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[Intervention Protocol]

Interventions for mood, anxiety disorders or self-harm in young offenders

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ABSTRACT

Objectives

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

The objective of this review is to assess the effects of interventions for mood disorders, anxiety disorders or self-harm behaviours in young offenders.



BACKGROUND

Description of the condition

Psychiatric disorders affect approximately 15% of adolescents globally (Polanczyk 2015) but in incarcerated juveniles, the prevalence is elevated to between 40% and 90% (Gaete 2018; Livanou 2016; Rijo 2016), with mood and anxiety disorders the most common (Underwood 2016). Those with mood or anxiety disorders are more likely to engage in self-harm (Hawton 2012a), which is associated with an increased risk of future suicide (Hawton 2020). Therefore the mental health of young offenders is of considerable concern. This review will focus on mood disorders, anxiety disorders or self-harm.

Mood disorders

Mood disorders, also called affective disorders, are a group of psychiatric illnesses where a disturbance in mood is the main feature. Although mood disturbance occurs in almost all psychiatric illnesses, only in affective disorders is it considered the defining feature (Ellenbroek 2016). Disturbances in mood can take the form of reduced mood (depression) or elevated mood (mania). In general, two major types of mood disorder can be distinguished: major depressive disorder (MDD) and bipolar disorder.

Major depressive disorder (MDD) is characterised by severe and pervasive low mood, leading to intense sadness and hopelessness. The diagnosis of MDD requires the presence of at least five different symptoms, one of which is either depressed mood or marked loss of interest or pleasure in daily activities (APA 2013). In adolescents, depression is often under-diagnosed, possibly due to fluctuating mood and irritability in this age group (Thapar 2014). The prevalence of depression in adolescents is estimated to be 11% (Merinkagas 2010) while in young offenders it is higher still at 20% (Chitsabesan 2006; Gaete 2018; Rijo 2016). Evidence from a 25year longitudinal study of a birth cohort of just under 1000 New Zealand children, showed that MDD in teenage years is associated with adverse mental health outcomes in early adulthood, including recurrence of depression, welfare dependence and unemployment (Fergusson 2007). Depression has been identified as a risk factor for self harm in adolescents (Hawton 2012a; Junker 2017; Mars 2014; Moran 2012).

Bipolar disorder consists of both manic and depressive episodes, separated by periods of normal mood (APA 2013). In adolescents, depression and mania can often occur simultaneously, making bipolar disorder harder to diagnose (Geller 2004; Lewinsohn 1995). In juvenile populations, manic episodes can first occur years after the initial MDD episode (Lewinsohn 1995), and therefore it is expected that some adolescents diagnosed with MDD will go on to receive a diagnosis of bipolar disorder in adulthood (Ryan 2004). Irritability, aggression, and impulsivity are major features of adolescent bipolar disorder. These behaviours can lead to offences dealt with by the youth criminal justice system (Ryan 2004). Indeed, bipolar disorder appears to be more common in the juvenile offender population with a prevalence of around 20% (Vermeiren 2003) compared to 3% to in the general adolescent population (Merinkagas 2010). It is a significant risk factor for suicide and attempted suicide (Simpson 1999), particularly among boys or when co-occurring with a substance use disorder (Hyman 2001).

Anxiety disorders

Anxiety disorder is a broad category of disorders, including generalised anxiety disorder (GAD), panic disorder, and phobias. Anxiety disorders have been less frequently investigated in young offenders than other psychiatric problems (Vermeiren 2003). Evidence suggests that between 22% and 82% of young offenders have some form of anxiety disorder (Carswell 2004; Chitsabesan 2006; Gaete 2018; Laporte 2017; Timmons 1997). Anxiety disorders are also recognised as risk factors for self-harm in adolescents (Hawton 2012a; Junker 2017; Mars 2014; Moran 2012).

Self-harm

Self-harm (SH) refers to "intentional self-poisoning or self-injury, irrespective of type of motive or the extent of suicidal intent" (NICE 2011). It most frequently takes the form of cutting, scratching, burning or overdoses but it can also be any behaviour that causes injury, no matter how minor, or high-risk. SH includes acts intended to result in death ('attempted suicide'), those without suicidal intent (for example, to communicate distress or to temporarily reduce unpleasant feelings), and those with mixed motivation. SH is associated with increased risk of future suicide. Recent data from the UK showed that children and adolescents who presented to hospital on at least one occasion following an episode of SH were 30 times more likely to die by suicide within a year (Hawton 2020). A history of SH, particularly with frequent repetition, is the strongest risk factor for suicide across a range of psychiatric disorders (Zahl 2004). SH (and suicide) in adolescents is the result of a complex interplay between genetic, biological, psychiatric, psychosocial, social, and cultural factors (Hawton 2012a). Relationship problems are common in adolescents who engage in SH, especially problems with family members. Relationship problems with partners are more common in older adolescents than in younger adolescents (Hawton 2012b); there may also be a history of emotional, physical, or sexual abuse (Madge 2011). Bullying, including cyber bullying, can also increase the risk of SH (Hinduja 2010). Psychiatric disorders are common in adolescents who present to hospital because of SH, with depression, anxiety, attention-deficit-hyperactivity disorder (ADHD), and eating disorders being particularly frequent (Hawton 2013).

Due to the sensitive nature of SH, and the fact that young people who engage in it do not always access services, estimates of the prevalence in this population varies widely from 6% to 20% (Madge 2009; Whitlock 2012). Depression, in particular, is strongly linked to SH and suicide in adolescents (Laporte 2017; Mars 2014; Moore 2015; Morgan 2017; Witt 2019), with suicide the third leading cause of death in 15 to 19 year olds (WHO 2017). In incarcerated juveniles and young offenders managed in the community, SH is elevated further, with prevalence rates ranging from 10% to 35% (Borschmann 2014; Gunter 2011; Laporte 2017; Moore 2015; Rijo 2016; Vermeiren 2003). Estimates suggest that up to one-third of young people serving a custodial sentence have had suicidal thoughts, and a quarter have attempted suicide at least once over their lifetime (Howard 2003; Putnins 2005; Sawyer 2010; Sedlak 2010). Fazel 2005 determined that 15 to 17 year olds in custody were 18 times more likely to die by suicide than their peers in the general population. It is clear that, in vulnerable adolescents with an underlying mental health disorder, interaction with the justice system, confinement and detention may exacerbate symptoms of



their disorder which, in turn, may make them more likely to engage in SH or suicidal behaviours (Ryan 2004).

