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Psychological interventions for emotional well-being in adults with advanced progressive life-limiting illness (Protocol)

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Psychological interventions for emotional well-being in adults with advanced progressive life-limiting illness

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ABSTRACT

Objectives

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

To determine the benefits and harms of psychological interventions compared to treatment as usual, waiting list, active control, or another psychological intervention to improve emotional well-being in adults with an advanced progressive life-limiting illness.

BACKGROUND

Description of the condition

An advanced progressive life-limiting illness refers to one or more health conditions that become serious or advanced enough that general health and function decline and treatments start to lose their impact, ultimately leading to the end of life (Stuart 2019). This refers to people in their last one or two years of life, or people accessing a service typically used in advanced disease stages, e.g. palliative care (Bayly 2021; NICE 2019). Advanced progressive life-limiting illnesses are heterogeneous in nature, and differ from person to person (Amblàs-Novellas 2016). Due to uncertainties in clinical trajectories of illnesses, e.g. heart failure, it is acknowledged that approaches to staging and identifying proximity to death can be difficult, and one approach may not be appropriate for all illnesses (Im 2019). The course of illnesses or prognoses can be impacted by one or more co-existing conditions (Amblàs-Novellas 2016). Variation in the course of a person's type and timing of decline in health presents challenges in how healthcare services can evaluate and prioritise treatments when required (Cohen-Mansfield 2018). People with chronic or long-term conditions, such as heart, lung, renal, and liver failure can experience gradual decline with sudden episodes of deterioration or improvement, which can last for months or years (Amblàs-Novellas 2016; Murray 2005). In contrast, cancer can be associated with a stable phase, or a slow decline lasting for weeks or months, followed by a severe decline in the last few weeks (Amblàs-Novellas 2016). The trajectory of a progressive neurological condition varies, depending on the condition. For example, multiple sclerosis can be characterised by an acute or relapse phase, followed by a slowly progressive neurological deterioration, which is independent of previous inflammatory episodes (also called the secondary progressive phase (Maca-Lallana 2021)). We will not include people with dementia in this review, because its prognosis is less predictable and has a more varied trajectory of illness compared to other terminal illnesses (Walsh 2021). Dementia affects cognition, functional abilities, and social skills, which lead to low mood and challenging behaviours (Walsh 2021). Advanced or end-stage dementia is characterised by profound cognitive impairment, inability to communicate verbally, and complete functional dependence (Walsh 2021). People with advanced dementia are not always able to express their wishes about their care and therefore, lack the capacity to make decisions, which adds to the complexity of providing care (Allen 2003; Walsh 2021).

People living with an advanced progressive life-limiting illness, or those progressing towards the end of life can experience multidimensional symptoms as a consequence of the illness itself, its treatment, and comorbidities, which can impact physical, social, spiritual, and psychological well-being (Almada 2018; Carduff 2018). Conscious and unconscious thoughts, including the threat of death, feelings of fear, grief, hopelessness, worry about the future, their existence, shock, denial, loneliness, loss of self-identity, and professional and familial roles, contribute to increased psychological distress (Almada 2018; Ingham 2020; Limonero 2018). For example, 42% of people with cancer suffer death anxiety, or the extreme fear of death, which is associated with psychological distress (Von Blanckenburg 2018). Higher rates of psychological distress are linked to an increased burden of physical symptoms, such as pain, fatigue, and breathlessness (Almada 2018; IIngham 2020; Limonero 2018; Soto-Rubio 2018). Collectively, psychological and physical distress lead to poorer quality of life, and the avoidance of end-of-life discussions (Ellis 2015; Hong 2022).

For people with advanced progressive life-limiting illnesses, it is important to identify approaches that will improve emotional, physical, psychological, and social well-being, and relieve distress (WHO 2020). This review will focus on psychological interventions for adults, aged 18 years and over, who have an advanced progressive life-limiting illness, including, but not limited to cancer, progressive organ dysfunction, and progressive neurological disorders, in all settings, e.g. hospitals, nursing homes, outpatient palliative care clinics, specialised clinics, hospices, or at home. We acknowledge that the approaches to define an advanced progressive life-limiting illness will be varied, and may be based on staging, prognosis, or proximity to death. We will include definitions of an advanced illness, and those expected to die within one to two years, as reported in the trials.

Description of the intervention

For the purposes of this review, psychological interventions are defined as any psychological or psychotherapeutic treatment or therapy designed to target cognitive, behavioural, and emotional symptoms or experiences to improve health outcomes, well-being, and quality of life, and to reduce psychological distress (Breitbart 2015; Chochinov 2011; Fraguell 2018; Guzmán-Castellanos 2016; Warth 2019).

Psychological therapies can be very broadly categorised into three main philosophical and theoretical schools, comprising cognitive behavioural, psychoanalytic or psychodynamic, and humanistic therapies (Beck 1979; Freud 1949; Jung 1963; Klein 1960; Lazarus 1971; Marks 1981; Maslow 1943; May 1961; Rogers 1951; Skinner 1953; Watson 1924).

Cognitive behavioural therapy (CBT) is founded on behavioural analysis and operant theory, cognitive theory, and social learning theory (Bandura 1977; Beck 1979; Bergin 1975; Skinner 1953). Associations between cognitions, emotions, and behaviours are emphasised, and are believed to interact to influence psychological distress or well-being. Consequently, interventions are focused on altering maladaptive social or environmental, behavioural, and cognitive factors in order to reduce psychological distress (Hofmann 2008). CBT is one of the most widely researched and used psychological interventions for treating anxiety and depression across the lifespan in people with mental health problems, and in people with physical health conditions, including those with advanced, life-limiting illness (Moorey 1996; Price 2009).

