Review protocol for review question 1.1: For adults with depression, what are the relative benefits and harms associated with different models for the coordination and delivery of services?

Table 27: Review protocol for different models of care

Field (based on PRISMA-P)	Content
Review question	For adults with depression, what are the relative benefits and harms associated with different models for the coordination and delivery of services?
Type of review question	Intervention review
Objective of the review	To identify the optimal model of delivery of services for adults with an acute episode of depression, or adults whose depression has responded fully or partially to treatment.
Population	• Adults with a diagnosis of depression according to DSM, ICD or similar criteria, or depressive symptoms as indicated by baseline depression scores on validated scales (and including those with subthreshold [just below threshold] depressive symptoms) For studies on relapse prevention: • Adults whose depression has responded to treatment (in full or partial remission) according to DSM, ICD or similar criteria, or indicated by below clinical threshold depression symptom scores on validated scales If some, but not all, of a study's participants are eligible for the review, for instance, mixed anxiety and depression diagnoses, then we will include a study if at least 80% of its participants are eligible for this review
Exclude	• Trials of women with antenatal or postnatal depression • Trials of children and young people (mean age under 18 years) • Trials of people with learning disabilities • Trials of adults in contact with the criminal justice system (not solely as a result of being a witness or victim)

Field (based on PRISMA-P)	Content
	• Trials that specifically recruit participants with a physical health condition in addition to depression (e.g. depression in people with diabetes)
Intervention	Models for the coordination and delivery of services: • Collaborative care (simple and complex) • Stepped care • Medication management • Attached professional model • Care coordination • Integrated care pathways (including primary care liaison or shared care) • Measurement-based care
Comparison	• Treatment as usual • Waitlist • Any other service delivery model
Outcomes and prioritisation	**Critical outcomes:** • Depression symptomatology (mean endpoint score or change in depression score from baseline) • Response (usually defined as at least 50% improvement from the baseline score on a depression scale) • Remission (usually defined as a score below clinical threshold on a depression scale) • Relapse (number of people who returned to a depressive episode whilst in remission) The following depression scales will be included in the following hierarchy: • MADRS • HAMD • QIDS • PHQ • CGI (for dichotomous outcomes only) • CES-D • BDI • HADS-D (depression subscale)

Field (based on PRISMA-P)	Content
	Important outcomes: • Antidepressant use • Discontinuation due to any reason Outcomes will be assessed at 6 months and 12 months.
Study design	• RCTs • Systematic reviews of RCTs
Include unpublished data?	Conference abstracts, dissertations and unpublished data will not be included unless the data can be extracted from elsewhere (for instance, from the previous guideline)
Restriction by date?	All relevant studies from existing reviews from the 2009 guideline and from previous searches (pre-2016) will be carried forward. No restriction on date for the updated search, studies published between database inception and the date the searches are run will be sought.
Minimum sample size	• Minimum sample size N = 10 in each arm • Studies with <50% completion data (drop out of >50%) will be excluded
Study setting	Primary, secondary, tertiary and social care settings. Non-English-language papers will be excluded (unless data can be obtained from an existing review).
Review strategy	**Coding Strategy** For this review, a coding system for classifying the complexity and type of service delivery model has been developed specifically for the purpose of this guideline. The service delivery model described in each study will be rated on this 17-item coding system which will generate an overall rating between 0-20 (see Table 1). Service delivery models which score above 6 will be considered a collaborative care intervention; those scoring 13+ will be coded as complex collaborative care and those scoring 6-12 will be coded as simple collaborative care. Service delivery models that score below 6 will be classified as an alternative service delivery model (e.g. care coordination) or a stand-alone psychological intervention (e.g. self-help with support). **Data Extraction (selection and coding)** Citations from each search will be downloaded into EndNote and duplicates removed. Titles and abstracts of identified studies will be screened by two reviewers for inclusion against criteria, until a good inter-rater reliability has been observed (percentage agreement =>90%). Initially 10% of references will be double-

Field (based on PRISMA-P)	Content
	screened. If inter-rater agreement is good then the remaining references will be screened by one reviewer. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). At least 10% of data extraction will be double-coded. Discrepancies or difficulties with coding will be resolved through discussion between reviewers or the opinion of a third reviewer will be sought. **Data Analysis** A meta-analysis using a random-effects model will be conducted to combine results from similar studies. An intention to treat (ITT) approach will be taken where possible. Risk of bias will be assessed at the study level using the Cochrane risk of bias tool. This assessment includes: adequacy of randomisation (sufficient description of randomisation method, allocation concealment and any baseline difference between groups); blinding (of participants, intervention administrators and outcome assessors); attrition ('at risk of attrition bias' defined as a dropout of more than 20% and completer analysis used, or a difference of >20% between the groups); selective reporting bias (is the protocol registered, are all outcomes reported); other bias (for instance, conflict of interest in funding). Risk of bias will also be assessed at the outcome level using GRADE. For heterogeneity, outcomes will be downgraded once if I^2>50%, twice if I^2 >80%. For imprecision, outcomes will be downgraded using rules of thumb. If the 95% CI is imprecise i.e. crosses the line of no effect and the threshold for clinical benefit/harm, 0.8 or 1.25 (dichotomous) or -0.5 or 0.5 SMD (for continuous), the outcome will be downgraded. Outcomes will be downgraded one or two levels depending on how many lines it crosses. If the 95% CI is not imprecise, we will consider whether the criterion for Optimal Information Size is met (for dichotomous outcomes, 300 events; for continuous outcomes, 400 participants), if not we will downgrade one level. **Coding system for service delivery models** **Collaborative Care Component Score Method**

