner, 2017)], we would note that these newer trials are characterized by the same limitations in sample representativeness, outcome measurement, particularly in relation to the inclusion of data on hypothesized mechanisms of action, and a lack participant involvement in the design and evaluation of the intervention.

CONCLUSIONS

Since we published our previous review of methodology of trials of therapeutic interventions for self-harm patients the number of trials in the field has grown substantially, and there has been some increase in their geographical spread worldwide. The size of trials has also increased somewhat. However, most trials are subject to considerable and often crucial methodological limitations. We hope that this report will assist those who are planning future trials in this field so that the results of investigations can provide greater guidance for clinicians and others responsible for planning clinical services, together with service users, about what treatments are likely to be most effective.

LIST OF ABBREVIATIONS

AOD: Alcohol and other drug.

BDI: Beck Depression Inventory.

BHS: Beck Hopelessness Scale.

BSSI: Beck Scale for Suicidal Ideation.

CBT: Cognitive behavioral therapy.

CCDANCTR: Cochrane Collaboration Depression, Anxiety, and Neurosis Controlled Trials Register.

CENTRAL: Cochrane Central Register of Controlled Trials.

CTL: Control group.

DBT: Dialectical behavioral therapy.

DBT-A: Dialectical behavioral therapy adapted for adolescents.

EUC: Enhanced usual care.

ICMJE: International Committee of Medical Journal Editors.

INV: Intervention group.

MBT-A: Mentalization-based therapy for adolescents.

NICE: National Institute for Clinical Excellence

NIHR: National Institute for Health Research.

NSSI: Non-suicidal self-injury.

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

RCT: Randomized controlled trial.

SBQ: Suicidal Behaviors Questionnaire.

SCS: Suicidal Cognition Scale.

SE: Standard error.

SH: Self-harm.

SIQ: Suicidal Ideation Questionnaire.

SSI: Schotte Scale of Suicidal Ideators.

TAU: Treatment as usual.

UK: United Kingdom.

USA: United States of America.

FIGURES & TABLES

Figure 1. PRISMA flow diagram of included and excluded studies for this version of the review.

Figure 2. Bubble plot of sample sizes in 66 trials of psychosocial therapies for self-harm in adults and children and adolescents by year of publication.

Figure 3. Effect of cognitive behavioral-based psychotherapy versus treatment as usual for repetition of self-harm at the final follow-up assessment subgrouped according to adequacy of the allocation concealment procedure used.

Figure 4. Effect of cognitive behavioral-based psychotherapy versus treatment as usual for repetition of self-harm at the final follow-up assessment subgrouped according to adequacy of the procedure used to blind outcome assessors used.

Figure 5. Effect of cognitive behavioral-based psychotherapy versus treatment as usual for suicides at the final follow-up assessment subgrouped according to adequacy of the procedure used to blind outcome assessors used.

DECLARATIONS

Ethical Approval and Consent to Participate

Ethical approval and participant consent were not required for this review, since the study involved review and analysis of previously published data.

Consent to Publish

All authors read and approved the final version of the manuscript for publication.

Availability of Data and Materials

This review involves analysis of previously published data available in the studies included in this review. The final dataset is available from the corresponding author upon reasonable request.

Competing Interests

KH authored two of the trials included in this article, and EA, DG, PH, and KVH authored one trial each. We declare no other competing interests.

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Authors' Contributions

KH had the idea for this article. All authors extracted data and assessed risk of bias for included trials. KW and TTS conducted the statistical analyses. KW and KH wrote the initial version of the article. All authors contributed to the interpretation of results and revisions of the article and also approved the final version.

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Table 1. Methodological characteristics and risk of bias for the 66 studies included in this version of the review.

Study and Year of Publication	Country	*N* INV	*N* CTL	Age (*SD*)	Female (%)	Participant Source	Exclusion Criteria	Intervention and Control Conditions	Outcome Ascertainment	Risk of Bias
ADULTS										
Allard (1992)	Canada	76	74		55.3	Patients presenting to hospital following a suicide attempt.	• Currently receiving treatment through another service; • Intellectual disability and/or organic disorder and/or unable to provide informed consent; • Presence of a physical illness and/or disability that would preclude attendance at follow-up appointments; and • Residing outside catchment area and/or homelessness; • Violence risk.	**Intensive outpatient therapy:** comprising a schedule of visits including at least one home visit. Either written and/or telephone reminders were sent to participants in the case of missed appointments. **TAU:** continuing treatment by the participants' regular psychiatrist within the hospital. Content of this therapy not specified.	**Repetition of SH:** self-report supplemented by collateral informant report and/or hospital records. **Suicide:** collateral informant report supplemented by Coroner's records. **Treatment use:** hospital records.	Unclear if random sequence was adequately generated. Nature of the trial suggests participants and clinical personnel not blind to treatment allocation. Unclear if outcome assessors blind to treatment allocation. Data on 24 participants lost to follow-up not reported and reasons for participant attrition not provided.
Bateman (2009)	UK	71	63		88.4	Consecutive referrals to one of two community outpatient psychiatric facilities, one of which specializes in the treatment of personality disorder.	• Aged less than 18 or older than 65; • Currently receiving treatment through another service; • Diagnosed with bipolar disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with substance dependency and/or misuse; and • Intellectual disability and/or organic disorder and/or unable to provide informed consent.	**Mentalization-based therapy:** comprising weekly individual and group psychotherapy sessions. Participants were also prescribed psychotropic medication as required. **Structured case management:** comprising three monthly individual and group therapy sessions based on a counselling model involving a supporting approach combined with case management, advocacy support, and problem-solving therapy. Participants were also prescribed psychotropic medication as required.	**Repetition of SH:** hospital records. **Depression:** Beck Depression Inventory (BDI). **Functioning:** Global Assessment of Functioning (GAF). **Mental health:** hospital records, including duration of hospital admission, perceptions for any psychotropic medication, Global Symptom Index (GSI), and Symptom Checklist-90 (SCL-90). **Problem-Solving:** Inventory of Interpersonal Problems, circumflex version. **Social Adjustment:** Social Adjustment Scale-self-report. **Suicide:** unclear how this outcome was ascertained.	Nature of the trial suggests participants and clinical personnel not blind to treatment allocation.
Beautrais (2010)	New Zealand	153	174	33.6 (*NS*)	66.1	Patients admitted to a psychiatric emergency service following an episode of self-harm or attempted suicide.	• Aged less than 16; and • Insufficient language ability.	**Postcards:** series of six postcards mailed at 2 and 6 weeks and again at 3, 6, 9, and 12 months post-discharge. Postcards offered outreach, encouraging participants to make contact	**Repetition of SH:** medical records and hospital records. **Suicide:** unclear how this outcome was ascertained.	Participants not blind to allocation. Imbalance between intervention and control groups for number with prior admissions for self-harm. Adjusting for this reduced effect on repetition

								with the service in times of distress. **TAU:** comprising crisis assessment and referral to inpatient and/or community-based mental health services as required.		of self-harm to non-significance.
Bennewith (2002)	UK	964	968		58.8	Patients presenting to hospital following an episode of self-harm and who are registered with one of the participating primary care practices.	• Aged less than 16; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Residing outside catchment area and/or homelessness; and • Residing in prison and/or custodial environment.	**Letter to general practitioner:** comprising a letter from the patient's treating general practitioner inviting the patient to a consultation. **TAU:** could comprise ongoing general practitioner care, referral for psychiatric treatment, and/or other referrals.	**Repetition of SH:** medical records.	Nature of the trial suggests participants and clinical personnel not blind to treatment allocation. Additionally, no information on outcome assessor blinded provided.
Brown (2005)	USA	60	60	35.0 (*10.3)*	60.8	Patients presenting to hospital following a suicide attempt.	• Aged less than 16; • Intellectual disability and/or organic disorder and/or unable to provide informed consent; • Insufficient language ability; and • Presence of a physical illness and/or disability that would preclude attendance at follow-up appointments.	**CBT-based psychotherapy:** comprising 10 sessions of manualized cognitive-behavioral therapy. **TAU:** no details provided.	**Repetition of SH:** self-report. **Depression:** BDI and Hamilton Rating Scale for Depression (HRSD). **Hopelessness:** Beck Hopelessness Scale (BHS). **Suicidal Ideation:** Beck Scale for Suicidal Ideation (BSSI). **Suicide:** unclear how this outcome was ascertained.	Participants, clinical personnel, and outcome assessors not blind to treatment allocation.
Carter (2005)	Australia	378	394	NS	67.9	Patients presenting to a hospital-based toxicology service following an episode of intentional self-poisoning.	• Aged less than 16; • Engaged in self-injury only; • Intellectual disability and/or organic disorder and/or unable to provide informed consent; • Insufficient language ability; • Residing outside catchment area and/or homelessness; and • Violence risk.	**Postcards:** series of eight postcards mailed 1, 2, 3, 4, 6, 8, 10, and 12 months post-discharge. Postcards offered outreach, encouraging participants to make contact with the service in times of distress. **TAU:** no details provided.	**Repetition of SH:** hospital records. **Suicide:** mortality register.	Participants and clinical personnel not blind to allocation. Twenty participants randomized to control group mistakenly received intervention but were included in control group for all analyses.
Cedereke (2002)	Sweden	107	109		66.2	Patients treated in general hospitals following a suicide attempt.	• Insufficient language ability; and • No telephone connection.	**Telephone contact:** comprising two telephone calls (20-45 minutes) at 4 and 8 months post-discharge encouraging participants to receive treatment at times of distress. **TAU:** no details provided.	**Repetition of SH:** self-report. **Functioning:** GAF. **Mental health:** SCL-90 and GSI. **Suicidal ideation:** BSSI. **Suicide:** mortality register.	Nature of the trial suggests participants and clinical personnel not blind to treatment allocation. Additionally, no information on outcome assessor blinded provided.