Third wave CBT expands upon traditional CBT, moving away from the goal to ameliorate maladaptive or negative cognitions and emotions, to focus more on the context, processes, and functions of how a person relates to their internal experiences, such as thoughts, emotions, urges, and sensations (Hayes 2017). These therapies have gained popularity within the context of psychological distress in people with physical health problems (Hulbert-Williams 2021). Examples of third wave therapies include acceptance and commitment therapy (ACT) and compassion focused therapy (Gilbert 2009; Kabat-Zinn 1990; Low 2016). ACT emphasises developing psychological flexibility, with a focus on valuing living in the present, rather than fearing the future (Low 2016). Compassion focused therapy emphasises

developing compassion for one's self and others (Gilbert 2009). Mindfulness based programmes, including mindfulness based stress reduction, are structured group programmes of mindfulness training, developed by Kabat-Zinn (Kabat-Zinn 1990). Dialectical behaviour therapy and schema therapy are examples of third wave CBT interventions that consist of therapeutic frameworks, and have been developed for people with personality vulnerabilities (May 2016; Jacob 2013). However, they can be used to assist people with significant distress, interpersonal challenges, and underdeveloped self-identity (Faraji 2015; Köhler 2017).

Psychoanalytic or psychodynamic based therapies are rooted in psychoanalytic theory, developed by Sigmund Freud (Freud 1949). A number of brief psychodynamic therapy approaches aim to enable insight and consider how previous experiences influence the present (Roth 2006). These approaches help people to understand and resolve their difficulties by increasing awareness of their internal world and its influence over relationships in the past and the present. The relationship with the therapist is central to the therapeutic approach, with transference and counter-transference seen as key therapeutic concepts (Hersoug 2014). Examples of these therapies include interpersonal therapy, which is based on a medical model, and defines major depression as a diagnosable and treatable psychiatric illness, and empirically derived interpersonal factors related to depression (Markowitz 1998; Weissman 2000). This is different from Hobson's conversational model, which involves a process of interpersonal training through a focused conversation with the therapist, based on the individual's feelings and interpersonal problems expressed in the 'here and now' of the therapeutic relationship, rather than being talked about in a detached way (Hobson 1977). Dynamic interpersonal therapy is a brief dynamic approach, informed by attachment and mentalisation, and views symptoms of depression and anxiety as responses to interpersonal difficulties or perceived threats to attachments, e.g. loss or separation, and threats to one's self (Fonagy 2020; Lemma 2013). Expressive therapy is based on a Core Conflictual Relationship Theme Method, which involves support from the therapist to understand the focal issue that the person is expressing (Luborsky 1984).

Humanistic psychotherapies are based on the theory that people 'self actualise', which is an inherent tendency to develop their potential (Rogers 1951; Maslow 1970). People are unique, self-aware entities who are free to choose how they live, and who need to be understood in the context of their individual experiences and characteristics (Cain 2002). Key humanistic therapies include existential therapy, transactional analysis, Gestalt therapy, and person centred, life review, and dignity therapy (Berne 1961; Butler 1974; Chochinov 2011; Perls 1976; Rogers 1951; Van Deurzen 1997). The therapist's core conditions of empathy, genuineness, and unconditional positive regard are the cornerstones of therapy (Rogers 1951). Humanistic therapies have been widely used in hospice settings (Almada 2018; Chochinov 2011).

Psychological interventions can be delivered on an individual or group basis, in either a community, hospital, or hospice setting. Many interventions have the potential to be delivered by telephone, by video conferencing software, or through online platforms where in-person interactions with clinical psychologists may not be available. Because there is lack of clarity about which modes of delivery are helpful in improving an individual's experience of receiving psychological interventions, we will explore any mode of delivery, e.g. face-to-face, technology-based, or a combination, or by virtual reality in any setting. We will not include spirituality, religious, or music therapy interventions, as they are covered by other Cochrane reviews (Bradt 2021; Candy 2012).

How the intervention might work

The proposed outcomes for different psychological interventions will vary, depending on the theoretical orientation and approach of the intervention.

CBT typically uses an integrated approach of two theories, to target cognitions and behaviours, by assessing unrealistic fears and maladaptive avoidance behaviours (Greer 2012; Hofmann 2008). CBT is frequently used to treat emotional distress (Moorey 1996). However, it is not clear which people would benefit from psychological interventions. CBT can be acceptable to some people with cancer who are experiencing depression, anxiety, and adjustment disorders in the palliative care setting, but less effective in reducing depression in other advanced cancer populations because of the burden of physical symptoms, such as low energy and reduced concentration (Anderson 2008; Serfaty 2020). In other advanced life-limiting illnesses, such as motor neurone disease, CBT with counselling has shown promising results (Zarroti 2021). CBT may help to reduce psychological symptoms in other advanced illnesses by encouraging people to think in a focused, positive, and hopeful manner about their illness throughout its course (Guzmán-Castellanos 2016). Flexibility in how CBT is delivered, such as shorter sessions, may be beneficial in this population (Anderson 2008).

Psychoanalytic and psychodynamic therapies encourage people to talk and become aware of how their experiences influence the present (Roth 2006). Psychoanalytic therapy assumes that symptoms can be reduced if the underlying conflict is resolved, by focussing on the unconscious or repressed thoughts and feelings. Psychodynamic therapy focusses on unconscious processes manifested in the person's behaviour to promote self-awareness and understanding of the influence of the past on present behaviour (McCarthy 1981). For example, through free association, i.e. a person talks about whatever comes into their mind, the therapist encourages the person to recognise their own origin of the conflict (Chamlou 2024). Psychoanalytic and psychodynamic therapies can have positive impacts on depression and anxiety (Huber 2013; Pitman 2020; Ribeiro 2018). These interventions may help to resolve emotional distress in people with advanced progressive life-limiting illnesses.