Field (based on PRISMA-P)	Content

Item	Score
1. Active and integrated case recognition/identification* (Systematic identification- from a clinical database or screened positive for depression)	0 1
2. Collaborative assessment and plan included (Collaborative assessment with the patient)	0 1
3. Case Management (Case manager present- can include pharmacist for medication management)	0 1
4. Active liaison with primary care and other services (System set up for structured liaison/ regular meetings)	0 1
5. Case Manager has MH background (A prior mental health background, not just training in mental health)	0 1
6. Supervision provided for case manager	0 1
7. Senior MH professional consultation/involvement (Broad definition- just need to be available)	0 1
8. Psychoeducation delivered	0 1
9. Algorithm(s) used to determine care*	0 1
10. Integration with physical health care where necessary	0 1
11. Social/psychosocial interventions provided	0 1
12. Case manager delivers intervention	0 1
13. Medication management provided	0 1
14. Routine outcome monitoring (Scheduled, using a tool)	0 1
15. Psychological interventions provided None Low intensity	 0 1

Field (based on PRISMA-P)	Content
	<table><tr><td>High intensity</td><td>2</td></tr><tr><td>16. Duration of programme contact ≤6 months 7-12months 1year plus</td><td> 0 1 2</td></tr><tr><td>17. Number of sessions (F-t-F and Telephone) ≤6 sessions 6 – 12 sessions 13 + sessions</td><td> 0 1 2</td></tr><tr><td>Total (maximum 20)</td><td></td></tr><tr><td colspan="2">*Including stepped care Rating <5 – not collaborative care 6-12 – simple collaborative care 13+ – complex collaborative care</td></tr></table>
Heterogeneity (sensitivity analysis and subgroups)	Where possible, the influence of the following subgroups will be considered: For the review of collaborative care only: • Type of collaborative care (simple vs complex) • Stepped care component included in collaborative care intervention • Case manager background • Psychological interventions delivered as part of the model of care • Number of contacts/sessions/follow-up visits provided as part of intervention (less than 13 sessions, 13+ sessions) For all reviews: • Chronic depression • Depression with coexisting personality disorder • Psychotic depression • Older adults • BME populations

Field (based on PRISMA-P)	Content
	• Men
Data management (software)	Endnote was used to sift through the references identified by the search, Excel was used for data extraction Pairwise meta-analyses and production of forest plots was done using Cochrane Review Manager (RevMan5). 'GRADEpro' was used to assess the quality of evidence for each outcome.
Notes	The committee identified one good quality systematic review of RCTs (Coventry et al., 2014) which reviewed collaborative care interventions. The review was used as a source to identify any additional eligible studies *Coventry PA, Hudson JL, Kontopantelis E, Archer J, Richards DA, et al. (2014) Characteristics of Effective Collaborative Care for Treatment of Depression: A Systematic Review and Meta-Regression of 74 Randomised Controlled Trials. PLoS ONE 9(9): e108114.* Separate reviews (if applicable) will be conducted for service delivery models which were aimed at: • Treating an episode of depression • Preventing relapse of a future episode of depression
Information sources – databases and dates	Database(s): Embase 1974 to Present, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; Cochrane Library; WEB OF SCIENCE
Identify if an update	Update of CG90 (2009)
Author contacts	For details please see the guideline in development web site.
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual 2014
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual 2014.

Field (based on PRISMA-P)	Content
	The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/.
Criteria for quantitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual 2014
Methods for quantitative analysis – combining studies and exploring (in)consistency	For details please see the methods chapter.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual 2014.
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual 2014
Rationale/context – what is known	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the evidence review. The committee was convened by the National Guideline Alliance (NGA) and chaired by Dr Navneet Kapur in line with section 3 of Developing NICE guidelines: the manual 2014. Staff from the NGA undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details please see the methods chapter.
Sources of funding/support	The NGA is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The NGA is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds NGA to develop guidelines for those working in the NHS, public health and social care in England
PROSPERO registration number	CRD42019151323

BDI: Beck Depression Inventory; BME: black, minority, ethnic; CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; CES-D: Centre of Epidemiology Studies – Depression; CGI: Clinical Global Impressions; CI: confidence interval; DARE: Database of Abstracts of Reviews of Effects; DSM: Diagnostic and Statistical Manual of Mental Disorders; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HADS-D: Hospital Anxiety and Depression Scale (-Depression); HAMD: Hamilton Depression Rating Scale ; ICD: International Statistical Classification of Diseases;ITT: intention to treat; MADRS: Montgomery–Åsberg Depression Rating Scale; N: number; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; PHQ: Patient Health Questionnaire; QIDS: Quick Inventory of Depressive Symptomatology; RCT: randomised controlled trial; RoB: risk of bias; SMD: standardised mean difference;