



# Psychosocial interventions following self-harm in adults: a systematic review and meta-analysis

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## Summary

**Background** Self-harm (intentional acts of non-fatal self-poisoning or self-injury) is common, particularly in young adults aged 15–35 years, often repeated, and strongly associated with suicide. Effective aftercare of individuals who self-harm is therefore important. We have undertaken a Cochrane systematic review and meta-analysis of the effectiveness of psychosocial interventions for self-harm in adults.

**Methods** We searched five electronic databases (CCDANCTR-Studies and References, CENTRAL, MEDLINE, Embase, and PsycINFO) between Jan 1, 1998, and April 29, 2015, for randomised controlled trials of psychosocial interventions for adults after a recent (within 6 months) episode of self-harm. Most interventions were assessed in single trials. We report results for interventions for which at least three randomised controlled trials comparing interventions with treatment as usual have been published and hence might contribute to clinical guidance. The primary outcome was repetition of self-harm at the conclusion of treatment and at 6, 12, and 24 months' follow-up analysed, when available, with the intention-to-treat method; if this was not possible, we analysed with all available case data.

**Findings** We identified 29 non-overlapping randomised controlled trials with three independent trials of the same intervention. Cognitive-behavioural-based psychotherapy (CBT; comprising cognitive-behavioural and problem-solving therapy) was associated with fewer participants repeating self-harm at 6 months' (odds ratio 0.54, 95% CI 0.34–0.85; 12 trials; n=1317) and at 12 months' follow-up (0.80, 0.65–0.98; ten trials; n=2232). There were also significant improvements in the secondary outcomes of depression, hopelessness, suicidal ideation, and problem solving. Patients receiving dialectical behaviour therapy (in three trials) were not less likely to repeat self-harm compared with those provided with treatment as usual at 6 months (odds ratio [OR] 0.59, 95% CI 0.16–2.15; n=267, three trials) or at 12 months (0.36, 0.05–2.47; n=172, two trials). However, the secondary endpoint of frequency of self-harm was associated with a significant reduction with use of dialectical behaviour therapy (mean difference –18.82, 95% CI –36.68 to –0.95). Four trials each of case management (OR 0.78, 95% CI 0.47–1.30; n=1608) and sending regular postcards (OR 0.87, 95% CI 0.62–1.23; n=3277) did not reduce repetition of self-harm.

**Interpretation** CBT seems to be effective in patients after self-harm. Dialectical behaviour therapy did not reduce the proportion of patients repeating self-harm but did reduce the frequency of self-harm. However, aside from CBT, there were few trials of other promising interventions, precluding firm conclusions as to their effectiveness.

**Funding** National Institute for Health Research.

## Introduction

Self-harm (non-fatal intentional acts of self-poisoning or self-injury irrespective of the extent of suicidal intent)<sup>1</sup> has been a growing problem in most countries over the past 40 years. In the UK, there are now estimated to be more than 200 000 presentations of self-harm to general hospitals each year.<sup>2</sup> Self-harm requires the use of considerable hospital resources in both developed<sup>3</sup> and developing<sup>4</sup> countries. Self-harm is most common in younger people between 15 years and 35 years of age.<sup>1–4</sup> Unlike suicide, self-harm usually occurs more frequently in women than men, although the female-to-male ratio appears to have narrowed over the past decade.<sup>5</sup> The sex ratio also decreases over the lifespan.<sup>6</sup>

Self-harm is often repeated, with 15–25% of individuals who present to hospital with self-harm re-presenting after a repeat episode within a year,<sup>7</sup> although the risk of repetition is lower in adults of older age (older than 60 years).<sup>8</sup> A history of self-harm is the strongest risk

factor for suicide across a range of psychiatric disorders.<sup>9</sup> Repetition of self-harm further increases the risk of suicide.<sup>10</sup>

Given the size of the problem of self-harm, the frequency with which it is repeated, and the risk of subsequent suicide, it is important that effective treatment interventions are developed for this patient population. We previously published a systematic review and meta-analysis<sup>11</sup> of both psychosocial and pharmacological treatment studies across the age spectrum in 1998, which was subsequently updated in an official guideline in 2011.<sup>12</sup> We have also done a major update of this review in conjunction with the Cochrane Collaboration.<sup>13–15</sup> In this Article we have focused on the results of psychosocial interventions for self-harm in adults investigated in a minimum of three independent trials compared with treatment as usual, because these data permitted meta-analysis, the results of which are likely to have clinical implications.

Lancet Psychiatry 2016;  
3: 740–50

Published Online  
July 12, 2016

[http://dx.doi.org/10.1016/S2215-0366\(16\)30070-0](http://dx.doi.org/10.1016/S2215-0366(16)30070-0)

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## Research in context

### Evidence before this study

We searched for trials of psychosocial treatments in adults after a recent (within 6 months) episode of self-harm indexed in five electronic databases (CCDANCTR-Studies and References, CENTRAL, MEDLINE, Embase, and PsycINFO) indexed between Jan 1, 1998, and April 29, 2015, with the search terms "auto mutilat\*", "automutilat\*", "cutt\*", "head bang\*", "headbang\*", "overdos\*", "self destruct\*", "selfdestruct\*", "self harm\*", "selfharm\*", "self immolat\*", "selfimmolat\*", "self inflict\*", "selfinflict\*", "self injur\*", "selfinjur\*", "selfmutilat\*", "self mutilat\*", "selfpoison\*", "self poison\*", or "suicid\*". Trials were eligible for inclusion if: participants were randomly assigned to the intervention and control groups; participants were 18 years or older at the point of randomisation; all participants had engaged in self-harm no more than 6 months before randomisation; the trial evaluated the effectiveness of a psychosocial intervention relative to treatment as usual, enhanced usual care, or other forms of lower intensity or alternative therapies. We focused on those interventions evaluated in a minimum of three independent trials. A total of 29 trials were included: 18 trials of cognitive behavioural-based psychotherapy (CBT; comprising cognitive behavioural or problem-solving therapy, or both), three of dialectical behaviour therapy, four of case management, and four of sending postcards to participants.