Clarke (2002)	UK	220	247	33.0 (*NS*)	56.3	Patients presenting to hospital following an episode of self-harm.	• Aged less than 16; • Currently enrolled in full-time secondary education; and • Residing outside catchment area and/or homelessness.	**Case management:** comprising psychosocial assessment, development of a negotiated care plan, and referral to a case managed who helped the patient identify and access suitable services as required. **TAU:** could involve triage, referral for medical and/or psychosocial assessment, and treatment as required.	**Repetition of SH:** hospital records. **Suicide:** unclear how this outcome was ascertained.	Participants and clinical personnel not blind to allocation. Data on suicides had to be requested from authors, suggesting selective reporting bias make have been present.
Crawford (2010)	UK	51	52		48.5	Consecutive admissions to an emergency department following an episode of self-harm and who were diagnosed with alcohol misuse according to scores on the Paddington Alcohol Test.	• Aged less than 18; • Currently receiving AOD treatment through another service and/or those who requested a referral for AOD treatment; • Intellectual disability and/or organic disorder and/or unable to provide informed consent; • Insufficient language ability; and • Residing outside catchment area and/or homelessness.	**Brief alcohol counselling:** comprising a one-off (30 minute) appointment with an alcohol treatment nurse specialist. Session involved assessment and discussion of both current and previous drinking behaviors, provision of a health information leaflet on the damaging effects of excessive alcohol consumption, recommended limits for alcohol consumption, and the contact details of a nationally-based alcohol misuse help line. Participants could also be referred to individual counselling or detoxification services as required. **TAU:** comprising a health information leaflet advising on the damaging effects of excessive alcohol consumption, and the contact details of a nationally-based alcohol misuse help line.	**Repetition of SH:** hospital records **Alcohol use:** Alcohol Use Disorders Identification Test (AUDIT). **Mental health:** General Health Questionnaire-12 (GHQ-12). **Personality disorder:** Assessment of Personality – Abbreviated Scale. **Suicide:** collateral informant report. **Treatment satisfaction:** Client Satisfaction Questionnaire.	Participants and clinical personnel not blind to treatment allocation. Data on suicides had to be requested from authors, suggesting selective reporting bias may have been present.
Davidson (2014)	UK	14	6	NS	Not reported.	Patients admitted to the medical receiving ward of the local accident and emergency department following an episode of self-harm.	• Aged less than 18 or older than 65; and • Intellectual disability and/or organic disorder and/or unable to provide informed consent.	**CBT-based psychotherapy:** manualized CBT comprising psychoeducation to help participants understand self-harm, potential alternative behaviors, and referral to further mental health care where necessary. **TAU:** could involve referral to community mental health teams, appointments with psychiatrists, a community psychiatric nurse, and/or	**Repetition of SH:** self-report according to Acts of Deliberate Self-Harm Inventory. **Alcohol use:** AUDIT. **Anxiety:** Hospital Anxiety and Depression Scale (HADS). **Depression:** HADS. **Suicidal ideation:** BSSI. **Suicide:** unclear how this outcome was ascertained.	Nature of trial suggests participants and clinical personnel not blind to treatment allocation. Imbalance between the intervention and control groups in terms of history of previous self-harm, anxiety, and depression scores. Authors did not adjust for these differences in their analyses. Data on repetition of self-harm and depression

								inpatient psychiatric treatment as required.	**Treatment use:** number of appointments ascertained from self-report.	had to be requested from authors, suggesting selective reporting bias may have been present.
Dubois (1999)	France	51	51	22.3 (*5.8*)	79.4	Patients attending any emergency department following self-harm	• Aged less than 15 or older than 34; • Currently receiving treatment through another service.	**CBT-based psychotherapy:** manualized CBT comprising 5 sessions delivered during the first month post-discharge. **TAU:** could involve assessment by a clinical psychiatrist and referral for follow-up with either a psychiatrist or a clinical psychologist.	**Repetition of SH:** unclear how this outcome was ascertained. **Functioning:** GAF. **Suicide:** unclear how this outcome was ascertained.	Nature of trial suggests participants and clinical personnel not blind to allocation. Unclear if outcome assessor also not blind to allocation. Less than two-thirds of participants in the intervention group attended all three treatment sessions.
Evans (1999a)	UK	417	410		55.4	Patients admitted to general hospitals following an episode of self-harm.	• Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with substance dependency and/or misuse; • Residing outside catchment area and/or homelessness; and • Violence risk.	**Emergency card:** comprising an emergency card offering a 24-hour service for crisis telephone consultation with an on-call psychiatrist at times of distress. **TAU:** no details provided.	**Repetition of SH:** hospital records. **Suicide:** Coroner's records and mortality statistics.	Nature of trial suggests participants and clinical personnel not blind to treatment allocation.
Evans (1999b)	UK	18	16	NS	61.8	Patients admitted to one of two general hospitals following an episode of self-harm.	• Aged less than 16 or older than 50; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with substance dependency and/or misuse; and • Intellectual disability and/or organic disorder and/or unable to provide informed consent.	**CBT-based psychotherapy:** comprising between 2 and 6 sessions of manualized assisted CBT including sessions on basic cognitive techniques, problem-solving, emotion regulation training, and relapse prevention in those diagnosed with personality disorders. **TAU:** could involve contact with social workers (25.0%), psychiatrists (31.3%), community mental health teams (18.9%). 12.5% of the TAU group did not receive any form of treatment, whilst the treatment received by the remaining 12.3% was not recorded.	**Repetition of SH:** self-report using the Linehan Parasuicide History Interview supplemented by hospital records. **Anxiety:** HADS. **Depression:** HADS. **Functioning:** Social Functioning Questionnaire.	Nature of trial suggests participants and clinical personnel not blind to allocation. Five participants in the intervention group did not see a therapist and instead received bibliotherapy whilst one further participant received no intervention. Authors undertook *per protocol* analyses only, as data from 2 participants who dropped out following randomization and treatment allocation was not analyzed.
Fleischmann (2008)	Multinational	922	945		58.2	Patients presenting to emergency care settings following an episode of self-harm or self-poisoning.	• Diagnosed with any physical illness and/or disability and/or any mental illness that would preclude assessment and/or attendance at follow-up appointments;	**Brief information and support:** comprising one-off information session on suicidal behavior as a signal of distress, risk and protective factors for suicide, basic epidemiology,	**Repetition of SH:** self-report using an instrument based largely on the European Parasuicide Study Interview Schedule. **All cause mortality:** collateral informant report.	Nature of trial suggests clinical personnel not blind to treatment allocation. No information on outcome assessor blinding provided. No data on reasons for participant attrition provided,

							• Insufficient language ability; • Refusal to provide informed consent; and • Residing outside catchment area and/or homelessness.	information on repetition risk, alternatives to suicidal behaviors, and referral options. Participants could also elect to receive telephone or home visits to provide referral support. **TAU:** typically involved acute treatment for medical complications following self-harm/self-poisoning without further treatment or support.	**Suicide:** collateral informant report.	nor were analyses conducted according to intention-to-treat principles. Some evidence of selective outcome reporting bias as information on treatment adherence, depression, hopelessness, impulsivity, suicidal intent, have been published for some (i.e., China, India, and the Islamic Republic of Iran) but not all (i.e., Australia, Vietnam) study sites.
Gibbons (1978)	UK	200	200	NS	71.0	Patients presenting to accident and emergency departments following an episode of deliberate self-poisoning.	• Aged less than 17; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Engaged in self-injury only; • Refusal to provide informed consent; and • Residing in prison and/or custodial environment.	**CBT-based psychotherapy:** crisis-oriented problem-solving based treatment provided in the home with additional emotional regulation treatment elements. **TAU:** could include referral to general practitioners (54.0%), psychiatric treatment services (33.0%), or another, unspecified treatment service (13.0%).	**Repetition of SH:** hospital and/or medical records. **Depression:** BDI. **Problem-solving:** self-reported problems. **Treatment use:** hospital and/or medical and/or social welfare records.	Nature of trial suggests participants and clinical personnel not blind to allocation.
Gratz (2006)	USA	13	11		100.0	Clinician referrals or self-referrals to a specialist personality disorder treatment service for women.	• Aged less than 18 or older than 60; • Attended a DBT skills program within the past 6 months; • Diagnosed with bipolar disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with substance dependency and/or misuse; • Males; and • Suicide risk.	**Emotion-regulation group psychotherapy:** involved weekly emotion-regulation group-based therapy and individual emotion regulation therapy sessions designed to develop awareness and understanding of self-harming behavior, skills to engage in goal-directed behaviors whilst inhibiting impulsive behaviors without experiencing negative emotions, and developing confidence in using situationally appropriate strategies to moderate either the intensity or duration of negative emotions, and gaining a sense of acceptance of negative emotional states. **TAU:** could include referral to individual emotion regulation therapy sessions	**Repetition of SH:** self-report using the Deliberate Self-Harm Inventory (DSHI). **Anxiety:** Depression Anxiety Stress Scale (DASS). **Depression:** DASS. **Emotion regulation:** Difficulties in Emotion Regulation Scale (DERS). **Experiential Avoidance:** Acceptance and Action Questionnaire (AAQ). **Personality disorder:** Borderline Evaluation of Severity over Time (BEST). **Stress:** DASS. **Suicide:** unclear how this outcome was ascertained.	No information on allocation concealment was provided. Nature of trial suggests participants and clinical personnel not blind to allocation. Additionally, outcome assessors not blind to treatment allocation. Authors undertook *per protocol* analyses only, as data from 2 participants who dropped out following randomization and treatment allocation was not analyzed.

