McMaster University
HEALTH RESEARCH METHODS, EVIDENCE, AND IMPACT

The Research Institute
St. Joseph's HEALTH SYSTEM
Unstoppable Discovery

Getting Pilot and Feasibility Studies Right: Design, Analysis, and Reporting

Lehana Thabane

Distinguished University Professor

Vice-President Research

St. Joseph's HEALTH SYSTEM
Unstoppable Compassion

St. Joseph's Healthcare Hamilton
Unstoppable Compassion

Land acknowledgement

- At McMaster/SJHH, we recognize the lands on which we learn and provide care are the traditional territories of the Mississauga and Haudenosaunee peoples. For thousands of years, the first people sought to steward the precious resources and share this land with others. These territories were the subject of the "Dish with One Spoon" Wampum Belt Agreement
- The "Dish" represents the shared land, while "One Spoon" reinforces the idea of peacefully sharing and caring for the lands around the Great Lakes in a spirit of mutual co-operation.
- At MC/SJHH, we pledge to continue to walk together with the Indigenous Peoples in building a more just society where their gifts and those of all people are nurtured and honored.

Disclaimer

- I get academic credit for giving presentations like this!
- I share the credit with Lawrence Mbuagbaw
- I have no industry-related conflict of interests to declare

Joint work with the PAFS Collaboration Group since 2011



Christine Bond

UNIVERSITY OF ABERDEEN



Michael Campbell

The University Of Sheffield.



Claire Chan



Sandra Eldridge

Queen Mary University of London



Sally Hopewell

UNIVERSITY OF OXFORD



Gill Lancaster

Keele University

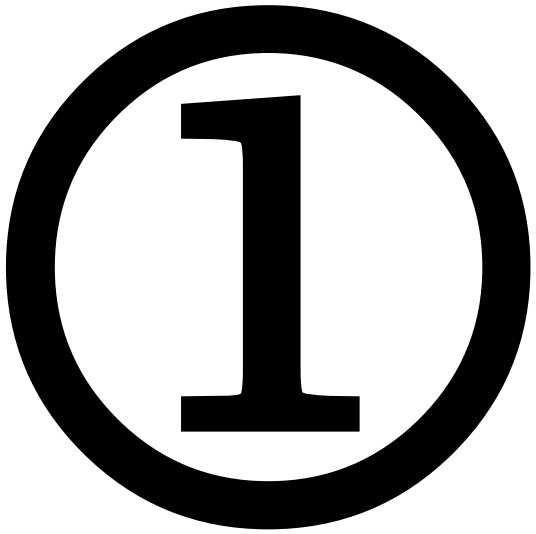


Lehana Thabane

McMaster University

HEALTH RESEARCH METHODS, EVIDENCE, AND IMPACT


2016-2023
Before 2016
PRESENT
PAST
FUTURE
2023-
forward



Before 2016

The design and interpretation of pilot trials in clinical research in critical care

Crit Care Med 2009 Vol. 37, No. 1 (Suppl.)

Donald M. Arnold, MD, MSc (Epid); Karen E. A. Burns, MD, MSc (Epid); Neill K. J. Adhikari, MD, MSc (Epid); Michelle E. Kho, BHSc (PT); Maureen O. Meade, MD, MSc (Epid); Deborah J. Cook, MD, MSc (Epid); for the McMaster Critical Care Interest Group

Thabane *et al. BMC Medical Research Methodology* 2010, **10**:1
http://www.biomedcentral.com/1471-2288/10/1

BMC Medical Research Methodology

COMMENTARY Open Access

A tutorial on pilot studies: the what, why and how

Lehana Thabane[1,2*], Jinhui Ma[1,2], Rong Chu[1,2], Ji Cheng[1,2], Afisi Ismaila[1,3], Lorena P Rios[1,2], Reid Robson[3], Marroon Thabane[1,4], Lora Giangregorio[5], Charles H Goldsmith[1,2]

Contemporary Clinical Trials 38 (2014) 130–133

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Pilot and feasibility studies: Is there a difference from each other and from a randomised controlled trial?

Amy L. Whitehead, Benjamin G.O. Sully, Michael J. Campbell *

Design, Trials and Statistics Group, School of Health and Related Research, University of Sheffield, Regent Court, 30 Regent Street, Sheffield S1 4DA, UK

There was substantial variation in practice

- Studies are not reported consistently
- Terms are used interchangeably and inconsistently

In research, words matter!

Most journals had no editorial policies on pilot studies

Arain *et al. BMC Medical Research Methodology* 2010, **10**:67
http://www.biomedcentral.com/1471-2288/10/67



CORRESPONDENCE Open Access

What is a pilot or feasibility study? A review of current practice and editorial policy

Mubashir Arain[1], Michael J Campbell*[1], Cindy L Cooper[1] and Gillian A Lancaster[2]





Pilot Trials in Clinical Research: Of What Value Are They?
Joseph Loscalzo

Circulation. 2009;119:1694-1696

There's some evidence that editors often arm-twist authors to add "pilot" to acknowledge small samples in their studies

Rogue Editor



Desperate Author

Although there is an increasing number of pilot/feasibility studies in the literature, **the reporting is very suboptimal**

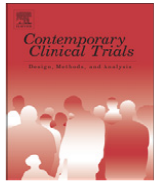
- Too much emphasis on hypothesis-testing
- No clear feasibility objectives/outcomes
- No progression criteria to the main study
- Inadequate descriptions of analytic plans
- **No explicit mention that they done to inform future studies**

Contemporary Clinical Trials 38 (2014) 130–133

Contents lists available at ScienceDirect

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journal homepage: www.elsevier.com/locate/conclintrial



Pilot and feasibility studies: Is there a difference from each other and from a randomised controlled trial?

Amy L. Whitehead, Benjamin G.O. Sully, Michael J. Campbell *

Journal of Evaluation in Clinical Practice, **10**, 2, 307–312

Design and analysis of pilot studies: recommendations for good practice

Gillian A. Lancaster MSc PhD,[1] Susanna Dodd MSc[2] and Paula R. Williamson PhD[3]
[1]Lecturer in Medical Statistics, [2]Research Assistant in Medical Statistics [3]Senior Lecturer in Medical Statistics, Department of Mathematical Sciences, University of Liverpool, Liverpool, UK

Others have worried that in the era of diminishing resources, PAFS could actually be a waste of resources

PLOS ONE

RESEARCH ARTICLE

Do feasibility studies contribute to, or avoid, waste in research?

Ben Morgan[1]*, Jennie Hejdenberg[1], Saba Hinrichs-Krapels[2], David Armstrong[3]

1 National Institute for Health Research Central Commissioning Facility, Twickenham, United Kingdom, **2** Policy Institute, King's College London, London, United Kingdom, **3** Department of Primary Care & Public Health Sciences, King's College London, London, United Kingdom

"We have estimated that …this may have saved the wider NIHR at least £20 million"

ELSEVIER

Journal of Clinical Epidemiology 160 (2023) 117–125

Journal of Clinical Epidemiology

ORIGINAL ARTICLE

Pilot trials may improve the quality of full-scale trials: a meta-research study

Xiangji Ying, Stephan Ehrhardt*

Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

Accepted 21 June 2023; Published online 28 June 2023

- Full-scale trials that were preceded by pilot trials tend to be published faster and in higher impact factor journals
- Pilot-tested trials demonstrate a lower risk of bias specifically concerning randomization, allocation concealment, and blinding of investigators

Empirical evidence shows that lack of, or inadequate assessment of feasibility is the main reason why trials fail

Poor accrual is the primary reason for early trial termination

CIHR IRSC Canadian Institutes of Health Research Instituts de recherche en santé du Canada

Submitted by CIHR
Déposé par les IRSC

Clin Trials. Author manuscript; available in PMC 2016 January 31.

Published in final edited form as:
Clin Trials. 2015 February ; 12(1): 77–83. doi:10.1177/1740774514558307.

Unsuccessful Trial Accrual and Human Subjects Protections: An Empirical Analysis of Recently Closed Trials

Benjamin Carlisle, MA[1], Jonathan Kimmelman, PhD[1], Tim Ramsay, PhD[2], and Nathalie MacKinnon, BSc[1]

PLOS ONE

RESEARCH ARTICLE

Terminated Trials in the ClinicalTrials.gov Results Database: Evaluation of Availability of Primary Outcome Data and Reasons for Termination

Rebecca J. Williams[1]*, Tony Tse[1], Katelyn DiPiazza[2], Deborah A. Zarin[1]

Why conduct a pilot or feasibility study?

Assessing feasibility of procedures and methods

Samaan *et al. Pilot and Feasibility Studies* (2015) 1:39
DOI 10.1186/s40814-015-0034-y

PILOT AND FEASIBILITY STUDIES

STUDY PROTOCOL Open Access

A pragmatic pilot randomized trial to investigate the effectiveness of behavioural activation group therapy in reducing depressive symptoms and improving quality of life in patients with depression: the BRAVE pilot trial protocol

Zainab Samaan[1,2,3,4*], Kathryn Litke[2], Kathleen McCabe[1,2], Brittany Dennis[3], Jeff Whattam[2], Laura Garrick[2], Laura O'Neill[1,2], Terri Ann Tabak[1,2], Scott Simons[2], Sandra Chalmers[2], Brenda Key[1,2], Meredith Vanstone[3], Feng Xie[3], Gordon Guyatt[3,5] and Lehana Thabane[3,6,7,8,9]

Feasibility Outcomes:

- ❑ Recruitment rates
- ❑ Retention rate
- ❑ Data completeness rates
- ❑ Feedback on intervention
- ❑ Resources required to conduct main study

Assessing feasibility of procedures and methods

Johnstone *et al. Pilot and Feasibility Studies* (2015) 1:19
DOI 10.1186/s40814-015-0013-3

PILOT AND FEASIBILITY STUDIES

STUDY PROTOCOL Open Access

*Pro*biotics: Prevention of *S*evere *P*neumonia and *E*ndotracheal Colonization *T*rial—PROSPECT: protocol for a feasibility randomized pilot trial

Jennie Johnstone[1,2,3], Maureen Meade[4,5], John Marshall[3,6,7], Daren K Heyland[8], Michael G Surette[4], Dawn ME Bowdish[9], Francois Lauzier[10], Lehana Thebane[5,11], Deborah J Cook[4,5*] and For the PROSPECT Investigators and the Canadian Critical Care Trials Group

Feasibility Outcomes:

- ❑ Recruitment rates
- ❑ High protocol adherence,
- ❑ Minimal contamination, and
- ❑ An acceptable VAP (ventilator associated pneumonia) rate.

