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## Psychosocial interventions for self-harm in adults (Protocol)

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[Intervention Protocol]

# Psychosocial interventions for self-harm in adults

Katrina G Witt<sup>1,2</sup>, Keith Hawton<sup>3</sup>, Sarah E Hetrick<sup>4</sup>, Tatiana L Taylor Salisbury<sup>5</sup>, Ellen Townsend<sup>6</sup>, Philip Hazell<sup>7</sup>

<sup>1</sup>Orygen, Parkville, Melbourne, Australia. <sup>2</sup>Centre for Youth Mental Health, The University of Melbourne, Melbourne, Australia. <sup>3</sup>Centre for Suicide Research, Department of Psychiatry, University of Oxford, Oxford, UK. <sup>4</sup>Department of Psychological Medicine, University of Auckland, Auckland, New Zealand. <sup>5</sup>Health Service and Population Research Department, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK. <sup>6</sup>Self-Harm Research Group, School of Psychology, University of Nottingham, Nottingham, UK. <sup>7</sup>Discipline of Psychiatry, The University of Sydney School of Medicine, Sydney, Australia

**Contact address:** Katrina G Witt, [katrina.witt@orygen.org.au](mailto:katrina.witt@orygen.org.au).

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## ABSTRACT

### Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the effects of psychosocial interventions for self-harm (SH) compared to comparison types of treatment (e.g. treatment as usual, routine psychiatric care, enhanced usual care, active comparator) for adults (aged 18 years or older) who engage in SH.

## BACKGROUND

### Description of the condition

Self-harm (SH), which includes all intentional acts of self-poisoning (such as intentional drug overdoses) or self-injury (such as self-cutting), regardless of degree of suicidal intent or other types of motivation (Hawton 2003), has been a growing problem in most countries. In Australia, for example, it is estimated that there are now more than 26,000 general hospitalisations for SH each year, or a rate of 116.7 per 100,000 persons (Harrison 2014), similar to rates observed in a number of other comparable countries (Canner 2018; Griffin 2014; Morthorst 2016; Ting 2012; Wilkinson 2002). However, it is notable that rates of emergency department presentations for SH are often higher than hospitalisations (Bergen 2010; Corcoran 2015). In the UK, for example, higher rates of emergency department presentations for SH in both females (442 per 100,000) and males (362 per 100,000) have been reported (Geulayov 2016). There are also many more episodes of SH occurring in the community that do not come to the attention of clinical services. Worldwide, for example, the World Health Organization (WHO) estimates that the rate of SH may be as high as 400 per 100,000, according to self-report data (WHO 2014).

In contrast to suicide rates, rates of hospital-presenting SH are higher in females than in males in most countries (Canner 2018; Griffin 2014; Masiran 2017; Morthorst 2016; Ting 2012; Wilkinson 2002), with rates peaking in younger adults up to 24 years of age (Perry 2012). However, this difference decreases across the life cycle (Hawton 2008). SH is less common in older people, but tends to be associated with higher suicidal intent (Hawton 2008), with consequent greater risk of suicide (Murphy 2012).

For those who present to hospital, the most common method of SH is self-poisoning. Overdoses of analgesics and psychotropics, especially paracetamol or acetaminophen, are common in some countries; particularly high-income countries. Self-cutting is the next most frequent method used by those who present to hospital. However, in the community, self-cutting and other forms of self-injury are far more frequent than self-poisoning (Müller 2016).

SH is often repeated. Up to one-quarter of those who present to hospital with SH return to the same hospital within a year (Carroll 2014; Owens 2002); although some individuals may present to another hospital. Others may not present to hospital at all given that studies identifying SH repetition via self-report suggest as many as one in five report further SH episodes following a hospital presentation (Carroll 2014). Repetition is more common in individuals who have a history of previous episodes of SH, personality disorder, psychiatric treatment, and alcohol or drug misuse (Larkin 2014). Risks of repeat SH may also be associated with method. Rates of repetition are higher among those who present to hospital following self-injury alone (Carroll 2014; Lilley 2008), or combined self-injury and self-poisoning (Perry 2012), compared to those who present for self-poisoning alone.

SH is associated with suicide. The risk of death by suicide within one year among people who present to hospital following SH varies across studies from nearly 1% to over 3% (Carroll 2014; Owens 2002). This variation reflects the characteristics of the population, and the background national suicide rate. In the UK, for example, during the first year after an episode of SH, the risk of suicide is around 50 times that of the general population (Geulayov 2019).

One quarter of these deaths are estimated to occur within one month after discharge, and almost 50% by three months (Forte 2019), although the risk of suicide appears to remain elevated for a number of years (Geulayov 2019). A history of SH is the strongest risk factor for suicide across a range of psychiatric disorders. Repetition of SH further increases the risk of suicide (Zahl 2004).

SH and suicide are the result of a complex interplay between genetic, biological, psychiatric, psychosocial, social, cultural, and other factors. Psychiatric disorders, particularly mood and anxiety disorders, are associated with the largest contribution to the risk of both SH (Hawton 2013), and suicide in adults (Ferrari 2014). Personality disorders, including borderline personality disorder, are also associated with SH, particularly frequent repetition. Alcohol use may also play an important role (Ferrari 2014). Both psychological and biological factors appear to further increase vulnerability to SH. Psychological factors may include difficulties in problem-solving, low self-esteem, impulsivity, vulnerability to having pessimistic thoughts about the future (i.e. hopelessness), and a sense of entrapment. Biological factors include disturbances in the serotonergic and stress response systems (van Heeringen 2014).