Description of the intervention

Treatment for mood and anxiety disorders and SH in children and adolescents may involve psychosocial interventions, pharmacological interventions, or a combination of the two approaches.

Psychosocial interventions

Psychosocial interventions (PSIs) include individual, group-based or family-oriented interventions (Hawton 2015a). Individual therapy is more commonly sought by a young person as it allows them to maintain privacy and confidentiality, while developing their independence (Anderson 2010; James 2007; Tylee 2008). Family involvement is often what clinicians aim to do in collaboration with the young individual, but barriers, such as finding time around work commitments, parents feeling overwhelmed by their child's symptoms and parents feeling blamed, judged or not listened to by therapists, can often impede the therapeutic process (Baker-Ericzén 2013; Cox 2017).

Treatment generally involves an initial assessment followed by a combination of individual PSIs, family involvement and therapist support. Treatment can vary in initial management, setting, duration, intensity, frequency of contact with therapists and in the availability of services by location. While there is no standard treatment, PSIs are recommended as a first-line approach for treating mood and anxiety disorders and SH in adolescents (NICE 2011).

Pharmacological interventions

Pharmacological treatments may include antidepressants, antipsychotics, anxiolytics, and mood stabilisers. Other pharmacological agents may also be trialled. However, treatment with pharmacological agents is generally less common than treatment with psychosocial interventions in this population, partly due to concerns about the risk of exacerbating self-harm (Miller 2014) or suicide ideation (Cipriani 2016; Hetrick 2012). Therefore, pharmacological treatment should be aimed at treating underlying psychiatric disorders that do not respond to psychosocial interventions (King 2019).

Psychosocial interventions

Psychosocial interventions embody a group of treatment approaches designed to help individuals tackle specific problems, improve their coping skills and self-esteem, and reduce impulsive and unhelpful reactions to distressing behaviours (Hawton 2015). There are a number of different therapeutic models and techniques used in children and adolescents that fall under the umbrella of PSIs. Examples below include some that have been widely used across a range of disorders, including depression and anxiety as well as for those who engage in self-harm, others are more specific to those who engage in self-harm.

Cognitive behavioural therapy

Cognitive behavioural therapy (CBT) is based on the cognitive model by Beck 1964, which "hypothesises that people's emotions and behaviours are influenced by their perceptions of events. It is not a situation in and of itself that determines what people feel

but rather the way in which they construe a situation". In other words, our thoughts determine our feelings and behaviour. CBT helps individuals identify and understand negative interpretations and behavioural patterns, and teaches them strategies to develop alternative ways of thinking to reduce their psychological distress (Fenn 2013; McLeod 2019). CBT has been shown to be effective for adolescents with depression (Crowe 2017; James 2015; Klein 2007; Weisz 2006). This was supported by a large systematic review and meta-analysis of 52 trials (Zhou 2015). In the UK, it is recommended as the first choice of treatment of MDD in adolescents aged 12 to 18 years (NICE 2019). CBT has also been shown to be effective in treating anxiety disorders in adolescents (Ale 2015; Crowe 2017; James 2015; Reynolds 2012; Weisz 2017). The evidence regarding CBT for SH is limited, as reflected in the Cochrane review by Hawton 2015 where only one small trial was found comparing individual CBT with treatment as usual in adolescents who engage in SH.

Problem-solving therapy (PST) is an integral part of CBT, although it can be delivered as a therapy in itself. It is often used with adolescents as it is direct, easily understood and can extend to the whole family. PST teaches problem-solving techniques and rehearsed coping strategies to help the adolescent when confronted with future crises (Hawton 2005). 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). Group-based PST has been assessed in vulnerable, incarcerated young offenders and results have shown significant reductions in levels of anxiety, depression and hopelessness (Biggam 2002)

Dialectal behaviour therapy

Dialectal behaviour therapy (DBT) is a multi-component CBT, in which an individual learns to manage difficult emotions by experiencing, recognising and accepting them, without judgement or attempts to alter, suppress or avoid them (Lynch 2006). Once they have learnt to accept and regulate emotions, the individual is more equipped to change an unwelcome or harmful thought or behaviour (Linehan 1993). DBT for Adolescents (DBT-A) is a clinical programme for adolescents with severe personality difficulties and comorbid mental health problems. DBT-A has been adapted by Miller 2007 from Linehan's initial conceptualisation of DBT which was developed for adults diagnosed with borderline personality disorder. DBT-A typically includes individual psychotherapy, family therapy sessions, telephone support and therapist team consultations (Mehlum 2019). Limited evidence has shown that DBT-A may be effective in reducing SH and suicide attempts in adolescents (Hawton 2015; McCauley 2018).

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). 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 (Rossouw 2018).

Mentalisation-based therapy for adolescents (MBT-A) is a relatively prolonged (one year) treatment which typically includes weekly individual sessions, and monthly family sessions (Fonagy 2019).



Interpersonal psychotherapy

Interpersonal psychotherapy (IPT) focuses on stressful life events, interpersonal disputes, life transitions, or social deficits that are associated with the onset or exacerbation of depressive symptoms, while helping patients to connect with social supports and to improve the quality of their relationships (Weissman 2007). IPT for depressed adolescents (IPT-A) was developed specifically for 12-18 year olds who are suffering from depression (Weissman 2000). While IPT-A recognizes that genetic, biological, and personality factors play a role in the development of depression, the focus of IPT-A is on how relationship issues are related to the onset or ongoing occurrence of depressive symptoms. The goals of IPT-A are to help adolescents to recognize their feelings and think about how interpersonal events or conflicts might affect their mood, improve communication and problem-solving skills, enhance social functioning and lessen stress experienced in relationships and decrease depressive symptoms (Weissman 2000).