Assessing feasibility of procedures and methods

JAMDA 15 (2014) 943–945

ELSEVIER

JAMDA

journal homepage: www.jamda.com



Brief Report

Implementing a Knowledge Translation Intervention in Long-Term Care: Feasibility Results From the Vitamin D and Osteoporosis Study (ViDOS)

Courtney C. Kennedy PhD [a], Lehana Thabane PhD [b], George Ioannidis PhD [a], Jonathan D. Adachi MD, FRCPC [a], Alexandra Papaioannou MD, MSc, FRCP (C) FACP [a,*] on behalf of the ViDOS Investigators

[a] Department of Medicine, McMaster University, Hamilton, ON, Canada
[b] Department of Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada

Feasibility Outcomes:

- ❑ Recruitment rates
- ❑ Retention rates
- ❑ Participation rate
- ❑ Completion of action plans, feedback reports
- ❑ Completeness of data

Assessing feasibility of procedures

Pai *et al. Implementation Science* 2013, **8**:1
http://www.implementationscience.com/content/8/1/1

IMPLEMENTATION SCIENCE

RESEARCH Open Access

Strategies to enhance venous thromboprophylaxis in hospitalized medical patients (SENTRY): a pilot cluster randomized trial

Menaka Pai[1,3*], Nancy S Lloyd[1], Ji Cheng[2,4], Lehana Thabane[2,4,5], Frederick A Spencer[1], Deborah J Cook[1,2], R Brian Haynes[1,2], Holger J Schünemann[1,2] and James D Douketis[1,2]

Feasibility Outcome:

- Adherence rates (i.e. Completion rates) to the risk assessment model and standardized order form

Criteria for progression to the main study

How does one determine the success of feasibility?

Assessing feasibility of procedures and methods

JAMDA 15 (2014) 943–945

ELSEVIER

JAMDA

journal homepage: www.jamda.com



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[a] Department of Medicine, McMaster University, Hamilton, ON, Canada
[b] Department of Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada

Feasibility Outcomes:

- ❑ Recruitment rates
- ❑ Retention rates
- ❑ Participation rate
- ❑ Completion of action plans, feedback reports
- ❑ Completeness of data

Key Points



- It is always important to state the criteria for success or feasibility

- Outcome can be:
  - ***Stop*** - main study not feasible
  - ***Continue****, but modify protocol* – feasible with modifications
  - ***Continue*** *without modifications, but monitor closely* – feasible with close monitoring
  - ***Continue*** *without modifications* – feasible as is

- The criteria should be based on key primary feasibility aims

Pai *et al. Implementation Science* 2013, **8**:1
http://www.implementationscience.com/content/8/1/1

IMPLEMENTATION SCIENCE

RESEARCH Open Access

Strategies to enhance venous thromboprophylaxis in hospitalized medical patients (SENTRY): a pilot cluster randomized trial

Menaka Pai[1,3*], Nancy S Lloyd[1], Ji Cheng[2,4], Lehana Thabane[2,4,5], Frederick A Spencer[1], Deborah J Cook[1,2], R Brian Haynes[1,2], Holger J Schünemann[1,2] and James D Douketis[1,2]

Criteria for success of feasibility

- ✓ **Objective:**
  - ❑ To determine adherence rates to the risk assessment model and standardized order form
- ✓ **Criterion for success:**
  - ❑ '*definitely feasible*' if the risk assessment form is completed for ≥70% of eligible patients.

JAMDA 15 (2014) 943–945

JAMDA

journal homepage: www.jamda.com

Brief Report

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[a] Department of Medicine, McMaster University, Hamilton, ON, Canada
[b] Department of Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada

Table 1
Feasibility Results for the ViDOS Trial

Measure	Target, %	Observed, %	Description
Recruitment	40	22	▪ Acceptance rate was low; took several months ▪ Accomplished target sample size (n = 40)
Retention	80	63	▪ 7 INT homes withdrew active participation.
Participation	80	25–100	▪ Overall: n = 164 participants from 12 active INT homes; 56% attended at least 2 meetings* **Key roles:** ▪ ≥ 2 meetings: Director/assistant director of care†; pharmacist = 100%; medical director† = 92% ▪ 3 meetings: Director/assistant director† = 83%; pharmacist = 92%; medical director† = 25%
Action plans	80	100	▪ Completed by all homes
Feedback reports	80	100	▪ Reviewed at all INT sessions (months 0, 6, 12)
Data completion	80	86–92	▪ All spreadsheets: 86% control/92% INT homes

EASI-SWITCH: recruitment progression criteria

Internal pilot of a multicentre trial of early oral antibiotics for low-risk neutropenic sepsis

1.7 patients per site per month

Allow a 50% reduction during the first 3 months after site opening.

≥75% of target	Proceed; address recruitment barriers.
50–74% of target	Consider opening additional sites.
<50% of target	Review trial viability with the Trial Steering Committee and funder.

Thresholds account for site start-up delays and specify an operational response.

McArdle, J. R., et al. (2024). Early switch from intravenous to oral antibiotic therapy in patients with cancer who have low-risk neutropenic sepsis: the EASI-SWITCH trial. Health Technology Assessment, 28(14).

Prepare for Kidney Care: progression criteria

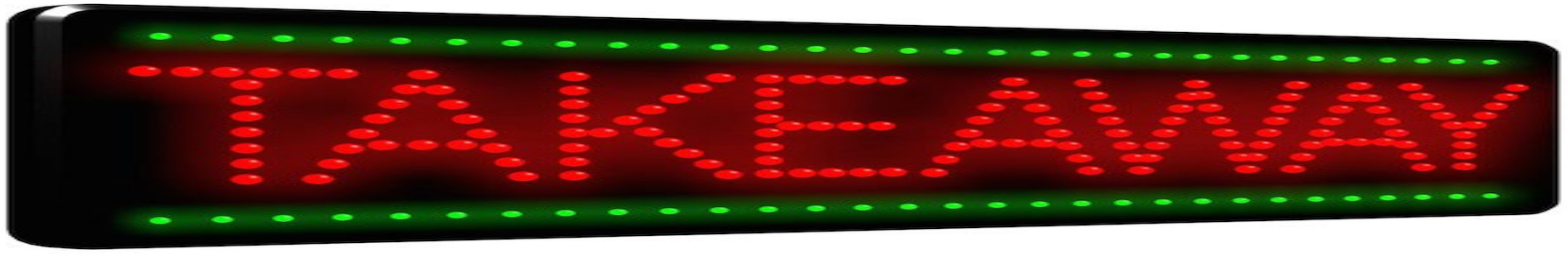
Internal pilot comparing preparation for conservative management and dialysis

	Planned recruitment	Sites recruiting	Participants per active site per month
🟢	≥85%	≥14 of 16	≥1.3
🟠	60–84%	10–13	0.9–1.2
🔴	<60%	≤9	≤0.8

All green: proceed | **Predominantly amber:** remedial action | **Predominantly red:** feasibility unlikely

Assess site activation and recruitment rate together.

Farrington, K., et al. (2021). The Prepare for Kidney Care Study: prepare for renal dialysis versus responsive management in advanced chronic kidney disease—a randomised controlled trial. Nephrology Dialysis Transplantation, 36(6), 975–982.



- The past practice in the conduct, analysis and reporting of pilot studies was inadequate,
- And may possibly be contributing to research waste
- Lack of, or inadequate assessment of feasibility is the #1 reason why trials are discontinued
- PAFS are useful in assessing feasibility of procedures, methods, and exploring other uncertainties about future trials



2016-2023

Methods paper

Describing the methods and processes for developing the guideline

Thabane *et al. Pilot and Feasibility Studies* (2016) 2:25
DOI 10.1186/s40814-016-0065-z

Pilot and Feasibility Studies

METHODOLOGY Open Access

Methods and processes for development of a CONSORT extension for reporting pilot randomized controlled trials

Lehana Thabane[1*], Sally Hopewell[2], Gillian A. Lancaster[5], Christine M. Bond[6], Claire L. Coleman[3], Michael J. Campbell[4] and Sandra M. Eldridge[3]

PLOS ONE

RESEARCH ARTICLE

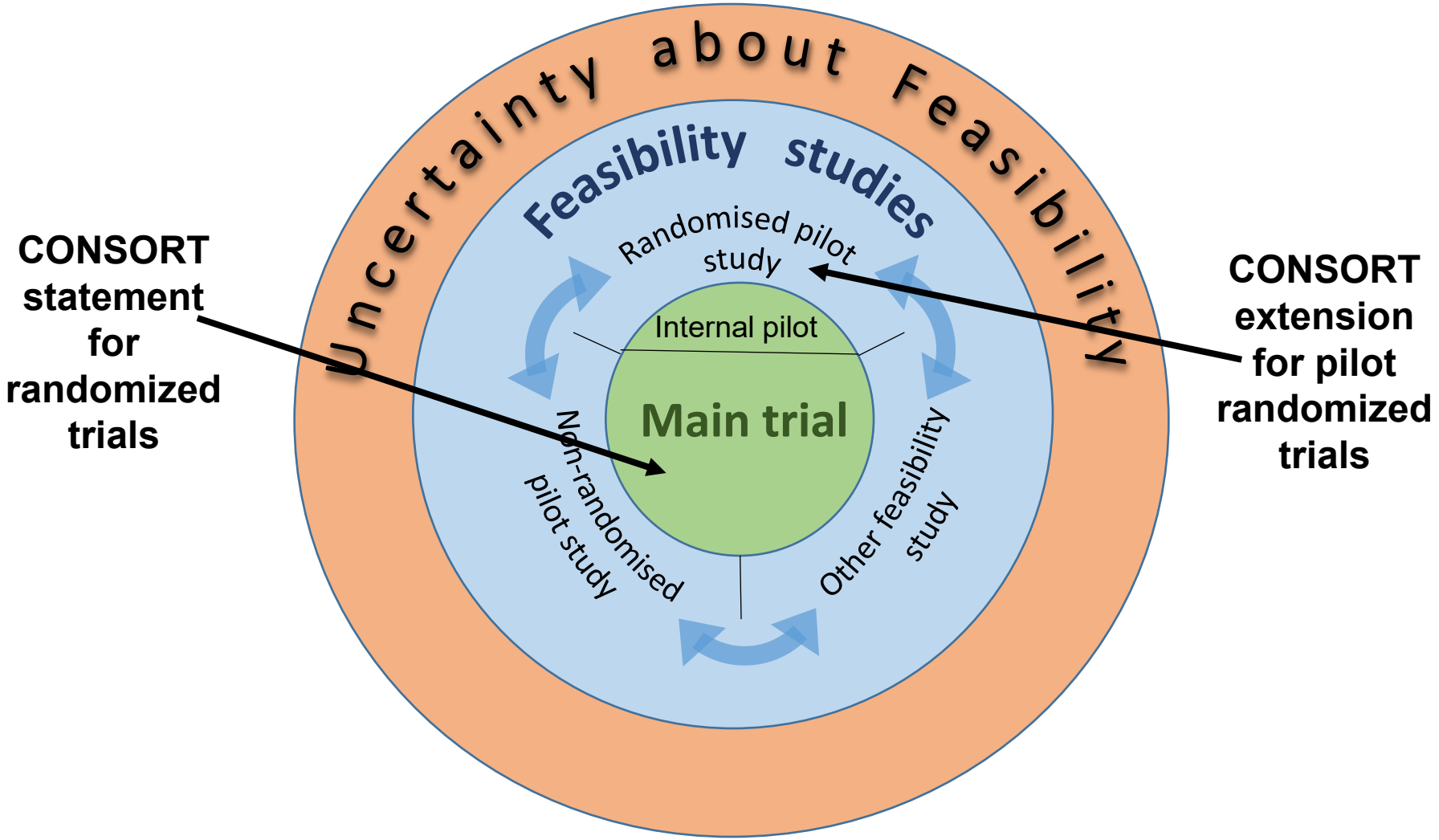
Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework

Sandra M. Eldridge[1]*, Gillian A. Lancaster[2], Michael J. Campbell[3], Lehana Thabane[4], Sally Hopewell[5], Claire L. Coleman[1], Christine M. Bond[6]

Definitions paper

We provide definitions for feasibility and pilot studies and define the conceptual framework

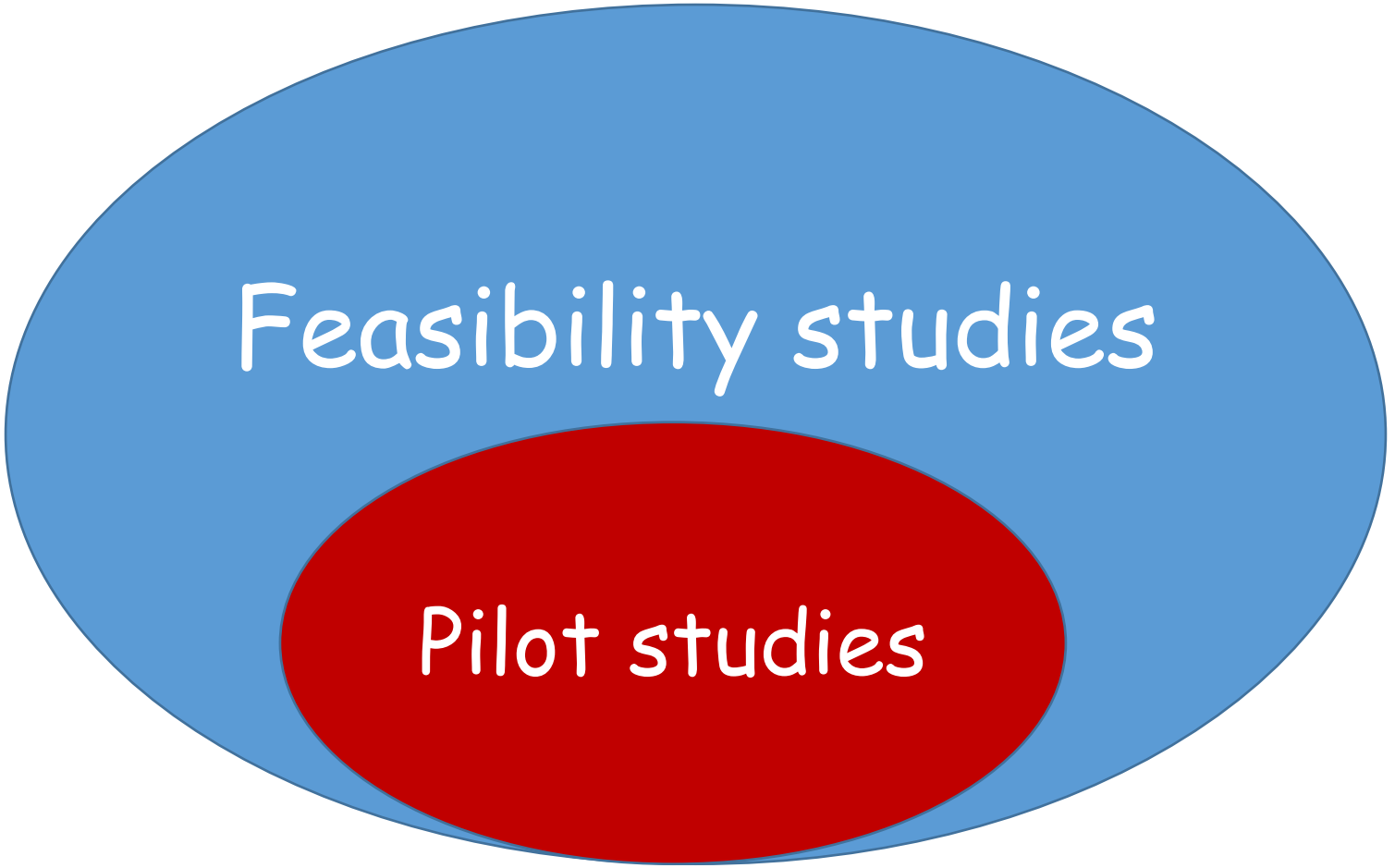
The framework and implications for reporting randomized pilot trials



- ***A feasibility study*** asks whether **something** can be done, should we proceed with it, and if so, how.
- ***A pilot study*** asks the same questions but also has a specific design feature: in a pilot study a future study, or part of a future study, is conducted on a smaller scale.

Corollary

All pilot studies are feasibility studies but not all feasibility studies are pilot studies



The paper is clearly already having impact: Over 100K views/downloads and 1,300 citations

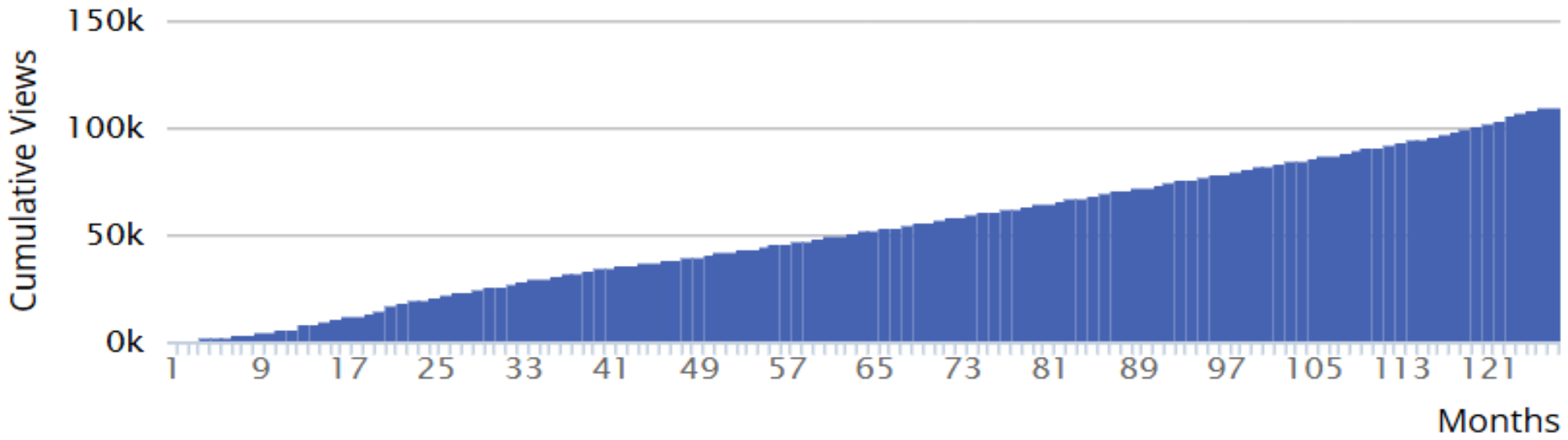
Total Article Views

109,828

Mar 15, 2016 (publication date) through Sep 04, 2026 *

HTML Page Views	PDF Downloads	XML Downloads	Total
72,225	36,859	744	**109,828**

51.034 % of article views led to PDF downloads



*Although we update our data on a daily basis, there may be a 48-hour delay before the most recent numbers are available.

We published the CONSORT extension to pilot RCT paper: >5400 Citations

Eldridge *et al. Pilot and Feasibility Studies* (2016) 2:64
DOI 10.1186/s40814-016-0105-8

Pilot and Feasibility Studies

RESEARCH Open Access

CONSORT 2010 statement: extension to randomised pilot and feasibility trials

Sandra M. Eldridge[1*], Claire L. Chan[1], Michael J. Campbell[2], Christine M. Bond[3], Sally Hopewell[4], Lehana Thabane[5], Gillian A. Lancaster[6] and on behalf of the PAFS consensus group

RESEARCH METHODS AND REPORTING

OPEN ACCESS

CONSORT 2010 statement: extension to randomised pilot and feasibility trials

Sandra M Eldridge,[1] Claire L Chan,[1] Michael J Campbell,[2] Christine M Bond,[3] Sally Hopewell,[4] Lehana Thabane,[5] Gillian A Lancaster[6] on behalf of the PAFS consensus group

the bmj | *BMJ* 2016;355:i5239 | doi: 10.1136/bmj.i5239

- Checklist applies to:
  - ✓ Pilot RCT conducted in preparation for a future definitive RCT
  - ✓ Primary aim: feasibility of the future definitive trial
  - ✓ No restrictions on terminology used to describe the preparatory trial
  - ✓ No restrictions on the designs
- Doesn't apply to internal pilot trials

#1: We provide standard CONSORT item and extension to pilot trials side-by-side

- Some items remain **unchanged**
- Some items have been **modified**
- **New items** are added
- Some items are deleted (**Not Applicable**)

Section/topic and item No	Standard checklist item	Extension for pilot trials
Title and abstract		
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)
Introduction		
Background and objectives:		
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial
Methods		
Trial design:		
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	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 pre-specified primary and secondary outcome measures, including how and when they were assessed	Completely defined pre-specified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons
6c		If applicable, pre-specified criteria used to judge whether, or how, to proceed with future definitive trial
Sample size:		
7a	How sample size was determined	Rationale for numbers in the pilot trial
7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation		
Sequence generation:		
8a	Method used to generate the random allocation sequence	
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(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	
Analytical methods:		
12a	Statistical methods used to compare group for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable
Results		
Participant flow (a diagram is strongly recommended):		
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	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 randomisation, together with reasons	
Recruitment:		
14a	Dates defining the periods of recruitment and follow up	
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped
Baseline data:		
15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed:		
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these analyses should be by randomised group

Outcomes and estimation:		
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses:		
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	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
Discussion		
Limitations:		
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility
Generalisability:		
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other pilot studies
Interpretation:		
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	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

Other information		
Registration:		
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry
Protocol:		
24	Where the full trial protocol can be accessed, if available	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	
26		Ethical approval/research review committee approval confirmed with reference number

#2: We provide E&E on all items

- Explanation and elaboration on why item is important
- Provide examples of best practices

Item 2b: Specific objective or research question for pilot trial

- Item 2b
- *Standard CONSORT item*: specific objectives or hypotheses
- *Extension for pilot trials*: specific objectives or research questions for pilot trial
- *Example 1 (listing objectives as primary and secondary)*

"In this feasibility trial, the research aim was to explore trial design, staff and resident acceptability of the interventions and outcome measures and to provide data to estimate the parameters required to design a definitive RCT . . . The primary objectives of the trial were as follows:

1. To assess how many care homes accepted the invitation to participate in research.
2. To determine whether the eligibility criteria for care home residents were too open or too restrictive by estimating feasible eligibility and recruitment rate.
3. To assess retention of care homes and residents by estimating 3 and 6-month follow-up rates.