### Added value of this study

We report that CBT was associated with fewer participants repeating self-harm at 6 months' (odds ratio 0.54,

95% CI 0.34–0.85) and 12 months' follow-up (0.80, 0.65–0.98). Patients receiving dialectical behaviour therapy had fewer repeat self-harm episodes post-intervention (mean difference –18.82, 95% CI –36.68 to –0.95), although these were no apparent effect on the proportion of patients repeating. Case management and sending regular postcards (four trials each) did not reduce repetition. Evidence suggested possible publication bias for CBT. Trial numbers were insufficient to test this bias in relation to the other interventions investigated. Quality of the evidence, as assessed by the Grading of Recommendations, Assessment, Development and Evaluation criteria, was in general moderate to very low, with biases most apparent for the domains of participant and clinical personnel blinding. However, it is generally not possible to blind participants or clinical personnel to psychosocial interventions.

### Implications of all the available evidence

Evidence seems to be sufficient to conclude that CBT is effective in adult patients following self-harm. Although this intervention might not be suitable for all patients who self-harm, it should be available in services for this patient population. Dialectical behaviour therapy can reduce the frequency of self-harm in patients with borderline personality disorder who engage in repeated acts of self-harm. Sending regular postcards might not reduce the proportion of patients repeating self-harm; however, it might hold promise in settings where community psychiatric services are limited.

## Method

### Search strategy and selection criteria

We searched for randomised controlled trials of psychosocial treatments in adults after a recent (within 6 months) episode of self-harm indexed in five electronic databases (CCDANCTR-Studies and References, CENTRAL, MEDLINE, Embase, and PsycINFO) between Jan 1, 1998, and April 29, 2015. The electronic search strategy for these databases is outlined in the appendix. Reference lists of major reviews in this area were also screened and authors active in this field were contacted to identify ongoing or unpublished trials.

Trials were eligible for inclusion provided that they met the following criteria: (1) used random allocation to assign participants to the intervention and control groups; (2) participants were 18 years or older at the point of randomisation; (3) all participants had engaged in self-harm no more than 6 months before randomisation; and (4) the trial evaluated the effectiveness of a psychosocial intervention relative to treatment as usual, enhanced usual care, or other forms of lower intensity or alternative treatments. Non-English language trials were eligible for inclusion and were translated by native speakers. Self-harm was defined as including any non-fatal act of self-poisoning or self-injury irrespective

of the extent of suicidal intent or other type of motivation.<sup>1</sup> Trials were independently screened for inclusion by KGW and one of TLTS, EA, DG, PH, ET, or KvH. Disagreements were resolved after discussion with KH. When insufficient information was recorded in the study report to determine eligibility, study authors were contacted to provide additional clarification.

Grouping of trials in terms of specific types of interventions was done, partly on the basis of standard categorisation of therapeutic approaches together with discussion and consensus within the review group and with other experts in the field, and also correspondence with some authors to clarify the nature of the interventions. We combined cognitive-behaviour therapy with problem-solving therapy as cognitive-behavioural-based psychotherapy because problem-solving therapy is an integral part of cognitive-behaviour therapy and both involve cognitive-behavioural treatment principles.

In this Article, we have focused on trials in which a specific psychosocial intervention has been compared with treatment as usual (or, in one case, enhanced usual care) and has been assessed in at least three trials. We list all other interventions for which we identified trials in the appendix. For our full Cochrane review see the Cochrane Library.<sup>13</sup>

See Online for appendix

### Data extraction

Quantitative information was extracted independently by KGW and one of TLTS, EA, DG, PH, ET, or KvH. Any disagreements were resolved after discussion with KH and study authors were contacted to provide additional information where data were missing or unclear.

We assessed risk of bias for each included trial with the approach favoured by the Cochrane Collaboration.<sup>16</sup> Each study was rated as high, unclear, or low risk of bias with respect to the following: adequacy of the random sequence generation procedure, adequacy of allocation concealment, presence of participant and clinical personnel blinding, presence of outcome assessor blinding, presence of incomplete outcome data, presence of selective outcome reporting, and presence of any other bias.

The primary outcome was repetition of self-harm at the conclusion of treatment (post-intervention) and at 6, 12, and 24 months' follow-up. Secondary outcomes included frequency of repeated episodes of self-harm, suicide, suicidal ideation, depression, hopelessness, and problem solving.

### Statistical analysis

Proportions of participants repeating self-harm and deaths by suicide were assessed with the summary odds ratio (OR) and accompanying 95% CIs. Data for frequency of self-harm, suicidal ideation, depression, hopelessness, and problem solving scores were pooled with the mean difference and its accompanying 95% CIs, where outcomes were assessed with the same psychometric scale for all studies included in the meta-analysis, or the standard mean difference and its accompanying 95% CIs where outcomes were assessed with different psychometric scales. Analyses were undertaken in RevMan for Windows (version 5.3), with the Mantel-Haenszel random effects model for dichotomous data and the inverted variance random effects model for continuous data.