In a systematic review of 20 studies (Duffy 2019) and a network meta-analysis of 52 studies (Zhou 2015), IPT-A was found to be an effective intervention for adolescent depression. However, the evidence regarding SH is limited as although there were significant reductions in depression, anxiety, and hopelessness over the course of IPT-A treatment, it is unclear whether these changes mediated reductions in SH (Tang 2009).

Group-based psychotherapy

Group-based psychotherapy integrates different techniques from a range of therapies, including CBT, DBT and PST. In children and adolescents, group-based psychotherapy provides individuals with a chance to work on skills related to developing interpersonal relationships and problem-solving (Kaess 2020; Laporte 2017). Evidence regarding group therapy in adolescents is mixed. Structured group therapy has been associated with a reduction in self-reported PTSD symptoms in incarcerated male juveniles (Ovaert 2003). However, in adolescents who SH, group therapy was shown to confer no benefit over treatment-as-usual (Green 2011; Hazell 2009).

Enhanced assessment approaches

Enhanced therapeutic assessment approaches, which have been particularly investigated in those who present with SH, combine standard psychosocial history and risk assessment techniques with brief cognitive analytic therapy and PST. Children and adolescents learn to identify sources of psychological pain and their connection to problem behaviours, such as SH, and identify ways to break this cycle (Ougrin 2012). The aim is to enhance adherence with subsequent treatment, and the potential benefit from it.

Compliance enhancement approaches

Of particular concern regarding after-care of children and adolescents who present to hospital following an episode of SH, is the fact that adherence to recommended treatment tends to be relatively poor; between 25% and 50% of children and adolescents will not attend any follow-up outpatient treatment sessions (Granboulan 2001). Efforts to maintain contact with children and adolescents, such as following up with them in the community, as well as efforts to address factors likely to impede attendance at treatment sessions, may be effective in improving

treatment engagement and adherence in this population (Yuan 2019).

Family therapy

Family therapy aims to draw on and mobilise the strength and resources of the child and family (Carr 2009). Typically, it involves conjoint sessions where goals and unwanted behaviours and problem-solving are discussed as a family. The aim is that by improving family cohesion, attachment, adaptability and support, the family functions better as a whole and can support the adolescent during challenging times (Ewing 2015; Fortune 2016). Recent evidence suggests that, in adolescents referred to Child and Adolescent Mental Health Service Centres in the UK after SH, family therapy intervention conferred no benefits over treatment-as-usual in reducing subsequent hospital attendance for SH (Cottrell 2018). The Hawton 2015 systematic review also found no significant effects of family therapy on SH, although this was based on limited and low quality evidence.

Remote contact interventions

Remote contact interventions, can include letters, text messages, telephone calls, and postcards, are low resource and non-intrusive interventions that seek to maintain long-term contact with children and adolescents. These interventions may mitigate the sense of social isolation reported by adolescents with mood or anxiety disorders or in those 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 children and adolescents to seek help when they feel distressed, and offer on-demand emergency contact with psychiatric services or inpatient care.

Pharmacological interventions

Antidepressants

Antidepressant medications are postulated to work via their effect on neurotransmitters. Each type of medication has a slightly different effect on various neurotransmitters. For example, tricyclic antidepressants (TCAs) prevent the reuptake by nerve cells of the neurotransmitters norepinephrine (noradrenaline), serotonin (5-hydroxytryptamine, or 5-HT) and to a lesser extent, dopamine. Selective serotonin reuptake inhibitors (SSRIs) block the reuptake of serotonin and also affect the neurotransmitters norepinephrine and dopamine. Newer antidepressants such as serotonin-norepinephrine reuptake inhibitors (SNRIs), work on both norepinephrine as well as serotonin reuptake processes. However, concern that newer antidepressants such as selective serotonin reuptake inhibitors (SSRIs) may increase suicidal ideation and nonfatal SH in children and adolescents (Cipriani 2016; Hetrick 2012), led to regulatory warnings in the UK (MHRA 2003), the USA (FDA 2004) and Europe (the European Medicines Agency; EMA 2005). More recently, a systematic review of 19 trials, suggested that suicide risks may be elevated regardless of antidepressant generation (Hetrick 2012).

Antipsychotics

Antipsychotics are used to treat heightened states of arousal, depression and anxiety, all of which are associated with SH in



adolescents (Mars 2014; Moran 2012). Evidence suggests that low potency second-generation antipsychotics may decrease the recurrence of SH in adolescents diagnosed with major depression (Good 2006).

Anxiolytics

Benzodiazepines and other anxiolytics treat anxiety (Boden 2007; Laporte 2017; Moran 2012; Stallard 2013). However, there is some evidence that in children and adolescents, benzodiazepines may be associated with an increased risk of suicide ideation and SH (Kandemir 2008).

Mood stabilisers

Mood stabilisers may be beneficial in children and adolescents diagnosed with bipolar or unipolar disorder (Cipriani 2013). Research indicates that lithium is favourable over the long-term (Geller 2010) but risperidone shows better results for treating acute mania in children and adolescents (Corell 2010; Geller 2012).

Other pharmacological preparations

Other pharmacological agents, such as ketamine, may also have beneficial effects in patients with major depression. Ketamine has been recently approved as an adjunctive treatment to antidepressant therapy, albeit in adults only (FDA 2019). In adults with treatment-resistant mood disorders, ketamine has been associated with reduced short-term suicidal ideation severity (Witt 2020) but little is known about its long-term efficacy, particularly in adolescents.

Current treatment guidance for adolescent depression is CBT for at least 3 months or if that is unsuitable or does not meet clinical needs, IPT-A, family therapy or psychodynamic psychotherapy is recommended (NICE 2019). If the depression is unresponsive to specific psychological therapy after 4-6 sessions, combined psychological therapy with the antidepressant fluoxetine should be considered although caution should be exercised as the effectiveness of this drug in this age group is not well established. Furthermore, a young person prescribed an antidepressant should be closely monitored for the appearance of suicidal behaviour, self-harm or hostility, particularly at the beginning of treatment (NICE 2019). For psychotic depression, psychological therapy may be augmented with a second-generation antipsychotic with careful monitoring for side effects.