Explanation

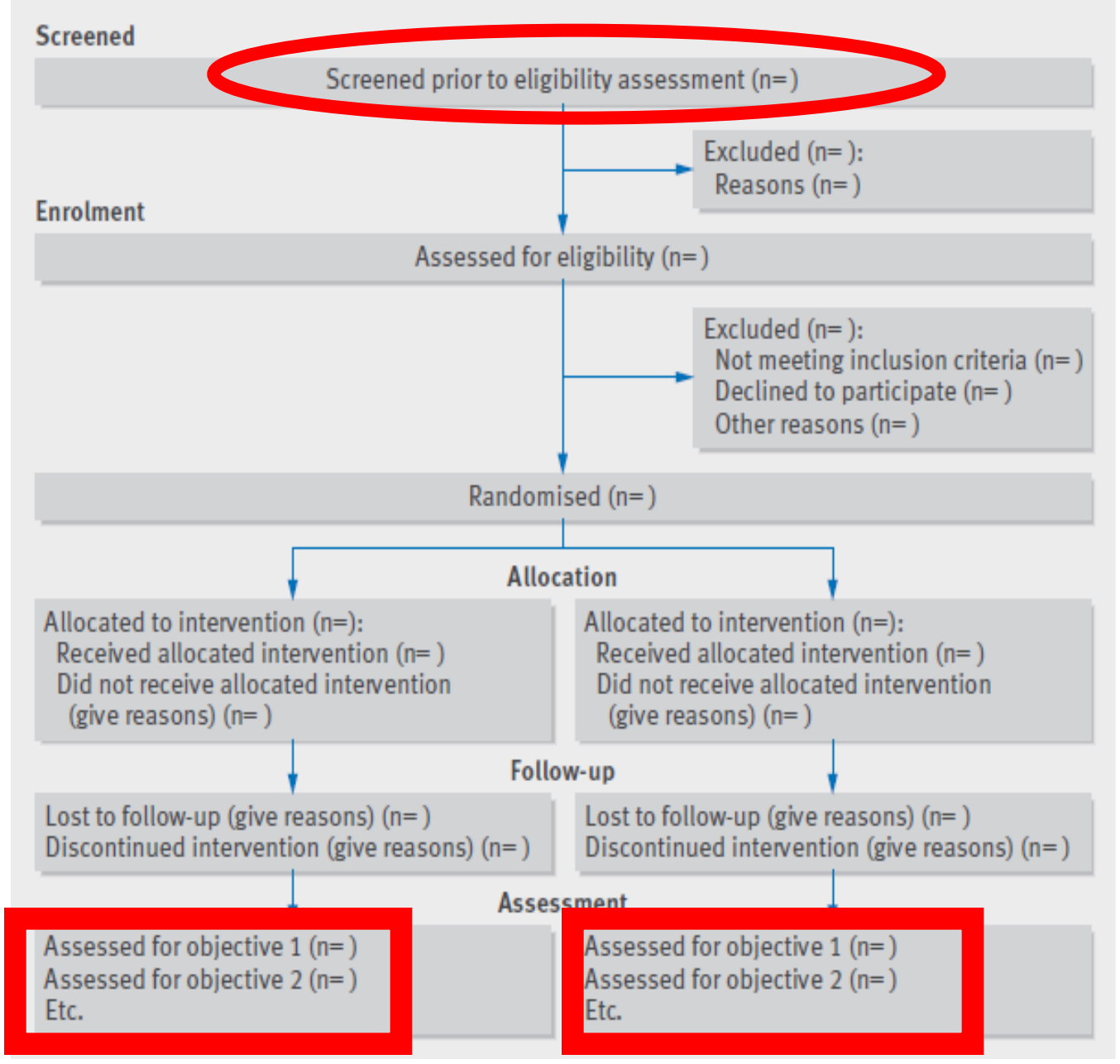
Although many aspects of feasibility may be related to each other, an articulation of specific objectives enables readers to understand the main areas of uncertainty to be addressed in the pilot trial and provides a working structure for presenting the methods and results in relation to these objectives. In addition, a comprehensive list of objectives enables other researchers to learn from and adopt similar approaches in their own studies.

It might be beneficial to separate the objectives into primary objectives (often those on which decisions about progressing to a future definitive RCT may be made) and secondary objectives, as in example 1, where feasibility objectives are primary and questions related to patient centred outcomes are treated as secondary.

#3: We suggest some changes on the flow-diagram

- Show the # of participants screened
- Report estimates of feasibility outcomes for each group

13a: Participant flow diagram



#4: We provide CONSORT for Abstracts: for reporting pilot and feasibility trials

Table 3 Extension of CONSORT for abstracts for reporting pilot trials

Item	Standard checklist item	Extension for pilot trials
Title	Identification of study as randomised	Identification of study as randomised pilot or feasibility trial
Trial design	Description of the trial design (eg, parallel, cluster, non-inferiority)	Description of pilot trial design (eg, parallel, cluster)
Methods:		
Participants	Eligibility criteria for participants and the settings where the data were collected	Eligibility criteria for participants and the settings where the pilot trial was conducted
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	Specific objectives of the pilot trial
Outcome	Clearly defined primary outcome for this report	Prespecified assessment or measurement to address the pilot trial objectives*
Randomisation	How participants were allocated to interventions	
Blinding (masking)	Whether or not participants, caregivers, and those assessing the outcomes were blinded to group assignment	
Results:		
Numbers randomised	Number of participants randomised to each group	Number of participants screened and randomised to each group for the pilot trial objectives*
Recruitment	Trial status†	
Numbers analysed	Number of participants analysed in each group	Number of participants analysed in each group for the pilot objectives*
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Results for the pilot objectives, including any expressions of uncertainty*
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	General interpretation of the results of pilot trial and their implications for the future definitive trial
Trial registration	Registration number and name of trial register	Registration number for pilot trial and name of trial register
Funding	Source of funding	Source of funding for pilot trial

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT**
†For conference abstracts

Original abstract – checklist items reported by the authors are in green

Title: "Not just another walking program": Everyday Activity Supports You (EASY) model – a randomized pilot study for a parallel randomized controlled trial

Background: Maintaining physical activity is an important goal with positive health benefits, yet many people spend most of their day sitting. Our Everyday Activity Supports You (EASY) model aims to encourage movement through daily activities and utilitarian walking. The primary objective of this phase was to test study feasibility (recruitment and retention rates) for the EASY model.

Methods: This 6-month study took place in Vancouver, Canada, from May to December 2013, with data analyses in February 2014. Participants were healthy, inactive, community-dwelling women aged 55–70 years. We recruited through advertisements in local community newspapers and randomized participants using a remote web service. The model included the following: group-based education and social support, individualized physical activity prescription (called Activity 4-1-1), and use of a Fitbit activity monitor. The control group received health-related information only. The main outcome measures were descriptions of study feasibility (recruitment and retention rates). We also collected information on activity patterns (ActiGraph GT3X+ accelerometers) and health-related outcomes such as body composition (height and weight using standard techniques), blood pressure (automatic blood pressure monitor), and psychosocial variables (questionnaires).

Results: We advertised in local community newspapers to recruit participants. Over 3 weeks, 82 participants telephoned; following screening, 68% (56/82) met the inclusion criteria and 45% (25/56) were randomized by remote web-based allocation. This included 13 participants in the intervention group and 12 participants in the control group (education). At 6 months, 12/13 (92%) intervention and 8/12 (67%) control participants completed the final assessment. Controlling for baseline values, the intervention group had an average of 2,080 [95% confidence intervals (CIs) 704, 4,918] more steps/day at 6 months compared with the control group. There was an average between group difference in weight loss of −4.3 [95% CI −6.22, −2.40] kg and reduction in diastolic blood pressure of −8.54 [95% CI −16.89, −0.198] mmHg, in favor of EASY.

Conclusions: The EASY pilot study was feasible to deliver; there was an increase in physical activity and reduction in weight and blood pressure for intervention participants at 6 months.

Trial registration: ClinicalTrials.gov identifier: NCT01842061

Pilot and Feasibility Studies. 2015, 1:4. doi:10.1186/2055-5784-1-4

Word count: 335

Item	Extension for pilot trials	Reported
Title	Identification of study as randomised pilot trial	✓
Trial design	Description of pilot trial design (e.g. parallel, cluster)	x
METHODS		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	✓
Interventions	*Interventions intended for each group*	✓
Objective	Specific objectives of the pilot trial	✓
Outcome	Pre-specified assessment or measurement to address the pilot trial objective(s)[1]	✓
Randomisation	*How participants were allocated to interventions*	✓
Blinding (masking)	*Whether or not participants, care givers, and those assessing the objectives were blinded to group assignment*	x
RESULTS		
Numbers randomised	Number of participants screened and randomised to each group for the pilot trial objective(s)[1]	✓
Recruitment	*Trial status*[2]	*N/A*
Numbers analysed	Number of participants analysed in each group for the pilot objective(s)[1]	✓
Outcome	Results for the pilot objective(s); including any expressions of uncertainty[1]	partly
Harms	*Important adverse events or side-effects*	x
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	partly
Trial registration	Registration number for pilot trial and name of trial register	✓
Funding	Source of funding for pilot trial	x

Items above in italics are pilot trial checklist items unchanged from the standard RCT checklist.
[1] Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those which are a priori agreed as the most important (main) to the decision to proceed with the future definitive trial. [2] For conference abstracts.

Fig 1 Example of abstract for report of pilot trial [21], shown alongside CONSORT for abstracts extension for pilot randomised trials

Revised abstract – items in red are added to meet the checklist requirements

Title: "Not just another walking program": Everyday Activity Supports You (EASY) model – a randomized pilot study for a parallel randomized controlled trial

Background: Maintaining physical activity is an important goal with positive health benefits, yet many people spend most of their day sitting. Our Everyday Activity Supports You (EASY) model aims to encourage movement through daily activities and utilitarian walking. The primary objective of this pilot trial was to test study feasibility (recruitment and retention rates) for the EASY model.

Methods: This 6-month parallel two-arm pilot trial took place in Vancouver, Canada (May to December 2013). Participants were healthy, inactive, community-dwelling women aged 55–70 years. We recruited through advertisements in local community newspapers and randomized participants using a remote web service. The model included: group-based education and social support, individualized physical activity prescription, and use of a Fitbit activity monitor. The control group received health-related information only. The main outcome measures were descriptions of study feasibility (recruitment and retention rates). We also collected information (blinded outcome assessment) on activity patterns, height and weight, blood pressure, and psychosocial variables.