### Description of the intervention

Given the role of psychological influences in people who engage in SH, psychological approaches typically involve brief individual or group-based psychological therapy. Treatment may vary in terms of initial management, location of treatment, continuity, and intensity or frequency of contact with therapists. There is also considerable variation among countries in the availability of services to provide such interventions. Consequently, there is no standard psychosocial treatment of SH. However, in high-income countries, treatment generally consists of a combination of assessment, support, and individual psychological therapies.

### How the intervention might work

Psychosocial interventions may address some of the underlying psychological risk factors associated with SH behaviours. The mechanisms of action of these interventions might help people improve their coping skills and tackle specific problems, manage psychiatric disorders, improve self-esteem, increase a sense of social connectedness, and reduce impulsivity and harmful reactions to distressing situations. What follows, is a description of the psychosocial interventions that are typically available for adults who engage in SH behaviours.

### Cognitive behavioural therapy-based psychotherapy

Cognitive behavioural therapy (CBT)-based psychotherapy helps people identify and critically evaluate the ways in which they interpret and evaluate disturbing emotional experiences and events, and aims to help them change the ways in which they deal with problems (Westbrook 2008). This is achieved in three steps: first, people are helped to change the ways in which they interpret and evaluate distressing emotions; second, they learn strategies to help them change the way in which they think about the meanings and consequences of these emotions; finally, with the benefit of modified interpretation of emotions and events, they are helped to change their behaviour and develop positive functional behaviour (Jones 2012).

Problem-solving therapy (PST) is an integral part of CBT, although it can be delivered as a therapy in and of itself. PST assumes that ineffective and maladaptive coping behaviours that drive SH might be overcome by helping the person to learn skills to actively, constructively, and effectively solve the problems he or she faces in their daily lives (Nezu 2010). PST typically involves identification of the problem, generation of a range of solutions, implementation of chosen solutions based on appraisal, and the evaluation of these solutions (D'Zurilla 2010). Treatment goals include helping people to develop a positive problem-solving orientation, use rational problem-solving strategies, reduce the tendency to avoid problem-solving, and reduce the use of impulsive problem-solving strategies.

### Dialectical behaviour therapy

In contrast to CBT and PST, which focus on changing behaviour and cognitive patterns, the focus of dialectical behavioural therapy (DBT) is to provide people with the skills to develop an awareness and acceptance of thoughts and emotions, including painful or distressing internal experiences, without judgement or attempts to alter, suppress, avoid, or otherwise change these experiences (Lynch 2006). The primary treatment goals of DBT are three-fold: to reduce SH, reduce behaviours that interfere with the success of treatment, such as treatment non-adherence, and reduce any other factors that may adversely affect the person's quality of life (e.g. frequency or duration of psychiatric hospitalisations) (Linehan 1993).

### Mentalisation-based therapy

Mentalisation refers to the ability to understand the behaviour of both one's self and others in terms of motivational and emotional states (Allen 2008). Maladaptive and impulsive coping behaviours, including SH, are presumed to arise from a disrupted ability to engage in these processes. In mentalisation-based therapy (MBT), the goal is to help people understand their emotions and behaviours, and develop strategies to regulate them to minimise the risk that they will engage in SH during times of distress.

### Case management

"In its simplest form...case management is a means of coordinating services. Each...person is assigned a 'case manager' who is expected to assess that person's needs, develop a care plan, arrange for suitable care to be provided, monitor the quality of the care provided, and maintain contact with the person" (Marshall 2000a). Case management might have a significant role in the aftercare of people who engage in SH because many of them demonstrate poor treatment adherence, and the varied nature of the problems these individuals are often facing (Lizardi 2010).

### Treatment adherence enhancement approaches

These approaches include specific efforts to maintain contact with people, such as following-up in the community with those who fail to attend outpatient appointments. It may also include strategies to encourage adherence with treatment.

Having the same clinician assess a person initially, and provide any aftercare treatment, may increase treatment adherence. It may also be advantageous, since the clinician is already acquainted with the person's problems and needs.

### Remote contact interventions

Remote contact interventions, which may include letters, brief text messages delivered by telephone, telephone calls, and postcards, are low resource and non-intrusive interventions that seek to maintain long-term contact with people. These interventions provide a sense of ongoing concern, and may mitigate the sense of social isolation reported by many people who engage in SH. They may also help to improve their knowledge about triggers and warning signs for SH, provide them with information on alternative coping behaviours to SH, and where they can access help (Milner 2016).

These interventions may also be combined with emergency card interventions, which encourage people to seek help when they feel distressed, and offer on-demand emergency contact with psychiatric services or inpatient care. The aim is to reduce the risk of SH by facilitating rapid access to care.

### Other multimodal interventions

Any of the above active psychosocial interventions may also be combined into a multimodal approach (Högberg 2008).