We did analyses with the intention-to-treat method when data were available to allow this. This analysis was usually possible with assessment of the outcomes of repetition of self-harm and suicide. When outcomes relied on patient interview, this method was generally not possible and we have instead used all available case data.

Between-study heterogeneity was assessed with the  $I^2$  statistic, which indicates the percentage of variance between studies attributable to genuine differences between studies rather than chance.<sup>17</sup> Investigation of potential causes of heterogeneity are typically undertaken only when  $I^2$  is 75% or higher.<sup>17</sup>

### Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. KH and KGW had full access to all the data in this study, and all authors had final responsibility for the decision to submit for publication.

### Results

We identified 23830 citations. An additional ten trials ongoing at the time of the systematic search were identified through correspondence with researchers in the field. After we removed duplications, this number was reduced to 16799. 16538 trials were excluded after screening and a further 237 were excluded after reviewing the full text. Seven trials were excluded because they evaluated the effectiveness of a pharmacological intervention<sup>14</sup> and a further 11 were excluded because they assessed an intervention for children and adolescents (figure 1).<sup>15</sup> A further 26 trials were excluded from this Article because fewer than three independent trials investigated the effectiveness of the same intervention. Our review<sup>13</sup> in the Cochrane Library provides information on the effectiveness of the remaining interventions not covered in this Article. 29 trials were therefore included in this systematic review and meta-analysis (figure 1; appendix), comprising 18 trials of cognitive-behavioural-based psychotherapy (CBT; including cognitive-behavioural or problem-solving therapy, or both),<sup>18–35</sup> three trials of dialectical behaviour therapy,<sup>36–38</sup> and four trials each of case management<sup>39–42</sup> and postcards sent periodically to participants over the course of a 12 month intervention period.<sup>43–46</sup>

The included trials comprised 8480 adult participants. The weighted mean age of participants at randomisation was 25.5 years (SD 15.7, range 22.3–42.3). Almost three-quarters of participants were women (70.7% in the 25 trials that recorded information about sex). Over half of participants had a history of multiple episodes of self-harm (58.4% in the 18 trials that recorded information about history of self-harm).

CBT was compared with treatment as usual in 18 independent trials.<sup>18–35</sup> Data for the proportion of patients repeating self-harm by the end of treatment were available for only one trial,<sup>27</sup> in which there was no apparent effect (23 of 171 in the CBT group vs 27 of 142 in the treatment as usual group, odds ratio [OR] 0.66, 95% CI 0.36–1.21,  $n=313$ ). However, CBT was associated with fewer participants repeating self-harm at the 6 month and 12 month follow-up assessments (figure 2). There was no evidence of a significant reduction in frequency of self-harm by the 12 month assessment period, however (mean difference  $-0.21$ , 95% CI  $-0.68$  to  $0.26$ ;  $n=594$ ; appendix).

By the conclusion of the follow-up period, there were nine deaths by suicide in patients allocated to CBT and 15 deaths in those allocated to treatment as usual. We noted no evidence of a significant reduction in suicides by this point (figure 2).

CBT was associated with significant improvements in scores for both depression and hopelessness at the 6 month and 12 month assessments, and for suicidal ideation and problem solving at 6 months (appendix).

Three trials<sup>36–38</sup> investigated the efficacy of dialectical behaviour therapy as compared with treatment as usual in participants diagnosed with personality disorder (predominately borderline personality disorder). There

was no evidence of a treatment effect for dialectical behaviour therapy on the proportions of participants repeating self-harm at post-intervention or at 12 months in two of these trials. However, there was a significant treatment effect on frequency of self-harm in favour of dialectical behaviour therapy at post-intervention (mean difference  $-18.82$ , 95% CI  $-36.68$  to  $-0.95$ ;  $n=292$ ; appendix).

There was no evidence of a significant treatment effect for dialectical behaviour therapy on suicide at post-intervention, although only one such event was observed (figure 3). There was also no evidence of a significant treatment effect for dialectical behaviour therapy on depression, hopelessness, or suicidal ideation scores, although these analyses only included one or two of the trials (appendix). None of the studies

