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[Intervention Protocol]

Psychological therapies for depression in older adults residing in long-term care settings

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ABSTRACT

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

To assess the effects of psychological therapies in comparison with treatment as usual, waiting list, attentional control, other psychological therapies, or cointervention for depression in older people living in long-term care (LTC) settings.

BACKGROUND

Description of the condition

There has been increasing awareness of the importance of addressing depression in long-term care (LTC) settings in recent years, with studies consistently documenting high rates of depression among residents. A systematic review of 26 international studies reported that the median prevalence of major depressive disorder (MDD) was 10%, while the median prevalence of subthreshold depressive symptoms was 29% (Seitz 2010). Comparisons with community surveys suggest that the prevalence of depression in LTC is three to four times higher than in populations of older adults living in their own homes (Jongenelis 2004). Depression appears to increase the risk of admission to long-term residential care and is often present at the point of entry to care (Achterberg 2006; Boyle 2004; Dorenlot 2005). In a longitudinal study of recently admitted nursing home residents (with and without dementia) in Australia, 24% met criteria for MDD and 20% for a non-MDD, with only 12% of cases remitting over a six-month period (McSweeney 2008). This confirms the persistence of depressive symptoms reported in other longitudinal natural studies in LTC settings (Barca 2010). Established risk factors for late-life depression, including multiple medical conditions, disability and functional decline, and cognitive impairment are ubiquitous in LTC settings (Davison 2012). However, there is a significant association between residing in LTC and increased depressive symptoms, even when controlling for these factors (Pot 2005).
Associations between late-life depression and increased mortality and medical morbidity, functional decline and disability, greater

dependence on personal care and health services, and poorer well-being and quality of life (Abrams 1992; Beekman 2002; Beerens 2013), highlight the importance of establishing effective treatments for depressive disorders in LTC settings. Subthreshold depressive symptoms that do not meet criteria for a formal diagnosis of MDD (also known variously as subsyndromal, subclinical or minor depression) are also associated with serious consequences in later life, including increased disability, greater healthcare utilisation, and increased suicidal ideation (Meeks 2011), and therefore are also important targets for treatment providers.

Description of the intervention

Management strategies for the treatment of late-life depression include both pharmacological and non-pharmacological interventions. Older adults living in LTC settings typically have more limited access to psychological treatment modalities than the broader older adult population, with treatment providers largely relying on antidepressant medications (George 2007). The range of psychological therapies that could be potentially used with older adults are similar to those that have been well established for use with younger adults, including:

- behaviour therapies (e.g. relaxation techniques, activity scheduling, and behaviour modification);
- cognitive behavioural therapies (CBT; e.g. cognitive restructuring, and skills training, such as stress management and problem-solving);
- third wave CBT (e.g. acceptance and commitment therapy (ACT), mindfulness-based cognitive therapy (MBCT));
- psychodynamic therapies (e.g. brief psychotherapy, psychoanalytic therapy and insight oriented therapy);
- humanistic therapies (e.g. existential therapy and non-directive therapy);
- integrative therapies (e.g. counselling and interpersonal therapy); and
- systemic therapies (e.g. family therapy, narrative therapy and solution focused brief therapy).

In addition, some interventions have been designed specifically for older adults, notably reminiscence therapies (e.g. life review). Psychological therapies may be performed by practitioners from a range of professional backgrounds, including psychologists, counsellors, social workers, psychiatrists, psychiatric nurses and occupational therapists. There is potential for LTC care staff (i.e. nurses, diversional therapists) to be trained to deliver structured psychological interventions, such as reminiscence programmes and activity scheduling.

How the intervention might work

Psychological therapies may be used as an adjunct to pharmacological treatment, or alternative treatment approach for MDD, other depressive disorders, or depressive symptoms in older adults. The proposed mechanisms of action vary with the underlying theoretical basis of individual psychological therapies. Behavioural therapy is based on the assumption that behaviour is learned, and employs methods that focus on changing maladaptive behaviour patterns. Activity scheduling is often used for combating passivity and withdrawal in depression and assists a depressed person to gradually re-engage in some of the routines of his or her daily life, with a focus on increasing activities that are pleasurable and associated with mastery. Various forms of relaxation techniques are available, such as progressive muscle relaxation, distraction and guided imagery, which have been described as helpful for managing depressive symptoms by younger adults in community surveys (Jorm 2008).

CBT programmes combine both behavioural and cognitive methods, and are future-directed, goal-oriented, systematic approaches. Cognitive restructuring is based on the theory that distressing emotions and maladaptive behaviours are due to unrealistic and unhelpful negative (or 'dysfunctional') patterns of thinking. The therapy aims to identify and modify an individual's thoughts, and assists the individual to replace dysfunctional thoughts with more adaptive cognitions. A range of skills training techniques fit within the CBT approach, such as problem-solving and stress management.