### Why it is important to do this review

SH is a major social and healthcare problem. It represents significant morbidity, is often repeated, and is linked with suicide. Many countries now have suicide prevention strategies, all of which include a focus on improved management of people presenting with SH (WHO 2014). SH also leads to substantial healthcare costs (Sinclair 2011). In the UK, the overall median cost per episode of SH has been estimated to be £809, although costs are significantly higher for cases of combined self-injury and self-poisoning, compared to either self-injury or self-poisoning alone. These costs are mainly attributable to health-service level contact (i.e. inpatient stay or admission to intensive care; Tsiachristas 2017).

In the UK, the National Collaborating Centre for Mental Health (NCCMH) produced the first guideline on the treatment of SH behaviours in 2004 (NCCMH 2004). This guideline focused on the short-term physical and psychological management of SH. They updated this guidance in 2011, using interim data from a previous version of this review as the evidence-base, and focused on the longer-term psychological management of SH (NICE 2011). Subsequently, similar guidelines have been published by the Royal College of Psychiatrists (Royal College of Psychiatrists 2014), the Royal Australian and New Zealand College of Psychiatrists (Carter 2016), and a number of German Professional Associations and Societies (Plener 2016), amongst others (Courtney 2019).

In 2021, the guidance contained in the 2011 NICE guidelines for the longer-term management of SH will be due for updating. Therefore, we are updating our review (Hawton 2016), in order to provide contemporary evidence to guide clinical policy and practice.

### OBJECTIVES

To assess the effects of psychosocial interventions for self-harm (SH) compared to comparison types of treatment (e.g. treatment as usual, routine psychiatric care, enhanced usual care, active comparator) for adults (aged 18 years or older) who engage in SH.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We will consider all randomised controlled trials (RCT) of specific psychosocial interventions versus treatment as usual, routine psychiatric care, enhanced usual care, active comparator, or a combination of these, in the treatment of adults with a recent (within six months of trial entry) hospital presentation for SH. We will include RCTs (including cluster-RCTs and cross-over trials), regardless of publication type or language; however, we will exclude quasi-randomised trials.

#### Types of participants

While exact eligibility criteria often differ both within and between regions and countries (Witt 2019), we will include participants of both sexes and all ethnicities, who are 18 years and older, with a recent (i.e. within six months of trial entry) hospital presentation for SH.

We will define SH as all intentional acts of self-poisoning (such as intentional drug overdoses) or self-injury (such as self-cutting), regardless of the degree of suicidal intent or other types of motivation (Hawton 2003). This definition includes acts intended to result in death ('attempted suicide'), those without suicidal intent (e.g. to communicate distress, to temporarily reduce unpleasant feelings; sometimes termed 'non-suicidal self-injury'), and those with mixed motivation. We will not distinguish between attempted suicide and non-suicidal self-injury in this review, because there is a high level of co-occurrence between them, and the two cannot be distinguished in any reliable way, including on levels of suicidal intent (Klonsky 2011). Lastly, the motivations for SH are complex and can change, even within a single episode (De Beurs 2018).

We will exclude trials in which participants were hospitalised for suicidal ideation only (i.e. without evidence of SH).

#### Types of interventions

Categorisation of the interventions in this review will be informed by the trials themselves, and based on consensus discussions among members of the review team, who have considerable experience in both research and clinical practice related to SH. However, based on the previous version of this review (Hawton 2016), we anticipate the following groupings:

#### Interventions

These could include:

1. Cognitive behavioural therapy-based psychotherapy;
2. Dialectical behavioural therapy;
3. Mentalisation-based therapy;
4. Case management;
5. Treatment adherence enhancement approaches;
6. Remote contact interventions;
7. Other multimodal interventions.

#### Comparators

Treatment as usual (TAU) is likely to vary widely between settings and between studies conducted over different time periods (Witt

2018). Based on previous work, we defined TAU as routine clinical care that the person would receive had they not been included in the study (i.e. routine care or 'standard disposition'; Hunt 2013). Other comparators could include no specific treatment, or enhanced usual care, which refers to TAU that has, in some way, been supplemented, such as by providing psychoeducation, assertive outreach, or more regular contact with case managers, and standard assessment approaches.

#### Types of outcome measures

For all outcomes, we are primarily interested in quantifying the effect of treatment assignment to the intervention at baseline, regardless of whether the intervention was received as intended (i.e. the intention-to-treat effect).

#### Primary outcomes

The primary outcome measure in this review will be the occurrence of repeated SH over a maximum follow-up period of two years. Repetition of SH may be identified through self-report, collateral report, clinical records, or research monitoring systems. As we wish to incorporate the maximum data from each trial, we will include both self-reported and hospital records of SH, where available. Preference will be given to clinical records over self-report where a study reports both measures. We will also report proportions of participants repeating SH, frequency of repeat episodes, and time to SH repetition (if available).

#### Secondary outcomes

Given increasing interest in the measurement of outcomes of importance to those who engage in SH, we plan to analyse data for the following secondary outcomes (where available) over a maximum follow-up period of two years (Owens 2020).

#### Treatment adherence

This may be assessed using a range of measures of adherence, including: pill counts, changes in blood measures, and the proportion of participants that both started and completed treatment.

#### Depression

This will be assessed as either continuous data, by scores on psychometric measures of depression symptoms, for example total scores on the Beck Depression Inventory (BDI; Beck 1961), or scores on the depression sub-scale of the Hospital Anxiety and Depression Scale (HADS; Zigmond 1983), or as dichotomous data as the proportion of participants who meet defined diagnostic criteria for depression.