For anxiety disorders, individual or group CBT is recommended for social anxiety in adolescents (NICE 2013) and trauma-focused CBT is recommended for adolescents with PTSD (NICE 2018). There are no current treatment guidelines for SH in adolescents.

Why it is important to do this review

Despite the high prevalence of mood and anxiety disorders and SH behaviour in young offenders, the effectiveness of the available interventions in this population is unclear. It is critical that the effectiveness of the available interventions is investigated within the criminal justice system, as young people in these settings are likely to have different and more complex needs than adolescents receiving these interventions outside of the criminal justice system. Furthermore, the vast majority of young offenders are supported in the community, including a large proportion who were previously incarcerated. However, it appears that although incarcerated young offenders and those in the community have similar mental health

needs, the needs of community-based offenders are not being met to the same degree as those in custodial settings (Chitsabesan 2006). Psychiatric disorders have been associated with higher reoffending rates (Dixon 2004; Gueberta 2014) and therefore it is imperative to treat such disorders to reduce recidivism in juvenile offenders.

In a systematic review on the same topic, evidence showed that CBT may help to reduce symptoms of depression in young offenders (Townsend 2010). However the meta-analysis was based on only three studies with a small sample size of 171 participants. Several reviews have measured the effectiveness of interventions for depression and anxiety (Weisz 2017), and self harm in adolescents (Hawton 2015), but none have specifically looked at the young offender population.

A systematic review is needed to determine whether interventions to treat mood and anxiety disorders and SH behaviours in young people are effective in alleviating the symptoms and associated problems inherent in these disorders in the young offending population. This review will evaluate interventions that focus on mood and anxiety disorders, and self-harm in young offenders. Given the range of interventions available to treat this group, this review will examine any type of psychosocial or psychopharmacological interventions that has been employed to treat mood or anxiety disorders or self-harm in young offenders.

OBJECTIVES

The objective of this review is to assess the effects of interventions for mood disorders, anxiety disorders or self-harm behaviours in young offenders.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) that have published in the time period 1950 to the present. We will also include trials employing a cross-over design and cluster-RCTs.

Types of participants

Males and females aged 19 years or younger, referred to or under the care of the Criminal Justice System, including secure settings, the community and under the care of probation and/or parole. Any offence will be considered. Where young offenders constitute part of the trial sample, we will include trials where over 75% of the participants were young offenders. We will include trials where participants have been diagnosed with a mood or anxiety disorder or where self-harm has been identified. Diagnosis of a mood or anxiety disorder must be determined by diagnostic interview and/ or above the cut-off point on established scales for depression, mood and anxiety (e.g. Patient Health Questionnaire-9 (PHQ9), Hospital Anxiety and Depression Scale (HADS), Beck Depression Inventory (BDI), Childrens Depression Inventory (CDI). Trials where young offenders have been diagnosed with comorbid conduct disorder will be excluded as the focus of this review is mood or anxiety disorders or self-harm.



Types of interventions

Trials that have examined interventions for mood or anxiety disorders, or self-harm in young offenders, will be included. Any type of intervention used with this population will be considered for inclusion in this review (e.g. psychosocial interventions such as CBT, group therapy, family therapy, and psychopharmacological therapies such as antidepressant medication, antipsychotics).

Experimental interventions

Psychosocial interventions

These include:

- Cognitive behavioural therapy (CBT);
- Dialectal behaviour therapy (DT);
- Mentalisation-based therapy;
- Interpersonal psychotherapy (IPT);
- · Group-based psychotherapy;
- Enhanced assessment approaches;
- · Compliance enhancement approaches;
- Family therapy;
- · Remote contact interventions;
- · Other psychotherapy interventions.

Comparator interventions

Treatment as usual (TAU) is likely to vary widely both between settings and between trials conducted over different time periods (Witt 2018). We defined TAU as routine clinical service provision that children and adolescents would receive had they not been included in the trial (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 providing psychoeducation, assertive outreach, or more regular contact with case managers, and standard assessment approaches.

Pharmacological interventions

These include:

- Tricyclic antidepressants (TADs, e.g. amitriptyline);
- Newer generation antidepressants (NGAs), such as selective serotonin reuptake inhibitor (SSRIs, e.g. fluoxetine), serotonin-norepinephrine reuptake inhibitors (SNRIs, e.g. venlafaxine), norepinephrine reuptake inhibitors (NRIs, e.g. reboxetine), tetracyclic antidepressants (e.g. maprotiline), noradrenergic specific serotonergic antidepressants (NaSSAs, e.g. mirtazepine), serotonin antagonist or reuptake inhibitors (SARIs, e.g. trazodone), or reversible inhibitors of monoamine oxidase type A (RIMAs, e.g. moclobemide);
- Other antidepressants, such as irreversible monoamine oxidase inhibitors (MAOIs, e.g. phenelzine);
- · Antipsychotics (e.g. quetiapine);
- Anxiolytics, including both benzodiazepines (e.g. diazepam), and non-benzodiazepine anxiolytics (e.g. buspirone);
- Mood stabilisers, including antiepileptics (e.g. sodium valproate) and lithium;
- Other pharmacological agents (e.g. ketamine).

Comparator interventions

In pharmacological trials, where a comparison with the specific effects of a drug is being made, the comparator is typically placebo, which consists of any pharmacologically inactive treatment, such as sugar pills or injections with saline. In some trials, another pharmacological intervention (such as another standard pharmacological agent, reduced dose of the intervention agent, or active comparator) is used.

Types of outcome measures

For all outcomes, we were 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). Outcome measures of interest are described below.