Results: We advertised in local community newspapers to recruit participants. Over 3 weeks, 82 participants telephoned; following screening, 68% (56/82) met the inclusion criteria and 45% (25/56) were randomized by remote web-based allocation: 13 participants in the intervention group and 12 in the control group (education). At 6 months, 12/13 (92%; 95% CI 65% to 100%) intervention and 8/12 (67%; 95% CI 35% to 90%) control participants completed the final assessment. This met our a priori recruitment and retention criteria for success. Of those who declined 21/30 gave reasons of timing of sessions within working hours. There were no adverse events related to study participation.

Conclusions: The EASY pilot study was feasible to deliver; there was an increase in physical activity and reduction in weight and blood pressure for intervention participants at 6 months. In a future definitive trial greater drop-out in the control arm may be reduced by using a different design and alternative sources of recruitment might be considered.

Trial registration: ClinicalTrials.gov identifier: NCT01842061

Trial funding: Canadian Institute of Health Research, Michael Smith Foundation, Australian National Health and Medical Research Council.

Word count: 340

Item	Extension for pilot trials	Reported
Title	Identification of study as randomised pilot trial	✓
Trial design	Description of pilot trial design (e.g. parallel, cluster)	✓
METHODS		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	✓
Interventions	*Interventions intended for each group*	✓
Objective	Specific objectives of the pilot trial	✓
Outcome	Pre-specified assessment or measurement to address the pilot trial objective(s)[1]	✓
Randomisation	*How participants were allocated to interventions*	✓
Blinding (masking)	*Whether or not participants, care givers, and those assessing the objectives were blinded to group assignment*	✓
RESULTS		
Numbers randomised	Number of participants screened and randomised to each group for the pilot trial objective(s)[1]	✓
Recruitment	*Trial status*[2]	*N/A*
Numbers analysed	Number of participants analysed in each group for the pilot objective(s)[1]	✓
Outcome	Results for the pilot objective(s); including any expressions of uncertainty[1]	✓
Harms	*Important adverse events or side-effects*	✓
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	✓
Trial registration	Registration number for pilot trial and name of trial register	✓
Funding	Source of funding for pilot trial	✓

Items above in italics are pilot trial checklist items unchanged from the standard RCT checklist.
[1] Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those which are a priori agreed as the most important (main) to the decision to proceed with the future definitive trial. [2] For conference abstracts.

Fig 2 Revised version of example abstract for report of pilot trial [21], shown alongside CONSORT for abstracts extension for pilot randomised trials

Updated in 2025!

SPIRIT

CONSORT

Enhancing the transparency and reporting of randomised trials: update of the SPIRIT 2013 and CONSORT 2010 Statements

Virtual consensus meeting • 1st - 2nd March 2023



Update on CONSORT 2025 FYI

- ❑ **New CONSORT 2025 Update**
  - ✓ BMJ: www.bmj.com/content/389/bmj-2024-081123
  - ✓ Lancet: www.thelancet.com/journals/lancet/article/PIIS0140-6736(25)00672-5/abstract
  - ✓ JAMA: https://jamanetwork.com/journals/jama/fullarticle/2832868
  - ✓ Nature Medicine: www.nature.com/articles/s41591-025-03635-5
  - ✓ PLoS Medicine: https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1004587
- ❑ **New CONSORT 2025 E&E**
  - ✓ BMJ E&E: https://www.bmj.com/content/389/bmj-2024-081124
- ❑ **BMJ has also published several editorials highlighting the importance of CONSORT (and Doug Altman's legacy and pivotal role) and reporting guidelines more generally:**
  - ✓ https://www.bmj.com/content/389/bmj.r734
  - ✓ https://www.bmj.com/content/389/bmj.r718
  - ✓ https://www.bmj.com/content/389/bmj.r494
- ❑ **New CONSORT/SPIRIT 2025 Website**
  - ✓ www.consort-spirit.org

Update on SPIRIT 2025 FYI

- ❑ **New SPIRIT 2025 Update**
  - ✓ BMJ: https://doi.org/10.1136/bmj-2024-081477
  - ✓ JAMA: https://doi.org/10.1001/jama.2025.4486
  - ✓ Lancet: https://doi.org/10.1016/S0140-6736(25)00770-6
  - ✓ PLOS Med: https://doi.org/10.1371/journal.pmed.1004589
  - ✓ Nature Med: https://doi.org/10.1038/s41591-025-03668-w
- ❑ **New SPIRIT 2025 E&E**
  - ✓ BMJ E&E: https://doi.org/10.1136/bmj-2024-081660
- ❑ **New CONSORT/SPIRIT 2025 Website**
  - ✓ www.consort-spirit.org

We launched PAFS in 2015!



Pilot and Feasibility Studies

As the only journal dedicated to pilot and feasibility studies in biomedicine, *Pilot and Feasibility Studies* is uniquely positioned to improve thedesign, conduct and reporting of these studies, along with the studies that they will directly influence. Edited by a highly-respected Editorial Board, the journal considers articles on general methodology, commentaries, study protocols and research papers - regardless of outcome or significance of findings. We are committed to reducing waste in research by providing a platform to build an evidence base for informing best practice in research designs across medical and health fields.

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Gillian Lancaster, Editor-in-Chief

Gillian Lancaster is Professor of Medical Statistics at the Institute of Primary Care and Health Sciences, Keele University. She has been engaged in many multidisciplinary clinical investigations over the past 25 years, most notably the Working Group that developed the CONSORT extension guideline for reporting pilot and feasibility trials. Her research scopes many medical and social issues, with a specific interest in methodology for developing Patient Reported Outcome Measures and assessment tools for use on children and young people. More broadly she has served on a wide range of research review, pediatric ethics, funding, data monitoring and trial steering committees, has sat on the Council of the Royal Statistical Society and has been Associate Editor for the RSS Journal Series A: Statistics in Society.



Lehana Thabane, Editor-in-Chief

Lehana Thabane is a Professor of Biostatistics and Associate Chair of the Department of Health Research Methods, Evidence, and Impact; associate member of the Departments of Pediatrics and Anesthesia at McMaster University (Hamilton, Ontario, Canada). He is the Director of Biostatistics at St Joseph's Healthcare—Hamilton (Ontario, Canada) and Senior Scientist at the Population Health Research Institute (PHRI) of the Hamilton Health Sciences and McMaster University. As a biostatistician and research methodologist, Professor Thabane's primary research interests include: i) design and analysis of clinical trials, pilot and feasibility trials, pragmatic trials, registry-based trials, and knowledge translation trials; ii) outcomes research; iii) evidence synthesis methods; and iv) mentorship in clinical trials. He is also interested in transparent reporting of trial findings, and he is a member of the Working Groups of the CONSORT extension to: a) Pilot and Feasibility Trials; and b) Cohort- and Registry-Based Trials.

All members of the Working group are founding editorial board members



Leadership Transition: New PAFS Editors-in-Chief



About the Editors

Stephen Bremner, Editor in Chief

Stephen Bremner is Professor of Medical Statistics in the Department of Primary Care and Public Health at the Brighton and Sussex Medical School, UK, and lead statistician at the Brighton and Sussex Clinical Trials Unit. His principal research interests centre on the design and analysis of pragmatic randomised controlled trials of complex interventions in community healthcare settings. He has worked on epidemiological research studies and randomised trials across diverse designs and specialties and has led the statistical and data analysis aspects of numerous pilot and feasibility studies. Stephen has also served on grant funding panels, trial oversight committees and as a peer reviewer for a wide range of journals and funders.



Lawrence Mbuagbaw, Editor in Chief

Dr. Lawrence Mbuagbaw (MD, MPH, PhD) is a Research Methods Scientist, Epidemiologist, and Director of the Research Methodology Centre at the Research Institute of St. Joseph's Healthcare Hamilton, where he supports study design, data analysis, and reporting. He is an Associate Professor at McMaster University, where he teaches biostatistics and randomized trials, and Associate Professor Extraordinary of Epidemiology and Biostatistics at Stellenbosch University. As principal investigator on numerous projects—including evidence syntheses, randomized trials, mixed-methods, and qualitative studies—he has authored over 350 peer-reviewed publications and technical reports. His research focuses on improving the design, analysis, and reporting of clinical research, with a particular interest in pilot and feasibility studies. He has served with Pilot and Feasibility Studies for over 10 years as Associate Editor and Senior Editor.

We continue run many workshops at conferences, and local institutions

PILOT AND FEASIBILITY STUDIES

GIVING YOUR RESEARCH THE BEST CHANCE OF SUCCESS

EXPLORE OUR NEW WEBSITE

www.pilotandfeasibilitystudies.qmul.ac.uk

News | Resources | Noticeboard

This website is designed to support those conducting pilot and feasibility studies using randomised and non-randomised designs and those carrying out methodological research on these types of studies.

We have also asked colleagues to write editorials to introduce the guidelines to various audiences

ELSEVIER



Journal of Clinical Epidemiology 84 (2017) 30–32

Journal of Clinical Epidemiology

A new CONSORT extension should improve the reporting of randomized pilot and feasibility trials

Peter Craig*

MRC/CSO Social and Public Health Sciences Unit, University of Glasgow, 200 Renfield Street, Glasgow G2 3QB, UK

Accepted 21 January 2017; Published online 16 February 2017

Coverage of the editorial

- Why was the extension needed?
- What does the extension add?
- What effect will the extension have?
- What else is needed to improve the conduct of pilot studies?

Abbade et al. Journal of Venomous Animals and Toxins including Tropical Diseases 2018, 24:4
DOI 10.1186/s40409-018-0142-2



Journal of Venomous Animals and Toxins including Tropical Diseases

EDITORIAL

Open Access

Introducing the CONSORT extension to pilot trials: enhancing the design, conduct and reporting of pilot or feasibility trials

Luciana P. F. Abbade[1*], Joelcio F. Abbade[2] and Lehana Thabane[3,4]

Abstract

This editorial provides a brief overview of the importance of pilot or feasibility trials or studies, the challenges with current practices in their conduct and reporting, an introduction to the Consolidated Standards of Reporting Trials (CONSORT) extension to pilot trials aimed at improving their reporting, along with some key resources on aspects related to pilot and feasibility studies.

American Journal of Physical Medicine & Rehabilitation Articles Ahead of Print
DOI: 10.1097/PHM.0000000000001797



Pilot and feasibility studies in rehabilitation research: a review and educational primer for the physiatrist researcher

Daeria O. Lawson, HBSc[1], Katie Mellor, BSc, MSc[2], Saskia Eddy, BSc, MSc[3], Christopher Lee, BMSc, MPH[4], Kwang Hyun Kim, BHSc[4], Kunmo Kim, BMSc[4], Lawrence Mbuagbaw, MD, MPH, PhD[1,5], Lehana Thabane, PhD[1,5]

More Editorials

- Bond C. When is a pilot not a pilot? International Journal of Pharmacy Practice 2017;25(2):105-6.
- McHugh J. CONSORT statement extended for pilot trials. Nature Reviews Rheumatology 2016;12:692.