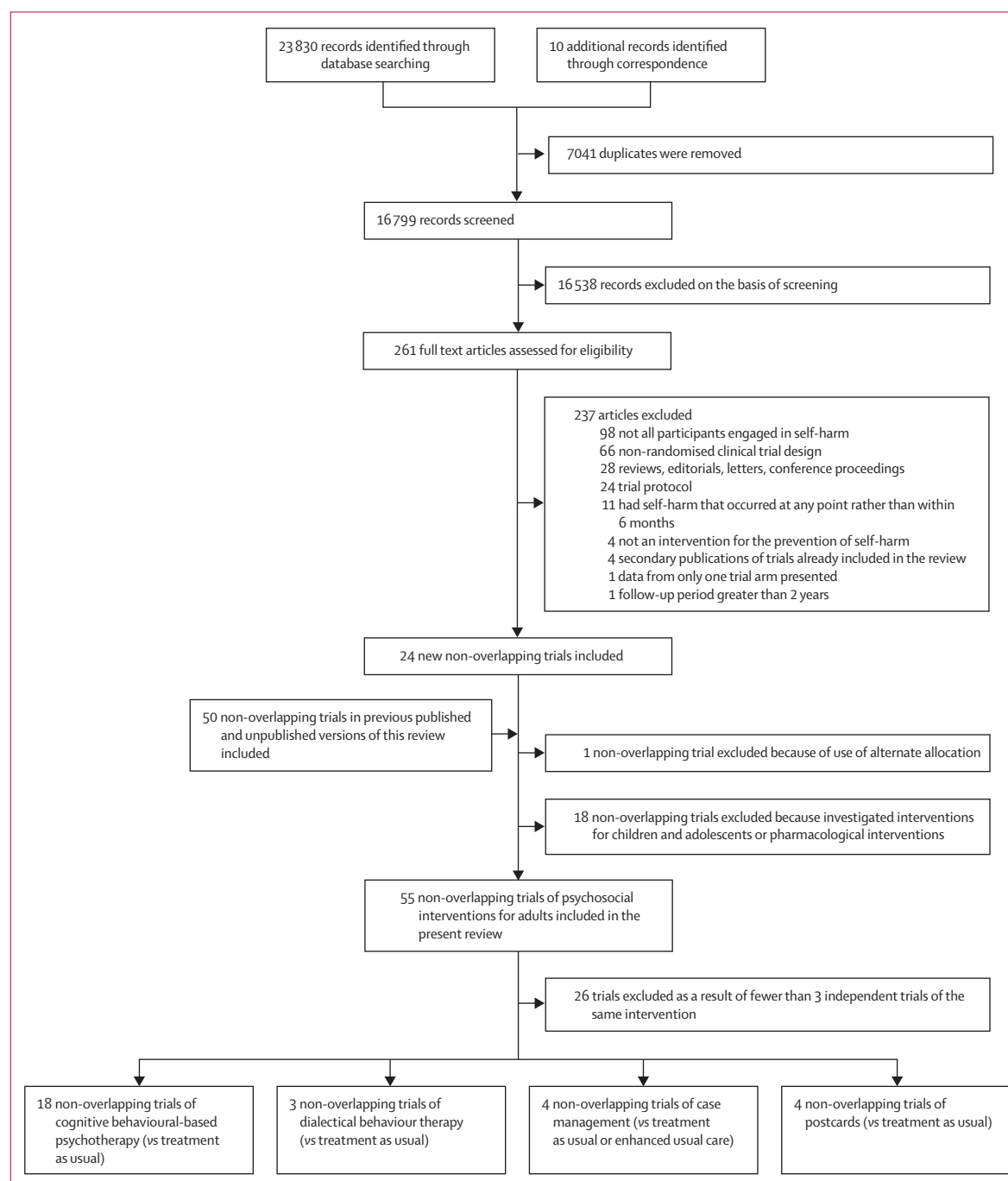
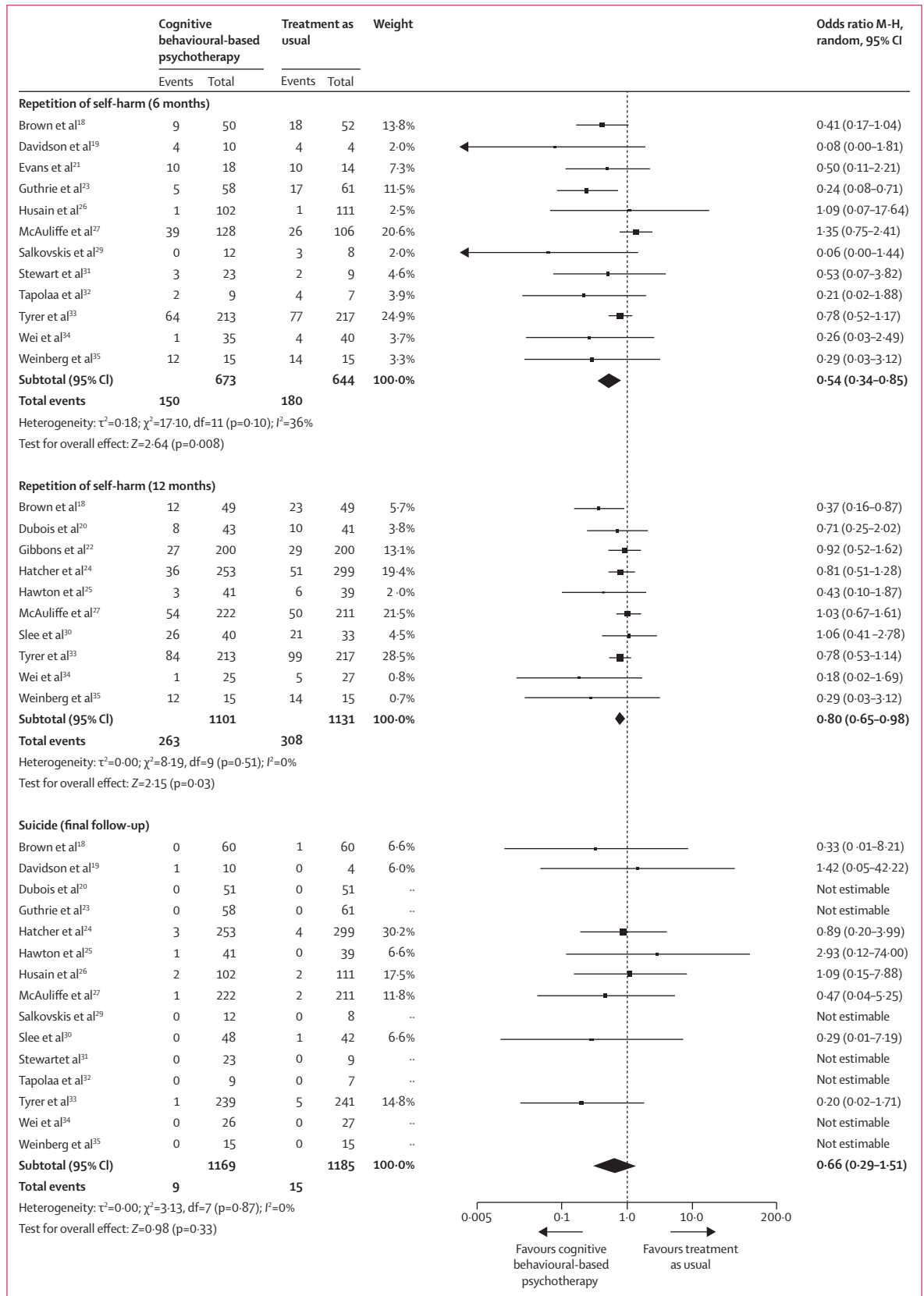