Primary outcomes

Mental health outcomes, to include:

- improvements in depressive symptoms, assessed as continuous data, by scores on psychometric measures of depression symptoms, for example measured by the endpoint score on a standardised observer rating scale for depression (e.g. HDRS (Hamilton 1960), MADRS (Montgomery 1979), Clinical Global Impressions Scale (CGI) (Guy 1976), PHQ-9 (Kroenke 2001) or any other validated scale) or change from baseline or end of treatment values for scales rated by participants (e.g. Beck Depression Inventory (BDI) (Beck 1961), Childrens Depression Inventory (CDI) (Kovacs 1992), Revised Child Anxiety and Depression Scale (RCADS) (Chorpita 2000), or any other validated scale);
- improvements in anxiety, assessed as continuous data, by scores on psychometric measures of anxiety symptoms, for example measured by the endpoint score on a standardised observer rating scale for anxiety (e.g. Hamilton Anxiety Scale (HAM-A) (Hamilton 1959) or any other validated scale), or change from baseline or end of treatment values for scales rated by participants (e.g. Trait sub scale of the Spielberger State-Trait Anxiety Inventory (STAI-T) (Spielberger 1983), Beck Anxiety Inventory (BAI) (Beck 1988), Revised Child Anxiety and Depression Scale (RCADS) (Chorpita 2000) or any other validated scale);
- occurrence of repeated self-harm. 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 selfreported 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 (where available).

Secondary outcomes

Other important issues known to be associated with mental health problems in young offenders, including:

 no longer having a depressive disorder, measured as dichotomous data as the proportion of participants who no longer meet defined standard criteria for depression based on diagnostic interview (e.g. Diagnostic Statisical Manual (DSM) III



(APA 1980), III-R (APA 1987), IV (APA 1994), IV-TR (APA 2000) and 5 (APA 2013), International Classification of Diseases (ICD-9) (WHO 1978) or ICD-10 (WHO 1992), Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADs) for depression and anxiety (Kaufman 1997)) or the proportion of participants who longer meet a threshold classified as remitted or responded;

- no longer having an anxiety disorder (remission), measured as dichotomous data as the proportion of participants who no longer meet defined standard criteria for an anxiety disorder based on diagnostic interview (e.g. Diagnostic Statisical Manual (DSM) III (APA 1980), III-R (APA 1987), IV (APA 1994), IV-TR (APA 2000) and 5 (APA 2013), International Classification of Diseases (ICD-9) (WHO 1978) or ICD-10 (WHO 1992), Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADs) for depression and anxiety (Kaufman 1997)) or the proportion of participants who longer meet a threshold classified as remitted or responded;
- general psychological functioning measured by e.g. Children's Global Assessment Scale (CGAS);
- quality of life, as assessed with the use of validated measures such as Short Form (SF)-36 (Ware 1993), World Health Organization Quality of Life (WHOQOL) (WHOQL 1998), EuroQoL (Brooks 1995) and Child Health and Illness Profile (CHIP-CE) (Starfield 1993);
- school attendance (e.g. from official records and self report);
- recidivism (e.g. from official records and self report);
- suicide ideation assessed as either continuous data, by scores
 on psychometric measures of suicidal ideation, for example,
 total scores on the Beck Suicide Ideation Scale (BSS) (Beck
 1993), or as dichotomous data as the proportion of children and
 adolescents reaching a defined cut-off for ideation;
- suicide. This included register-recorded deaths, or reports from informants, such as family members or neighbours.

Search methods for identification of studies

Electronic searches

The Information Specialist with Cochrane Common Mental Disorders (CCMD) will search the Group's Controlled Trials Register (the CCMDCTR) (Appendix 1) together with the following bibliographic databases, using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource:

- Cochrane Central Register of Controlled Trials (CENTRAL) (current issue);
- Ovid MEDLINE (1946 onwards) (Appendix 2);
- Ovid Embase (1974 onwards);
- Ovid PsycINFO (1806 onwards);
- Web of Science Core Collection (1900 onwards).

We will search the Joanna Briggs Institute Database of Systematic Reviews and Implementation Reports (JBISRIR).

International trial registers (ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP)) will be searched for additional unpublished and/or ongoing studies via CENTRAL on the Cochrane Library.

No restriction on date, language or publication status will be applied to the search.

Grey literature

The Information Specialist with CCMD will search the grey literature for dissertations and theses using the following databases:

- DART-Europe E-theses Portal (www.dart-europe.eu);
- EThOS the British Libraries e-theses online service (ethos.bl.uk);
- Networked Digital Library of Theses and Dissertations (NDLTD) (search.ndltd.org);
- Open Access Theses and Dissertations (oatd.org);
- ProQuest Dissertations and Theses Global.

Conference proceedings will be searched via Ovid Embase and the Web of Science Core Collection, as listed above (all available years).

Reference lists

We will check the reference lists of all included studies and relevant systematic reviews to identify additional studies missed from the original electronic searches (for example unpublished or in-press citations).

Correspondence

We will contact trialists and subject experts for information on unpublished or ongoing studies, or to request additional trial data.

Data collection and analysis

We will follow guidance on data collection and analysis provided by the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019a).

Selection of studies

Two review authors (LR, AA) will independently screen titles and abstracts of trials identified by the search and code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. We will obtain the full-text trial reports/publication of all potentially eligible trials. Two review authors (LR, AA) will independently screen the full text and identify trials for inclusion. We will resolve any disagreement through discussion with a third author (AP). We will record reasons for excluding records at this stage.

We will identify and exclude duplicate records and we will collate multiple reports that relate to the same trial so that each trial rather than each report is the unit of interest in the review. We will record the selection process in sufficient detail to complete a PRISMA flow diagram and 'Characteristics of excluded studies' table.

Data extraction and management

Two review authors (LR, AA) will independently complete data extraction using a data collection form pre-piloted on at least one trial in the review. We will extract the following trial characteristics:

- methods: trial design, trial setting, date of trial, total duration
 of trial, details of any 'run-in' period, number of trial centres
 and location, number of participants recruited, number of
 participants randomised, attrition rates;
- participants: number, mean age, age range, sex, socioeconomic status, ethnicity, criminal justice setting (e.g. incarcerated vs. community), type of offence, length of sentence, diagnostic



tools used to make diagnosis, inclusion criteria, and exclusion criteria;

- interventions: intervention, comparison, who delivered the intervention, concomitant medications, and excluded medications;
- outcomes: primary outcomes, secondary outcomes, time frame;
- notes: funding for trial, and notable conflicts of interest of trial authors.

