Review protocol for review question 1.2 For adults with depression, what are the relative benefits and harms associated with different settings for the delivery of care?

Table 28: Review protocol for different settings for the delivery of care

Field (based on PRISMA-P)	Content
Review question	For adults with depression, what are the relative benefits and harms associated with different settings for the delivery of care?
Type of review question	Intervention review
Objective of the review	To identify the optimal settings for the delivery of care for adults with depression
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) • If the evidence specific to depression is limited then the inclusion criteria may be expanded to include those with non-psychotic severe mental illness. • If some, but not all, of a study's participants are eligible for the review, then we will include a study if the majority (at least 51%) 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) • Trials that specifically recruit participants with a physical health condition in addition to depression (e.g. depression in people with diabetes)
Intervention	Settings for the delivery of care, which may include: • Primary care • Crisis resolution and home treatment teams • Inpatient setting • Acute psychiatric day hospital care • Non-acute day hospital care and recovery centres

Field (based on PRISMA-P)	Content
	• Specialist tertiary affective disorders settings • Community Mental Health Teams • Residential services •
Comparison	Any other setting for the delivery of care
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) **Important outcomes:** • Service utilisation/resource use (e.g. antidepressant use) • Psychological functioning • Social functioning • Satisfaction • Carer distress Outcomes will be assessed at endpoint and follow-up.
Study design	Only published full-text papers of the following types of studies: systematic reviews of RCTs; RCTs If no RCT evidence is identified that specifically addresses the following settings: primary care, and inpatient care, then indirect evidence will be considered in the form of sub-analyses of the NMA dataset (first-line treatment of depressive episodes)
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

Field (based on PRISMA-P)	Content
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	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-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 I2>50%, twice if I2 >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
Heterogeneity (sensitivity analysis and subgroups)	Where possible, the influence of the following subgroups will be considered: • Chronic depression • Depression with coexisting personality disorder • Psychotic depression

Field (based on PRISMA-P)	Content
	• Older adults
Data management (software)	STAR was used to sift through the references identified by the search, and 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.
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. 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

Field (based on PRISMA-P)	Content
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	Not applicable

CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; 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; ICD: International Statistical Classification of Diseases;ITT: intention to treat; N: number; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; NMA: network meta-analysis; RCT: randomised controlled trial; RoB: risk of bias; SMD: standardised mean difference;