Interventions described as 'third wave CBT' incorporate concepts such as acceptance, mindfulness and personal values. Two of the more commonly used approaches are mindfulness-based cognitive therapy (MBCT), which employs mindful meditation as a therapeutic technique to interrupt patterns of rumination and negative thinking, and acceptance and commitment therapy (ACT), which facilitates acceptance of those components of life that are beyond one's control. ACT teaches individuals to focus on their remaining resources and commit to courses of action that are in accordance with their core values.

In contrast to CBT, psychodynamic therapy focuses on an individual's past experiences and aims to understand the impact of early events and unconscious processes on the current mood and behaviour of the individual.

Humanistic therapies focus on self-development and personal growth, and aim to facilitate self-awareness and enable an individual to recognise his or her strengths and develop towards their full potential. For example, non-directive therapy provides a therapeutic relationship, whereby an individual feels valued, listened to and understood, and works by enabling the individual to reflect on their problems and seek solutions.

Integrative therapies, such as counselling, combine components of different psychological therapy models. One such approach, interpersonal psychotherapy assists the individual in understanding how their interpersonal problems, such as disputes, role transitions, grief and interpersonal deficits, contribute to their well-being, and provides strategies to improve interpersonal skills.

Systemic therapies, such as couple and family therapy, focus be-

yond the level of the individual, and aim to improve the functioning of a larger unit, such as marital unit or a family, typically by altering interactions between or among members of these units. Narrative therapy is based on understanding the 'stories' that people use to describe their lives. The therapist helps the individual to consider how these stories may restrict them from overcoming their present difficulties. It sees problems as being separate from the individuals themselves and assists the client to recognise the range of skills, beliefs and abilities they already have (but may not recognise) and which can be applied to current problems in their lives. Solution-focused brief therapy helps individuals find tools to manage symptoms and cope with challenges. It works by assisting the individual to clarify their goals and develop a series of steps to achieve them, based on enhancing their internal abilities and experimenting with new approaches.

Reminiscence therapy is typically used with only older adults, and is a recognised evidence-based treatment for late-life depression (Scogin 2005). It aims to evoke pleasant or shared memories and problem-solving successes, and to develop an integrated account of one's life. Such treatments are variously referred to as simple reminiscence, life review and life review therapy.

Why it is important to do this review

Despite the significance of the problem, there remains a lack of evidence regarding appropriate treatments for depression among older people living in LTC facilities. A number of experts have challenged the effectiveness of commonly used antidepressant medications in this setting, especially for people with dementia, and questioned their long-term use in people with multiple comorbidities (Banerjee 2011; Snowdon 2010). A 2012 review of studies evaluating antidepressants in nursing homes included two randomised trials with a control group, which did not demonstrate a statistically significant benefit for antidepressant pharmacotherapy over placebo (Boyce 2012). While six of the seven non-randomised studies identified a response to an antidepressant, the authors explained, "their results must be interpreted with caution as they lacked a comparison group". Limited information is available on the efficacy of antidepressants among residents with cognitive impairment and dementia (Boyce 2012; Snowden 2003), which is problematic given the high prevalence of these conditions in the LTC population. Surveys have indicated that many residents continue to have high symptom counts, despite taking an antidepressant (Davison 2007; O'Connor 2010). While many older adults report a preference for psychological treatment over medications (Gum 2006), there continues to be a lack of clear evidence of the effectiveness of psychological treatment approaches for depression among older people living in LTC facilities. A systematic review of the available evidence is required to inform appropriate service provision for the LTC population.

Several reviews have reported promising results of psychological therapies for older people in the general community, particularly using CBT and problem-solving therapy (Cuijpers 2014; Wilson 2008). However, the LTC population is substantially older and more cognitively and functionally disabled than is typically the case for older people who are able to remain in their own homes. Trials in community settings often recruit participants as young as 50 to 55 years, with mean ages of trial samples substantially below those found in LTC, where more than half of the residents are aged 85 years and over (AIHW 2012). Generalising findings from community studies to the LTC population is therefore problematic, and a review of research specifically targeting LTC residents is required.