We will compare the data extraction results and resolve any disagreements with an additional review author (AP). If necessary, we will contact the authors of the trials for further information. We will note in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. One review author (LR) will transfer data into the Review Manager (Review Manager 2014) file. We will double-check that data are entered correctly by comparing the data presented in the systematic review with the trial reports. Two review authors (LR, AA) will spot-check trial characteristics for accuracy against the trial report.

Main comparisons

We planned the following main comparisons:

- Individual CBT-based psychotherapy (e.g. CBT, PST) versus treatment as usual (TAU) or other comparator;
- Dialectical behaviour therapy (DBT) versus TAU or other comparator;
- Mentalisation-based therapy versus TAU or other comparator;
- Interpersonal psychotherapy (IPT) versus TAU or other comparator;
- Group-based psychotherapy versus TAU or other comparator;
- Enhanced assessment approaches versus TAU or other comparator;
- Compliance enhancement approaches versus TAU or other comparator;
- Family interventions versus TAU or other comparator;
- Remote contact interventions versus TAU or other comparator:
- Other psychotherapy versus TAU or other comparator;
- Tricyclic antidepressants versus placebo or other comparator drug or dose;
- Newer generation antidepressants versus placebo or other comparator drug or dose;
- Any other antidepressants versus placebo or other comparator drug or dose;
- Antipsychotics versus placebo or other comparator drug or dose;
- Anxiolytics, including both benzodiazepines and nonbenzodiazepine anxiolytics, versus placebo or other comparator drug or dose;
- Mood stabilisers, including antiepileptics and lithium, versus placebo or other comparator drug or dose;
- Other pharmacological agents versus placebo or other comparator drug or dose.

Assessment of risk of bias in included studies

Two review authors (LR, KW) will independently assess risk of bias for each trial using the criteria outlined in the using the Cochrane Risk of Bias, version 2 (RoB2), tool (Sterne 2019). We will consider risk of bias for the primary outcomes of our review (improvements in depressive symptoms, improvement in anxiety, and occurrence of repeated self-harm), using the following domains:

- Bias in the randomisation process;
- Deviations from the intended intervention (assignment to intervention);
- · Missing outcome data;
- Bias in the measurement of the outcome;
- Bias in the selection of the reported result.

For cluster-RCTs, we will also evaluate:

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

Each source of potential bias will be judged as "low risk", "high risk", or "some concerns". An overall 'Risk of bias' judgement will then be made for each study by combining ratings across these six domains. Specifically, if any of the above domains are rated as at high risk, the overall risk of bias judgement will similarly be rated as at high risk. This overall judgement, which can also range from "low risk", "high risk", or "some concerns", will be reported in the text of the review, as well as in the 'Risk of bias' tables.

Where inadequate details are provided in the original report, we will contact corresponding trial authors to provide clarification. Disagreements will be resolved following discussions with a third author (AA).

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

Measures of treatment effect

Dichotomous data

For dichotomous (yes/no) outcomes, the overall odds ratios (ORs), with their 95% confidence intervals (CIs), will be calculated. In addition, we will calculate the number needed to treat for an additional beneficial outcome (NNTB) with 95% CIs for all dichotomous outcomes to facilitate interpretation; this is the expected number of people who need to receive the intervention rather than the comparator for one additional person to achieve a beneficial outcome (Schünemann 2017a).

Continuous data

Where trials use the same outcome measure for comparison, we will pool data by calculating the mean difference (MD). Where trials use different measures to assess the same outcome, we will pool data calculating the standardised mean difference (SMD) and 95% confidence intervals (95% CIs). We will present data on a scale with a consistent direction of effect. We plan to describe skewed data reported as medians and interquartile ranges in a narrative, and when multiple trial arms are reported in a single trial, we plan to include only the relevant arms.

Where possible, a random-effects model will be used. Statistical analyses will be carried out on an intention-to-treat basis.



Timing of outcome assessment

Primary time point will be the end of treatment. Secondary time points are 3, 6 and 12 months post-treatment.

Hierarchy of outcomes

Due to the great likelihood of more than one reported eligible outcome, we will include data as per the following rules:

- in case of available data from both observer-rating scales and self-report questionnaires, we will prioritise data from observerrating scales;
- in case of several outcome measures of the same hierarchy level used in one trial, we will select the outcome measure most frequently used across all trials;
- in case of several outcome measures of the same hierarchy level and the same availability across trials, we will randomly select the outcome measure.

Cluster-randomised trials

We plan to include cluster-randomised trials as long as proper adjustment for the intracluster correlation could be conducted in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019a).

Cross-over trials

We plan to include trials employing a cross-over design in the review, but we would only use data from the first active treatment phase to avoid carry-over effects.

Trials with multiple treatment groups

For trials with more than two eligible arms, we will manage the data as follows:

Multiple experimental intervention groups versus a single control group

If trials compare multiple eligible experimental interventions with a single control group, we will combine the experimental intervention groups to enable pairwise comparisons.

One or more experimental intervention groups versus multiple control group

If trials use multiple 'active' comparator interventions, we will combine these comparator groups to compare to the experimental intervention group.

Dealing with missing data

We will contact trial authors to request missing outcome data and verify key trial characteristics, wherever possible. We will document all correspondence. Where we fail to obtain data for intention-to-treat analyses, the trial will be excluded from the intention-to-treat meta-analysis. It may also be possible to derive means and standard deviations from test statistics where these are reported. We will attempt to impute missing data from other available information, in line with guidance provided by the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019a). This procedure has been carried out by two of the reviewers in another systematic review (Townsend 2001).

Assessment of heterogeneity

We will assess trials for clinical heterogeneity in terms of variability in experimental and comparator interventions, participants (gender and ethnicity) of the participants, setting (custodial setting of the intervention (where possible)) and outcomes.