#### Hopelessness

This will be assessed as either continuous data, by scores on psychometric measures of hopelessness, for example, total scores on the Beck Hopelessness Scale (BHS; Beck 1974), or as dichotomous data as the proportion of participants reporting hopelessness.

#### General functioning

This will be assessed as either continuous data, by scores on psychometric measures of general functioning, for example, total scores on the Global Assessment of Functioning (GAF; APA 2000),

or as dichotomous data as the proportion of participants reporting improved general functioning.

#### **Social functioning**

This will be assessed as either continuous data, by scores on psychometric measures of social functioning, for example, total scores on the Social Adjustment Scale (SAS; [Weissman 1999](#)), or as dichotomous data as the proportion of participants reporting improved social functioning.

#### **Suicidal ideation**

This will be assessed as either continuous data, by scores on psychometric measures of suicidal ideation, for example, total scores on the Beck Scale for Suicidal Ideation (BSS; [Beck 1988](#)), or as dichotomous data as the proportion of participants reaching a defined cut-off for ideation.

#### **Suicide**

This may include register-recorded deaths, or reports from collateral informants, such as family members or neighbours.

### **Search methods for identification of studies**

#### **Electronic searches**

We will search the following databases, using relevant subject headings (controlled vocabularies) and search syntax as appropriate for each resource: Cochrane Common Mental Disorders Specialized Register ([Appendix 1](#)), Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE Ovid, Embase Ovid, and PsycINFO Ovid ([Appendix 2](#)).

As we are updating a previous version of this review ([Hawton 2016](#)), we will apply a date restriction of 2015 onwards. However, we will not apply any restrictions on language or publication status to the searches.

We will search for retraction statements and errata once we have selected the included studies, and will rerun all searches close to publication if the initial search date is longer than 12 months.

We will also search the World Health Organization International Clinical Trials Registry Platform, and the US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov to identify ongoing trials.

#### **Searching other resources**

##### **Conference abstracts**

In addition to conference abstracts retrieved via the main electronic search, we will also screen the proceedings of recent (last five years) conferences organised by the largest scientific committees in the field:

1. International Association for Suicide Prevention (both global congresses and regional conferences), and;
2. Joint International Academy of Suicide Research and American Foundation for Suicide Prevention International Summits on Suicide Research.

#### **Reference lists**

We will check the reference lists of all relevant RCTs, and the reference lists of major reviews that included a focus on psychosocial interventions for SH in adults.

#### **Correspondance**

We will consult the corresponding authors of trials, and other experts in the field to find out if they are aware of any ongoing or unpublished RCTs on the treatment of adults who engage in SH which are not identified by the electronic searches.

### **Data collection and analysis**

#### **Selection of studies**

Review authors KW, KH, and one of either SH, TTS, ET, or PH, will independently assess the titles of reports identified by the electronic search for eligibility. We will distinguish between:

1. Eligible or potentially eligible trials for retrieval, in which any psychosocial intervention is compared with a comparator (i.e. TAU, routine care, standard disposition, no specific treatment, enhanced usual care);
2. Ineligible, general treatment trials, not for retrieval (i.e. where there is no control treatment).

All trials identified as potentially eligible for inclusion will then undergo a second screening. Pairs of review authors, working independently from one another, will screen the full text of eligible or potentially eligible trials to identify whether the trial meets our inclusion criteria. We will resolve disagreements in consultation with the senior review author (KH). Where disagreements cannot be resolved from the information reported in the trial, or where it is unclear whether the trial satisfied our inclusion criteria, we will contact corresponding trial authors for additional clarification.

We will identify and exclude duplicate records, and collate multiple reports of the same trial, so that each trial, rather than each report, represents the unit of interest in the review. We will record the selection process in sufficient detail to complete a PRISMA flow diagram, and will complete a 'Characteristics of excluded studies' table ([Liberati 2009](#)).

#### **Data extraction and management**

KW and one of either SH, TTS, ET, or PH will independently extract data from the included trials, using a standardised extraction form. Where there are any disagreements, they will resolve them in consensus discussions with KH.

Data extracted from each eligible trial will include:

1. Participant information: number randomised, number lost to follow-up or withdrawn, number analysed, mean or median age, sex composition, diagnoses, diagnostic criteria, inclusion criteria, and exclusion criteria;
2. Methods: trial design, total duration of the trial, details of any 'run in' period (if applicable), number of trial centres and their location, setting, and date;
3. Intervention(s): details of the intervention, including dose, duration, whether concomitant treatments were permitted and details of these treatments, and any excluded treatments;

4. Comparator(s): details on the comparator, including dose, duration, whether concomitant treatments were permitted and details of these treatments, and any excluded treatments;
5. Outcomes: raw data for each eligible outcome (see [Types of outcome measures](#)), details of other outcomes specified and reported, and time points at which outcome were reported;
6. Notes: source of trial funding, and any notable conflicts of interest of trial authors.

We will extract both dichotomous and continuous outcomes data from eligible trials. As the use of non-validated psychometric scales is associated with bias, we will extract continuous data only if the psychometric scale used to measure the outcome of interest has been previously published in a peer-reviewed journal, and was not subjected to item, scoring, or other modification by the trial authors ([Marshall 2000b](#)).