A number of previous reviews, both narrative and systematic, indicated that psychological therapies may impact on depressive symptomatology in LTC (Bharucha 2006; Cody 2013; Hyer 2005; Powers 2008; Simning 2017; Snowden 2003). However, many of these reviews had a broader aim than the current review, for example, (i) evaluating interventions designed to improve well-being in general, rather than focusing specifically on those that aimed to treat depression (Bharucha 2006), (ii) evaluating a broad range of non-pharmacological or psychosocial interventions, such as bright light therapy or exercise-related therapies, rather than restricting the review to psychological treatment trials (Hyer 2005; Snowden 2003); or (iii) including both non-pharmacological and pharmacological interventions (Simning 2017). Some reviews aimed to exclude residents with dementia (Simning 2017), despite the high prevalence of dementia in this population (Seitz 2010). In addition, previous reviews commonly included studies of convenience samples of LTC residents (rather than only studies that recruited participants with clearly defined subthreshold depressive symptoms or depressive disorders). One review focused only on nursing homes and excluded studies of lower-level dependency facilities (assisted-living facilities; Simning 2017). Cody and Drysdale's finding of a medium effect size of psychotherapy on symptoms of depression in LTC is highly encouraging (Cody 2013). The authors' suggestion that those interventions that were implemented with the involvement of LTC facility staff (i.e. using an integrated care model) were more effective than therapies delivered without facility staff involvement, is of particular interest.

Our review will collect and examine high quality and up-to-date evidence on the effect of psychological therapies for depression in LTC settings. Given the impact of subthreshold depressive symptoms, we will include treatment studies for subthreshold depressive symptoms (based on scores above a defined cut-off on validated depression scales), as well as studies for MDD. This review will address the gap in our knowledge of the relative effectiveness of different psychotherapeutic interventions in the LTC population, as well as synthesise evidence regarding the effectiveness of psychotherapy on residents with varying levels of cognitive impairment

OBJECTIVES

To assess the effects of psychological therapies in comparison with treatment as usual, waiting list, attentional control, other psychological therapies, or cointervention for depression in older people living in long-term care (LTC) settings.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) in this review. We will include studies with cluster allocation, but will exclude those with only one or two clusters in each intervention group because randomisation is unlikely to achieve balance in factors (e.g. characteristics of residents in each facility, as well as organisational climate or care-related factors) that could affect outcomes in this situation. We will include trials using a cross-over design but we will only use data from the first treatment phase, due to the potential for maintenance of treatment outcomes. We will include quasi-RCTs (where allocation to an intervention condition is not strictly random, e.g. by resident record number, alternation) only if we do not locate any eligible RCTs.

Types of participants

Participant characteristics

We will include studies with participants aged 65 and older regardless of their gender, ethnicity or religion. We will consider studies if the age range begins under 65 years but the mean age is over 65. We will also consider studies that include a subset of participants aged 65 years and over, but only if the participants were randomised on the level of the subset and the data for participants aged 65 years and over are reported separately.

Diagnosis

Participants will present with (a) major depressive disorder (MDD) according to Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Statistical Classification of Diseases and Related Health Problems (ICD) criteria (APA 2000; WHO 1992), or (b) subthreshold depressive symptoms, based on a score over a cut-off on a validated depression instrument, as defined by the study authors. Given that there is no established cut-off score on gold standard instruments to determine the presence of substantial depression symptoms among older adults in long-term care (LTC) settings, and the anticipated heterogeneity in both the instruments selected in studies as well as the cut-off points employed, we will not attempt to specify the instruments (provided there is published evidence of its validity with older adults) or cut-off points that we will accept for inclusion in the review.

Comorbidities

Participants may have normal cognitive functioning, mild cognitive impairment, or any type or severity of dementia. We will accept any definitions used to define cognitive impairment or dementia as long as the criteria used were included in the publication. Studies involving participants with comorbid physical conditions or other psychological disorders will be eligible for inclusion as long as the treatment of depression is a primary aim of the study.

Setting

The study setting will be LTC facilities, including nursing homes, assisted-living facilities, and residential aged care facilities, where some level of day-to-day care is provided to older adults by staff employed in the facility (i.e. to assist in activities of daily living) in addition to provision of accommodation. We will include studies with samples from multiple settings only if outcomes relevant for the review are reported separately for the LTC residents.

Types of interventions

Experimental interventions

We will include studies assessing any forms of psychological therapy for the treatment of depression, where this is compared with an alternative condition (see list of comparator interventions below). We will include both group and individual psychological therapies, with no restrictions on frequency, intensity or duration of the intervention. We will include studies in which the psychological therapy is delivered in combination with another intervention (cointervention, including pharmacotherapy and exercise) only if there is a separate comparison group that receives the cointervention alone. We will include interventions facilitated by a range of professionals, including psychologists, social workers, occupational therapists, nurses, therapists in supervised training and other trained professionals, including LTC staff trained to implement the intervention. Psychological interventions will be grouped into the following categories, according to the Cochrane Common Mental Disorders Group topic list.