Humanistic psychotherapy, i.e. person centred, assumes that people have the inherent tendency to develop their potential (Maslow 1970; Rogers 1951). People are self-aware. They are free to choose how they live, are responsible for choices they make, are their own being, and they need to be understood in the context of their individual experiences and characteristics (Cain 2002). In clinical practice, humanistic psychotherapy is not structured or manualised for psychological disorders, but it emphasises the 'growth-inducing power' of the therapeutic relationship with the therapist (Cain 2002). The therapist has an unconditional, positive, empathetic, and genuine role that helps to create an environment in which the person gains insight, accepts, and changes, with the potential to address existential distress and reduce psychological disorders, such as depression (Cain 2002). Although the main aim of humanistic psychotherapy is not to address depression, it

can be reduced by talking through life history and current issues in the context of the individual's life story, past strengths and accomplishments, which increases self-acceptance and personal growth (Cain 2002; Davies 2010; Lee 2020).

Other interventions based on psychological theory, such as art psychotherapy, contribute to change and development in people by means of visual art, within a psychotherapeutic relationship with an art therapist (British Association of Art Therapists 2022; De Witte 2021). Art therapy helps individuals to express their thoughts and feelings when it is difficult to verbalise their experiences, to improve self-awareness, cope with symptoms, and overcome distress and psychological shock (Walsh 2003). People can gain a sense of dignity, confidence, and accomplishment in light of their illness by completing artwork (Park 2020).

Psychological interventions have the potential to improve outcomes. However, it is unclear whether these interventions represent the conditions and characteristics in real world clinical practice (Kazdin 2008). Factors that may not be considered include comorbidities, tailoring of care, addressing non-physical needs, communication, preparation and acceptance of death, how the care is delivered, skills and qualifications of therapists delivering psychological therapies, honouring the individual's wishes, and relationship development (Koslov 2018; Mistry 2015).

Another challenge is access to traditional face-to-face psychotherapy, due to limited resources, and the inability to attend hospital consultations due to poor health or living in remote areas (Nazanin 2021). There has been a demand for technology-based interventions as an alternative approach to providing psychological support. However, results of effectiveness are varied (Finucane 2021). A recent review of virtual care interventions for end-of-life and palliative care showed that technology-based interventions improved quality of life when used as a supplement to face-to-face care, but findings were mixed for anxiety and depression (Dolan 2021).

Why it is important to do this review

International and national health organisations recognise the importance of end-of-life care and make recommendations to address the psychological needs of this population (BPS 2020; Payne 2022; ESMO 2021; NICE 2004; WHO 2020; WPCA 2014). However, the majority of specific palliative care guidelines do not make evidence-based recommendations for psychological interventions.

Evidence for the clinical effectiveness of psychological interventions for people with advanced progressive life-limiting illnesses is uncertain and conflicting, due to small sample numbers in trials (Von Blanckenburg 2018). Most reviews of psychological interventions report psychological therapies in the cancer population, with limited information about non-cancer illnesses. The reduction of depression and anxiety through CBT, mindfulness, and meaning-based interventions varies. However, the observed effects are mostly in cancer populations (Von Blanckenburg 2018). There are challenges in methodological research that may contribute to uncertainty, or even in the generation of meaningful evidence. These may include loss of participants from studies (due to illness or death), difficulty taking part in standard psychological therapy (due to illness or disability), and questions about the applicability of outcomes validated in non-palliative care settings (Chen 2014). It is important to identify the applicability of psychological interventions, and gaps in the evidence for which future research is required.

There are interventions currently used in practice that are not based on psychological theory. However, for the purpose of this review, we will only focus on interventions that are based on psychological theory, and that are delivered either directly by, or under the supervision of a psychological specialist, e.g. a psychological specialist, a talking therapist, or an arts psychotherapist. The skill level of healthcare professionals can impact the effectiveness of psychological interventions (Evans 2013). Therefore, we will report this information and a description of the psychological interventions, using the template for intervention and replication checklist to guide discussion of the identified evidence (Hoffman 2014). As there is no formal classification of psychological interventions available in the literature, it will be important to categorise interventions according to the evidence that we find. Discussion and exploration of other available guidance will help to understand whether interventions can be grouped.

This is the first Cochrane review to investigate the effectiveness of psychological interventions for emotional well-being in people with advanced progressive life-limiting illness. This topic has been identified as a high priority through a priority setting process in the Cochrane Pain, Palliative, and Supportive Care review group, which involved multiple stakeholders. We will use up-to-date Cochrane methods to provide completeness in the reporting of psychological interventions.

OBJECTIVES

To determine the benefits and harms of psychological interventions compared to treatment as usual, waiting list, active control, or another psychological intervention to improve emotional well-being in adults with an advanced progressive life-limiting illness.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) only, as they are the best design to minimise bias when evaluating the effectiveness of interventions. We will include parallel-, cross-over, and cluster-RCTs.

We will include published clinical trial results, summaries of otherwise unpublished clinical trials, and abstracts; if there are insufficient data for analysis in the abstracts, we will attempt to locate the full study (e.g. by contacting the study authors). We will add abstracts to Studies awaiting classification if data from the full study are unavailable.

We will exclude non-randomised studies, quasi-randomised studies, case reports, and clinical observations. We will exclude equivalence or non-inferiority trials, as their aim is to find no difference in effectiveness between the intervention and the comparator. Similarly, we will exclude studies comparing one psychological intervention with another in equivalence or non-inferiority studies. Although these study designs may be considered useful, they are often inadequately powered, and effectiveness may

be difficult to interpret if, for example, a standard care group is not part of the trial.