We plan the following main comparisons:

1. Cognitive behavioural therapy (CBT)-based psychotherapy (e.g. CBT, problem-solving therapy [PST]) versus TAU or another comparator;
2. Dialectical behaviour therapy (DBT) versus TAU or another comparator;
3. Mentalisation-based therapy (MBT) versus TAU or another comparator;
4. Case management versus TAU or another comparator;
5. Treatment adherence enhancement approaches versus TAU or another comparator;
6. Remote contact interventions versus TAU or another comparator;
7. Other multimodal interventions versus TAU or another comparator.

#### Assessment of risk of bias in included studies

Highly biased studies are more likely to overestimate treatment effectiveness ([Moher 1998](#)). KW and one of either SH, TTS, ET, or PH will independently evaluate the risk of bias for the primary outcome (i.e. repetition of SH at post-intervention) by using the Cochrane Risk of Bias tool, version 2.0 ([Sterne 2019](#)). This tool encourages consideration of the following domains:

1. Bias in the randomisation process;
2. Deviations from the intended intervention (assignment to intervention);
3. Missing outcome data;
4. Bias in the measurement of the outcome;
5. Bias in the selection of the reported result.

For cluster-RCTs, we will also evaluate:

1. Bias arising from the timing of identification and recruitment of participants.

Two review authors will independently judge each source of potential bias low risk, high risk, or some concerns. They will then make an overall risk of bias judgement for each study, by combining ratings across these six domains. Specifically, if any of the above domains are rated at high risk, the overall risk of bias judgement will be rated at high risk. We will report this overall judgement, which

can also be low risk, high risk, or some concerns, in the text of the review, and in the 'Risk of bias' tables.

Where inadequate details are provided in the original report, we will contact corresponding trial authors to provide clarification. We will resolve disagreements through discussions with KH.

We will process the 'Risk of bias' assessments using the recommended template, and make them available as electronic supplements.

#### Measures of treatment effect

##### Dichotomous outcomes

We will summarise dichotomous outcomes, such as the number of participants engaging in a repeat SH episode, or number of deaths by suicide, using the summary odds ratio (OR) and the accompanying 95% confidence interval (CI), as the OR is the most appropriate effect size statistic for summarising associations between two dichotomous groups ([Fleiss 1994](#)).

##### Continuous outcomes

For outcomes measured on a continuous scale, we will use mean differences (MD) and accompanying 95% CI where the same outcome measure is used. Where different outcome measures are used, we will use the standardised mean difference (SMD) and its accompanying 95% CI.

We will aggregate trials in a meta-analysis only if treatments are sufficiently similar. For trials that cannot be included in a meta-analysis, we will provide narrative descriptions of the results.

##### Hierarchy of outcomes

Where a trial measures the same outcome, for example depression, in two or more ways, we plan to use the most common measure across trials in any meta-analysis. We also plan to report scores from other measures in a supplementary table.

##### Timing of outcome assessment

The primary end point for this review will be post-intervention (i.e. at the conclusion of the treatment period). We will also report outcomes for the following secondary end points (where data are available):

1. Between zero and six months after the conclusion of the treatment period;
2. Between six and 12 months after the conclusion of the treatment period;
3. Between 12 and 24 months after the conclusion of the treatment period.

Where there is more than one outcome assessment within a time period, we will use data from the last assessment in the time period, unless different outcomes are assessed at different time points. For treatment adherence, we also plan to use within-treatment results.

#### Unit of analysis issues

##### Zelen design trials

Trials in this area are increasingly using Zelen's method, in which consent is obtained subsequent to randomisation and treatment allocation ([Witt 2019](#)). This design may lead to bias if,

for example, participants allocated to one particular arm of the trial disproportionately refuse to provide consent for participation or, alternatively, if participants only provide consent if they are allowed to cross over to the other treatment arm (Torgerson 2004). Given the uncertainty of whether to use data for the primary outcome based on all those randomised to the trial, or only those who consent to participation, should we identify a trial using Zelen's method, we plan to extract data using both sources of data, where possible. We also plan to conduct sensitivity analyses to investigate what impact, if any, the inclusion of these trials may have on the pooled estimate of treatment effectiveness.

### Cluster-randomised trials

Cluster randomisation, for example by clinician or general practice, can lead to overestimation of the significance of a treatment effect, resulting in an inflation of the nominal type I error rate, unless appropriate adjustment is made for the effects of clustering (Donner 2002; Kerry 1998). Should any included trial use this design, we will follow the guidance outlined in Higgins 2019a. Specifically, where possible, we will analyse data using measures that statistically accounted for the cluster design. Where this is not possible, we will analyse data using the effective sample size.

### Cross-over trials

A primary concern with cross-over trials is the carry-over effect, in which the effect of the intervention treatment (e.g. pharmacological, physiological, psychological) influences the participant's response to the subsequent control condition (Elbourne 2002). As a consequence, on entry to the second phase of the trial, participants may differ systematically from their initial state, despite a wash-out phase. In turn, this may result in a concomitant underestimation of the effectiveness of the treatment intervention (Curtin 2002a; Curtin 2002b). Should we identify any cross-over trials, we will only extract data from the first phase of the trial, prior to cross-over, to protect against the carry-over effect.