- Behaviour therapies (e.g. relaxation techniques, activity scheduling, and behaviour modification).
- Cognitive behavioural therapies (CBTs; e.g. cognitive restructuring, and skills training, such as stress management and problem-solving).

- Third wave CBTs (e.g. acceptance and commitment therapy (ACT), and mindfulness-based cognitive therapy (MBCT)).
- Psychodynamic therapies (e.g. brief psychotherapy, psychoanalytic therapy, and insight oriented therapy).
- Humanistic therapies (e.g. existential therapy and non-directive therapy).
- Integrative therapies (e.g. counselling and interpersonal therapy).
- Systemic therapies (e.g. family therapy, narrative therapy, and solution focused brief therapy).
- Reminiscence therapies (e.g. simple reminiscence, life review, and life review therapy).

We will exclude treatments identified as pharmacotherapy or exercise. We will exclude music, art or drama therapies, and other psychosocial interventions that are not clearly psychological therapies. We will also exclude self-help interventions, delivered without therapist involvement.

Comparator interventions

- Treatment as usual or standard care
- On waiting list: the control group will not receive any treatment until the intervention group completes the treatment
- Non-specific attentional control (e.g. friendly visits from volunteers or current events discussion group), to control for the effects of social interaction
- An alternative active psychological therapy
- Cointervention (if also used in the intervention arm of the study), including pharmacotherapy or exercise.

Types of outcome measures

We will include studies that meet the above inclusion criteria, regardless of whether they report on the following outcomes.

Primary outcomes

- Efficacy outcome - level of depressive symptomatology
  - We will measure depressive symptomatology using a variety of validated instruments, including those administered through self-report, structured clinical interview or informant report, with the informant being a staff or family member. Commonly used scales in LTC settings include the self-rated Geriatric Depression Scale (GDS) (Yesavage 1982), the Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos 1988), and the Hamilton Rating Scale for Depression (HAM-D) (Hamilton 1960). The score we use will reflect the protocol used to administer the instrument in the study. To illustrate, in the guidelines for CSDD (Alexopoulos 1988), the total score represents the clinical opinion of the rater, based on interviews with the participant and an informant.
- Treatment non-acceptability
  - We will consider the rate of participants who drop out of therapy a proxy measure for treatment acceptability. We will not include in this measure dropouts that are clearly attributable to reasons unrelated to the study or intervention, such as decline in physical health, death or relocation during the course of the study, and which impact on the participants' eligibility to participate in the study.

Secondary outcomes

- Depression remission
  - We will consider the presence or absence of MDD, according to DSM or ICD criteria, a secondary efficacy outcome. We will include studies if they employed structured or semi-structured diagnostic clinical interviews (e.g. the Structured Clinical Interview for DSM-5 (SCID-5) (First 2016); or the Mini International Neuropsychiatric Interview (MINI) (Sheehan 1998)), either by a mental health clinician (e.g. psychiatrist, clinical psychologist) or a trained researcher. If the studies did not employ a structured interview schedule, we may include studies if the diagnostic interview was conducted by a mental health clinician and appropriate psychometric data were assessed and reported (e.g. acceptable inter-rater reliability).
- Quality of life or psychological well-being
  - We will measure this outcome using standardised scales, such as the Short Form 36 (SF-36) (Ware 1992), the World Health Organization Quality of Life (WHOQOL) assessment (WHOQOL Group 1998), and the Satisfaction with Life Scale (SWLS) (Diener 1985). Instruments may be self- or informant-rated, with the informant being a staff or family member.
- Level of anxious symptomatology
  - We will measure this outcome using standardised measurement instruments such as the Geriatric Anxiety Inventory (GAI) (Pachana 2007), the Rating Anxiety in Dementia (RAID) Scale (Shankar 1999), and the Hamilton Anxiety Scale (HAM-A) (Hamilton 1959).
- Physical functioning
  - We will assess this outcome using scales of basic activities of daily living, such as the Katz Index of Independence in activities of daily living (Katz ADL) (Katz 1963), and instrumental activities of daily living, such as the Lawton Instrumental Activities of Daily Living (IADL) Scale (Lawton 1969).
- Agitation
  - We will assess agitation using standardised scales, such as the Agitation subscale of the Neuropsychiatric Inventory (NPI) (Cumming 1994), and the Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield 1989).
- Adverse effects
  - We will define adverse effects as defined by individual studies.

Timing of outcome assessment

We will summarise post-treatment outcomes at each reported follow-up point. In addition, we will report follow-up outcomes, where available. If the data allow, we will categorise follow-up outcomes as short-term (up to 3 months), medium-term (3 to 6 months) and long-term (more than 6 months). If a study reports follow-up outcomes at more than one time point, within one of these time frames, we will select the outcome reported at the latest point within the time frame. We will report outcomes at the first assessment post-intervention in the Abstract and 'Summary of findings' table.