We see more attention to PAFS in many clinical disciplines

Received: 7 February 2018 | Accepted: 20 April 2018

DOI: 10.1002/rth2.12117

TUTORIAL

Pilot trials in thrombosis: Purpose and pitfalls

Rick Ikesaka MD[1,2] | Nicole Langlois MSc[2] | Marc Carrier MD, MSc[1,2] |
Clive Kearon MB, PhD[3] | Grégoire Le Gal MD, PhD[1,2]

Thrombosis

Spinal Cord (2018) 56:723–724
https://doi.org/10.1038/s41393-018-0184-x

EDITORIAL

Editor-in-Chief

Feasibility and pilot studies pave the way for definitive trials

L. A. Harvey[1]

© International Spinal Cord Society 2018



Spinal cord research

Unfortunately, more remains to be done!

Reporting of pilot and feasibility trials remains suboptimal in many clinical areas



Khan et al. Pilot and Feasibility Studies (2022) 8:224
https://doi.org/10.1186/s40814-022-01182-1

RESEARCH

The reporting of pilot
studies in the top der
is suboptimal

Mohammed I. U. Khan[1,2*], Hartirath K. Brar[1], Cyr
Katie Mellor[6], Lehana Thabane[2,5] and Carlos Quiñonez[

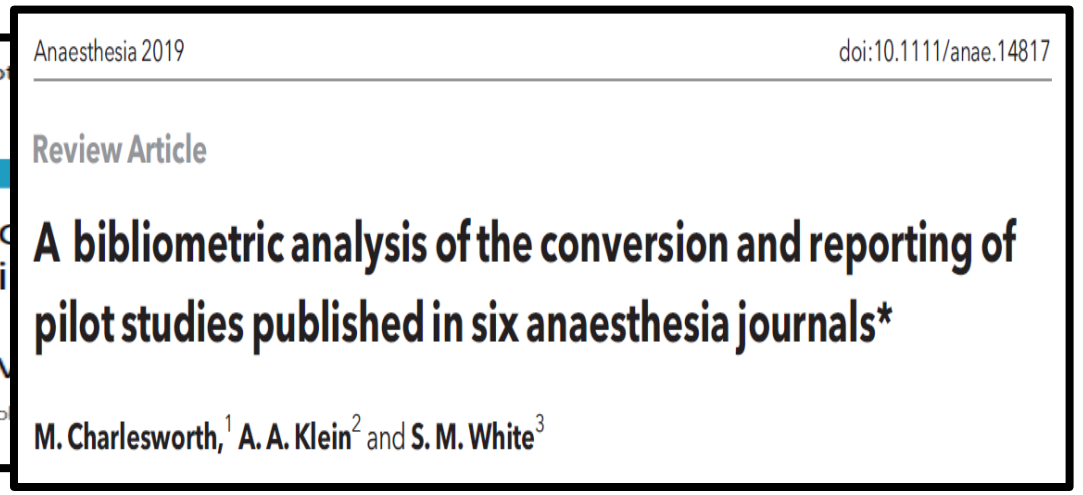
Chung et al. Pilot and Feasibility Studies (2026) 12:114
https://doi.org/10.1186/s40814-026-01859-x

Pilot

REVIEW

The reporting of CONSORT items and
feasibility elements in pilot and feasi
studies in hip and knee arthroplasty
is suboptimal: a methodological surv

Zinnia Chung[1], Leigh-Ann Grant[1], Lawrence Mbuagbaw[2,3,4,5,6,7], Lipalo Mokete[8], Mo
Lehana Thabane[1,2,10,11*]



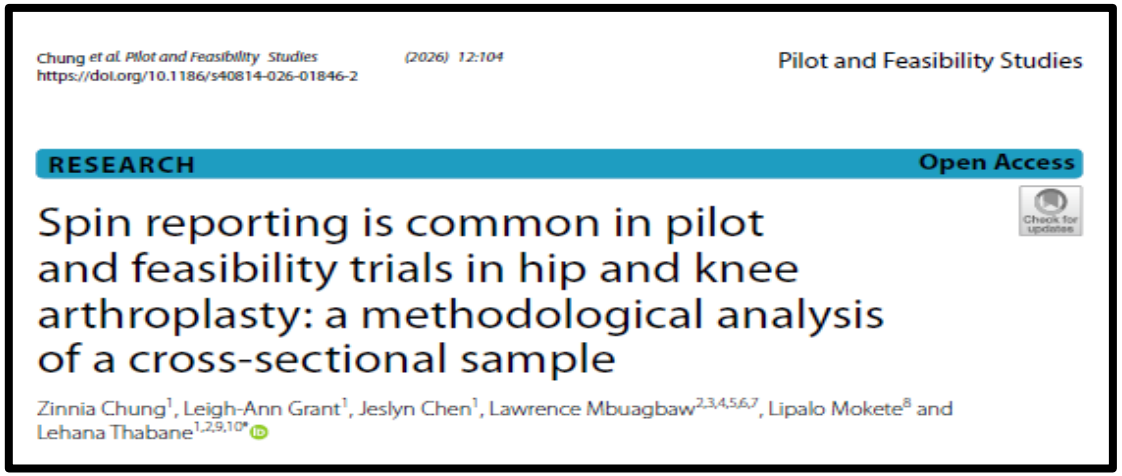
Anaesthesia 2019 doi:10.1111/anae.14817

Review Article

A bibliometric analysis of the conversion and reporting of pilot studies published in six anaesthesia journals*

M. Charlesworth,[1] A. A. Klein[2] and S. M. White[3]

Spin reporting of pilot and feasibility trials remains common in many clinical areas



Chung et al. Pilot and Feasibility Studies (2026) 12:104
https://doi.org/10.1186/s40814-026-01846-2

Pilot and Feasibility Studies

RESEARCH Open Access

Spin reporting is common in pilot and feasibility trials in hip and knee arthroplasty: a methodological analysis of a cross-sectional sample

Zinnia Chung[1], Leigh-Ann Grant[1], Jeslyn Chen[1], Lawrence Mbuagbaw[2,3,4,5,6,7], Lipalo Mokete[8] and Lehana Thabane[1,2,9,10*]



JOURNAL OF SURGICAL RESEARCH • FEBRUARY 2025 (306) 16–25

ELSEVIER

Available online at www.sciencedirect.com
ScienceDirect
journal homepage: www.JournalofSurgicalResearch.com

JSR

Review

Spin Reporting Is Common in Pilot Randomized Controlled Trials in Surgery: A Methodological Survey

Check for updates

Tyler McKechnie, MD, MSc,[a,b,*] Tania Kazi, BScH,[c] Victoria Shi, MA,[c] Austine Wang, BHSc,[c] Sophia Zhang, BSc,[c] Alex Thabane, MSc,[b] Keean Nanji, MD,[b,d] Phillip Staibano, MD, MSc,[b,e] Lily J. Park, MD, MSc,[a,b] Aristithes Doumouras, MD, MPH,[a,b,c] Cagla Eskicioglu, MD, MSc,[a,c] Lehana Thabane, PhD,[b,f,g] Sameer Parpia, PhD,[b,h] and Mohit Bhandari, MD, PhD[b,i]

There is inadequate reporting of progression criteria in protocols and final reports of pilot trials

Mbuagbaw *et al. Pilot and Feasibility Studies* (2019) 5:120
https://doi.org/10.1186/s40814-019-0500-z

Pilot and Feasibility Studies

RESEARCH Open

The reporting of progression criteria in protocols of pilot trials designed to assess the feasibility of main trials is insufficient: a meta-epidemiological study



Lawrence Mbuagbaw[1,2,3*], Sarah Daisy Kosa[1,4], Daeria O. Lawson[1], Rosa Stalteri[1], Oluwatobi R. Olaiya[5], Ahlam Alotaibi[6] and Lehana Thabane[1,2,7,8,9]

Open access Original research

BMJ Open



Progression from external pilot to definitive randomised controlled trial: a methodological review of progression criteria reporting

Katie Mellor [1], Saskia Eddy,[2] Nicholas Peckham,[1] Christine M Bond,[3] Michael J Campbell [4], Gillian A Lancaster,[5] Lehana Thabane,[6] Sandra M Eldridge,[2] Susan J Dutton,[1] Sally Hopewell[1]

Bond *et al. Pilot and Feasibility Studies* (2023) 9:24
https://doi.org/10.1186/s40814-023-01233-1

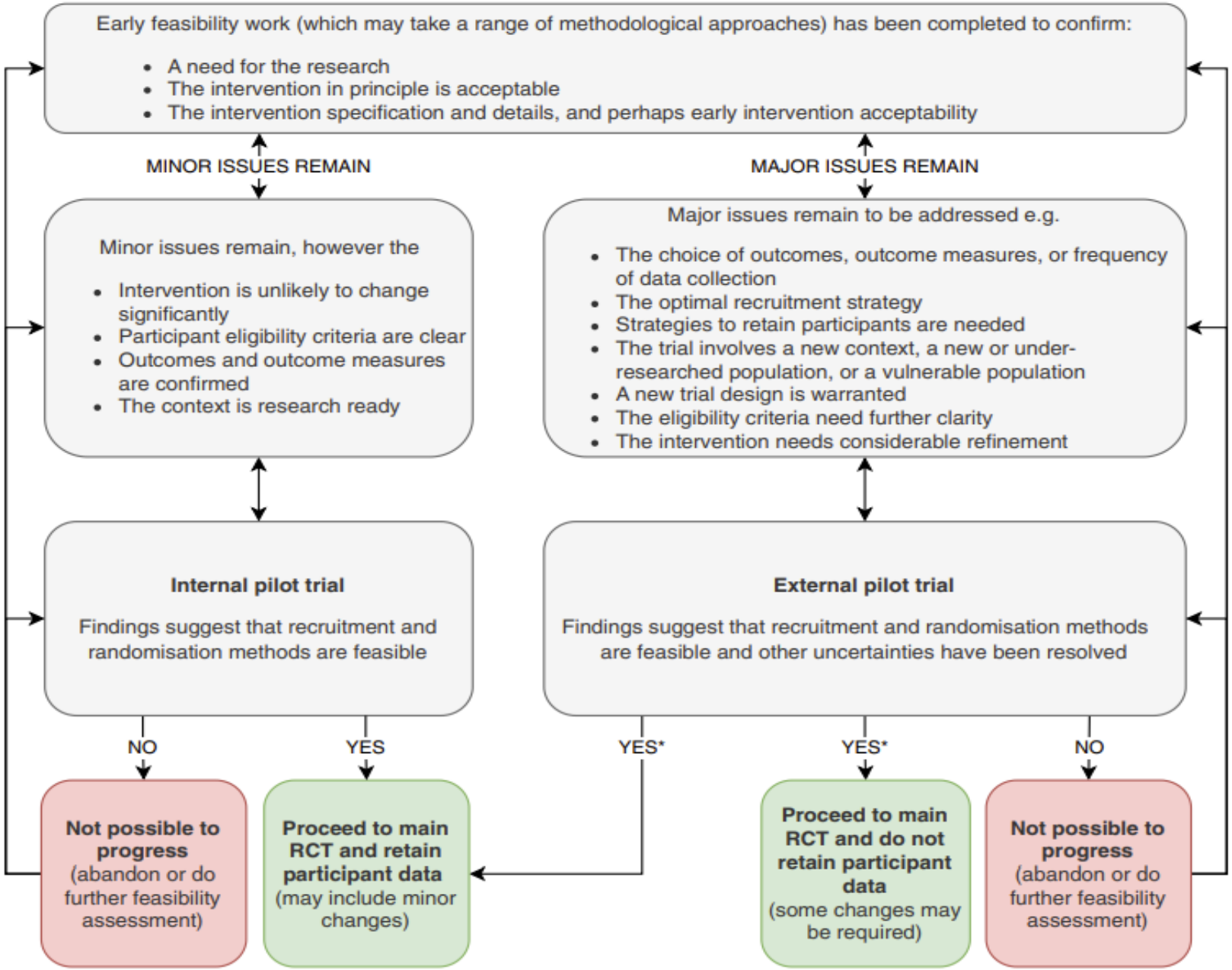
Pilot and Feasibility Studies

METHODOLOGY Open Access

Pilot and feasibility studies: extending the conceptual framework

Christine Bond[1*], Gillian A. Lancaster[2], Mike Campbell[3], Claire Chan[4], Saskia Eddy[5], Sally Hopewell[6], Katie Mellor[6], Lehana Thabane[7,8,9] and Sandra Eldridge[5]