### Studies with multiple treatment arms

Should any trial include multiple treatment groups where the intervention arms are sufficiently similar, for example, where comparison is made between two interventions of the same type, we will combine dichotomous data. For outcomes reported on a continuous scale, we will combine data using the formula in Higgins 2011.

Where the interventions are not sufficiently similar, we will split the comparator arm data following the advice in Higgins 2011.

### Studies with adjusted effect sizes

Where trials report both unadjusted and adjusted effect sizes, we will only include observed, unadjusted effect sizes.

### Dealing with missing data

We will not impute missing data, as we consider that the bias that would be introduced by doing this would outweigh any benefit of increased statistical power that may have been gained by including imputed data. However, where authors omitted standard deviations (SD) for continuous measures, we first plan to contact corresponding authors to request missing data. If missing data are not provided, we will calculate missing SD using other data from the trial, such as CIs, based on methods outlined in Higgins 2019b.

### Assessment of heterogeneity

Between-study heterogeneity can be assessed using either the Chi<sup>2</sup> or I<sup>2</sup> statistics. However, in this review, we will only use only the I<sup>2</sup> statistic to quantify inconsistency, as this is considered to be more reliable (Deeks 2019). The I<sup>2</sup> statistic indicates the percentage of between-study variation due to chance, and can take any value from 0% to 100% (Deeks 2019).

We will use the following values to denote relative importance of heterogeneity, as per Deeks 2019:

1. Unimportant: 0% to 40%;
2. Moderate: 30% to 60%;
3. Substantial: 50% to 90%;
4. Considerable: 75% to 100%.

We will take the magnitude and direction of effects and strength of evidence for heterogeneity into account (e.g. the CI for I<sup>2</sup>).

Where we find substantial levels of heterogeneity, we will explore reasons for this heterogeneity (see [Subgroup analysis and investigation of heterogeneity](#) for details).

### Assessment of reporting biases

Reporting bias occurs when the decision to publish a particular trial is influenced by the direction and significance of the results (Egger 1997). Research suggests, for example, that trials with statistically significant findings are more likely to be submitted for publication, and subsequently, be accepted for publication, leading to possible overestimation of the true treatment effect (Hopewell 2009).

To assess whether trials included in any meta-analysis are affected by reporting bias, we plan to enter data into a funnel plot when a meta-analysis includes results of at least ten trials. Should evidence of any small study effects be identified, we plan to explore reasons for funnel plot asymmetry, including the presence of possible publication bias (Egger 1997).

### Data synthesis

For the purposes of this review, we will calculate the pooled OR and accompanying 95% CI using the random-effects model, as this is the most appropriate model for incorporating heterogeneity between studies (Deeks 2019). We will use the Mantel-Haenszel method for dichotomous data, and the inverse variance method for continuous data. We will conduct all analyses in Review Manager 5.4 (Review Manager 2020).

### Subgroup analysis and investigation of heterogeneity

#### Subgroup analyses

We plan to undertake the following subgroup analyses where there are sufficient data to do so:

1. Sex (males versus females);
2. Repeater status (first SH episode versus repeat SH episode).

It will only be possible to undertake these subgroup analyses providing that randomisation has been stratified by these factors, otherwise, there is the risk that doing so will lead to confounding.

Given the increasing use of enhanced usual care, rather than TAU in trials in this area, we also plan to undertake subgroup analyses

to determine whether comparator choice influences the pattern of results observed (Witt 2019).

Formal tests for subgroup differences will be undertaken in Review Manager 5.4 (Review Manager 2020).

### Investigation of heterogeneity

Should any meta-analysis be associated with substantial levels of between-study heterogeneity (i.e.  $I^2 \geq 75\%$ ), or visual inspection of the forest plot identifies a trial that has a very different result to the general pattern of the others, KW and KH will firstly independently triple-check data to ensure these were correctly entered. Assuming data were entered correctly, we will investigate the source of this heterogeneity using a formal statistical approach as outlined in Viechtbauer 2020.

### Sensitivity analysis

We plan to carry out the following sensitivity analyses, where appropriate, to test whether key methodological factors or decisions may have influenced the main result:

1. Where a trial made use of Zelen's method of randomisation (see [Unit of analysis issues](#));
2. Where a trial contributed to substantial between-study heterogeneity (see [Subgroup analysis and investigation of heterogeneity](#)).

### Summary of findings and assessment of the certainty of the evidence

#### Summary of findings table

For each comparison we plan to construct a 'Summary of findings' table for our primary outcome measure, repetition of SH post-intervention, following the recommendations outlined in Schünemann 2019. These tables provide information concerning the overall quality of the evidence from all included trials that measured the outcome. We will assess the quality of evidence across the following domains:

1. Risk of bias assessment;
2. Indirectness of evidence;
3. Unexplained heterogeneity or inconsistency of results;
4. Imprecision of effect estimates;
5. Potential publication bias.