Hierarchy of outcome measures

We will separately analyse depression symptoms (typically assessed using continuous measures) and MDD diagnosis (typically assessed using dichotomous measures), and will consider depressive symptoms the primary outcome. If a trial reports use of more than one instrument assessing depression symptoms, then we will prioritise in the following order: clinician-rated scale, informant-rated scale, and self-rated scale, given concerns regarding the reliability of reported symptoms of depression in the LTC population (Davison 2009). If multiple outcome measures are employed of the same type (e.g. two self-report measures), we will choose the outcome measure that is most frequently used across studies (namely availability across studies). If multiple outcome measures of the same type have equivalent availability across studies, we will choose the one with strongest psychometric evidence in previous research in LTC settings.

Search methods for identification of studies

Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR)

The Cochrane Common Mental Disorders Group (CCMD) maintains two archived clinical trials registers at its editorial base in York, UK: a references register and a studies-based register. The CCMDCTR-References Register contains over 40,000 reports of RCTs in depression, anxiety and neurosis. Approximately 50% 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 are collated from routine (weekly), generic searches of MEDLINE (1950 to 2016), Embase (1974 to 2016) and PsycINFO (1967 to 2016); quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) and review-specific searches of additional databases. Reports of trials are also sourced from international trial registers via the World Health Organization's trials portal (the International Clinical Trials Registry Platform (ICTRP)), pharmaceutical companies, the handsearching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses. Details of CCMD's core search strategies (used to identify RCTs) can be found on the Group's website with an example of the core MEDLINE search displayed in Appendix 1. The CCMDCTR is current to June 2016 only.

Electronic searches

A Cochrane Information Specialist will search the Group's controlled trials registers CCMDCTR-Studies and CCMDCTR-References (Appendix 2). The search of the references register will be based on condition and treatment setting, or specific types of psychological therapy designed for older adults. The latter will help identify studies where the treatment setting is ambiguous or not stated in the summary abstract.

The information specialist will also run a top-up search of Ovid MEDLINE and Ovid Embase (2016 to date) to cover the period when the CCMDCTR fell out of date due to the relocation of the Group from Bristol to York.

We will conduct complementary searches on the following bibliographic databases using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource.

- Abstracts in Social Gerontology (EBSCO) (1966 onwards);
- AgeLine (EBSCO) (all available years);
- CENTRAL (Cochrane Central Register of Controlled Trials) (current issue);
- CINAHL (Cumulative Index to Nursing & Allied Health) (EBSCOhost) (1937 onwards);
- PsycINFO (OVID) (all available years);
- PubMed (current year only, to identify journal articles not yet indexed in MEDLINE and CENTRAL);
- Social Services Abstracts (Proquest) (1980 onwards);
- Sociological Abstracts (Proquest) (1974 onwards).

We will not apply restrictions on date, language or publication status to the searches (unless otherwise stated).

We will search international trial registries via the World Health Organization's trials portal (ICTRP), and ClinicalTrials.gov to identify additional unpublished or ongoing studies.

Searching other resources

Grey literature

We will search the following sources of grey literature (all available years).

- ProQuest Dissertations and theses database.
- Open Acces Theses and Dissertations (oatd.org).

- DART-Europe E-theses Portal (www.dart-europe.eu).
- EThOS - the British Libraries e-theses online service (ethos.bl.uk).
- Open Grey (www.opengrey.eu).

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). We will also conduct a cited reference search on the Web of Science Science Citation Index (SCI) for reports of included studies.

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

Selection of studies

Two review authors (EY, YW) will independently screen titles, or abstracts, or both, for inclusion of all potential studies identified as a result of the search and code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. After retrieving the full-text study reports/publications, the two review authors will independently screen the full-text and identify studies for inclusion, and identify and record reasons for exclusion of the ineligible studies. The two review authors (EY, YW) will resolve any disagreement through discussion or, if necessary, consultations with a third review author (TD). We will identify and exclude duplicate records, and we will collate multiple reports that relate to the same study so that each study 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 (Liberati 2009).

Data extraction and management

We will use a piloted data extraction form, based on the Cochrane Effective Practice and Organisation of Care (EPOC) data extraction form (EPOC 2017), to extract study characteristics and outcome data. The two review authors (EY, YW) will independently extract study characteristics and outcome data from included studies. We will extract the following study characteristics.