								and/or group-based psychotherapy (not emotion-focused).		
Gratz (2014)	USA	31	31		100.0	Clinician referrals or self-referrals to a specialist personality disorder treatment service for women.	• Aged less than 18 or older than 60; • Diagnosed with bipolar disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with substance dependency and/or misuse; and • Males.	**Emotion-regulation group psychotherapy:** involved weekly emotion-regulation group-based therapy and individual emotion regulation therapy sessions designed to develop awareness and understanding of self-harming behavior, skills to engage in goal-directed behaviors whilst inhibiting impulsive behaviors without experiencing negative emotions, and developing confidence in using situationally appropriate strategies to moderate either the intensity or duration of negative emotions, and gaining a sense of acceptance of negative emotional states. **TAU:** could include referral to individual emotion regulation therapy sessions and/or group-based psychotherapy (not emotion-focused).	**Repetition of SH:** self-report using the DSHI and the Self-Harm Inventory. **Anxiety:** DASS. **Depression:** BDI and DASS. **Emotion regulation:** DERS. **Experiential Avoidance:** AAQ. **Quality of life:** Quality of Life Inventory (QLI). **Personality disorder:** Zanarini Rating Scale for Borderline Personality Disorder and the BEST. **Problem-solving:** Inventory of Interpersonal Problems scores. **Social Functioning:** Sheehan Disability Scale. **Stress:** DASS. **Suicide:** unclear how this outcome was ascertained.	No information on allocation concealment was provided. Nature of trial suggests participants and clinical personnel not blind to allocation.
Guthrie (2001)	UK	58	61	31.2 (*1.5*)	55.5	Patients presenting to hospital following an episode of deliberate self-poisoning.	• Aged less than 18 or older than 65; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Insufficient language ability; • Not registered with a GP; and • Residing outside catchment area and/or homelessness.	**CBT-based psychotherapy:** weekly (50 minute) sessions of individual, home-based psychodynamic interpersonal therapy. **TAU:** typically this involved assessment by the treating doctor in the emergency department, referral to outpatient psychiatric treatment, addiction services, or general practitioner management.	**Repetition of SH:** self-report supplemented by medical records. **Depression:** BDI. **Suicidal ideation:** BSSI. **Suicide:** unclear how this outcome was ascertained. **Treatment satisfaction:** 10-point idiosyncratic scale. **Treatment use:** medical records.	Nature of trial suggests participants and clinical personnel not blind to allocation. Although outcome assessors blind to allocation, data on repetition of SH obtained from self-report.
Harned (2014)	USA	19	7		100.0	Patients seeking treatment from a specialist service for suicidal women with comorbid borderline personality disorder and post-traumatic stress disorder.	• Aged less than 18 or older than 60; • Diagnosed with bipolar disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms;	**DBT (prolonged exposure):** weekly individual psychotherapy sessions, group skills training, and telephone counselling as required. The prolonged exposure protocol enabled participants to receive longer	**Repetition of SH:** self-report using the Suicide Attempt Self-Injury Interview (SASII). **Anxiety:** HADRS. **Depression:** HADRS.	Participants and clinical personnel not blind to treatment allocation.

							• Intellectual disability and/or organic disorder and/or unable to provide informed consent; • Legally mandated to a specific form of psychiatric treatment; and • Males.	individual therapy sessions per week. **DBT (regular exposure):** DBT delivered according to the original exposure protocol. Involved weekly individual psychotherapy sessions, group skills training, and telephone counselling as required.	**Dissociation experiences:** Dissociative Experiences Scale-Taxon. **Mental health:** GSI and Brief Symptom Inventory (BSI). **Post-traumatic stress disorder:** PTSD Symptom Scale-Interview. **Shame:** Experiences of Shame Scale. **Suicide:** unclear how this outcome was ascertained. **Trauma cognitions:** Trauma-Related Guilt Inventory. **Treatment satisfaction:** Client Satisfaction Questionnaire-8.	
Hassanian-Moghaddam (2011)	Islamic Republic of Iran	1150	1150	24.1 (*8.1*)	66.4	Admissions to a specialist poisons hospital.	• Aged less than 12; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Intellectual disability and/or organic disorder and/or unable to provide informed consent; • Insufficient language ability; • Residing outside catchment area and/or homelessness; and • Violence risk.	**Postcards:** series of eight postcards sent 1, 2, 4, 5, 6, 8, 10, and 12 months post-discharge encouraging participants to make contact with the investigators during times of distress. **TAU:** correspondence with study authors revealed that follow-up care in the Islamic Republic of Iran is typically poor. Contact is mainly hospital- or office-based; community-based mental health services are virtually non-existent. Additionally, psychiatric inpatient beds are often at 100% occupancy, necessitating the use of short admissions and frequent readmissions.	**Repetition of SH:** self-report supplemented by hospital records. **Suicidal Ideation:** self-report. **Suicide:** collateral informant report supplemented by official death records. **Treatment use:** self-report.	Nature of trial suggests participants not blind to allocation. Outcome assessors not blind to allocation. Data on suicides had to be obtained from study authors, suggesting the presence of selective outcome reporting bias.
Hatcher (2011)	New Zealand	253	299	33.7 (*12.9*)	68.8	Patients admitted to hospital following an episode of self-harm.	• Aged less than 16; • Attended a DBT skills program and/or other specific treatment for borderline personality disorder; • Currently enrolled in full-time secondary education; and • Intellectual disability and/or organic disorder and/or	**CBT-based psychotherapy:** involved problem-solving therapy with sessions focused on problem orientation, problem listing, definition, brainstorming alternative coping strategies, and development of a crisis plan. **TAU:** involved a one-off psychosocial assessment	**Repetition of SH:** hospital records **Anxiety:** HADRS. **Depression:** HADRS. **Hopelessness:** BHS. **Problem-solving:** Social Problem Solving Inventory-Revised. **Suicidal Ideation:** BSSI. **Suicide:** Coroner's records.	Use of Zelen's post-consent design suggests participants not blind to allocation. Nature of the trial suggests clinical personnel not blind to treatment allocation. Data on suicides had to be obtained from study authors, suggesting the presence of selective outcome reporting bias.

						unable to provide informed consent.	conducted by a mental health professional.		
Hatcher (2015)	New Zealand	327	357	67.8	Patients admitted to hospital following an episode of self-harm.	• Aged less than 17; • Currently enrolled in full-time secondary education; • Intellectual disability and/or organic disorder and/or unable to provide informed consent; and • Self-identify as having Māori ancestry (these patients were eligible for inclusion in Hatcher, 2016).	**Multimodal intervention:** between 4 and 6 sessions of problem-solving therapy, series of eight postcards sent 1, 2, 3, 4, 6, 8, 10, and 12 months post-discharge, between 1 and 2 face-to-face or telephone support sessions, improved access to primary care through the provision of a voucher that could be used to access one free consultation with a general practitioner, development of a risk management strategy, and a cultural assessment. **TAU:** could involve referral to multidisciplinary treatment teams for psychiatric risk/needs assessment, psychiatric intervention, or both, referral to a crisis team, or referral to community-based alcohol and drug treatment teams as required.	**Repetition of SH:** self-report supplemented by hospital and medical records. **Anxiety:** HADS. **Cultural identity:** Sense of Belonging Instrument-P and Multi-Ethnic Identity. **Depression:** HADS. **Hopelessness:** BHS. **Quality of life:** EuroQual-5D. **Treatment use:** self-report supplemented by medical records. **Social Functioning:** Social Functioning Questionnaire-36. **Suicidal Ideation:** BSSI. **Suicide:** Coroner's records.	Use of Zelen's post-consent design suggests participants not blind to allocation. Nature of the trial suggests clinical personnel not blind to treatment allocation. Data on suicides had to be obtained from study authors, suggesting the presence of selective outcome reporting bias.
Hatcher (2016)	New Zealand	95	72	65.3	Patients admitted to hospital following an episode of self-harm and who self-identify as having Māori ancestry.	• Aged less than 17; • Currently enrolled in full-time secondary education; and • Intellectual disability and/or organic disorder and/or unable to provide informed consent.	**Culturally-adapted multimodal intervention:** between 4 and 6 sessions of problem-solving therapy, series of eight postcards sent 1, 2, 3, 4, 6, 8, 10, and 12 months post-discharge, between 1 and 2 face-to-face or telephone support sessions, improved access to primary care through the provision of a voucher that could be used to access one free consultation with a general practitioner, development of a risk management strategy, and a cultural assessment. This intervention was designed to be culturally appropriate for persons of Māori ethnicity. **TAU:** could involve referral to multidisciplinary	**Repetition of SH:** self-report supplemented by hospital and medical records. **Anxiety:** HADS. **Cultural identity:** Sense of Belonging Instrument-P, Multi-Ethnic Identity, and Cultural Impact Profile. **Depression:** HADRS. **Hopelessness:** BHS. **Quality of life:** EuroQual-5D. **Treatment use:** self-report supplemented by medical records. **Social Functioning:** Social Functioning Questionnaire-36 scores. **Suicide:** Coroner's records.	Use of Zelen's post-consent design suggests participants not blind to allocation. Nature of the trial suggests clinical personnel not blind to treatment allocation. Data on suicides had to be obtained from study authors, suggesting the presence of selective outcome reporting bias.