For each of these domains, we will downgrade the evidence from high quality by one level (for serious) or by two levels (for very serious). For risk of bias, we will downgrade this domain by one level when we rate any of the sources of risk of bias (as described in [Assessment of risk of bias in included studies](#)) at high risk for any of the studies included in the pooled estimate, or by two levels when we rate multiple studies at high risk for any of these sources. For indirectness of evidence, we will consider the extent to which trials included in any meta-analysis use proxy measures to ascertain repetition of SH; we will downgrade this domain by one level if one

study uses proxy measures, and by two levels if multiple studies use proxy measures. For unexplained heterogeneity or inconsistency of results, we will downgrade this domain by one level where the  $I^2$  value indicates substantial levels of heterogeneity, or by two levels where the  $I^2$  value indicates considerable levels of heterogeneity. For imprecision, we will downgrade this domain by one level where the 95% CI for the pooled effect includes the null value. Finally, for the potential publication bias domain, we will consider any evidence of funnel plot asymmetry (if available), as well as other evidence such as suspected selective availability of data, and will downgrade by one or more levels where publication bias is suspected.

We will use these domains to rate the overall quality of evidence for the primary outcome according to the following:

1. High quality: further research is very unlikely to change our confidence in the estimate of effect;
2. Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect, and may change the estimate;
3. Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect, and may change the estimate;
4. Very low quality: we are very uncertain about the estimate.

We will construct 'Summary of findings' tables using GRADEpro GDT software (GRADEpro GDT 2015).

### Reaching conclusions

We will base our conclusions only on findings from the quantitative or narrative synthesis of the studies included in this review. Our recommendations for practice and research will suggest priorities for future research, and outline the remaining uncertainties in the area.

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## APPENDICES

### Appendix 1. Cochrane Common Mental Disorders Specialized Register

The Cochrane Common Mental Disorders Group (CCMD) maintains an archived controlled trials register known as the CCMDCTR. This specialized register contains over 40,000 reference records (reports of RCTs) for anxiety disorders, depression, bipolar disorder, eating disorders, self-harm, and other mental disorders within the scope of this Group. The CCMDCTR is a partially studies-based register with more than 50% of reference records tagged to around 12,500 individually PICO-coded study records. Reports of studies for inclusion in the register were collated from (weekly) generic searches of key bibliographic databases to June 2016, which included: MEDLINE (1950 onwards), Embase (1974 onwards), PsycINFO (1967 onwards), quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL), and review-specific searches of additional databases. Reports of studies were also sourced from international trials registries, drug companies, the handsearching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-

analyses. Details of [CCMD's core search strategies](#) (used to identify RCTs) are on the Group's website, with an example of the core MEDLINE search displayed below.

[MeSH Headings]: eating disorders/ or anorexia nervosa/ or binge-eating disorder/ or bulimia nervosa/ or female athlete triad syndrome/ or pica/ or hyperphagia/ or bulimia/ or self-injurious behavior/ or self mutilation/ or suicide/ or suicidal ideation/ or suicide, attempted/ or mood disorders/ or affective disorders, psychotic/ or bipolar disorder/ or cyclothymic disorder/ or depressive disorder/ or depression, postpartum/ or depressive disorder, major/ or depressive disorder, treatment-resistant/ or dysthymic disorder/ or seasonal affective disorder/ or neurotic disorders/ or depression/ or adjustment disorders/ or exp antidepressive agents/ or anxiety disorders/ or agoraphobia/ or neurocirculatory asthenia/ or obsessive-compulsive disorder/ or obsessive hoarding/ or panic disorder/ or phobic disorders/ or stress disorders, traumatic/ or combat disorders/ or stress disorders, post-traumatic/ or stress disorders, traumatic, acute/ or anxiety/ or anxiety, castration/ or koro/ or anxiety, separation/ or panic/ or exp anti-anxiety agents/ or somatoform disorders/ or body dysmorphic disorders/ or conversion disorder/ or hypochondriasis/ or neurasthenia/ or hysteria/ or munchausen syndrome by proxy/ or munchausen syndrome/ or fatigue syndrome, chronic/ or obsessive behavior/ or compulsive behavior/ or behavior, addictive/ or impulse control disorders/ or firesetting behavior/ or gambling/ or trichotillomania/ or stress, psychological/ or burnout, professional/ or sexual dysfunctions, psychological/ or vaginismus/ or Anhedonia/ or Affective Symptoms/ or \*Mental Disorders/ OR [Title/ Author Keywords]: (eating disorder\* or anorexia nervosa or bulimi\* or binge eat\* or (self adj (injur\* or mutilat\*)) or suicide\* or suicidal or parasuicid\* or mood disorder\* or affective disorder\* or bipolar i or bipolar ii or (bipolar and (affective or disorder\*)) or mania or manic or cyclothymic\* or depression or depressive or dysthymi\* or neurotic or neurosis or adjustment disorder\* or antidepress\* or anxiety disorder\* or agoraphobia or obsess\* or compulsi\* or panic or phobi\* or ptsd or posttrauma\* or post trauma\* or combat or somatoform or somati#ation or medical\* unexplained or body dysmorphi\* or conversion disorder or hypochondria\* or neurastheni\* or hysteria or munchausen or chronic fatigue\* or gambling or trichotillomania or vaginismus or anhedoni\* or affective symptoms or mental disorder\* or mental health).tw,kf. AND [RCT filter]: (controlled clinical trial.pt. or randomised controlled trial.pt. or (randomi#ed or randomi#ation).ab,ti. or randomly.ab. or (random\* adj3 (administ\* or allocat\* or assign\* or class\* or control\* or determine\* or divide\* or distribut\* or expose\* or fashion or number\* or place\* or recruit\* or subsitut\* or treat\*)).ab. or placebo\*.ab,ti. or drug therapy.fs. or trial.ab,ti. or groups.ab. or (control\* adj3 (trial\* or study or studies)).ab,ti. or ((singl\* or doubl\* or tripl\* or trebl\*) adj3 (blind\* or mask\* or dummy\*)).mp. or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or randomised controlled trial/ or pragmatic clinical trial/ or (quasi adj (experimental or random\*)).ti,ab. or ((waitlist\* or wait\* list\* or treatment as usual or TAU) adj3 (control or group)).ab.)