- Description of the study: authors, publication year and country of origin.
- Study design: sampling, randomisation, details of any 'run in' period, follow-ups/withdrawals, study setting(s), date of data collection, and duration of study.
- Study population: sample size (numbers randomised, numbers treated, and numbers followed up), age (mean/median and range), gender, comorbidities, level of cognitive function, and history of depression.
- Diagnosis and assessment of depression: diagnostic criteria for disorder, or cut-off used to operationalise subthreshold depression symptoms, as well as criteria used to define severity of symptoms (if available).
- Interventions: description of intervention, intervention type, duration, number of sessions, and methods of delivery. These data are extracted for both experimental interventions and comparator interventions.
- Treatment fidelity: whether treatment fidelity was assessed by the trial authors.
- Outcomes: description of primary and secondary outcomes at different time points, including dropouts.
- Notes: funding for trial, and notable conflicts of interest of trial authors.

We will note in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. The two review authors (EY, YW) will resolve any disagreement by consensus or by involving a third review author (TD). One of the two review (EY) authors will transfer data into the Review Manager 5 file (Review Manager 2014). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports. The second review author (YW) will spot-check study characteristics for accuracy against the trial report.

Main comparisons

We will undertake the following comparisons.

- Psychological therapies versus treatment as usual/standard care.
- Psychological therapies versus waiting list.
- Psychological therapies versus non-specific attentional control.
- Psychological therapies versus alternative active psychological therapy.
- Psychological therapies plus cointervention versus cointervention alone (see details in the 'Types of interventions' section).

Assessment of risk of bias in included studies

Two review authors (SB, CD) will independently assess risk of bias for each study using the criteria outlined in Higgins 2017. Any disagreements will be resolved by discussion between the two review authors and if necessary by involving a third review author (TD). We will assess risk of bias according to the following domains.

- Random sequence generation.
- Allocation concealment.

- Blinding of participants and personnel.
- Blinding of outcome assessment.
- Incomplete outcome data, e.g. due to loss to follow-up.
- Selective outcome reporting.
- Other bias.

We will rate each potential source of bias as high, low or unclear and provide a supporting quotation from the study report together with a justification for our judgement in the 'Risk of bias' table. We will summarise the risk of bias judgements across different studies for each of the domains listed. Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'Risk of bias' table.

When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome. For cluster-randomised trials (if identified), we will assess the risk of bias by considering recruitment bias, baseline imbalance, loss of cluster, incorrect analysis and comparability with individually randomised trials (Higgins 2017).

Measures of treatment effect

Dichotomous data

We will analyse dichotomous data as odds ratios (ORs) and 95% confidence intervals (CIs). Where reported as risk ratios (RRs), we will convert them to ORs (Deeks 2017).

Continuous data

We will analyse continuous data by calculating the mean differences (MDs) between groups if studies use the same outcome measure for comparison. However, we will calculate standardised mean differences (SMDs) and 95% CIs if studies use different outcome measures to assess the same outcome. We will enter data presented as a scale with a consistent direction of effect.

We will undertake meta-analyses only where this is meaningful (i.e. if the treatments, participants and the underlying clinical question are similar enough for pooling to make sense). We will narratively describe skewed data reported as medians and interquartile ranges. Where multiple trial arms are reported in a single trial, we will include only the relevant arms.

Unit of analysis issues

Cluster-randomised trials

We will include cluster-RCTs where LTC facilities are the unit of allocation if there are more than two clusters in each group. Where possible we will include data adjusted with an intracluster correlation coefficient (ICC) from each cluster-randomised trial. Nevertheless, if the ICC is not reported or not available from the study authors, we will use 0.1 in line with the literature (Higgins 2011b; Purgato 2015).

Cross-over trials

For cross-over trials, we will only use data from the first treatment phase to avoid any carry-over effects.

Studies with multiple treatment groups

If any multiple-arm studies (e.g. psychological intervention A, psychological intervention B, and control) are included in the meta-analysis, we will combine the intervention groups to create a single pair-wise comparison, in order to avoid possible bias caused by multiple comparisons with one control group. We will combine groups using appropriate formulae depending on whether the outcome is continuous (Higgins 2011a), or dichotomous (Higgins 2011b). However, in the subgroup analysis, when investigating the impact of each type of psychological therapy, for multiple-arm studies we will divide out the shared intervention groups approximately evenly among the comparators to avoid double counting.

Dealing with missing data

We will contact investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible (e.g. when a study is identified as abstract only). We will document all correspondence with trialists and report which trialists responded in the full review. For cluster-RCTs, we will contact study authors for an ICC if data were not adjusted and cannot be obtained from the trial report.

We will analyse missing dichotomous data using an intention-to-treat analysis (ITT), assuming that participants who dropped out after randomisation would have experienced negative outcomes by the end of the trial.