Types of participants

We will include studies recruiting adults, aged 18 years and over, with advanced progressive life-limiting illness (described as being at a later stage of disease, in the last one to two years of life, and who may or may not be engaged with palliative care services (Bayly 2021; NICE 2019)). Participants can be included from any setting: hospital, nursing home, outpatient palliative care clinic, specialised clinic, hospice, or at home. It is likely that the approaches to define an advanced progressive life-limiting illness will vary, and may be based on staging, prognosis, or proximity to death. We will include definitions of advanced illness, and those who are terminally ill and expected to die within the next one to two years, as reported by the trialists.

Diagnosis of the illness will include, but will not be limited to, cancer, progressive neurological conditions (e.g. multiple sclerosis), or progressive organ dysfunction (e.g. advanced kidney failure, liver cirrhosis, heart and respiratory disease). We will exclude studies in which participants have dementia or significant cognitive impairment, as interventions are likely to be different in this population.

We will include studies in which only a subset of participants is eligible, if characteristics and outcomes of those participants can be extracted separately. If we find studies in which only a subset of relevant participants is included, we will contact the study authors to obtain information and relevant data.

Types of interventions

We will include credible psychological interventions that are intended to improve or promote emotional well-being, reduce psychological distress, and improve the quality of life in people with an advanced progressive life-limiting illness. Based on judgement and discussion, if psychological interventions are clinically similar (e.g. CBT-based interventions) we will group them in analyses.

Psychological interventions are defined as any psychological or psychotherapeutic treatment informed by psychological theory or based on an existing psychological model or framework; which is designed to target cognitive, behavioural, and emotional symptoms or experiences; and is developed or delivered either directly by, or under the supervision of, a healthcare professional. For example, we may find coping skills training based on cognitive theory, developed by a clinical psychologist, and delivered by a junior psychologist under the supervision of an experienced senior psychologist (Williams 2020). Psychological interventions can be delivered face-to-face or through technology-mediated communication (e.g. email, phone, teleconferencing, online chat) with a health professional. We will include studies that include psychological interventions delivered by virtual reality (e.g. cognitive behavioural therapy to target and strengthen emotional regulation and psychological well-being delivered by virtual reality (Seon 2023)).

Supportive care is often not clearly defined for non-cancer advanced progressive life-limiting illnesses, and the majority of research has been in cancer. We acknowledge that the definition of supportive care used in cancer cannot be applied to all populations. One study defined supportive care as "multidisciplinary holistic care of patients with malignant and non-malignant chronic diseases and serious illnesses, and those that matter to them, to ensure the best possible quality of life. It extends as a right and necessity for all patients, is available throughout the course of the condition, concurrent to condition management, and is given equal priority alongside diagnosis and treatment. It should be individualised, taking into account a person's past life experiences, their current situation, and personal goals" (Cramp 2013). We will include supportive care interventions that are clearly defined for cancer and non-cancer study populations, are based on psychological or psychotherapeutic content, and aim to target psychological distress.

We will compare psychological interventions to usual care, waiting list, active control, or another psychological intervention using trialists' classifications. Waiting list and usual care are likely to vary between trials, as this implies regular care. Whether individuals seek care other than regular consultation to access care is likely to vary in trials. Therefore, individuals may receive different treatment, which in some cases, may be similar to active control. Active control is defined as a non-psychological treatment designed to change behaviour, e.g. physical therapy or education (Williams 2020).

We acknowledge that control groups that receive usual care may receive psychological therapy as part of that care, which may not be reported in the publication. While this information may not be possible to ascertain, this is not a reason to exclude a study. We will assess and interpret this limitation as part of the discussion and conclusion of the review.

We will include comparisons of psychological interventions with active control groups, e.g. education about the illness, or discussions about managing the illness. We acknowledge that it may not be possible to ascertain whether the active control group is a true control. We will contact study authors for clarification of the active control, if required. We will include trials that compare one psychological intervention with another, provided that it is not an equivalence trial.

We will include multi-component interventions, of which psychological intervention is a key part of the intervention.

We will exclude the following studies.

- Equivalence or non-inferiority studies in which the aim is not to find a difference in effectiveness between the intervention and the comparator
- Studies in which the control group has explicit psychotherapeutic content beyond what would be expected in usual care for people at the advanced stage of their illness
- Studies in which the intervention has insufficient psychological content, refers only to the provision of education or mediation practice, and is not based on a theory that supports behaviour change (Williams 2020)
- Studies in which the psychological intervention is delivered by an unsupervised non-psychologist, and has no psychological content
- Studies in which supportive care is not clearly defined for the participant group, does not target psychological distress, and is not based on psychological or psychotherapeutic content

Types of outcome measures

We will compare psychological interventions to control groups, e.g. usual care, waiting list, active control, or another psychological intervention, using the following post-intervention time point categories:

- Post-intervention: immediate; end of intervention to 4 weeks
- Post-intervention: medium-term; end of intervention, more than 4 weeks to less than 12 weeks
- Post-intervention: long-term; end of intervention, more than 12 weeks to less than 26 weeks

We will extract outcomes that are measured using scales for palliative care or related populations, such as severe progressive illnesses, e.g. cancers or chronic obstructive pulmonary disease. Examples of palliative care specific scales include the Palliative care Outcome Scale (POS) as a measure of quality of life (Bausewein 2011). Where there are no specific palliative care scales, we will look at similar outcome measures.

We will extract outcome data when data for intervention and control groups are available and matched for time point(s) reported in studies. If studies report multiple time points, we will extract post-intervention data for both intervention and control groups at the first time point closest to immediately after the end of treatment, at 6 weeks post-intervention, and at 12 weeks post-intervention.

Primary outcomes

We will extract data for the following primary outcomes.