Figure 1: PRISMA search flow diagram of included and excluded studies



**Figure 2: Cognitive behavioural-based psychotherapy versus treatment as usual**  
 Random effects odds ratio and accompanying 95% CIs for effectiveness on repetition of self-harm at 6 months' and 12 months' follow-up and on suicide at final follow-up.  
 M-H=Mantel-Haenszel random effects model for dichotomous data.

of dialectical behaviour therapy measured changes in problem solving.

The effectiveness of case management was compared with treatment as usual<sup>39,40,42</sup> or enhanced usual care<sup>41</sup> in four independent trials. There was no evidence of a significant treatment effect for case management at the post-treatment assessment (figure 4). There was also no indication of a significant treatment effect for case management on suicide at post-intervention (figure 4). No data for the other secondary outcomes were reported for these trials.

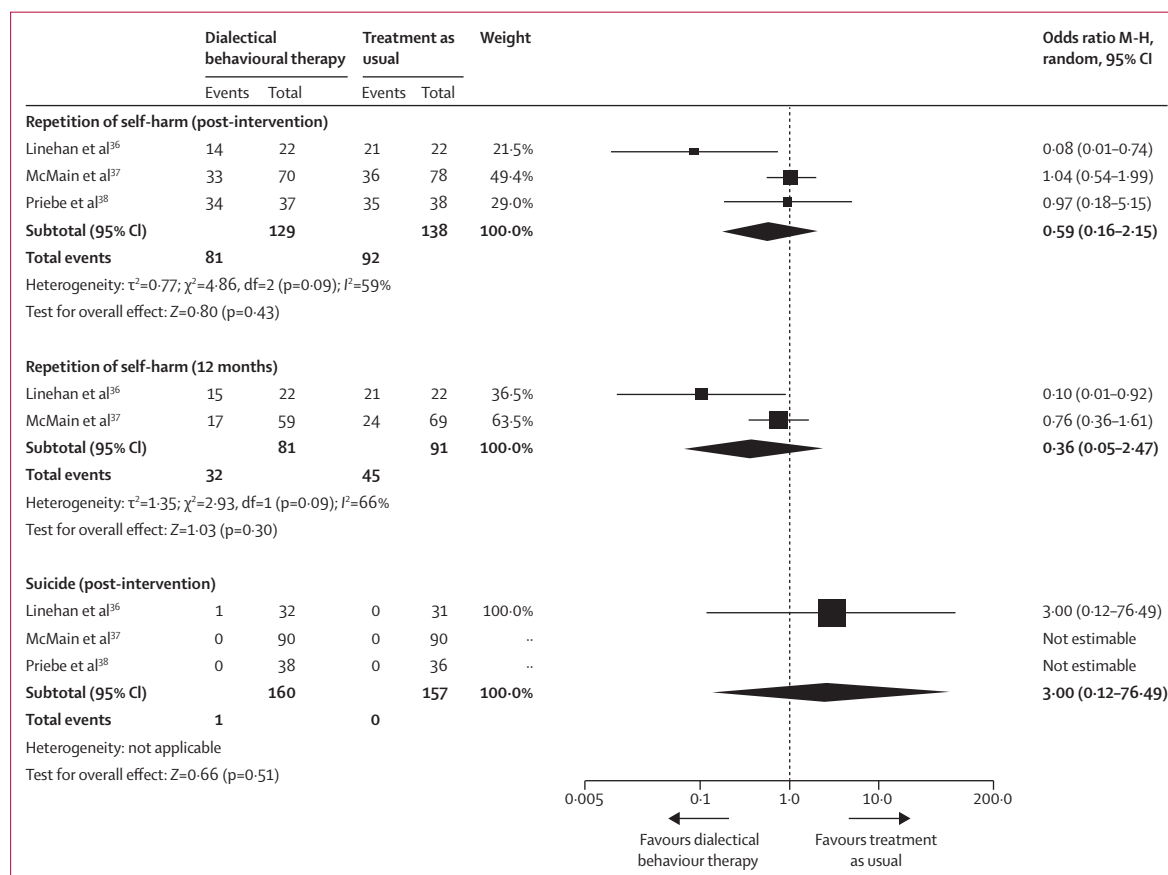
The effectiveness of sending regular postcards to patients over a 12 month period in addition to treatment as usual was compared with treatment as usual alone in four trials.<sup>43–46</sup> Sending postcards did not have a significant effect on the proportion of participants repeating self-harm by the post-intervention (figure 5) or 12 month follow-up assessments in two of these studies (figure 5).<sup>44,45</sup>

Visual inspection of figure 5 would suggest that the result for one trial at post-intervention might be an outlier.<sup>46</sup> Omitting this relatively small pilot trial reduced heterogeneity from 51% to 0% and indicated a significant