								treatment teams for psychiatric risk/needs assessment, psychiatric intervention, or both, referral to a crisis team, or referral to community-based alcohol and drug treatment teams as required.		
Hawton (1981)	UK	48	48		69.8	Patients admitted to general hospitals following an episode of deliberate self-poisoning.	• Aged less than 16; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Currently receiving AOD treatment and/or referred for AOD treatment; • Engaged in self-injury only; • Refusal to provide informed consent; • Residing outside catchment area and/or homelessness; and • Suicide risk.	**Home-based psychotherapy:** series of home-based, therapy sessions with a flexible schedule delivered according to the treating therapists' assessment of risk/needs. Open telephone access to the local general hospital was also available. **TAU:** weekly outpatient therapy sessions delivered at the local general hospital.	**Repetition of SH:** self-report. **Anxiety:** Lorr and McNair Mood Scale sub-scale. **Depression:** Lorr and McNair Mood Scale sub-scale. **Social Adjustment:** modified version of the Social Adjustment Scale. **Suicidal Ideation:** idiosyncratic 7-item Suicide Ideation Scale. **Suicidal Intent:** Beck Suicide Intent Scale (BSIS). **Suicide Risk:** Buglass Risk of Repetition Scale. **Treatment use:** medical records.	Nature of the trial suggests participants and clinical personnel not blind to treatment allocation. Participant attrition was 6/96 (6.2%) at post-treatment and 15/96 (15.6%) at the 6-month follow-up assessments. No information on whether analyses were conducted according to intention-to-treat principles provided.
Hawton (1987)	UK	41	39	29.3 (*NS*)	66.3	Patients admitted to a general hospital following an episode of self-poisoning.	• Aged less than 16; • Engaged in self-injury only; • Not in need of ongoing psychiatric treatment; • Not registered with a GP; and • Residing outside catchment area and/or homelessness.	**CBT-based psychotherapy:** up to 8 sessions (up to 45 minutes) of problem-solving therapy. **TAU:** general practitioner-led care which could include individual support, marriage counselling, and referral for psychiatric treatment, as required.	**Repetition of SH:** self-report supplemented by hospital and medical records. **Depression:** BDI. **Mental health:** General Health Questionnaire-28. **Problem-solving:** self-report. **Social Adjustment:** modified version of the Social Adjustment Scale. **Suicide Intent:** BSIS. **Suicide Risk:** Buglass Risk of Repetition Scale. **Suicide:** collateral informant report. **Treatment satisfaction:** scores on an idiosyncratic scale of attitudes towards treatment.	Nature of trial suggests participants and clinical personnel not blind to allocation.
Husain (2014)	Pakistan	108	113	23.1 (*5.5*)	68.8	Patients admitted to the medical unit of a university hospital following an episode of self-harm.	• Aged less than 16 or older than 64; • Currently receiving treatment through another	**CBT-based psychotherapy:** manualized, culturally-adapted, problem-solving therapy involving sessions on evaluating the self-harm	**Repetition of SH:** self-report using the (SASII). **Depression:** BDI **Hopelessness:** BHS.	Participants and clinical personnel not blind to allocation.

							service and/or referred for psychiatric treatment; • Diagnosed with bipolar disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with substance dependency and/or misuse; and • Intellectual disability and/or organic disorder and/or unable to provide informed consent; and • Residing outside catchment area and/or homelessness.	attempt, development of crisis management skills, training in the use of problem-solving and cognitive-behavioral techniques, emotion regulation skills, interpersonal skills, and relapse prevention. **TAU:** not clearly specified, however, control patients are not routinely referred to psychiatric or psychological services.	**Quality of life:** EuroQual-5D. **Problem-solving:** Coping Resource Inventory. **Suicidal Ideation:** BSSI scores. **Suicide:** unclear how this outcome was ascertained. **Treatment use:** Client Service Receipt Inventory.	
Hvid (2011)	Denmark	69	64	37.1 (*17.9*)	84.1	Patients admitted to an emergency or clinical department following an episode of self-harm.	• Aged less than 12; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Intellectual disability and/or organic disorder and/or unable to provide informed consent; and • Insufficient language ability.	**Case management:** delivered according to the Baerum model. Sessions involved solution-focused problem-solving therapy, adherence therapy, therapist continuity. Assertive outreach via home visits, telephone calls, email measures, text messages, was also used to improve treatment adherence. **TAU:** general practitioner-led management with referral to further psychiatric or psychological treatment as required.	**Repetition of SH:** hospital records. **Suicide:** Coroner's records.	Participants and clinical personnel not blind to allocation.
Kapur (2013)	UK	33	33	NS	Not reported.	Admissions to emergency departments following an episode of self-harm.	• Currently receiving treatment through another service and/or referred for psychiatric treatment; • No telephone connection; and • Residing outside catchment area and/or homelessness.	**Postcards:** series of letters mailed at 1, 2, 3, 6, 8, and 12 months post-discharge, mailing of an information leaflet listing both local and national sources of support, and two semi-structured telephone calls all designed to facilitate referral to appropriate sources of specialist treatment as required. **TAU:** could involve referral to mental health services, social services, or voluntary sector services as appropriate.	**Repetition of SH:** hospital records **Suicide:** unclear how this outcome was ascertained.	No information on allocation concealment provided. Nature of trial suggests participants and clinical personnel not blind to treatment allocation.

Kawanishi (2014)	Japan	460	454	42.3 (*14.9*)	56.2	Admissions to emergency departments following a suicide attempt.	• Aged less than 20; • Diagnosed with any personality disorder without any comorbid axis one mental disorder; • Intellectual disability and/or organic disorder and/or unable to provide informed consent; • Insufficient language ability; • Residing outside catchment area and/or homelessness; and • Unable to commit to schedule of regular face-to-face in-hospital appointments.	**Case management:** involving contact with patients at week 1 and months 1, 2, 3, 6, 12, and 18 post-discharge. Sessions were designed to collect information on treatment status, identify any problems that could interfere with adherence, and to coordinate referral to psychiatric treatment, general practitioners, social services, and other treatment services as needed, Participants also received access to a dedicate website designed to provide further information and resources. **EUC:** no details on content provided.	**Repetition of SH:** unclear how this outcome was ascertained **All cause mortality:** mortality register. **Hopelessness:** BHS. **Quality of life:** SFQ-36. **Suicide:** mortality register. **Treatment use:** medical records.	Participants and clinical personnel not blind to allocation. Data on some pre-specified outcomes (i.e., number of repeat self-harm episodes, hopelessness scores) are yet to be published. Selective outcome reporting bias therefore cannot be ruled out at present. Additionally, the sample was biased towards more compliant patients.
Lieberman (1981)	USA	12	12		66.7	Referrals from psychiatric emergency services and/or accident and emergency departments following an episode of self-harm.	• Aged less than 18 or older than 47; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with substance dependency and/or misuse; and • Intellectual disability and/or organic disorder and/or unable to provide informed consent.	**Brief behavioral therapy:** sessions covered social skills training, anxiety management, and family therapy. Patients were treated in a therapeutic milieu with a token economy. Aftercare was arranged through a community mental health center and/or a private therapist as required. **Insight-oriented therapy:** sessions involved individual therapy, group therapy, psychodrama, and family therapy. Patients were treated in a therapeutic milieu with a token economy. Aftercare was arranged through a community mental health center and/or a private therapist as required.	**Repetition of SH:** self-report. **Assertiveness:** Assertiveness Questionnaire. **Depression:** Zung Depression Rating Scale, BDI, and the Minnesota MultiPhasic Inventory, depression subscale (MMPI-D). **Reinforcing Behaviors:** Reinforcement Survey Schedule. **Fear:** Fear Survey Schedule.	No information on allocation concealment provided. Nature of trial suggests clinical personnel not blind to treatment allocation. No information on outcome assessor blinding provided. Four participants who dropped out of treatment were not included in subsequent analyses suggesting *per protocol* analyses were undertaken.
Linehan (1991)	USA	32	31	NA	100.0	Referrals to a personality disorder service	• Aged less than 18 or older than 45; • Diagnosed with bipolar disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms;	**DBT:** weekly sessions of individual therapy (1 hour), group skills training (2.5 hours), telephone consultation as required, and weekly therapist team meetings. **TAU:** referral to alternative forms of therapy (no	**Repetition of SH:** self-report using the Linehan Parasuicide History Interview. **Depression:** BDI. **Hopelessness:** BHS and the Reasons for Living Inventory **Suicidal Ideation:** Schotte Scale for Suicidal Ideators.	Nature of trial suggests participants and clinical personnel not blind to allocation. Data from 24/63 (38.1%) participants omitted from 24 month follow-up assessment suggesting analyses were