To further assess heterogeneity, we will perform a formal statistical test (Chi²), describe the extent of heterogeneity (I² statistic) and visually inspect the forest plots, to determine whether it is appropriate to synthesise these data. We will use the following scale suggested by the *Cochrane Handbook for Systematic Reviews of Interventions* as a guide to interpretation of the I² statistic (Higgins 2019a):

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

The I² statistic will be interpreted with consideration of the size and direction of effects, as well as the strength of evidence for heterogeneity. Forest plots generated in Review Manager 5 will provide an estimate of tau², the between-trial variance in a random-effects meta-analysis (Deeks 2017; Review Manager 2014).

Assessment of reporting biases

If sufficient trials are available in a meta-analysis (10 or more), we will prepare funnel plots and examine these for signs of asymmetry. If asymmetry is identified, we will consider other possible reasons for this.

Data synthesis

We will undertake meta-analyses only when it is meaningful to do so (i.e. when treatments, participants, and the underlying clinical question are sufficiently similar). Meta-analysis will be conducted in Review Manager 2014. All eligible trials will be included in meta-analyses regardless of 'Risk of bias' assessments. Where possible, a random-effects model will be used. Statistical analyses will be carried out both on an intention-to-treat and per protocol basis. Trials will first be grouped by the type of disorder they are investigating (e.g. depression, anxiety or self-harm) and then by the type of intervention they are examining (e.g. psychological or pharmacological).

Data synthesis will involve exploring differences between different diagnostic tools and specific interventions. Descriptive analyses (for example, whether rating scales used as outcome measures have been published, properly validated and are reliable) will also be provided.

Subgroup analysis and investigation of heterogeneity

Wherever possible, subgroup analyses will be carried out to account for differences in outcomes between:

- males and females;
- ethnicity;
- incarcerated vs community-based young offenders;
- · exposure to traumatic events;
- individual vs group therapy.



We intend to keep subgroup analyses to a minimum to avoid issues related to multiple testing, and to only conduct these analyses on primary outcome measures.

Sensitivity analysis

We will consider sensitivity analysis to explore possible causes of methodological heterogeneity, if sufficient data allowed. We will base analyses on the following criteria:

- testing the robustness of the overall findings to the decisions that were made in the conducting of the main meta-analysis (e.g. excluding poorer quality trials at high risk of bias);
- excluding trials where not all participants were young offenders.

'Summary of findings' tables

We will construct 'Summary of findings' tables to present the main findings of the review. We will follow standard methods as described in the *Cochrane Handbook for Systematic Reviews of Interventions* to prepare the tables (Schünemann 2017b). Where possible, we will present a 'Summary of findings' table for each comparisons and include information on the three primary outcomes of our review: improvements in depressive symptoms, improvement in anxiety and occurrence of self harm. We will assess the quality of evidence across the following domains:

- risk of bias assessment;
- indirectness of evidence:
- · unexplained heterogeneity or inconsistency of results;
- · imprecision of effect estimates;
- · 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). Specifically, for risk of bias we will downgrade this domain by one level when any of the sources of risk of bias (as described in the Assessment of risk of bias in included studies section) are rated as "high risk" for any of the studies included in the pooled estimate, or by two levels when multiple studies are rated as "high risk" for any of these sources. For indirectness of evidence, we will consider the extent to which trials included in any metaanalysis use proxy measures to ascertain self-harm repetition, and 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 I² value indicates substantial levels of heterogeneity ($I^2 = 50-75\%$) or by two levels where the I² value indicated considerable levels of heterogeneity $(I^2 \ge 75\%)$. For imprecision, we will downgrade this domain by one level where the 95% CI for the pooled effect included the null value or when the optimal information size is not met. Finally, for the potential publication bias domain, we considered any evidence of funnel plot asymmetry (if available), as well as other evidence such as suspected selective availability of data, and downgraded 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 outcomes according to the following categories:

- high quality: further research is very unlikely to change our confidence in the estimate of effect;
- moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect, and may change the estimate;
- low quality: further research is very likely to have an important impact on our confidence in the estimate of effect, and is likely to change the estimate;
- very low quality: we are very uncertain about the estimate.

Summary of findings tables will be constructed using GRADEpro software (GRADEpro GDT).

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APPENDICES

Appendix 1. CCMDCTR Search/Description

Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR)

The CCMDCTR-Studies Register will be searched using the following controlled vocabulary terms: Setting = *Prison** and Age-group = (Child or Adolescent)

The CCMDCTR-References Register will be searched using a more sensitive set of free-text terms for population/setting, to find additional untagged/uncoded reports of trials:

(convic* or correctional or crimin* or custody or custodial or delinqu* or detainee* or detained or detention* or felon* or justice or "high dependency" or prison* or imprison* or incarcerat* or inmate* or remand* or jail* or gaol* or offend* or offenc* or reoffen* or penal or penology



or penitent* or reformato* or ("secure accommodation" or "secure facilitat*" or "secure unit*" or "secure psychiatric" or "secure forensic" or "secure hospital" or "secure in-patient") or "forensic psychiatry")

Description of the Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR)

The Cochrane Common Mental Disorders Group (CCMD) retains two clinical trials registers at its editorial base (current to June 2016); a references register and a studies-based register. The CCMDCTR-References Register contains over 40,000 reports of randomised controlled trials (RCTs) in mood, anxiety disorders, psychological trauma and self-harm. Approximately half of these references have been tagged to individual coded trials. The coded trials are held in the CCMDCTR-Studies Register and records are linked between the two registers through the use of unique Study ID tags. Coding of trials is based on the EU-Psi coding manual, using a controlled vocabulary. (Please contact the CCMD Information Specialists for further details). Reports of trials for inclusion in the Group's registers were collated from routine (weekly), generic searches of MEDLINE (1950 -), Embase (1974 -) and PsycINFO (1967 -), quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) and review-specific searches of additional databases. Reports of trials were also sourced from international trial registers, pharmaceutical companies, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses.

Details of CCMD's generic search strategies (used to identify RCTs) can be found on the Group's website, with an example of the core MEDLINE search displayed below.

Core search strategy used to inform the Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR): OVID MEDLINE A weekly search alert based on condition + RCT filter only

- 1. [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 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/
- 2. [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).ti,kf.
- 3. [RCT filter]: (controlled clinical trial.pt. or randomized 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 randomized 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.)
- 4. (1 and 2 and 3)

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. Similar weekly search alerts were also conducted on OVID Embase and PsycINFO, using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource.