We will analyse missing continuous data using a last observation carried forward to the final assessment (LOCF) analysis if the LOCF data are available, or on an end point basis, including only participants with a final assessment.

Assessment of heterogeneity

We will assess heterogeneity by visual inspection, the Chi^2 statistic and I^2 statistic. We will quantify heterogeneity using the I^2 statistic, which calculates the percentage of variability because of heterogeneity rather than chance. It should be noted that using a flat 50% threshold for I^2 is not appropriate and one main reason is that the value of the I^2 depends on the sample size of the included studies. Following the guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017), we will use the following thresholds for the interpretation of I^2.

- 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 importance of the observed value of I^2 depends on (i) the magnitude and direction of effects and (ii) the strength of evidence for heterogeneity (e.g. P value from the Chi^2 test, or a CI for I^2). Thus, if the I^2 value is below 50% and the direction and magnitude of treatment effects suggests important heterogeneity, we will investigate the sources.

Assessment of reporting biases

We will use the funnel plots technique to assess possible publication bias if we identify more than 10 studies, using the search strategies described above. However, we will take into account the limitations of the funnel plots because they may not necessarily indicate publication bias and are prone to other causes of asymmetry (Forsma 2009). As detailed below, we will conduct a sensitivity analysis for allocation concealment.

We will also attempt to identify outcome reporting bias by comparing planned and reported outcomes. Where we find evidence of missing outcomes, we will contact the study authors for any available data.

Data synthesis

We will use random-effects models given the potential heterogeneity of the included trials. We will consult expert advice regarding the combination of treatment groups to ensure that the findings are clinically meaningful.

If we cannot combine studies because of insufficient data, or substantial heterogeneity of the included trials, or both, we will provide a narrative summary of the evidence by intervention type.

Subgroup analysis and investigation of heterogeneity

If data allow, we will conduct the following subgroup analyses for primary outcomes.

- Baseline depression severity: this may impact on the primary outcome of interventions. In the heterogeneity analyses we will test for differences between LTC residents with MDD and subthreshold depressive symptoms at baseline. We will also classify baseline levels of depressive symptoms as mild, moderate and severe, if data are available and there is suitable information on the employed outcome measures to enable this classification.
- Types of psychological therapies: different therapies may have a different effect size and acceptability to participants. We will test for differences between different psychological therapies.
- Types of LTC residents: cognitive impairment may impact on the effect size and acceptability of interventions. We will test for differences in outcomes between LTC residents with and without dementia, and between residents with different levels of cognitive impairment.
- LTC facility staff involvement in the psychological therapy: a previous review indicated that interventions implemented with the involvement of staff from the LTC facility, in addition to the therapist, were more effective than interventions delivered without staff involvement (Cody 2013). We will test for the effectiveness of facility staff involvement in the delivery of psychological therapies compared to no facility staff involvement.
- Therapeutic contact: the duration and number of sessions may impact on the effectiveness and acceptability of psychological interventions. We will test for differences between therapies that vary in the level of therapeutic contact, calculated by multiplying the number of sessions by the average session duration.

It should be noted that subgroup analyses are observational and usually involve multiple analyses which might increase the likelihood of incorrect, positive results. Therefore, we will interpret results with caution.

Sensitivity analysis

To test the robustness of the results of the primary outcome, we will conduct the following sensitivity analyses.

- Bias: excluding studies that we rated as having high or unclear risk of bias for allocation concealment.
- Attrition: excluding studies with the dropout rate being over 30%.
- Missing data: excluding studies that impute missing data.
- Treatment fidelity: excluding studies that did not measure treatment fidelity of the psychological models.

'Summary of findings' table

We will use the GRADE approach to assess the quality of the body of evidence as described in the *Cochrane Handbook for Systematic Reviews of Intervention* (Schünemann 2017). We will use GRADEprofiler to create a 'Summary of findings' table (GRADEpro GDT 2015). This table will include the following information.