- **Emotional well-being** (continuous data, measured with, for example, the Profile of Mood States scale (McNair 1971))
- **Quality of life** (continuous data, measured with, for example, the EuroQoL-5D)
- **Anxiety** (continuous data, measured with, for example, the Generalised Anxiety Disorder-7, Hospital Anxiety and Depression Scale; if trials only present dichotomous data, we will contact authors of trials for the raw data, with the aim of converting it to continuous data)
- **Depression** (continuous data, measured with, for example, the Patient Health Questionnaire-9, Hospital Anxiety and Depression Scale, Beck Depression Inventory; if trials only present dichotomous data, we will contact authors of trials for the raw data, with the aim of converting them to continuous outcomes)
- **Adverse events** (dichotomous data, measured with, for example, withdrawals, the number of people admitted to hospital, or the number of deaths due to suicide)

Secondary outcomes

We will extract data for the following secondary outcomes.

- **Participant satisfaction** (continuous data, measured with, for example, the numerical rating scale)
- **Symptom burden** (e.g. pain, fatigue, or other outcomes as reported in trials; continuous data, measured with, for example, the numerical rating scales, verbal rating scales, or visual analogue scales)

Search methods for identification of studies

Electronic searches

We will search the following databases without date or language restrictions. We will seek translation assistance when needed.

- The Cochrane Central Register of Controlled Trials (CENTRAL; in the Cochrane Library; latest issue)
- MEDLINE Ovid (1946 to present)
- Pubmed
- Embase Ovid (1974 to present)
- PsycINFO EBSCO (1806 to present)
- CINAHL (Cumulative Index to Nursing and Allied Health Literature; 1937 to present)

We will tailor searches to individual databases. The search strategy for MEDLINE is in Appendix 1.

The search strategy was developed by the Cochrane Pain, Palliative and Supportive Care (PaPaS) Review Group's Information Specialist and was independently peer-reviewed. An information specialist at the University of the West of England has agreed to perform the searches.

Adverse events

We will not perform a separate search for adverse events of the target intervention(s). We will only consider adverse events described in the included studies.

Searching other resources

We will search clinicaltrials.gov (www.clinicaltrials.gov) and the World Health Organization International Clinical Trials Registry Platform (ICTRP; http://apps.who.int/trialsearch/) for ongoing trials or completed trials not yet published in a peer-reviewed journal. We will also search for grey literature (i.e. recent conference proceedings), check reference lists of identified reviews and included studies for additional studies, and perform citation searches on key articles. We will contact experts in the field for unpublished and ongoing trials. We will contact study authors for additional information when necessary.

Data collection and analysis

Selection of studies

We will use Rayyan to manage search results and screen the references (Ouzzani 2016). Three review authors, in pairs (SJ, DC, DM), will independently determine the eligibility of each study identified by the search. They will eliminate studies that clearly do not satisfy inclusion criteria, and will obtain full copies of the remaining reports. Three review authors (SJ, DC, DM) will independently read these reports to select relevant studies. In the event of disagreement, a fourth review author will adjudicate (BC). All review authors will agree on all the included studies. We will not anonymise the studies in any way before assessment. We will include a PRISMA flowchart in the full review (Liberati 2009). We will include studies regardless of whether they reported outcome data we can use in analysis.

Data extraction and management

Three review authors, in pairs (SJ, DC, DM), will independently extract data using a standard piloted form, and check for agreement before entry into Review Manager (RevMan 2024). In the event of disagreement, a fourth review author will adjudicate (BC). We will collate multiple reports of the same study, so that each study, rather than each report, is the unit of interest in the review. We will collect characteristics of the included studies in sufficient detail to complete the characteristics of included studies tables in the full review.

We will extract the following information.

- Methods: study design, total duration of study, details of any run-in period (if applicable), number of study centres and location, study setting, and date of study
- Participants: number randomised, number lost to follow-up/ withdrawn, number analysed, mean age, age range, gender, severity of condition, diagnostic criteria, inclusion criteria and exclusion criteria, and other characteristics that are provided
- Interventions: intervention, comparison, concomitant medications/treatment, and excluded medications
- Outcomes: outcomes specified and collected, and time points reported
- Notes: funding for trial and notable conflicts of interest of trial authors; information needed to assess bias
- Information needed to assess GRADE (e.g. baseline risk in the control group for key outcomes)

Template for intervention description and replication (TiDieR checklist)

We will use the TiDieR checklist to help provide completeness in the reporting of psychological therapies (Hoffman 2014). A summary of the items in the checklist are:

- Name or phrase that describes the intervention;
- Description of the rationale, theory, or goal of the elements essential to the intervention;
- Description of any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers;
- Description of each procedure, activities, and processes used in the intervention, including any enabling or support activities;
- Description of expertise, background, and specific training of the intervention provider, if provided;
- Mode of delivery of intervention and whether it was provided individually or in a group;
- Type of location where the intervention occurred, including any necessary infrastructure or relevant features;
- Number of times the intervention was delivered and over what period of time, including number of sessions, schedule, duration, intensity, or dose;
- Tailoring of intervention, e.g. planning of personalisation, titrated or adapted, and description of what, why, when and how;
- Modification of intervention during the course of the study, description of the changes (what, why, when and how);
- Assessment of intervention adherence or fidelity, description of how and by whom, and if any strategies were used to maintain or improve fidelity, and description;
- Description of the extent to which the intervention was delivered as planned.

Assessment of risk of bias in included studies

We will assess risk of bias using the Cochrane RoB 1 tool for randomised trials. Three review authors, in pairs (SJ, DC, DM), will independently assess the risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Disagreements will be resolved by discussion, or by consulting with a fourth review author (BC). We will complete a risk of bias table for each included study in Review Manager (RevMan 2024).

We will assess the following biases for each included study.

