

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. xxxxxxxxxx

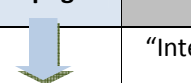
A detailed Explanation and Elaboration document is available [here](#) which provides the rationale and exemplar text for all these items.

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every 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	page1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	2	page2	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	page4	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	4	page5-6	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).	page4	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	page6	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	6	page7	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	page7	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	page7	The characteristics of the targeted ‘site(s)’ (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	page8	The population targeted by the intervention and any eligibility criteria.
Description	9	page9	A description of the implementation strategy	page9	A description of the intervention
Sub-groups	10	page9	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	11	page10	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	page10	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	page10	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	13	page10	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	page10	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	14	page12	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	15	page12	Methods of analysis (with reasons for that choice)		
Sub-group analyses	16	page12	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	page12	Proportion recruited and characteristics of the recipient population for the implementation strategy	page12	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	18	page13	Primary and other outcome(s) of the implementation strategy	page13	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	19	page13	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	20	page13	Resource use, costs, economic outcomes and analysis for the implementation strategy	page13	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	21	page13	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/adaptation	22	page13	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	page13	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	23	page13	Contextual changes (if any) which may have affected outcomes		
Harms	24	page13	All important harms or unintended effects in each group		
Discussion					
Structured discussion	25	page14	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	26	page16	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	page16	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	27	page17	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		