- Populations: people aged 65 years and over with MDD according to DSM or ICD criteria, or score over an established cut-off on a validated depression instrument.
- Settings: LTC facilities or multiple settings that include LTC facilities.
- Interventions: behaviour therapies, CBT, third wave CBT, psychodynamic therapies, humanistic therapies, integrative therapies, systemic therapies, and reminiscence interventions.
- Comparisons: treatment as usual or standard care, waiting list, non-specific attentional control, alternative active psychological therapy, and cointervention.
- Outcomes: we will report outcomes at the post-treatment assessment. These will include level of depressive

symptomatology, presence or absence of MDD, treatment acceptability, quality of life or psychological well-being, and level of anxious symptomatology.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. CCMDTCTR - Core MEDLINE search

CCMD's core search strategy used to inform the Group's Specialised Register: OVID MEDLINE (1950 to date)

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 depression, postpartum/ or depressive disorder, major/ or depressive disorder, treatment-resistant/ or dysthymic disorder/ or seasonal affective disorder/ or neurotic disorders/ or depression/ or adjustment disorders/ or exp antidepressive agents/ or anxiety disorders/ or agoraphobia/ or neurocirculatory asthenia/ or obsessive-compulsive disorder/ or obsessive hoarding/ or panic disorder/ or phobic disorders/ or stress disorders, traumatic/ or combat disorders/ or stress disorders, post-traumatic/ or stress disorders, traumatic, acute/ or anxiety/ or anxiety, castration/ or koro/ or anxiety, separation/ or panic/ or exp anti-anxiety agents/ or somatoform disorders/ or body dysmorphic disorders/ or conversion disorder/ or hypochondriasis/ or neurasthenia/ or hysteria/ or munchausen syndrome by proxy/ or munchausen syndrome/ or fatigue syndrome, chronic/ or obsessive behavior/ or compulsive behavior/ or behavior, addictive/ or impulse control disorders/ or firesetting behavior/ or gambling/ or trichotillomania/ or stress, psychological/ or burnout, professional/ or sexual dysfunctions, psychological/ or vaginismus/ or Anhedonia/ or Affective Symptoms/ or *Mental Disorders/

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 are screened for reports of RCTs within the scope of the Cochrane Common Mental Disorders Group. Secondary reports of RCTs are tagged to the appropriate study record.
Similar weekly search alerts are conducted on OVID Embase and PsycINFO, using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource.

Appendix 2. CCMDCTR - review search

Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR)

1. CCMDCTR-Studies Register
A Cochrane Information Specialist will search the Group's specialised studies register to identify relevant studies for this review by using the following terms (linked to a controlled vocabulary used to code the register):
Condition = (*depress* or dysthymi* or "affective disorder*" or "affective symptoms" or "mood disorder*" or "low mood"*)
AND
Intervention = *(behavi* or care or cogni* or counsel* or educat* or group or manage* or psycho* or *therap* or train*)*
AND
Treatment setting = *("nursing home" or "residential home" or "care home" or "residential care" or "long term care" or "aged care" or "nursing facility" or "care facility" or "assisted living" or "assisted-living")*
2. CCMDCTR-References Register
The information specialist will search the Group's references register using a more sensitive set of terms to identify additional untagged/uncoded reports of RCTs. The search will be based on condition and treatment setting or specific types of psychological therapy designed for older adults. The latter will help identify studies where the treatment setting is ambiguous or not stated in the summary abstract:
#1 *(depress* or "affective disorder*" or "affective symptoms" or "mood disorder*" or "low mood"):*ti,ab,kw,ky,emt,mh,mc
#2. (*gerontopsych* or institutionali* or resident* or ((care or communit* or elder* or geriatri* or retirement or nursing) near2 (home or facilit* or "long term")) or (assist* near3 (housing or living)) or ((day or daily) near3 care"))):*ti,ab,kw,ky,emt,mh,mc
#3 (#1 and #2)
#4 *(reminiscence or "life review" or "problem sol*" or "stress manage*" or "pleasant events" or "activity scheduling" or relaxation or psychoeducat* or ("daily living" and educat*)):*ti,ab,kw,ky,emt,mh,mc
#5 (*psychotherapy or "cognitive behavi*" or "behavi* therap**"):ti,emt,mh
#6 *(geriatri* or geronto* or (old* near2 (people or adult* or men or women)) or elder* or seniors or "late* life" or "senior citizen*" or "old old" or "very old"):*ti,ab,kw,ky,emt,mh,mc
#7 *(aged or "aged 80 and over" or "frail elderly" or "very elderly"):*kw,ky,emt,mh
#8 (#1 and (#4 or #5) and (#6 or #7))
#9 (#3 or #8)
[Key to field tags. *ti:title*; *ab:abstract*; *kw:keywords*; *ky:other keywords*; mh:*MeSH headings*; *mc:MeSH check words*; *emt:EMTREE headings*]
The CCMDCTR search will be translated across to all the other databases (as appropriate) using relevant subject headings (controlled vocabularies) and search syntax.

CONTRIBUTIONS OF AUTHORS

TD and SB conceptualised this paper. TD, EY, and CD drafted the manuscript, with contributions from SB, YW and LF in revising the manuscript. All authors approved the submission.

DECLARATIONS OF INTEREST

Tanya Davison: no known conflicts of interest to declare.

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