- Random sequence generation (checking for possible selection bias). We will assess the method used to generate the allocation sequence as:
  - low risk of bias (any truly random process; e.g. random number table, computer random number generator);
  - unclear risk of bias (insufficient detail about the method of randomisation to be able to judge);
  - high risk of bias (studies using a non-random process, e.g. odd or even date of birth; hospital or clinic record number).
- Allocation concealment (checking for possible selection bias). The method used to conceal allocation to interventions prior to assignment determines whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We will assess the methods as:
  - low risk of bias (e.g. telephone or central randomisation, consecutively numbered sealed opaque envelopes);
  - uncertain risk of bias (insufficient detail about the method of randomisation to be able to judge);
  - high risk of bias (studies that do not conceal allocation, e.g. open list).
- Blinding of participants and personnel (checking for performance bias). We will assess the methods used to blind study participants and personnel from the knowledge of which intervention a participant received. We will assess the methods as:
  - low risk of bias (the study states that it is blinded and describes the method used to achieve blinding);
  - unclear risk of bias (the study states that it was blinded but did not provide an adequate description of how this was achieved);
  - high risk of bias (the study states that it was not blinded to the intervention received).
- Blinding of outcome assessment (checking for possible detection bias). We will assess the methods used to blind outcome assessors from knowledge of which intervention a participant received. We will assess the methods as:
  - low risk of bias (the study has a clear statement that outcome assessors were unaware of treatment allocation, and ideally describes how this was achieved);
  - unclear risk of bias (the study states that outcome assessors were blind to treatment allocation but lacked a clear statement on how it was achieved);

- high risk of bias (the study states that outcome assessors were not blinded to treatment allocation).

- Incomplete outcome data (checking for possible attrition bias due to the amount, nature, and handling of incomplete outcome data). We will assess the methods used to deal with incomplete data as:
  - low risk (no missing outcome data; reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; missing data has been imputed using baseline observation carried forward analysis);
  - unclear risk of bias (insufficient reporting of attrition/ exclusions to permit a judgement of low risk or high risk (e.g. number randomised not stated, no reasons for missing data provided, or the study did not address this outcome));
  - high risk of bias (reason for missing outcome data is likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; as-treated analysis done with substantial departure of the intervention received from that assigned at randomisation; potentially inappropriate application of simple imputation).
- Selective reporting (checking for reporting bias). We will assess reporting biases due to selective outcome reporting. We will judge studies as:
  - low risk of bias (study protocol is available, and all the study's prespecified (primary and secondary) outcomes that are of interest to the review have been reported in the prespecified way);
  - unclear risk of bias (insufficient information available to permit a judgement of low risk or high risk);
  - high risk of bias (not all the study's prespecified primary outcomes have been reported; one or more primary outcomes have been reported using measurements, analysis methods, or subsets of the data (e.g. subscales) that were not prespecified; one or more reported primary outcomes were not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcomes of interest to the review have been reported incompletely so that they cannot be entered in a meta-analysis; the study report failed to include results for a key outcome that would be expected to be reported for such a study).

Measures of treatment effect

We anticipate that outcomes of interest will be reported by study authors as continuous data. We will extract and analyse such data when reported. We will evaluate treatment effects for continuous data as mean differences (MD) and 95% confidence intervals (CIs) when multiple studies report a common measure. We will evaluate treatment effects for continuous data as standardised mean differences (SMDs) and 95% CIs when there are different scales measuring an outcome, thus requiring standardisation to a uniform scale before they can be combined. We will interpret effect sizes as small (0.2), moderate (0.5), and large (0.8), according to Cohen (Cohen 1988). We will ensure that all scales are measuring their effect in the same direction, and we will convert any that run counter to others (e.g. a high value for a scale indicates a poorer outcome for the participant and a low value indicates a good outcome).

If trials report outcomes as dichotomous data (e.g. anxiety and depression), we will convert the data to continuous outcomes. We will contact authors for raw data, specifically the scales on which clinical cut points are imposed.

We will extract dichotomous data for adverse events should they be reported in studies, and present them as risk ratios (RRs) with 95% CIs.

If data in an RCT are not reported in a format that can be entered directly into a meta-analysis, we will convert them to the required format as described in the *Cochrane Handbook* (Higgins 2023a).

Unit of analysis issues

We expect that studies will randomise participants at the individual level, and most studies will allocate each participant to a single intervention for comparison with one or more alternative interventions (i.e. parallel design).

If we identify studies in which the participant is allocated to a sequence of interventions (i.e. a randomised controlled trial with a cross-over design), we will include such studies if there is a sufficient gap between the first phase treatment and the second phase treatment (wash-out period), and a correlation coefficient statistic between both phases has been accounted for. If this information is not available, we will only include data from the first phase, before the cross-over occurs, as we would be unaware of carry-over effects of the intervention before the cross-over into the second phase.

Cluster-randomised controlled trials involve randomisation of groups of individuals to different interventions, where the unit of allocation is the group of individuals or cluster (e.g. hospitals, medical practices). We will only include cluster-randomised controlled trials if they have been adjusted to account for clustering. Should we find cluster randomised controlled trials, we will follow guidance provided in the *Cochrane Handbook* (Higgins 2023b).

If a study includes three or more intervention arms of interest, or control groups, or both, we will separate the arms into intervention and control groups. We will split the control group across the intervention arms to avoid double counting.

Dealing with missing data

If outcome data are missing, we will contact study authors, investigators, or study sponsors to request them (e.g. studies reporting only a P value, a statement of statistical significance, or only the direction of effect). If we are unable to obtain the data, we will use available data to calculate the necessary data (e.g. standard deviations from confidence intervals), according to the *Cochrane Handbook* (Higgins 2023a). We will not impute missing variables in analyses when outcome data are not available or calculable. If it is not possible to obtain missing data, and we think the missing data will introduce serious bias, we will explore the impact of including such studies in the meta-analysis through a sensitivity analysis.