							• Diagnosed with substance dependency and/or misuse; and • Diagnosed with an intellectual disability and/or organic disorder and/or unable to provide informed consent.	additional information provided).	**Suicide:** unclear how this outcome was ascertained. **Treatment use:** self-report using the Treatment History Interview.	based on *per protocol* principles.
Linehan (2006)	USA	52	49		100.0	Clinical referrals to inpatient units, emergency rooms, and outpatient clinics.	• Aged less than 18 or older than 45; • Diagnosed with bipolar disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with an intellectual disability and/or organic disorder and/or unable to provide informed consent; • Legally mandated to a specific form of psychiatric treatment; and • Males.	**DBT:** weekly sessions of individual therapy (1 hour), group skills training (2.5 hours), telephone consultation as required, and weekly therapist team meetings. **Treatment by expert:** therapists were free to decide on the type, duration, intensity, and dose of therapy they believed was most suited to the patient (minimum of 1 individual therapy session per week).	**Repetition of SH:** self-report using the SASII. **Depression:** HRS-D, 17 item **Hopelessness:** Reasons for Living Inventory (reverse scored). **Suicidal ideation:** Suicidal Behaviors Questionnaire (SBQ). **Suicide:** unclear how this outcome was ascertained. **Treatment use:** self-report using the Treatment History Interview.	No information on allocation concealment provided. Nature of trial suggests participants and clinical personnel not blind to allocation.
Marasinghe (2012)	Sri Lanka	34	34		50.0	Admissions to a general hospital following an episode of self-harm.	• Aged less than 15 or older than 74; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with psychosis and/or experiences psychotic symptoms; and • Diagnosed with an intellectual disability and/or organic disorder and/or unable to provide informed consent.	**Brief mobile-telephone-based psychotherapy:** up to 10 sessions of problem-solving therapy, social support, alcohol/drug counselling, and meditation delivered over mobile telephone. Participants also received a series of up to 26 text messages designed to encourage participants to practice of these techniques. **Waitlist:** participants waited 6 months and then received the intervention.	**Repetition of SH:** unclear how this outcome was ascertained. **Alcohol use:** AUDIT. **Alcohol/drug dependency:** Severity of Dependence Scale, and the Drug Check Problem List. **Drug use:** Drug Check Problem List. **Depression:** BDI. **Social support:** Medical Outcomes Study. **Suicidal ideation:** BSSI. **Suicide:** unclear how this outcome was ascertained.	Nature of trial suggests participants and clinical personnel not blind to allocation. Data on repetition of self-harm, suicide reattempts, and suicides had to be obtained from study authors, suggesting the presence of significant selective outcome reporting bias.
McAuliffe (2014)	Republic of Ireland	222	211	33.5 (*11.8*)	63.0	Admissions to emergency department or an acute psychiatric unit.	• Aged less than 18 or older than 64; • Diagnosed with any physical illness and/or disability that would preclude assessment and/or attendance at appointments; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with an intellectual disability and/or	**Group CBT-based psychotherapy:** manualized sessions of problem-solving skills training and interpersonal problem-solving skills training delivered in a group format. **TAU:** could involve assessment by mental health staff, referral to acute inpatient and/or community-based mental health services,	**Repetition of SH:** self-report (at 6-weeks and 6-months follow-up) and hospital records (at 12 months). **Anxiety:** Beck Anxiety Inventory (BAI). **Depression:** BDI. **Hopelessness:** BHS. **Impulsiveness:** Barratt Impulsivity Scale (BIS).	Participants and clinical personnel not blind to allocation. Analyses were based on *per protocol* principles.

							organic disorder and/or unable to provide informed consent; • Diagnosed with substance dependency and/or misuse; • Residing outside catchment area and/or homeless; and • Residing in prison and/or custodial environment.	psychotherapy, and pharmacotherapy as required.	**Problem-solving:** Self-Rated Problem-Solving Scale (SRPSS), Means-Ends Problem-Solving Procedure (MEPS), Optional Thinking Test (OTT), and the Current Problems List. **Self-efficacy:** Generalized Self-Efficacy Scale. **Social Functioning:** Social Life Scale. **Suicidal Ideation:** BSSI. **Suicide:** hospital records.	
McLeavey (1994)	Republic of Ireland	19	20		74.3	Admissions to the accident and emergency department following an episode of self-poisoning.	• Aged less than 15 or older than 45; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with an intellectual disability and/or organic disorder and/or unable to provide informed consent; and • Engaged in self-injury only.	**Interpersonal problem-solving skills training:** manualized sessions involving instruction, active discussion, reflective listening, modelling, formulating alternative coping strategies, role playing, sentence completion, and prompting exercises. **Brief problem-solving therapy:** sessions focus on patients' current problems, and aim to prove patients gain insight into the causes and consequences of these problems. Patients do not receive any form of specific skills training.	**Repetition of SH:** collateral informant report. **Hopelessness:** BHS. **Problem-solving:** MEPS, OTT, SRPSS, Awareness of Consequences Test, and Problems Questionnaire. **Self-concept:** Self-Perception Scale. **Suicide:** unclear how this outcome was ascertained.	Random sequence generation may have led to selection bias as an open numbers table was used. Treatment allocation also could not be concealed as a consequence. Nature of trial suggests participants and clinical personnel not blind to allocation. Data from 11/50 (22.0%) participants who either dropped out of treatment and/or were lost to follow-up not analyzed. Analyses therefore based on *per protocol* principles.
McMain (2009)	Canada	90	90	30.4 (*9.9*)	86.1	Referrals to specialist Centre for Additional and Mental Health, as well as presentations to general hospitals following an episode of self-harm.	• Aged less than 18 or older than 60; • Diagnosed with any physical illness and/or disability that would preclude use of psychoactive medications and/or is highly likely to necessitate hospital treatment; • Diagnosed with bipolar disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with an intellectual disability and/or organic disorder and/or	**DBT:** manualized sessions of weekly individual therapy (1 hour), group skills training (2 hours), and telephone-based coaching (2 hours). **TAU:** general psychiatric management involving sessions of weekly individual therapy focused on improving medication management. Psychoeducation was also provided.	**Repetition of SH:** self-report using the SASII. **Anger:** State-Trait Anger Inventory (STAI). **Depression:** BDI. **Mental health:** SCL-90. **Personality disorder:** Zanarini Rating Scale for Borderline Personality Disorder (ZRS-BPD). **Problem-solving:** Inventory of Interpersonal Problems-64. **Quality of life:** EQ-5D. **Suicide:** unclear how this outcome was ascertained. **Treatment adherence:** Reasons for Early	Participants and clinical personnel not blind to allocation.

							unable to provide informed consent; • Diagnosed with substance dependency and/or misuse; • Did not meet criteria for a diagnosis of borderline personality disorder; and • Residing outside catchment area and/or homeless.		Termination from Treatment Questionnaire. **Treatment use:** self-report using the Treatment History Interview.	
Morgan (1993)	UK	101	111		25.0	Admissions to general hospitals following a first recorded episode of self-harm.	• No history of self-harm prior to the index episode (unclear how this was ascertained); and • Residing outside catchment area and/or homeless.	**Emergency card:** provision of a card that outlined a doctor was always available by telephone and could be contacted during times of distress. **TAU:** referral to general practitioners, primary healthcare teams, psychiatric outpatient treatment, or impatient admission as required.	**Repetition of SH:** medical records. **Treatment use:** medical records.	Nature of trial suggests participants and clinical personnel not blind to allocation. No information on outcome assessor blinding provided.
Morthorst (2012)	Denmark	123	120	30.8 (*13.2*)	75.7	Admissions to acute emergency units, intensive care, pediatric units or psychiatric emergency rooms.	• Aged less than 12; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Currently receiving outreach through social services; • Diagnosed with bipolar disorder; • Diagnosed with major depression; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with an intellectual disability and/or organic disorder; • Residing in prison and/or custodial environment; and • Residing in other institutional environments.	**Case management:** case manager-facilitated sessions of crisis intervention, problem-solving therapy, and assertive outreach based on motivational support. Participants were also assisted to attend these sessions to improve adherence. **TAU:** referral to a range of different treatments depending on diagnostic, clinical, and social needs. Treatment could include psychiatric assessment, substance abuse treatment, psychological therapy, general practitioner referral, and pharmacological treatment as required.	**Repetition of SH:** self-report, hospital and medical records. **All cause mortality:** mortality register. **Suicide:** mortality register. **Treatment use:** medical records.	Participants and clinical personnel not blind to allocation.
Patsiokas (1985)	USA	10	5	NS	Not reported.	Admissions to a psychiatric ward.	• Diagnosed with psychosis and/or experiences psychotic symptoms; and • Diagnosed with substance dependency and/or misuse.	**CBT-based psychotherapy:** up to 10, 1 hour sessions of cognitive restructuring. **TAU:** non-directive therapy involving open discussions about suicidal behavior, problems, and daily life.	**Repetition of SH:** N/A. **Cognitive Flexibility:** Alternate Uses Scale. **Hopelessness:** BHS. **Problem-solving:** MEPS. **Suicidal ideation:** Self-Monitoring of Suicidal Ideation and BSSI.	No information on allocation concealment provided. Nature of trial suggests participants and outcome assessors not blind to allocation. As same therapist delivered intervention and control therapies, clinical