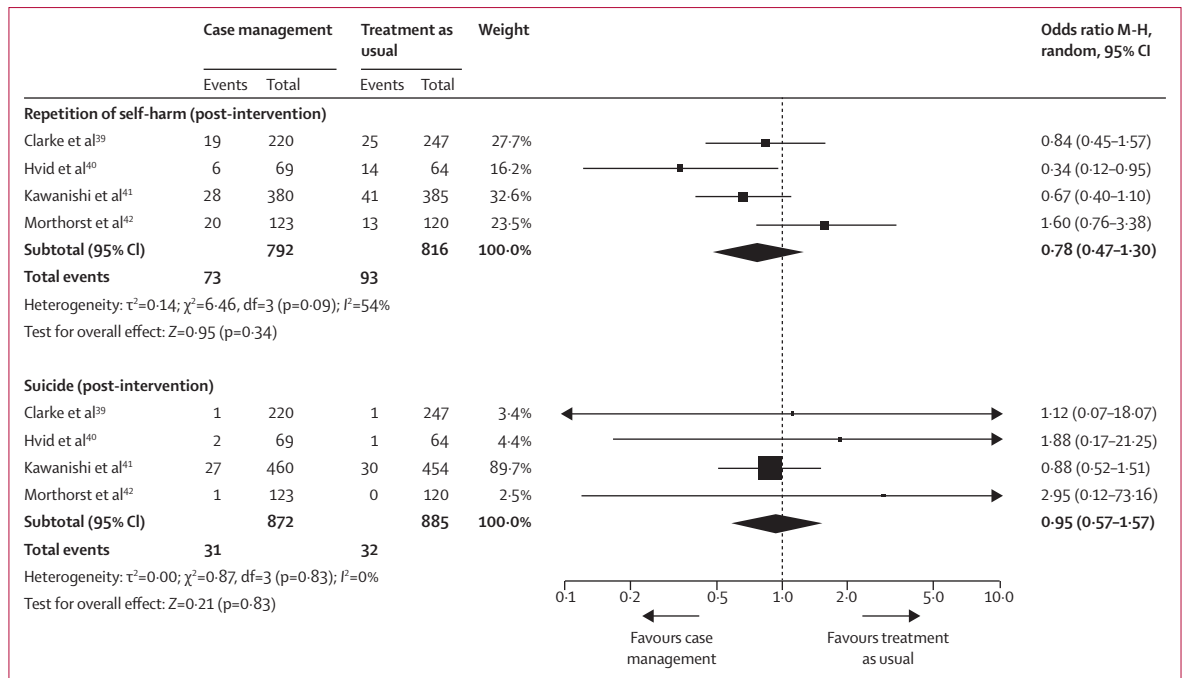
treatment effect for postcards (OR 0.78, 95% CI 0.62–0.97; three trials; n=3212). Additionally, it is noticeable that, in the very large trial from Iran,<sup>45</sup> there was a significant reduction in the proportion of participants who were sent postcards repeating self-harm at both timepoints (figure 5). No evidence of benefit was found in terms of frequency of repetition at post-intervention in three trials, at 12 months' follow-up in two trials, or at 24 months' follow-up in one trial (appendix), although a 5 year follow-up of one of these trials suggested an effect at this stage.<sup>47</sup>

Our related review in the Cochrane Library provides information about the effectiveness of this intervention by sex and repeater status.<sup>13</sup> When there was any evidence of a difference in treatment effect by sex or repeater status, interventions tended to be more beneficial for women and for individuals who had a history of multiple episodes of self-harm.<sup>13</sup>

There was no evidence of a significant effect for postcards on deaths by suicide in all four trials at post-intervention (figure 5), or in one trial at the 12 month follow-up assessment (figure 5). No data for changes in depression, hopelessness, or problem solving were reported for any of the included trials. Dichotomous data



**Figure 3: Dialectical behaviour therapy versus treatment as usual**  
 Random effects odds ratio and accompanying 95% confidence intervals for the effectiveness on repetition of self-harm at post-intervention and at 12 months' follow-up and on suicide at post-intervention. M-H=Mantel-Haenszel random effects model for dichotomous data.



**Figure 4: Case management versus treatment as usual**  
Random effects odds ratio and accompanying 95% CIs for effectiveness on repetition of self-harm and suicide at post-intervention. M-H=Mantel-Haenszel random effects model for dichotomous data.

for the number of participants self-reporting an episode of suicidal ideation were available for one trial,<sup>45</sup> with a significant treatment effect favouring the postcard group in comparison to the treatment as usual group at the post-intervention assessment (302 of 1043 in the postcard group vs 446 of 1070 in the treatment as usual group; OR 0.57, 95% CI 0.48-0.68;  $n=2113$ ), an effect that was maintained at the 12 month follow-up assessment (465 of 997 vs 588 of 1004; OR 0.62, 0.52-0.74;  $n=2001$ ).<sup>48</sup>