If both per protocol and intention-to-treat analyses are presented in published manuscripts, we will extract intention-to-treat data in preference to per-protocol data.

Assessment of heterogeneity

We will pool data using meta-analysis when studies are considered to be methodological or clinically similar enough, based on populations, interventions, or other factors, and provided there are two or more studies in the meta-analysis. We will assess the degree of statistical heterogeneity by examining Tau^2 and the Chi^2 test with a significance level at $P < 0.1$, and visually examining forest plots to consider the direction and magnitude of effects and the degree of overlap between CIs. We will quantify possible heterogeneity by using the I^2 statistic, according to these thresholds, reported in the *Cochrane Handbook* (Deeks 2023):

- 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.

When the I^2 is at a moderate, substantial, or considerable (i.e. 50% or more) level of heterogeneity, we will interpret this value according to the size and direction of effect, and the strength of the evidence for heterogeneity, based on the P value derived from the Chi^2 test, or the confidence interval for I^2 (uncertainty in the value of I^2 is substantial when the number of studies is small (Deeks 2023)). We will explore causes of heterogeneity through subgroup analyses (Subgroup analysis and investigation of heterogeneity).

We will not pool results if there is substantial clinical diversity (e.g. variation in type of interventions) or methodological differences (e.g. variation in study design or outcome measurement tools) amongst included studies, or inconsistency in the direction of effect. We will not report pooled results from a meta-analysis, but will instead use a descriptive approach to data synthesis (i.e. SWiM (McKenzie 2023)).

Assessment of reporting biases

We will assess reporting biases as part of the risk of bias assessment in this review. We will also assess funnel plots according to guidance in the *Cochrane Handbook,* provided there are at least 10 studies included in each meta-analysis (Page 2023).

Data synthesis

Meta-analysis of numerical data

We will analyse data using Review Manager (RevMan 2024). We will analyse outcome data using a random-effects model. We will only perform meta-analysis when it is clinically or methodologically meaningful to do so, that is, if two or more studies are sufficiently homogeneous for participants, interventions, and outcomes.

Based on judgement, discussion, and reference to published clinical guidance, we will combine psychological interventions in analyses, provided they are clinically similar, or the mechanisms of action are similar. We will combine usual care, and waiting list control groups, as these are likely to be similar. When it is not possible to meta-analyse data, we will describe the findings from studies. The following comparisons are examples for analysis:

- Psychological intervention versus usual care, or waiting list (up to 4 weeks post-treatment);
- Psychological intervention versus active control (up to 4 weeks post-treatment);
- Psychological intervention versus usual care, or waiting list (between 4 and 12 weeks post-treatment);
- Psychological intervention versus active control (between 4 and 12 weeks post-treatment);
- Psychological intervention versus usual care, or waiting list (between 12 and 26 weeks post-treatment);
- Psychological intervention versus active control (between 12 and 26 weeks post-treatment).

We will use the same duration thresholds for other psychological interventions that we identify in the included studies.

Synthesis using other methods

We plan to use SWiM guidance if data cannot be included in meta-analyses for a prespecified comparison due to clinical or methodological differences. We will present the available effects using tables, or describe results narratively using this approach (McKenzie 2023).

- Grouping studies for synthesis: description of, and rationale for, the groups used in synthesis (e.g. grouping of populations, interventions, outcomes, study design); detail and rationale for any changes made after the protocol, in the groups used in the synthesis
- Description of standard metric and transformation methods used (e.g. for each outcome, why the metric was chosen and methods used to transform intervention effects, as reported in the study, to the standard metric, citing any methodological guidance consulted)
- Description of synthesis methods: description and justification of methods used to synthesise effects for each outcome when it was not possible to undertake meta-analysis for effect estimates
- Criteria for prioritising results for summary and synthesis: description of criteria used with supporting justification, to select particular studies, or study, for main synthesis, or to draw conclusions from the synthesis (e.g. based on study design, risk of bias assessments, directness in relation to the review question)
- Heterogeneity in reported effects: methods used to examine heterogeneity in reported effects when it is not possible to conduct meta-analysis for effect estimates, and its extensions to investigate heterogeneity
- Certainty: description of methods used to assess certainty of the synthesis findings
- Presentation of data: describe graphical and tabular methods to present direction of effects (e.g. effect direction plot); specific key study characteristics (e.g. study design, risk of bias) used to order studies, in text, tables or graphs, clearly referencing the studies included
- Reporting results: description of synthesised findings for each comparison and outcome, and certainty of findings. Describe using language consistent with the question the synthesis addresses, and indicate which studies contribute to the synthesis.
- Discussion: report limitations of the synthesis methods and groupings used in the synthesis, and how these affect the conclusions that can be drawn in relation to the original review question

Subgroup analysis and investigation of heterogeneity

We plan to conduct subgroup analyses that are clinically meaningful and informative. Provided that at least 10 eligible studies are available, we will explore these subgroups.

- Delivery of intervention (e.g. individual versus group). The rationale for considering these subgroups is that interventions delivered individually or in a group may have different effects on outcomes. From a mechanistic, and for subsequent economic purposes, this information will be useful to health professionals when considering intervention delivery options, and for health service providers when considering the most cost-effective intervention options for people with advanced progressive life-limiting illness.
- Type of intervention (e.g. CBT versus third wave interventions versus supportive expressive interventions). The rationale for considering these subgroups is that interventions with different underlying mechanisms of action may have different effects on outcomes. This information will be useful to health professionals when considering intervention options for people with advanced progressive life-limiting illness.

We plan to explore these outcomes in subgroup analyses.