										personnel also not blind to allocation.
Priebe (2012)	UK	40	40	32.2 (*10.8*)	87.5	Referrals to a specialist DBT treatment service.	• Aged less than 16; • Diagnosed with an intellectual disability and/or organic disorder; • Did not meet criteria for any personality disorder; • Insufficient language ability; and • Residing outside catchment area and/or homeless.	**DBT:** sessions of individual and group-based cognitive behavioral therapy, mindfulness, validation, supportive therapy, and skills training. Out of hours telephone skills training was also available as required. **TAU:** referral back to the referee agency where the participant was encouraged to engage with any therapy aside from DBT. Treatment therefore could include referral to psychiatrists, mental health teams, counsellors, general practitioners, or other user-run services as required.	**Repetition of SH:** self-report. **Mental health:** BPRS and the BSI. **Personality disorder:** ZRS-BPD. **Quality of life:** Manchester Short Assessment of Quality of Life. **Suicide:** unclear how this outcome was ascertained. **Treatment use:** Client Service Receipt Inventory.	No information on allocation concealment provided. Participants and clinical personnel not blind to allocation. Data on repetition of self-harm and suicides had to be obtained from study authors, suggesting the presence of significant selective outcome reporting bias.
Salkovskis (1990)	UK	12	8	27.2 (*6.7*)	50.0	Referrals from the duty psychiatrist following an episode of self-poisoning involving antidepressants that necessitated admission to the accident and emergency department.	• Aged less than 16 or older than 65; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; and • Residing outside catchment area and/or homeless.	**CBT-based psychotherapy:** up to 5, 1 hour sessions of home-based cognitive-behavioral and problem-solving therapy. **TAU:** no information on content provided.	**Repetition of SH:** hospital records. **Depression:** BDI. **Hopelessness:** BHS. **Mental health:** Profile of Mood States. **Problem-solving:** Personal Questionnaire Rapid Scaling Technique. **Suicidal Ideation:** BSSI. **Suicide:** unclear how this outcome was ascertained.	Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to allocation. Data on suicides had to be obtained from study authors, suggesting the presence of selective outcome reporting bias.
Slee (2008)	Netherlands	40	42	24.7 (*5.5*)	93.9	Admissions to emergency departments or mental health centers	• Aged less than 15 or older than 35; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Insufficient language ability; and • Residing outside catchment area and/or homeless.	**CBT-based psychotherapy:** up to 12 sessions of manualized CBT. **TAU:** referral for psychotherapy, inpatient hospital treatment, and/or psychotropic medication as required.	**Repetition of SH:** self-report. **Anxiety:** SCL-90, anxiety sub-scale. **Depression:** BDI. **Problem-solving:** Coping Inventory for Stressful Situations. **Self-esteem:** Robson Self-Concept Questionnaire, 8-item. **Suicidal Ideation:** SCS. **Suicide:** unclear how this outcome was ascertained.	Participants, clinical personnel, and outcome assessors not blind to allocation. Of the 90 participants randomized, eight did not receive the intervention. Reasons for this were not stated. Analyses based on the last observation carried forward method which may have introduced bias. Data on suicides had to be obtained from study authors, suggesting the presence of selective outcome reporting bias.

Stewart (2009)	Australia	23	9	NS	53.1	Admissions to hospital.	• Aged less than 18; • Diagnosed with an intellectual disability and/or organic disorder; and • Diagnosed with psychosis and/or experiences psychotic symptoms.	**CBT-based psychotherapy:** up to 4 weekly sessions of manualized individual CBT or up to 7 weekly sessions of manualized individual problem-solving therapy. **TAU:** referral to treatment by the local hospital acute care team.	**Repetition of SH:** hospital records **Hopelessness:** BHS. **Problem-solving:** Social Problem Solving Inventory-Revised. **Treatment satisfaction:** Client Satisfaction Questionnaire, 8 item. **Suicidal ideation:** BSSI. **Suicide:** unclear how this outcome was ascertained	No information on allocation concealment provided. Participants, clinical personnel, and outcome assessors not blind to allocation. Correspondence with study authors revealed 10 patients dropped out of the TAU arm, 12 from the CBT arm, and 11 form the PST arm. Data were therefore collected for treatment completers only; analyses were therefore based on *per protocol* principles. Data on suicidal ideation, hopelessness, repetition of self-harm, and suicides had to be obtained from study authors, suggesting the presence of significant selective outcome reporting bias.
Tapolaa (2010)	Finland	9	7	33.2 (*NS*)	100.0	Admissions to emergency department.	• Aged less than 18 or older than 65; • Insufficient language ability; and • Residing outside catchment area and/or homeless.	**CBT-based psychotherapy:** sessions of acceptance and commitment therapy, solution-focused brief therapy, meditation, problem-solving therapy, frustration tolerance exercises, and identity assimilation exercises. **TAU:** psychiatric outpatient treatment in the form of supportive sessions with a mental health nurse in addition to pharmacological management as required.	**Repetition of SH:** self-report using the SASII. **Anxiety:** BAI. **Depression:** BDI. **Emotion Regulation:** DERS. **Experiential Avoidance:** AAQ. **Quality of life:** Health-Related Quality of Life-15D. **Suicide:** unclear how this outcome was ascertained.	Nature of trial suggests participants and outcome assessors not blind to allocation. Outcome assessor not blind to allocation. Data only collected on treatment completers suggesting analyses based on *per protocol* principles. Data on repetition of self-harm and suicides had to be obtained from study authors, suggesting the presence of significant selective outcome reporting bias.
Torhorst (1987)	Germany	68	73		63.1	Admissions to hospital following a suicide attempt.	• Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with psychosis and/or experiences psychotic symptoms; and • Engaged in self-injury only.	**Treatment adherence intervention:** brief inpatient admission followed by sessions of outpatient psychotherapy led by the same treating clinician as referred to in the hospital. Sessions consisted of motivational interviewing. **Different therapist:** brief inpatient admission followed by sessions of outpatient psychotherapy led by a different treating clinician.	**Repetition of SH:** unclear how this outcome was ascertained. **Treatment Adherence:** number of therapy sessions attended. **Suicide:** unclear how this outcome was ascertained**.**	No information on allocation concealment provided. Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to allocation. A greater number of participates in the control arm dropped out of treatment compared to the number in the experimental arm. No information on whether analyses were conducted according to intention-to-

								Sessions also consisted of motivational interviewing.		treat principles provided. Additionally, the authors note "[t]here is some evidence that patients of the experimental group . . . had more risk factors for further suicidal behaviour than did patients of the control group. . . despite randomization" (p. 56).
Torhost (1988)	Germany	40	40		Not reported.	Admissions to a general hospital following an episode of deliberate self-poisoning who were referred to the liaison service of the toxicological ward.	• Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with substance dependency and/or misuse; and • Residing outside catchment area and/or homeless.	**Long-term therapy:** 1 session per month over a period of 12 months in addition to a brief crisis intervention session delivered within 3 days of admission. **Short-term therapy:** 12 weekly therapy sessions delivered over a period of 3 months in addition to a brief crisis intervention session delivered within 3 days of admission.	**Repetition of SH:** self-report. **Depression:** self-report. **Mental health:** Inpatient Multi-Dimensional Psychiatric Scale. **Social Adjustment:** SAS. **Treatment adherence:** number of therapy sessions attended.	No information on allocation concealment provided. Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to allocation. Of the 80 participants, data on 50-67% were available at 3 months, and data on 97.5%were available at 12 months. Unclear whether analyses were according to intention-to-treat principles, however. Data on depression scores had to be obtained from study authors, suggesting the presence of significant selective outcome reporting bias.
Turner (2000)	USA	12	12		79.2	Admissions to hospital following a suicide attempt.	• Currently receiving AOD treatment and/or referred for AOD treatment; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; and • Did not meet criteria for a diagnosis of borderline personality disorder.	**Modified DBT:** up to 6 sessions of interpersonal skills training, and individual DBT modified from the original manualized protocol to include sessions on psychodynamic techniques. There were no group-based DBT sessions. **Client-centered therapy:** up to 6 sessions of interpersonal skills training and client-centered therapy based on Carkhuff's emphatic understanding model. Treatment also included a no-suicide contract.	**Repetition of SH:** self-report. **Anxiety:** BAI. **Depression:** HRSD and BDI. **Mental health:** BPRS. **Problem-solving:** Target Behavior Ratings. **Suicidal ideation:** BSSI.	No information on allocation concealment provided. Nature of trial suggests participants and clinical personnel not blind to allocation.
Tyrer (2003)	UK	239	241	32.0 (*11.0*)	67.9	Admissions to hospital.	• Currently receiving treatment through another service and/or referred for psychiatric treatment;	**CBT-based psychotherapy:** sessions of manual-assisted CBT including sessions on cognitive techniques for emotion regulation, negative	**Repetition of SH:** self-report supplemented by medical records. **Anxiety:** HADS and BAI.	Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to

