

Appendix

Appendix A. CONSORT extension for reporting abstracts of pilot trials¹

Section	Item	Description	Present (Y/N)	Score (1 or 0)
Title and abstract	1a	Identification of study as randomized pilot or feasibility trial		
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)		
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomized pilot trial		
	2b	Specific objectives or research questions for pilot trial		
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio		
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons		

Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
	4c	How participants were identified and consented
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial
Sample size	7a	Rationale for numbers in the pilot trial
	7b	When applicable, explanation of any interim

		analyses and stopping guidelines
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomization(s); details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative

Participant flow (diagram strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective
	13b	For each group, losses and exclusions after randomization, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the pilot trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analyzed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomized group
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by

		randomized group
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
	19a	If relevant, other important unintended consequences
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility
Generalizability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence
	22a	Implications for progression from pilot to

		future definitive trial, including any proposed amendments
Registration	23	Registration number for pilot trial and name of trial registry
Protocol	24	Where the pilot trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders
Ethics	26	Ethical approval or approval by research review committee, confirmed with reference number

***We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.*

Appendix B. Key feasibility items checklist (triage checklist)

Item	Description	Check all that apply
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Scope	The manuscript appears to be out of scope: it is not reporting the results of pilot, feasibility or proof-of-concept
Title	The title does NOT have the terms “feasibility” or “pilot” OR “proof-of-concept”
Abstract	1.The abstract does NOT report the feasibility objectives results. 2. The conclusions do NOT relate to feasibility
Key messages on feasibility	The three key messages on feasibility are missing: a. What uncertainties existed regarding the feasibility? b. What are the key findings on feasibility? c. What are the implications of the findings for the design of the main study?
Main text	The main text does not have the key elements on feasibility a. Objectives: The primary objectives are NOT on feasibility assessment b. Feasibility outcome and Progression criteria: The feasibility outcomes are NOT specified along with corresponding criteria for determining success of feasibility c. Sample size: The sample size justification is NOT based on feasibility objectives

- d. Analysis: The analysis description does NOT include analysis of feasibility outcomes
- e. Results: The feasibility results are NOT reported

Overall quality Overall quality of the manuscript does NOT appear to be of high quality (based on the abstract, nature of the main text)

Appendix C. PubMed Search Strategy

Search terms	Results
#1 ("Feasibility studies"[MeSH Terms] OR "feasibility project*"[Text Word] OR "feasibility trial*"[Text Word] OR "feasibility trials"[Text Word] OR "feasibility stud*"[Text Word]) AND (2017:2023[pdat])	36,414
#2 ("Pilot projects"[MeSH Terms] OR "pilot project*"[Text Word] OR "Pilot projects"[Text Word] OR "pilot trial*"[Text Word] OR "pilot trials"[Text Word] OR "pilot stud*"[Text Word]) AND (2017:2023[pdat])	70,673
#3 ("arthroplasty, replacement, knee"[MeSH Terms] OR "knee replacement*"[Text Word] OR "knee replacements"[Text Word] OR "knee arthroplast*"[Text Word]) AND (2017:2023[pdat])	22,216
#4 ("arthroplasty, replacement, hip"[MeSH Terms] OR "hip replacement*"[Text Word] OR "hip replacements"[Text Word] OR "hip arthroplast*"[Text Word]) AND (2017:2023[pdat])	20,347

#5	#1 OR #2	102,447
#6	#3 OR #4	37,735
#7	#5 AND #6	426