We extend our original framework to incorporate the various feasibility pathways open to researchers, which include internal pilot studies



* See caveats outlined in the Discussion below

Fig. 2 Simplified flow chart incorporating both internal and external pilot studies

The Ethics of Pilot Studies: Tough Questions

- ✓ Is it ethical to conduct a study whose feasibility can not be guaranteed?
- ✓ What obligation do we have to patients to disclose the feasibility nature of pilot studies?

Consent form should be explicit about feasibility nature

The overall purpose of this pilot study is to assess the feasibility of conducting a large study to …[state primary objective of the main study] .

A feasibility or pilot study is a study that… [state a general definition of a feasibility study].

The specific feasibility objectives of this study are …[state the specific feasibility objectives of the pilot study].

We will determine that it is feasible to carry on the main study if …[state the criteria for success of feasibility]."

Informed consent process in PAFS is inadequate



Open access Protocol

BMJ Open

Assessing the transparency of informed consent in feasibility and pilot studies: a single-centre quality assurance study protocol

Mohammed I Khan [1], Matthew Holek,[1] Faris Bdair,[1] Lawrence Mbuagbaw [1,2] Sandra M Eldridge,[3] Claire L Chan,[4] Michael J Campbell [5] Christine M Bond,[6] Sally Hopewell,[7] Gillian A Lancaster,[8] Lehana Thabane[1,2]

Khan *et al. Pilot and Feasibility Studies* (2021) 7:96
https://doi.org/10.1186/s40814-021-00828-w

Pilot and Feasibility Studies

RESEARCH Open Access

Transparency of informed consent in pilot and feasibility studies is inadequate: a single-center quality assurance study

Mohammed I.U. Khan[1,2], Lawrence Mbuagbaw[1,3], Matthew Holek[1], Faris Bdair[1], Zoha H. Durrani[4], Katie Mellor[5], Saskia Eddy[6], Sandra M. Eldridge[6], Claire L. Chan[6], Michael J. Campbell[7], Christine M. Bond[8], Sally Hopewell[5], Gillian A. Lancaster[9] and Lehana Thabane[1,3*]

- Pilot and feasibility studies are addressed in Article 6.11 and Article 10.1 and Chapter 11 (Clinical Trials)
- researchers have an ethical responsibility to communicate the purpose and nature of pilot studies to participants when seeking consent



TCPS2 2014

TRI-COUNCIL POLICY STATEMENT

Ethical Conduct for Research Involving Humans

2014

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council of Canada

Government of Canada / Gouvernement du Canada

Canada



2023-onwards

We have written editorials for guidance on reporting of protocols of pilot RCTs—based adaptation of both the SPIRIT guideline plus the CONSORT extension to pilot RCTs

Thabane and Lancaster *Pilot and Feasibility Studies* (2019) 5:37
https://doi.org/10.1186/s40814-019-0423-8

Pilot and Feasibility Studies

EDITORIAL Open Access

A guide to the reporting of protocols of pilot and feasibility trials

Lehana Thabane[1*] and Gillian Lancaster[2]

Item supplementation

SPIRIT	CONSORT Extension to pilot trials
Item 6a Justification for undertaking the trial	Item 2a Reasons for randomized pilot trial
Item 7 Specific objectives or hypotheses	Item 2b Specific (feasibility) objectives or research questions
Item 12 Methods - Primary and secondary outcome measures	Item 6a Assessments to address each pilot trial objectives (primary and secondary)
	Item 6c If applicable, pre-specified criteria used to judge whether, or how, to proceed with future definitive trial
Item 14 Sample size	Item 7a Rationale for sample size
Item 20a Statistical methods	Item 12a Methods (of analysis) used to address each pilot trial objective

Interim guidance on reporting of non randomized pilot studies—based on adaptation of the CONSORT extension to pilot trials and guidelines for reporting of the non-RCTs (eg. STROBE)

Lancaster and Thabane *Pilot and Feasibility Studies* (2019) 5:114
https://doi.org/10.1186/s40814-019-0499-1

Pilot and Feasibility Studies

EDITORIAL Open Access

Guidelines for reporting non-randomised pilot and feasibility studies

Gillian A. Lancaster* and Lehana Thabane

First:

One can use the CONSORT extension to pilot trials checklist, and ignore the parts that deal with randomization as not applicable

Table 1 Main types of non-randomised feasibility studies submitted to the journal, where to find guidance and published examples

Type of study	Equator website checklists and other helpful guidance	Published examples
Intervention development	TIDieR http://www.equator-network.org/reporting-guidelines/tidier/ Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers (O'Cathain et al): https://pilotfeasibilitystudies.biomedcentral.com/articles/10.1186/s40814-015-0026-y	Thematic series on intervention development available at: https://www.biomedcentral.com/collections/interventiondevelopment
Patient-Reported Outcome Measures (PROMS) development	CONSORT PRO (adapt alongside CONSORT extension to pilot trials) http://www.equator-network.org/reporting-guidelines/consort-pro/ COSMIN User Manual (comprehensive reference, useful risk of bias tool) https://cosmin.nl/wp-content/uploads/COSMIN-syst-review-for-PROMs-manual_version-1_feb-2018.pdf	Thematic series on pilot and feasibility testing of patient-reported outcome measures available at: https://www.biomedcentral.com/collections/pilotfeasibilityPROMs
Piloting several components of the trial	CONSORT extension to pilot trials (ignoring items not applicable) http://www.equator-network.org/reporting-guidelines/consort-2010-statement-extension-to-randomised-pilot-and-feasibility-trials/	Aging, Community and Health—Community Partnership Program before-after study [25]: https://pilotfeasibilitystudies.biomedcentral.com/articles/10.1186/s40814-016-0063-1 POWeR-RN non-randomised study with wait-list control [26] https://pilotfeasibilitystudies.biomedcentral.com/articles/10.1186/s40814-017-0122-2#Sec16

Lancaster *et al. Pilot and Feasibility Studies* (2026) 12:136
https://doi.org/10.1186/s40814-026-01927-2

Pilot and Feasibility Studies

EDITORIAL Open Access

Celebrating the 10th anniversary of *Pilot and Feasibility Studies*—what have we achieved?

Gillian A. Lancaster[1], Lehana Thabane[2], Lawrence Mbuagbaw[2] and Stephen A. Bremner[3*]

Pilot and Feasibility Studies:

10 years and what comes next

2015 — 2026 — Next decade



1

A dedicated journal

An outlet for pilot and feasibility research across disciplines.



2

Reporting guidance

CONSORT extension and protocol guidance improved standards.



3

Methodological growth

Guidance expanded to design, analysis, sample size and qualitative work.



4

Remaining gaps

Consent should explain feasibility aims and progression criteria.



5

Next priorities

Update reporting guidance and include underserved populations.

Lancaster et al., *Pilot and Feasibility Studies* (2026) 12:136

Unresolved issues in pilot and feasibility studies

DESIGN

1. Sample size estimation guidance



2. Use of qualitative data



3. Progression criteria for main studies



PROTOCOLS & CONDUCT

4. Adapt SPIRIT for external pilot and feasibility trial protocols



5. Consent processes for pilot and feasibility studies



SYNTHESIS & REPORTING

6. Include pilot and feasibility studies in systematic reviews



7. Reporting guidance for non-randomised external studies



OUTREACH

8. Engage funders, students, clinicians and practitioners





Other important aspects about feasibility and pilot studies

Pilot vs Proof-of-concept study

- **Proof-of-concept (POC) study:**
  - To determine if a treatment (drug) is biologically active or inactive (Stat Med 2005;24:1815-35)
- **Usually based on surrogate makers as endpoints**

Proof of concept is not necessarily proof of feasibility

Proof of concept vs pilot study

PROOF OF CONCEPT

Can we detect an effect?



Is an effect measurable with the available tools?

Focus: signal and measurement

PILOT STUDY

Can we run a larger study?