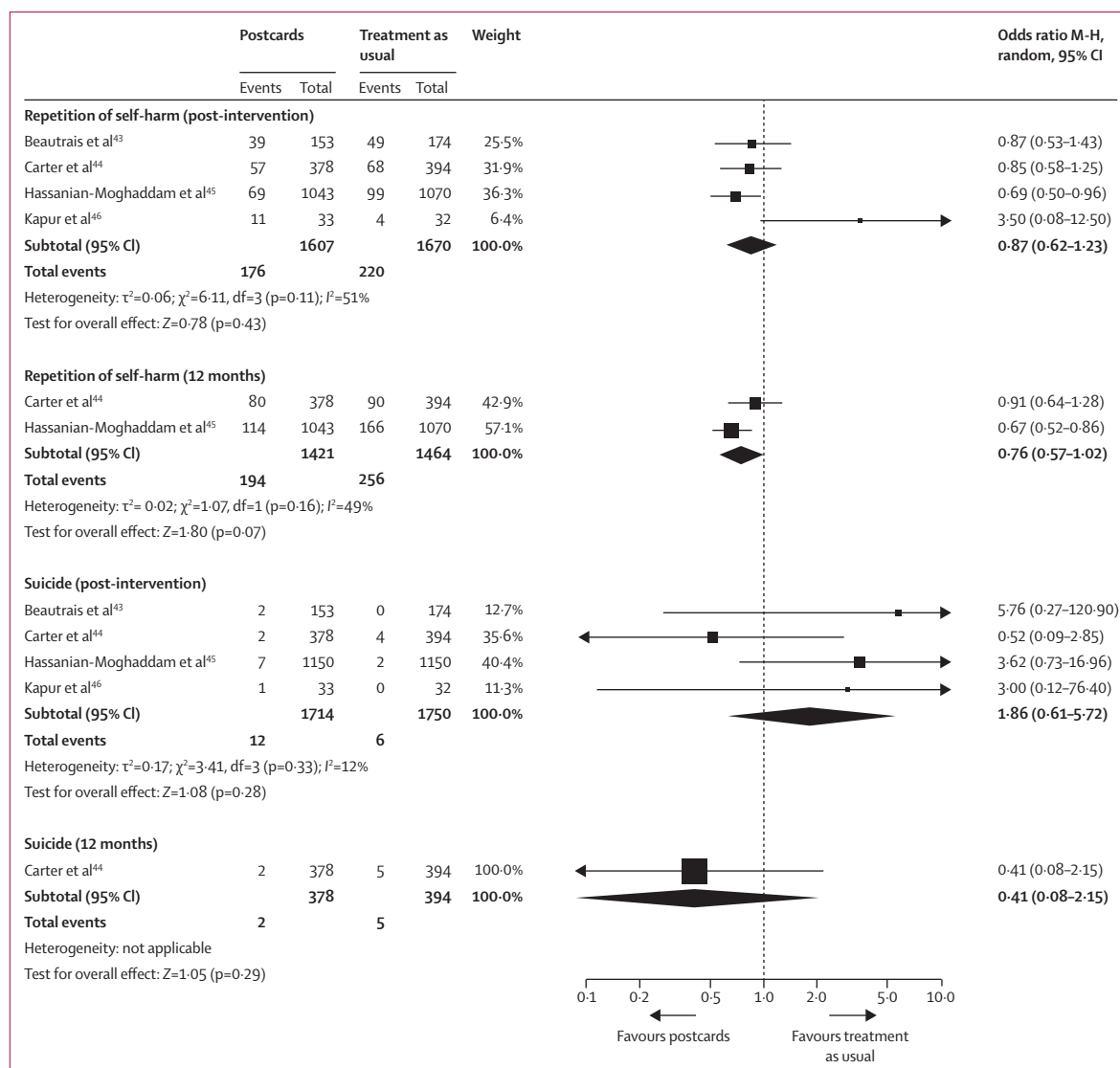
Presence of publication bias could only be formally evaluated for CBT (inclusion of ten trials minimum) with respect to repetition of self-harm at 6 months and 12 months (appendix). The relative absence of smaller studies showing no beneficial effect for CBT (to the right lower side of the funnel plots) suggested publication bias (appendix). Therefore there could be unpublished trials in which the experimental treatment was ineffective, although other potential causes of funnel plot asymmetry include differences in methodological quality between trials, true heterogeneity, and artefactual sampling variation.

**Discussion**

Since our first review in 1998,<sup>11</sup> there has been a considerable increase in the number of trials of psychosocial treatments for adults who self-harm and in the types of interventions that have been evaluated. This increase reflects concerns internationally about this issue, partly reflected in the increased attention given to the prevention of self-harm and suicide,<sup>49</sup> and

involvement of more countries in this research area, especially in Asia. However, few intervention approaches have been evaluated in multiple studies,<sup>13</sup> and therefore are not amenable to meta-analysis. We have focused on interventions for adults who have self-harmed for which there have been at least three comparable studies, thus allowing meta-analysis and hence reasonably substantiated conclusions.

There were 18 trials in which cognitive-behavioural-based psychotherapy, comprising cognitive-behavioural therapy or problem-solving therapy, or both, were compared with treatment as usual. Meta-analysis of these trials showed that fewer participants in the CBT group repeated self-harm at both 6 months and 12 months after trial entry. However, no significant treatment effect was recorded for the frequency of self-harm. There was evidence of beneficial effects for depression and hopelessness at 6 months and 12 months after treatment and for suicidal ideation and problem solving at 6 months (appendix). On the basis of data from 15 trials, there was no evidence of a significant effect of CBT on deaths by suicide, although few such events were recorded. Our finding of repetition of self-harm is consistent with those of a previous review<sup>50</sup> and a 2015 study in the US military (although not all participants engaged in self-harm in this study).<sup>51</sup> Findings from a 2015 large-scale, non-randomised, epidemiological study in Denmark<sup>52</sup> also supported the effectiveness of psychological interventions, although the actual nature of the treatment provided was not specified.



**Figure 5: Postcards versus treatment as usual**

Random effects odds ratio and accompanying 95% CIs for effectiveness on repetition of self-harm at post-intervention and at 12 months' follow-up.

M-H=Mantel-Haenszel random effects model for dichotomous data.

In three trials,<sup>36-38</sup> dialectical behaviour therapy was compared with treatment as usual in patients with predominately borderline personality disorder but with no apparent overall effect on the proportion of patients repeating self-harm at 12 months and 24 months after trial entry. There was, however, a significant treatment effect for dialectical behaviour therapy on frequency of repetition of self-harm. Most of the participants in these trials were women (appendix).