Records were screened for reports of RCTs within the scope of the Cochrane Common Mental Disorders Group. Secondary reports of RCTs were tagged to the appropriate study record

The information specialist with CCMD will cross-search the CCMDCTR-Studies and References register using the following terms (all fields):

(suicid\* or parasuicid\* or "auto mutilat\*" or automutilat\* or "self destruct\*" or selfdestruct\* or self-harm\* or selfharm\* or "self immolat\*" or selfimmolat\* or "self inflict\*" or selfinflict\* or "self injur\*" or selfinjur\* or selfmutilat\* or "self mutilat\*" or "self poison\*" or selfpoison\* or (self adj2 (cut or cuts or cutting or cutter? or burn or burns or burning or bite or bites or biting or hit or hits or hitting)) or "head bang\*" or headbang\* or "over dose\*" or overdos\* or NSSI\* or nonsuicid\* or non-suicid\*)

## Appendix 2. MEDLINE, Embase, PsycINFO Ovid search strategy

We will perform an Ovid cross-search on MEDLINE, PsycInfo, and Embase (2015 onwards), using the following terms:

1. Automutilation/ or Self-injurious Behavior/ or Self-destructive Behavior/ or Self-mutilation/ or Self-inflicted Wounds/
2. Suicidal Behavior/ or Suicide/ or Suicidal Ideation/ or Attempted Suicide/ or Suicide, Attempted/ or Self Poisoning/ or Suicide Prevention/ or Suicide Prevention Centers/ or Suicidology/
3. (suicid\* or parasuicid\* or auto mutilat\* or automutilat\* or self destruct\* or selfdestruct\* or self-harm\* or selfharm\* or self immolat\* or selfimmolat\* or self inflict\* or selfinflict\* or self injur\* or selfinjur\* or selfmutilat\* or self mutilat\* or self poison\* or selfpoison\* or (self adj2 (cut or cuts or cutting or cutter? or burn or burns or burning or bite or bites or biting or hit or hits or hitting)) or head bang\* or headbang\*).ti,ab,kf,kw,id.
4. (NSSI? or ((nonsuicid\* or non-suicid\*) adj2 (self\* or injur\*))).ti,ab,kf,kw,id.
5. (Overdose/ or Drug Overdose/ or Drug Overdoses/) and prevent\*.af.
6. or/1-5
7. Randomized Controlled Trial/
8. Randomized Controlled Trial.pt.
9. Randomization/
10. Random Allocation/
11. Controlled Clinical Trial/
12. Controlled Clinical Trial.pt.
13. Double-blind Method/ or Single-blind Method/
14. (randomi#ed or randomi#ation or randomi#ing).ti,ab,kf,kw,id.
15. (RCT or "at random" or (random\* adj3 (administ\* or allocat\* or assign\* or class\* or cluster or crossover or cross-over or control\* or determine\* or divide\* or division or distribut\* or expose\* or fashion or number\* or place\* or pragmatic or quasi or recruit\* or split or subsitut\* or treat\*))).ti,ab,kf,kw,id.
16. trial.ti.

17. placebo/ or (placebo and (allocat\* or assign\* or control\* or group\*)).ti,ab,kf,kw,id.
  18. (control\* adj3 group\*).ab.
  19. (control\* and (trial or study or group\*) and (waitlist\* or wait\* list\* or ((treatment or care) adj2 usual))).ti,ab,kf,kw,id.
  20. ((single or double or triple or treble) adj2 (blind\* or mask\* or dummy)).ti,ab,kf,kw,id.
  21. treatment effectiveness evaluation/
  22. or/7-21
  23. 6 and 22
  24. (2015\* or 2016\* or 2017\* or 2018\* or 2019\* or 2020\*).yr,dc,dp,dt,ep,ez.
  25. 23 and 24
- [De-duplicate line 25 within Ovid]

## WHAT'S NEW

Date	Event	Description
1 July 2020	New citation required and major changes	We updated the protocol developed for <a href="#">Hawton 2016</a>

## HISTORY

Protocol first published: Issue 7, 2020

## CONTRIBUTIONS OF AUTHORS

KH had the idea for the review. KW wrote the initial version of the protocol, and all authors contributed to the writing of drafts. All authors approved the final version of the protocol for publication.

## DECLARATIONS OF INTEREST

KW: no declarations of interest to report in relation to this protocol  
 KH: no declarations of interest to report in relation to this protocol  
 SH: no declarations of interest to report in relation to this protocol  
 TTS: no declarations of interest to report in relation to this protocol  
 ET: no declarations of interest to report in relation to this protocol  
 PH: no declarations of interest to report in relation to this protocol

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### Internal sources

- No sources of support supplied

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- National Institute of Health Research (NIHR), UK

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