Appendix 2. MEDLINE Search Strategy

For this review, MEDLINE will be searched (on the Ovid platform) using the following terms for population (*young offenders*), condition (*mood, anxiety disorders*, *self-harm*) and study design (*RCTs*). The search will be translated across to the other databases using relevant subject headings and search syntax, as appropriate.

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 onwards> Search Strategy:



[Population]

- 1 Juvenile Delinquency/
- 2 ((adolesc* or child* or juveni* or teen* or young or youth?) adj offender?).ti,ab,kf.
- 3 ((adolesc* or juveni* or teen* or (young adj (adult? or person? or criminal?)) or youth?) adj5 (court? or custod* or convict* or detaine* or detention* or justice or remand*)).ti,ab,kf.
- 4 (child* adj (court? or custod* or convict* or detaine* or detention* or justice or remand*)).ti,ab,kf.

5 or/1-4

6 Criminals/

7 Prisons/ or Prisoners/

8 Recidivism/

9 (criminal? or convict or convicts or felon* or prison* or imprison* or inmate?).ti,ab,kf.

10 (offender* or reoffen* or re-offend* or recidivism).ti,ab,kf.

11 ((correctional adj (facilit* or institution* or psychiatr* or setting* or officer*)) or incarcerat* or jail* or gaol* or probation* or penal or penology or penitent* or reformato*).ti,ab,kf.

12 (custodial or (court? adj (adjudicat* or refer*)) or criminal justice or justice system or judicial).ti,ab,kf.

13 delinquency.mp.

14 or/6-13

[Age Group]

15 child/ or adolescent/ or young adult/

16 (adolesc* or preadolesc* or pre-adolesc* or boy* or girl* or child* or juvenil* or minors or teen* or (young adj (adult? or person? or criminal? or men or male? or women or female?)) or youth*).ti,ab,kf.

17 (child* or adolescen* or juveni*).jw.

18 or/15-17

19 (5 or (14 and 18))

[Condition]

20 mood disorders/ or "bipolar and related disorders"/ or bipolar disorder/ or depressive disorder/ or depressive disorder, major/ or depressive disorder, treatment-resistant/ or dysthymic disorder/ or anxiety disorders/ or agoraphobia/ or anxiety, separation/ or neurocirculatory asthenia/ or neurotic disorders/ or obsessive-compulsive disorder/ or hoarding disorder/ or panic disorder/ or phobic disorders/ or phobia, social/ or "trauma and stressor related disorders"/ or adjustment disorders/ or stress disorders, traumatic/ or combat disorders/ or psychological trauma/ or stress disorders, post-traumatic/ or stress disorders, traumatic, acute/ or self-injurious behavior/ or self mutilation/ or suicide/ or suicidal ideation/ or suicide, attempted/

21 (acute stress or adjustment disorder* or ADNOS or affective disorder* or (affective psychosis or bipolar or mani* or hypomani* or rapid cycling or schizoaffective) or anxiety disorder? or agoraphobi* or phobi* or GAD or separation anxi* or social anxi* or (combat adj (disorder* or fatigue or neuros* or syndrom*)) or compulsi* or obsessive or OCD or depressed or depression or depressive or dysphori* or dysthymi* or melanchol* or emotional trauma or fear or health anxiety or hysteri* or MDD or mental* or mood? or neurastheni* or neurotic or neuros* or panic or ((post-trauma* or posttrauma* or post trauma) adj stress*) or PTSD or flashback* or flash-back* or ((acute or trauma) adj (avoidance or grief or nightmare* or stress*)) or (psych* adj (stress or trauma*)) or psychotrauma* or ((sever* or serious* or major* or chronic* or complex* or critical* or endur* or persist* or resist* or acute) adj2 anxiety) or psychopathol* or selfharm* or self-harm* or selfinjur* or self-injur* or selfmutilat* or self-poison* or overdos* or suicid* or parasuicid*).ti,ab,kf.

22 (psychiatric comorbid* or ((comorbid* or co-morbid* or co-occur* or ((dual* or doubl*) adj diagnos*)) and (addict* or alcohol* or substance? or SUD? or (drug adj (abus* or depend* or use* or tak*)) or PWID))).ti,ab,kf.

23 or/20-22

24 (23 and 19)

25 child psychiatry/ or psychology, child/ or adolescent psychiatry/ or psychology, adolescent/

26 (25 and (5 or 14))

27 (24 or 26)

[RCT Filter]

28 controlled clinical trial.pt.

29 randomized controlled trial.pt.

30 clinical trials as topic/

31 (randomi#ed or randomi#ation or randomi#ing).ti,ab,kf.

32 (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.

33 placebo.ab,ti,kf.

34 trial.ti.

35 (control* adj3 group*).ab.

36 (control* and (trial or study or group*) and (waitlist* or wait* list* or ((treatment or care) adj2 usual))).ti,ab,kf,hw.

37 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).ti,ab,kf.



38 double-blind method/ or random allocation/ or single-blind method/ 39 or/28-38 40 exp animals/ not humans.sh. 41 (39 not 40) 42 (27 and 41)

HISTORY

Protocol first published: Issue 10, 2020

CONTRIBUTIONS OF AUTHORS

LR: contributed to the background and methodology of the protocol and updated the protocol.

AA: contributed to the background of the protocol. Developed the selection criteria and the methodology.

DMW: contributed to the background and commented on the methodology of the protocol.

PV: contributed to the background and commented on the methodology of the protocol.

IC: contributed to the background and commented on the methodology of the protocol.

KGW: contributed to the background and commented on the methodology of the protocol.

AEP: contributed to the background of the protocol. Developed the selection criteria and the methodology.

ET: lead author of the 2008 protocol (Townsend 2008). Developed the selection criteria and the methodology.

DECLARATIONS OF INTEREST

LR: none know.

AA: none know.

DMW: none know.

PV: none know.

IC: none know.

KGW: none know.

AEP: none know.

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