There was no evidence that case management resulted in better outcomes than treatment as usual. Similarly, no evidence was found for greater effectiveness of postcards sent on a regular basis over a 12 month period in addition to treatment as usual compared with treatment as usual alone. However, the results of a small pilot trial<sup>46</sup> might

have been an outlier. Removal of this trial from the analysis resulted in a significant treatment effect for postcards in terms of the proportions of participants repeating self-harm by the end of the intervention period. The single largest trial of this intervention appeared to show a noticeably beneficial effect of postcards.<sup>5,48</sup> This finding is particularly interesting given that more limited psychiatric resources would probably have been available in the control group (treatment as usual) in Iran, where this study was conducted, as compared with Australia, New Zealand, and the UK, all of which have better resourced services. This finding raises the possibility that such an intervention might be more useful in such low-resource settings, although further trials in countries with poorly resourced psychiatric services are desirable



to determine generalisability of the findings from the Iranian study. Additionally, the postcards used in this trial were very different from those in the other trials in that they included religious and philosophical messages in addition to general support.

As far as we are aware, we identified all trials meeting our inclusion criteria that had been completed and published up to the end of our search period. We have considerably expanded the range of outcome variables compared with the original version of our review,<sup>11</sup> which often required correspondence with authors to obtain unpublished data. Different measures were used in the assessment of some outcome variables, which might have affected the results.

Participants and clinical personnel were not blind to treatment allocation in any trial. However, we believe it is generally not possible to blind participants or clinicians to psychosocial therapy. For ten trials, moreover, outcome assessors were not blind to treatment allocation. Performance or detection bias, or both, therefore cannot be ruled out. Further biases specific to the trials included in this review are outlined in the appendix. There was evidence of possible publication bias for CBT, however, there were insufficient trials to test this in relation to the other approaches.

There have been several reviews of the efficacy of psychosocial interventions for adults who self-harm. None of those in which systematic review methodology has been used to identify interventions have included meta-analyses of treatment efficacy across multiple interventions,<sup>53–56</sup> aside from an official guideline that included data supplied by the lead author from a previous update.<sup>12</sup> One meta-analysis<sup>50</sup> that specifically focused on cognitive-behavioural interventions concluded that there was evidence for the effectiveness of brief psychological therapy. Another that focused on contact-based interventions found no evidence of effectiveness in terms of repetition of self-harm but pooled together several different types of contact-based intervention, including letters, green cards (which provided participants with emergency access to psychiatric services), and postcards, and also included trials in which not all participants had engaged in self-harm.<sup>57</sup>

There is sufficient evidence to conclude that CBT is effective in adult patients after self-harm. This approach is usually brief (maximum of ten therapy sessions with an average of three to five sessions). Although this intervention is not suitable for all patients who engage in self-harm, it should be available in services for this patient population.<sup>2</sup> Dialectical behaviour therapy can reduce the frequency of self-harm in patients with borderline personality disorder who engage in repeated acts of self-harm. The usual format for dialectical behaviour therapy is quite lengthy (a year) and includes both individual and group-based approaches.<sup>6</sup> Although sending regular postcards to patients in the year after an episode of self-harm might not reduce the proportion of

patients repeating self-harm, the findings from the trial in Iran suggest that postcard interventions might hold promise in reducing the frequency of self-harm repetition in settings where there are limited psychiatric services. Possible mechanisms for this, such as reduced distress and feeling contained or supported, might be investigated in future trials.

In view of the apparent positive benefits of CBT, studies should be conducted to identify which types of patients are most likely to benefit from this approach. Researchers evaluating psychosocial treatments should investigate whether the intervention results in changes in the psychological or social mechanisms that are the targets of treatment (eg, improved problem solving, regulating emotions, and changes in interpersonal skills) and the extent to which such changes relate to positive outcomes.<sup>58</sup> Such knowledge will help to clarify the mediators of treatment efficacy and allow therapy to be modified so that it might be more effective.

In view of the development of online therapy for a range of psychological problems,<sup>59</sup> and the apparent effectiveness of CBT in reducing repetition of self-harm, development of online programmes or tools providing this intervention should be a priority, especially given the findings of a recent trial of online self-help for people with suicidal thoughts.<sup>60</sup>

#### Contributors

KH had the idea for this Article. All authors extracted data and assessed risk of bias for included trials. KGW and TLTS conducted the statistical analyses. KH and KGW wrote the initial version of the report. All authors contributed to the interpretation of results and revision of the report and also approved the final version.

#### Declaration of interests

KH authored two of the trials included in the report and EA and DG authored one trial each. We declare no other competing interests.

#### Acknowledgments

KH is a National Institute for Health Research (NIHR) senior investigator and is supported by Oxford Health National Health Service (NHS) Foundation Trust. His personal funding from NIHR helped support this work. DG is also a NIHR senior investigator and is supported by the NIHR Collaboration for Leadership in Applied Health Research and Care West at University Hospitals Bristol NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, NIHR, or Department of Health. We thank the following for providing us with unpublished data and other information: Annette Beautrais, Greg Carter, Kate Davidson, Elspeth Guthrie, Simon Hatcher, Nusrat Husain, Nav Kapur, Chiaki Kawanishi, Marsha Linehan, Shelley McMain, Stefan Priebe, Carmen Stewart, Vojna Tapolaa, Peter Tyrer, and August Wang. We also thank Andrea Cipriani, Jessica Sharp, and Catriona Shatford for advice on data extraction and management issues.

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