

Standards for Reporting Implementation Studies: the StaRI checklist for completion

Implementation of optimized kangaroo care for infection prevention and control in neonatal intensive care units (NeolPC): Protocol for the implementation elements of a multicenter parallel cluster randomized hybrid type 2 implementation-effectiveness study



Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			“Implementation strategy” refers to how the intervention was implemented		“Intervention” refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	1	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	2	3	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	3	5	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	4	5-6	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	5	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	5	6	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	6	6-9	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	7	7-8	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		

Targeted 'sites'	8	8	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	8-9	The population targeted by the intervention and any eligibility criteria.
Description	9	10-14	A description of the implementation strategy	9	A description of the intervention
Sub-groups	10	7	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	11	14-19	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	9	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	12	16-19	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	13	19	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	20-21	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	14		Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	15	20-21	Methods of analysis (with reasons for that choice)		
Sub-group analyses	16	7	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	17		Proportion recruited and characteristics of the recipient population for the implementation strategy		Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	18		Primary and other outcome(s) of the implementation strategy		Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	19		Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	20		Resource use, costs, economic outcomes and analysis for the implementation strategy		Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	21		Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	22		Fidelity to implementation strategy as planned and adaptation to suit context and preferences		Fidelity to delivering the core components of intervention (where measured)
Contextual changes	23		Contextual changes (if any) which may have affected outcomes		
Harms	24		All important harms or unintended effects in each group		
Discussion					
Structured discussion	25	21-24	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	26	22-23	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	21-22	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	27	24-26	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		