						• Diagnosed with bipolar disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; and • Diagnosed with substance dependency and/or misuse.	thinking management, and the development of relapse prevention strategies. Sessions on crisis skills problem-solving therapy were also provided. **TAU:** referral for psychiatric assessment, psychiatric outpatient treatment, occasional day-patient care, partial hospitalization, general practitioner management, or a combination of these.	**Depression:** HADS and Montgomery-Åsberg Depression Rating Scale (MADRS). **Quality of life:** EuroQoL. **Personality:** Quick Personality Assessment Schedule (PAS-Q). **Social Functioning:** GAF. **Suicide:** Coroner's records.	allocation. Of the 480 participants randomized, study authors could not obtain 12-month data for 78 (16.2%) participants for the following reasons: i) could not be traced (n = 27); ii) refused follow-up assessment (n = 19); iii) did not attend follow-up assessment (n = 9); iv) died (n = 8); v) withdrew (n = 4); vi) other reasons (n = 11). No information on whether analyses were based on intention-to-treat principles was provided, however.
Vaiva (2006)	France	293	312	72.9	Presentations to general hospitals following an intentional drug overdose.	• Aged less than 18 or older than 65; • Diagnosed with substance dependency and/or misuse; • Engaged in self-injury only; • Not registered with a GP; • No telephone connection; and • Residing outside catchment area and/or homeless.	**Telephone contact:** at least one telephone call to encourage participants to adhere to their discharge treatment plan. **TAU:** referral to the general practitioner.	**Repetition of SH:** self-report supplemented by hospital records. **Treatment use:** self-report supplemented by hospital records. **Suicide:** collateral informant report supplemented by hospital, medical, or mortality records.	Nature of trial suggests participants and clinical personnel not blind to allocation. Of the 605 participants, 89 (14.7%) did not complete the intervention, and 121 (20.0%) were lost to follow-up at 13 months for the following reasons: i) died; ii) unstated reasons. No information on whether analyses were based on intention-to-treat principles was provided, however.
Van Der Saande (1997)	Netherlands	140	134	65.7	Admissions to hospital following a suicide attempt.	• Aged less than 15; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with substance dependency and/or misuse; • Engaged in habitual self-cutting only; • Insufficient language ability; • Residing outside catchment area and/or homeless; and • Residing in prison and/or custodial environment.	**Brief inpatient admission:** inpatient admission for a period of between 1-4 days. Participants then offered referral to outpatient problem-solving therapy. **TAU:** inpatient psychiatric treatment (25.0%), or referral to outpatient psychiatric services (75.0%).	**Repetition of SH:** hospital records. **Anxiety:** SCL-90. **Depression:** SCL-90. **Hopelessness:** BHI. **Mental health:** SCL-90. **Suicide:** collateral informant report supplemented by mortality records. **Treatment use:** self-report supplemented with collateral informant report.	Nature of trial suggests participants not blind to allocation.
Van Heeringen	Belgium	258	258	56.6	Admissions to the accident and emergency department following a suicide attempt.	• Aged less than 15; • Residing outside catchment area and/or homeless; and	**Compliance enhancement:** series of home visits to participants to encourage them to keep scheduled	**Repetition of SH:** self-report supplemented by collateral informant report. **Suicide:** mortality register.	Random sequence generation may have led to selection bias as an open numbers table was used. Treatment

							• Residing in prison and/or custodial environment.	outpatient psychiatric treatment appointments. **TAU:** referral for outpatient psychiatric treatment. Non-compliant participants did not receive home visits.	**Treatment use:** self-report supplemented by collateral informant report.	allocation also could not be concealed as a consequence. Of the 516 participants, 125 (24.2%) were lost to follow-up. Reasons given for dropouts included: i) refused follow-up assessment (n = 97); ii)moved from catchment area without leaving a forwarding address (n = 22); iii) death following a somatic illness (n = 2); iv) admitted to hospital with a terminal illness (n = 2); v) imprisoned (n = 2). No information on whether analyses were based on intention-to-treat principles was provided, however.
Waterhouse (1990)	UK	38		39	Not reported.	Admissions to the accident and emergency department following an episode of self-harm.	• Aged less than 16; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Engaged in self-injury only; and • Residing outside catchment area and/or homeless.	**General hospital admission:** admission to a general hospital ward without further referral to psychiatric, social, or other services. **Discharge:** participants discharged from hospital as soon as medically stable.	**Repetition of SH:** hospital records. **Anxiety:** Psychiatric Status Schedule, sub-scale. **Depression:** Psychiatric Status Schedule, sub-scale. **Hopelessness:** BHI. **Functioning:** Psychiatric Status Schedule. **Social Functioning:** Social Behavior Assessment Schedule. **Treatment use:** General Practitioner Questionnaire, supplemented with medical records.	Nature of trial suggests participants and clinical personnel not blind to allocation. Outcome assessors not blind to treatment allocation.
Wei (2013)	China	162	77	31.8 (*12.9*)	76.1	Admissions to emergency department.	• Aged less than 15; • Diagnosed with an intellectual disability and/or organic disorder; • Insufficient language ability; and • Without at least two contact persons (to facilitate attendance at follow-up appointments).	**CBT-based psychotherapy:** sessions of cognitive therapy. **Telephone contact:** psychological support via telephone. **TAU:** no intervention.	**Repetition of SH:** self-report. **Depression:** HDRS. **Quality of life:** idiosyncratic scale. **Suicidal ideation:** BSSI. **Suicide:** collateral informant report. **Treatment use:** self-report.	Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to allocation.
Weinberg (2006)	USA	15	15	28.2 (*8.2*)	100.0	Community referrals.	• Aged less than 18 or older than 40; • Diagnosed with bipolar disorder;	**CBT-based psychotherapy:** up to 6 sessions of manualized cognitive therapy, crisis skills training, problem-solving skills	**Repetition of SH:** self-report using the SASII. **Suicidal ideation:** Suicide Behaviors Questionnaire, ideation sub-scale.	Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to allocation. Data on suicides

						• Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with substance dependency and/or misuse; • Did not meet criteria for a diagnosis of borderline personality disorder; • Males; and • Suicide risk	training, emotion regulation, negative thinking management, and relapse prevention training. **TAU:** no information provided.	**Treatment use:** Treatment Utilization Intervention, Follow-Along Version. **Suicide:** unclear how this outcome was ascertained.	had to be obtained from study authors, suggesting the presence of significant selective outcome reporting bias.
Welu (1977)	USA	63	57	Not reported.	Admissions to the accident and emergency department following an episode of self-harm.	• Aged less than 16; • Residing outside catchment area and/or homeless; and • Residing in other institutional environments.	**Outreach:** weekly/bi-weekly community mental health team contact. **TAU:** psychiatric consultation on request of the treating physician and referral for a next day appointment at the community mental health center.	**Repetition of SH:** hospital records. **Alcohol use:** self-report. **Drug use:** self-report. **Treatment use:** number of therapy sessions attended.	No information on allocation concealment provided. Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to allocation. Of the 120 participants, 6 (9.5%) in the experimental arm and 26 (45.6%) in the control arm were lost to follow-up for unstated reasons. No information on whether analyses were based on intention-to-treat principles was provided, however.
CHILDREN & ADOLESCENTS									
Cooney (2010)	New Zealand	14	15	75.9		• Aged less than 13 or older than 19; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Insufficient language ability; • No history of self-harm prior to the index episode (unclear how this was ascertained); and • No adult caregiver willing and/or able to attend family therapy sessions.	**DBT-A:** comprising weekly individual therapy sessions (50-60 minutes), weekly group skills training (110 minutes), and family therapy and telephone counselling as required. **TAU:** comprising individual and family sessions provided by a multidisciplinary treatment team, medication management, and hospital or respite care as required.	**Repetition of SH:** self-report using the SASII and according to hospital records. **Alcohol and/or drug use:** Substances And Choices Scale (SACS). **Emotion regulation:** DERS. **Hopelessness:** Reasons for Living Inventory for Adolescents (reverse scored). **Suicidal Ideation:** BSSI. **Treatment use:** number of therapy sessions attended.	Participants and clinical personnel not blind to treatment allocation.
Cotgrove (1995)	UK	47	58	84.8		• Aged less than 16; and • Residing outside catchment area and/or homeless.	**Emergency card:** comprising one card that could be used, on demand, to allow re-admission to a pediatric ward at the local hospital at times of distress.	**Repetition of SH:** hospital records. **Treatment use:** collateral informant report.	An open numbers table was used to generate the random sequence, leading to possible bias in the random sequence generation and allocation concealment. Additionally, the nature of the trial

							TAU: referral for standard follow-up, including treatment from a specialist clinic or child psychiatry department as required.		suggests participants and outcome assessors not blind to allocation. Also, unclear if outcome assessors were blind to treatment allocation, Five participants in one center either received their emergency card after a delay of several weeks, or not at all. It is unclear whether and how data from these participants was analyzed. Finally, the authors claim this intervention as effective even when comparison of repetition rates (the primary outcome) was not significant.
Donaldson (2005)	USA	21	18	82.0	Patients presenting to a general pediatric emergency department or inpatient unit of an affiliated child psychiatric hospital after a suicide attempt.	• Aged less than 12 or older than 17; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; and • Insufficient language ability.	**Skills-based, problem-solving treatment:** up to 12 sessions of problem-solving and affective management therapy, including cognitive restructuring, and relaxation. **Supportive relationship therapy:** up to 12 sessions of unstructured therapy, including exploratory questioning, encouraging affect, connecting affect to events, and reviewing changes obtained by therapy. Participants were not taught any specific therapeutic techniques.	**Repetition of SH:** self-report and/or collateral informant report. **Anger:** STAXI. **Depression:** Centre for Epidemiologic Studies, Depression (CES-D) scale. **Problem-solving:** Social Problem Solving Inventory-Revised, and the MEPS. **Suicidal ideation:** SIQ. **Suicide:** collateral informant report.	Not information on allocation concealment provided. Nature of trial suggests participants not blind to treatment allocation. Additionally, as the same therapists provided both the intervention and control treatments, clinical personnel blinding could not be achieved. Intervention contamination also may have occurred. No information on outcome assessor blinding provided. Data on suicides had to be obtained following correspondence with study authors.
Green (2011)	UK	183	183	88.5	Patients presenting to local child and adolescent services with a history of at least two episodes of self-harm within the previous 12 months.	• Aged less than 12 or older than 16 years, 11 months; • Diagnosed with anorexia nervosa (and with severe low body mass); • Diagnosed with psychosis and/or experiences psychotic symptoms; • Enrolled in a school for students with intellectual disabilities; • Insufficient language ability; • No history of self-harm prior to the index episode (unclear how this was ascertained); and	**Group-based psychotherapy:** Developed by Wood (2001), this is a manualized developmental psychotherapy program delivered in a group format. Sessions involve elements of CBT, DBT, and group psychotherapy. **TAU:** comprising any form of therapy with the exception of any group-based intervention, recommended by the adolescents' child and adolescent mental health service team.	**Repetition of SH:** self-report using a standardized interview. **Depression:** Mood and Feelings Questionnaire (MFQ). **Functioning:** Health of the Nation Outcome Scales for Children and Adolescents (HoNOSCA). **Suicidal Ideation:** SIQ. **Suicide:** medical records. **Treatment use:** medical and social services records.	Participants and clinical personnel not blind to treatment allocation. Not all participants included in analyses for primary and secondary outcomes, although the authors claim to have used an intention-to-treat approach. Attrition bias therefore cannot be ruled out.