- Emotional well-being
- Quality of life
- Anxiety
- Depression
- Adverse events

Sensitivity analysis

We plan to conduct the following sensitivity analyses using the 'investigate sensitivity' function in Review Manager to assess the consistency of results when different studies are removed from the analyses:

- Excluding studies judged to be at high risk of bias (in any domain), to determine whether their exclusion alters the findings
- Excluding studies with fewer than 50 participants, to determine whether their exclusion alters the findings
- Excluding outlier studies in cases where there is substantial heterogeneity in analyses (I^2 above 75%) to determine whether their exclusion alters the findings
- Excluding studies with missing data (e.g. lack of intention-to-treat) to determine whether their exclusion alters the findings

Summary of findings and assessment of the certainty of the evidence

Three review authors, in pairs (SJ, DC, DM), will independently rate the certainty of the body of evidence for the outcomes, with disagreements resolved by discussion or involving a fourth review author (BC). We will justify, document, and incorporate judgements into the reporting of results for each outcome. We will use the GRADE system to rank the certainty of the evidence using GRADEpro GDT software (GRADEpro GDT), and the guidelines provided in the *Cochrane Handbook* (Schünemann 2023).

The GRADE approach uses five considerations (study limitations (risk of bias), unexplained heterogeneity and inconsistency of effect, imprecision, indirectness, and publication bias) to assess the certainty of the body of evidence for each outcome. Based on the GRADE assessment, we will assign the certainty of evidence.

- High: we are very confident that the true effect lies close to that of the estimate of the effect.
- Moderate: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
- Low: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
- Very low: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

The GRADE system considers study design as a marker of quality. Randomised controlled trials are considered to be high quality of evidence and can be downgraded for important limitations.

These factors may decrease the certainty of a body of evidence by at least one level.

- Serious or very serious study limitations (risk of bias)
- Important or serious inconsistency of results
- Some or major indirectness of evidence
- Serious or very serious imprecision
- Probability of publication bias

We plan to include at least three summary of findings tables to present the main findings for each psychological intervention (e.g. CBT) compared to a usual care and waiting list control group, an active control group, and another psychological intervention group. We will include key information concerning certainty of the evidence, the magnitude of effect of the interventions examined, and the sum of available data on the key outcomes including emotional well-being, quality of life, anxiety, depression, and adverse events.

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Editorial contributions

The following people conducted the editorial process for this article:

Sign-off Editor (final editorial decision): Toby Lasserson, Cochrane Central Editorial Unit

Managing Editor (reviewed authors' rebuttal document, provided editorial guidance to authors, edited the article): Anupa Shah, Cochrane Central Editorial Service

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APPENDICES

Appendix 1. MEDLINE OVID search strategy

1 Palliative Care/

2 palliat*.tw.

3 Terminally Ill/

4 Terminal Care/

5 (terminal* adj6 care*).tw.

6 ((terminal* adj6 ill*) or terminal-stage* or dying or (close adj6 death)).tw.

7 (terminal* adj6 disease*).tw.

8 (end adj6 life).tw.

9 hospice*.tw.

10 (end-stage disease* or end-stage illness*).tw.

11 (advanced disease* or advanced cancer* or advanced illness*).tw.

12 (incurable or life-limiting).tw.

13 (advanced directive* or living will* or "do-not-resuscitate order* ").tw.

14 Hospices/

15 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14

16 exp Psychotherapy/

17 exp Biofeedback, Psychology/

18 ((behavio?r* or cognit* or relax*) adj2 (therapy or therapies or intervention* or approach* or technique* or mechanism*)).tw.

19 (meditat* or "expressive writing" or (compassionate adj2 training) or (compassionate adj2 therapy) or (emotion* adj2 disclos*)).tw.

20 (psychotherap* or psycho-therap* or counsel*).tw.

21 (psycholog* adj2 (treatment* or therapy or therapies)).tw.

22 "group therapy".tw.

23 "selfâ€□regulation training".tw.

24 coping skill*.tw.

25 pain related thought*.tw.

26 (behavio#r* adj2 rehabilitat*).tw.

27 (psychoeducation* or psych-education* or psychosocial or psycho-social).tw.

28 (mind adj2 body relaxation technique*).tw.

29 exp Mind-Body Therapies/

30 Emotional Adjustment/

31 counseling/ or directive counseling/ or distance counseling/

32 exp Mindfulness/

33 mindful*.tw.

34 or/16-33

35 randomized controlled trial.pt.

36 controlled clinical trial.pt.

37 randomized.ab.

38 placebo.ab.

39 drug therapy.fs.

40 randomly.ab.

41 trial.ab.

42 35 or 36 or 37 or 38 or 39 or 40 or 41

43 exp animals/ not humans.sh.

44 42 not 43

45 15 and 34 and 44

CONTRIBUTIONS OF AUTHORS

SJ: will oversee the project and will be responsible for writing the draft and final version of the protocol

SJ, CD, DC, DM, AT, BC: were involved in discussion of PICO inclusion criteria, editing the protocol, and providing comments before final submission

CD, DM, AT, MM and BC: provided clinical input in the discussion of the PICO inclusion criteria

DECLARATIONS OF INTEREST

2014 Commercial Sponsorship Policy

SJ: none known

DC: none known

AT: none known

BC: none known

DM: received grants from the Economic and Social Research Council and Marie Curie for a co-funded PhD studentship. DM has not been involved in any randomised controlled trials of the preliminary interventions, nor published work eligible for inclusion in the review, nor involvement in further development/evaluation work of the intervention following PhD completion.

CD: none known

MM: none known

2020 Conflicts of Interest Policy

SJ: none known

DC: none known

AT: none known. AT is a field editor for the Cochrane Pain, Palliative and Supportive Care review group.

BC: none known

DM: has a PhD on development and preliminary feasibility testing of a psychological intervention for people living with terminal illness receiving hospice care

CD: none known

MM: none known

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