Review protocol for 8.1 What radiotherapy techniques are effective for excluding the heart from the radiation field without compromising coverage of the whole breast target volume for people with early or locally advanced breast cancer?

Field (based on PRISMA-P)	Content
Actual review question	What radiotherapy techniques are effective for excluding the heart from the radiation field without compromising coverage of the whole breast target volume for people with early or locally advanced breast cancer?
Type of review question	Intervention review
Objective of the review	The objective of this review is to determine which heart-sparing breast radiotherapy techniques are effective without compromising the treatment of the whole breast volume. Recommendations will aim to cover which techniques should be offered to spare the heart during radiotherapy.
Eligibility criteria – population/disease/condition/issue/domain	Adults (18 or over) with invasive breast cancer (M0) and/or DCIS receiving whole breast radiotherapy
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	Heart sparing techniques: • Deep inspiration breath-hold • Prone radiotherapy • Shielding • Proton beam radiotherapy
Eligibility criteria – comparator(s)/control or reference (gold) standard	• Heart sparing techniques • No heart sparing technique
Outcomes and prioritisation	Critical (up to 3 outcomes) • Mean heart dose (MID: GRADE default values) • Target coverage (MID: GRADE default values) Important but not critical • Local recurrence rate (MID: any statistically significant difference)

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	• Treatment-related morbidity (e.g., pulmonary toxicity [MID: any statistically significant difference], lung cancer [MID: any statistically significant difference]) • Treatment-related mortality (MID: any statistically significant difference) Immediate outcomes will be prioritised for mean heart dose and target coverage.
Eligibility criteria – study design	• Systematic reviews/meta-analyses of RCTs • RCTs • Controlled, non-randomised studies • Prospective cohort studies (minimum no. of participants 30)
Other inclusion exclusion criteria	Foreign language studies, conference abstracts, and narrative reviews will not routinely be included.
Proposed sensitivity/sub-group analysis, or meta-regression	N/A
Selection process – duplicate screening/selection/analysis	Sifting, data extraction, appraisal of methodological quality and GRADE assessment will be performed by the reviewing team. Quality control will be performed by the senior systematic reviewer. Dual sifting will be performed on at least 10% of records and where possible all records due to the inclusion of controlled non-RCTs and prospective cohort studies; 90% agreement is required and any discussions will be resolved through discussion and consultation with senior staff where necessary.
Data management (software)	Study sifting and data extraction will be undertaken in STAR. Pairwise meta-analyses will be performed using Cochrane Reviewer Manager (RevMan 5). GRADEpro will be used to assess the quality of evidence for each outcome.
Information sources – databases and dates	The following key databases will be searched: Cochrane Library (CDSR, DARE, CENTRAL, HTA) through Wiley, Medline & Medline in Process and Embase through OVID. Additionally Web of Science may be searched and consideration will be given to subject-specific databases and used as appropriate. Searches will be undertaken from 2008 onwards as it is an update from the previous version of this guideline. A general exclusions filter and methodological filters (RCT and systematic review) will also be used as it is an intervention question.
Identify if an update	N/A

Field (based on PRISMA-P)	Content
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
Search strategy	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 appendix 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 appendix 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 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
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.
Confidence in cumulative evidence	For details please see Sections 6.4 and 9.1 of Developing NICE guidelines: the manual
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 guideline. The committee was convened by the NGA and chaired by Dr Jane Barrett in line with section 3 of Developing NICE guidelines: the manual. Staff from 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 of the full guideline.
Sources of funding/support	NGA is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	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 the NHS in England.
PROSPERO registration number	N/A

DCIS, Ductal carcinoma in-situ; GRADE, Grading of Recommendations Assessment, Development and Evaluation; MID, minimally important difference; N/A, not applicable; NGA, National Guideline Alliance; NHS, National Health Service; NICE, National Institute of Health and Care Excellence; RCT, randomised controlled trial