Harrington (1998)	UK	85	77	89.5	Patients referred to mental health teams from one of four hospitals.	• Residing in prison and/or custodial environment. • Aged less than 16; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Engaged in self-injury only; • No adult caregiver willing and/or able to attend family therapy sessions; and • Suicide risk.	**Home-based family therapy:** comprising a manualized family therapy intervention involving one assessment session and up to four home visits. **TAU:** no details provided.	**Repetition of SH:** self-report using a standardized interview. **Family Functioning:** Family Assessment Device. **Hopelessness:** Hopelessness Questionnaire. **Problem-solving:** SPSI generation of alternative solutions subscale. **Suicidal Ideation:** SIQ. **Suicide:** unclear how this outcome was ascertained.	Nature of trial suggests participants not blind to allocation. Additionally, clinical personnel not blind to treatment allocation. Authors' state analyses conducted according to intention-to-treat principles. However, outcome assessment were conducted with 154/162 (95.1%) cases to two months, and with 149/162 (92.0%) cases at six months.
Hazell (2009)	Australia	35	37	90.3	Patients referred to a child and adolescent mental health service who had reported at least two episodes of SH in the past year, with one of these in the past three months.	• Aged less than 12 or older than 16; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with substance dependency and/or misuse; • No history of self-harm prior to the index episode (unclear how this was ascertained); and • Suicide risk.	**Group-based psychotherapy:** Developed by Wood (2001), this is a manualized developmental psychotherapy program delivered in a group format. Sessions involve elements of CBT, DBT, and group psychotherapy. **TAU:** could involve individual counselling, family therapy sessions, medication assessment and review, and/or other care co-ordination.	**Repetition of SH:** self-report using a standardized interview. **Alcohol and/or drug use:** K-SADS scores. **Depression:** MFQ and the Schedule for Affective Disorders and Schizophrenia for School-Age Children (K-SADS). **Functioning:** Children's Global Assessment Scale, Strengths and Difficulties Questionnaire, and the HoNOSCA. **Suicidal Ideation:** SIQ. **Suicide:** medical records. **Treatment use:** medical records.	Participants and clinical personnel not blind to treatment allocation. Data analyzed according to intention-to-treat principles, however, method used last observation carried forward which may introduce bias.
Mehlum (2014)	Norway	39	38	88.3	Patients referred to a child and adolescent mental health service who reported at least two episodes of self-harm in the past year, with one of these in the past 16 weeks.	• Aged less than 12 or older than 18; • Diagnosed with bipolar disorder; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Did not meet criteria for a diagnosis of borderline personality disorder and/or borderline traits; and	**DBT-A:** comprising weekly individual therapy sessions, weekly group skills training, weekly multifamily skills training, weekly family therapy, and telephone counselling as required. **EUC:** no less than one weekly individual therapy session.	**Repetition of SH:** self-report and hospital records. **Depression:** Short Mood and Feelings Questionnaire (SMFQ) and MADRS. **Hopelessness:** BHS. **Personality disorder:** Borderline Symptom List, 23 item. **Suicidal Ideation:** SIQ. **Suicide:** unclear how this outcome was ascertained.	Participants and clinical personnel not blind to treatment allocation.

						• No history of self-harm prior to the index episode (unclear how this was ascertained).			
Ougrin (2011)	UK	35	35	80.0	Patients admitted to emergency departments following an episode of self-harm.	• Aged less than 12 or older than 18; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Diagnosed with substance dependency and/or misuse; • Insufficient language ability; • Suicide risk; and • Violence risk.	**Therapeutic assessment:** manualized assessment involving standard psychosocial history and suicide risk assessment, identification of reciprocal roles, core pain, and maladaptive behaviors based on a cognitive analytic therapy paradigm. Participants also identify their target problems, think of ways to change these problems, motivations for change, and explore alternative coping strategies. The session concludes with writing of an understanding letter summarizing these steps which is sent to parents. **TAU:** standard psychosocial history and suicide risk assessment based on NICE principles.	**Repetition of SH:** hospital records. **Functioning:** Children's Global Assessment Scale, and Strengths and Difficulties Questionnaire. **Treatment use:** medical records supplemented by collateral informant report. **Suicide:** unclear how this outcome was ascertained.	Participants and clinical personnel not blind to treatment allocation. Data analyzed according to intention-to-treat principles, however, method used last observation carried forward which may introduce bias.
Rossouw (2012)	UK	40	40	85.0	Patients presenting to community health services or acute hospital accident and emergency departments following an episode of self-harm.	• Aged less than 12 or older than 17; • Currently receiving treatment through another service and/or referred for psychiatric treatment; • Diagnosed with an eating disorder; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; and • Diagnosed with substance dependency and/or misuse.	**Mentalization-based therapy:** manualized psychodynamic psychotherapy involving sessions for both the adolescent and his/her family. **TAU:** could involve individual therapy (28.0%), counselling (38.0%), supportive therapy (24.0%), CBT (19.0%), psychodynamic psychotherapy (19.0%), combination of individual and family therapy (25.0%), or a psychiatric review alone (27.5%).	**Repetition of SH:** self-report using the Risk-Taking and Self-Harm Inventory and the Childhood Interview for DSM-IV Borderline Personality Disorder. **Attachment:** Experience of Close Relationships Inventory. **Depression:** MFQ. **Personality Disorder:** Childhood Interview for DSM-IV Borderline Personality Disorder. **Mentalization:** How I Feel Questionnaire. **Risk-taking:** Risk-Taking and Self-Harm Inventory. **Suicide:** unclear how this outcome was ascertained.	Nature of the study suggests clinical personnel not blind to treatment allocation. Some participants in the control group (19.0%) receive sessions of psychodynamic psychotherapy similar to that offered within the intervention condition.
Spirito (2002)	USA	36	40	94.1	Patients presenting to hospital following a suicide attempt.	• Aged less than 12 or older than 18; and	**Compliance enhancement:** one-hour session reviewing expectations for outpatient	**Repetition of SH:** self-report. **Anger:** STAXI.	No information on allocation concealment provided. Nature of the study suggests

						• Residing outside catchment area and/or homeless.	treatment, addressing the factors likely to impede attendance, and addressing treatment misconceptions. Verbal contract between adolescent, parents, and staff to attend all treatment sessions. Participants also contacted by telephone at 1, 2, 4, and 8 weeks post-discharge to review compliance with treatment. **Standard disposition planning:** comprising treatment based on judgement of treating psychiatrist. Some participants had a brief inpatient stay prior to receiving outpatient care, whilst the remainder received outpatient care at a local mental health center.	**Depression:** CES-D. **Hopelessness:** Hopelessness Scale for Children. **Family Functioning:** McMaster Family Assessment Device. **Treatment barriers:** Barriers to Service Questionnaire, Family Barriers according to an idiosyncratic scale, and Service Barriers according to an idiosyncratic scale. **Treatment use:** self-report supplemented by collateral informant report. **Suicide Intent:** SIS. **Suicide:** unclear how this outcome was ascertained.	participants and clinical personnel not blind to treatment allocation. No information on outcome assessor blinding provided. Data on suicides had to be requested from study authors, suggesting possible selective reporting bias.
Wood (2001)	UK	32	31	77.8	Patients referred to child and adolescent mental health services following an episode of self-harm.	• Aged less than 12 or older than 16; • Diagnosed with an intellectual disability and/or organic disorder; • Diagnosed with psychosis and/or experiences psychotic symptoms; • Residing in prison and/or custodial environment; and • Suicide risk.	**Group-based psychotherapy:** a manualized developmental psychotherapy program delivered in a group format. Sessions involve elements of CBT, DBT, and group psychotherapy. Treatment comprises a one-off initial assessment, followed by 6 acute group-therapy sessions, and weekly therapy sessions continuing until the young person feels ready to leave the intervention. **TAU:** could comprise non-specific counselling, family therapy sessions, and psychotropic medication as required.	**Repetition of SH:** self-report using a standardized interview. **Depression:** SMFQ and K-SADS. **Functioning:** HoNOSCA. **Suicidal ideation:** SIQ. **Suicide:** unclear how this outcome was ascertained.	Nature of trial suggests participants and clinical personnel not blind to allocation. Data on suicides had to be requested from study authors, suggesting possible selective reporting bias.

Table Notes: *AOD:* alcohol and other drug; *CBT:* cognitive behavioral therapy; *DBT:* dialectical behavior therapy; *DBT-A:* dialectical behavior therapy for adolescents; *SH:* self-harm; *TAU:* Treatment as usual; *UK:* United Kingdom; *USA:* United States of America.

Table 2. Power calculations for trials to assess impact of cognitive behavioral-based psychotherapy in adults on repetition of self-harm and suicide over a 12-month follow-up period.

Outcome	Event rate (%)		Sample size (per arm)
	Usual Care Group	*Intervention Group*	
Repetition of self-harm	16.3	3.3	1,862
Suicide	1.6	0.05	8,757

Note: Based on actual rates of repetition of self-harm and suicide over a 12 month follow-up period for cognitive behavioral-based psychotherapy in the recent Cochrane review of psychological interventions for adults (Hawton et al., 2016b), with alpha set at 5% and power at 80%.

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