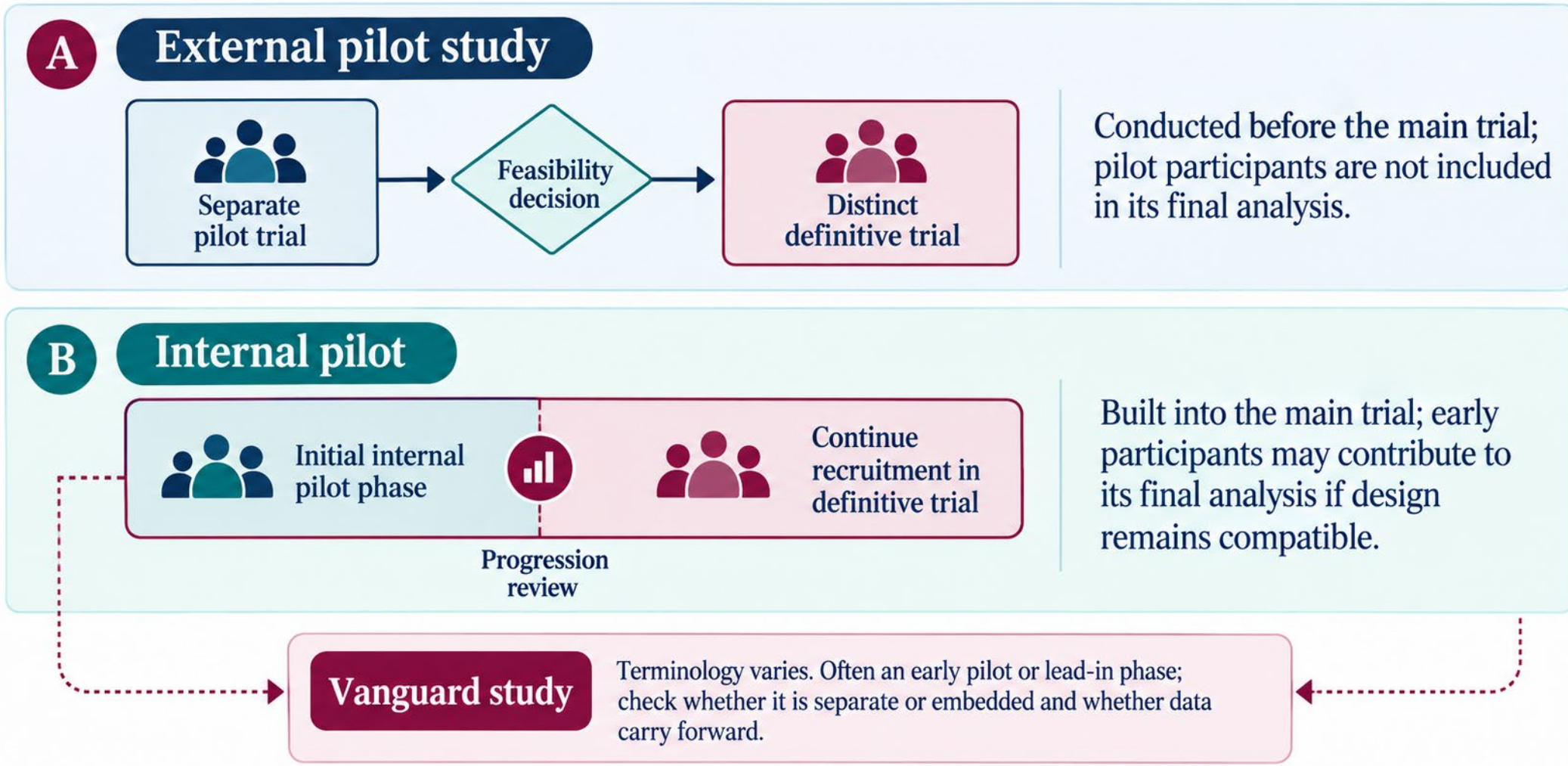


Is the planned larger study feasible?

Focus: recruitment, delivery and follow-up

A **pilot study tests study processes;** it does not establish **effectiveness.**

Pilot study, internal pilot and vanguard study



Key Design Issue

Like all research studies, the **sample size justification** for pilot and feasibility studies is required, and should be based on primary feasibility objectives

Paper summarizes existing approaches with recommendations



ELSEVIER

Journal of Clinical Epidemiology 66 (2013) 197–201

Journal of Clinical Epidemiology

Sample size calculations for pilot randomized trials: a confidence interval approach

Kim Cocks, David J. Torgerson*

York Trials Unit, Department of Health Sciences, University of York, Heslington, York YO10 5DD, UK

Accepted 5 September 2012; Published online 27 November 2012

Table 1. Summary of recommendations for sample size calculations for pilot trials

Study	Recommended sample size	Justification for sample size	Internal/external pilot	Method of analysis and findings
Wittes and Brittain [9]	50% of total sample size of main trial.	To confirm estimates of variance used to power main study. The study should be large enough to be confident in the variance estimates.	Internal	Estimate of variance. If larger than expected, increase sample for main trial, and if lower, retain original sample size. No estimate of treatment effect.
Birkett and Day [6]	10 patients per group 40 maximum. Larger sample sizes for larger main studies.	Extension to Wittes and Brittain but argued that good estimates of study variance can be obtained with a smaller sample size.	Internal	Estimate of variance. No estimate of treatment effect.
Browne [7]	Not clear.	Sample size ''rule of thumb'' of 30 is too small if one uses pilot sample estimate of variance. Need to be more conservative and use upper confidence intervals.	Internal/external	Calculate 80% and 90% confidence interval of standard deviation, and use this to plan main study's sample size.
Sandvik et al.[a]	Minimum of 20 patients in total.	Sample size depends on sample of original study that provided estimate of standard deviation.	Internal	Estimate of a new standard deviation.
Julious [5]	12 patients per group.	Number is divisible by 2, 3, 4, and 6, which can be used as block sizes in restricted randomization. Further reductions in variance decline after 12.	Internal/external	Use point estimate of variance.
Sim and Lewis [13]	At least 55.	Smaller sample sizes are likely to underestimate the variance and lead to an underpowered main trial.	Internal/external	Use upper 95% one-sided confidence limit of pilot standard deviation.
Present study	At least 9% of main trial's sample size.	This allows a one-sided 80% confidence interval to exclude a clinically important difference.	Internal/external	Obtain treatment estimate if above zero proceed to main trial. No hypothesis tests.

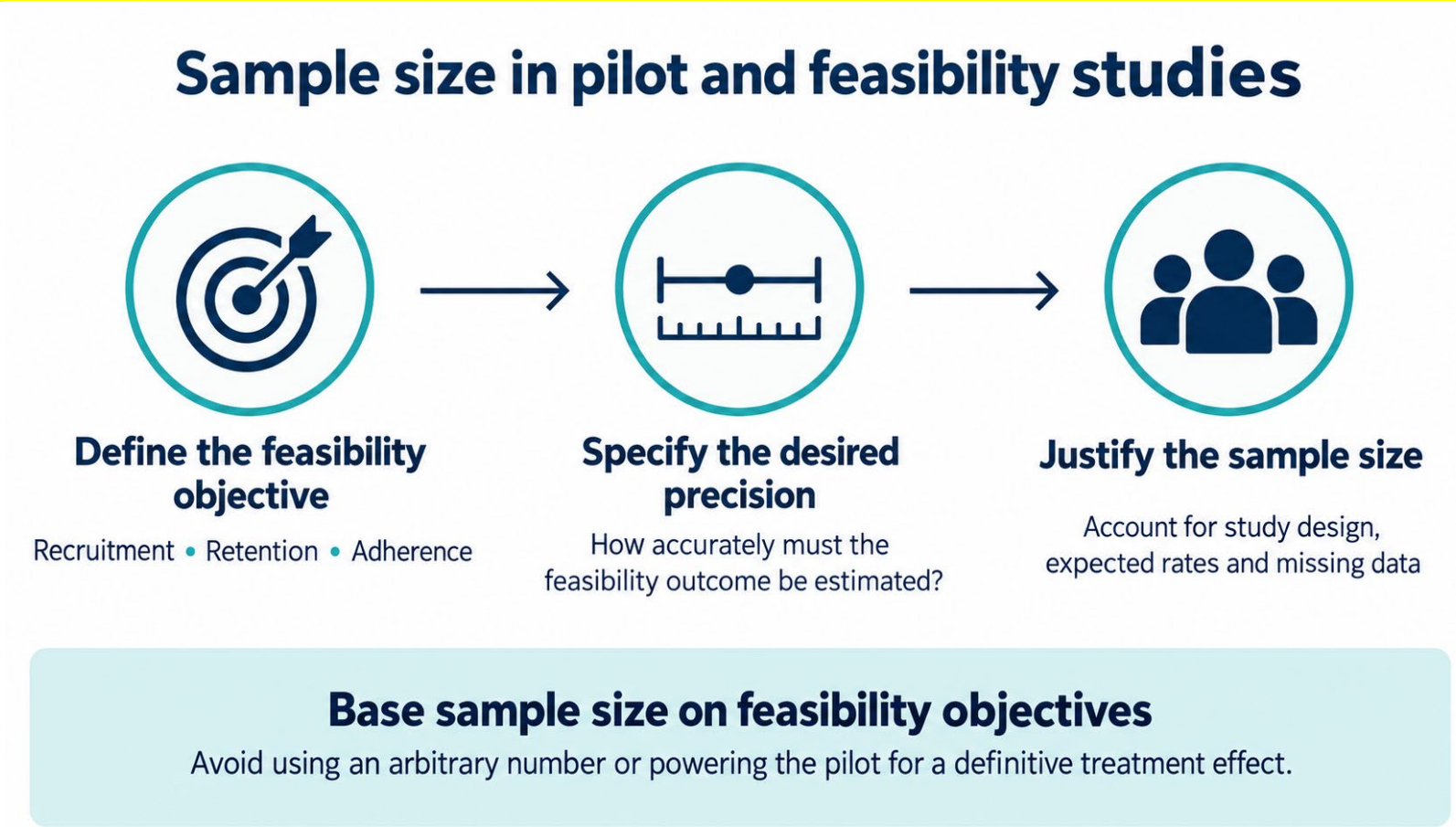
[a] Sandvik L, Erikssen J, Mowinckel P, Rodland EA. A method for determining size of internal pilot studies. *Statistics in Medicine* 1996; 1587–90.



- ✓**Estimate feasibility outcomes** with a specified precision.
- ✓**Assess progression criteria** using predefined thresholds and error rates.
- ✓**Detect feasibility problems** with a high probability.
- ✓**Estimate variability** to inform the definitive trial.
- ✓**Minimize the combined sample size** of the pilot and definitive trial.
- ✓**Rule out interventions unlikely to achieve clinically important effects.**

Bottom Line:

Sample size justification is required and must be tied to feasibility objectives



Common misconceptions

- ✓ **A small study that can be completed quickly**
  - ❑ A small study done by a student/intern

- ✓ **A small study that does not require any funding**
  - ❑ I don't have any funding to do a big study!
  - ❑ My boss told me to do it!

- ✓ **A small study that has limited funding**
  - ❑ I have funding for only 10 patients!
  - ❑ I have limited seed funding!

- ✓**A small single-centre study**
  - ❑I don't have the resources for a large multi-centre study!
- ✓**A small study that is similar in size as someone else's published study**
  - ❑So-and-so did a similar study with 6 patients and got statistical significance – ours uses 12 patients (double the size)!
- ✓**We did a similar pilot before (got it published!)**
  - ❑Pilot studies should always be viewed in the context of the main study



Frequently Asked Questions



- ✓**Can I publish the results of a pilot study?**
  - ❑Yes, every attempt should be made to publish them

- ✓**Why is it important to publish the results of pilot studies?**
  - ❑To provide information about feasibility to the research community
  - ❑To save resources (avoid duplication of efforts)
  - ❑We have ethical and scientific obligation to do so

Most pilot studies do not show statistically significant results. What should I do?

- The focus in reporting the results of a pilot should be on **feasibility, NOT statistical significance**
- New CONSORT checklist for reporting emphasizes this point

"No evidence of effect" is not "evidence of no effect"

(BMJ 1995; 311: 485)

- ✓**Can I combine data from a pilot with data from the main study?**
  - ❑Yes, provided the sampling frame is the same and so is the methodology
- ✓**Can I combine the results of a pilot with the results of another study or in a meta-analysis?**
  - ❑Yes, same conditions as above
  - ❑Also depends on whether the main study is reported
- ✓**Can a pilot ever exist on its own?**
  - ❑Yes, if the results show that it is not feasible to go to the main study or there is no funding for the main study
- ✓**Can I apply for funding for a pilot study?**
  - ❑Yes, like any grant it is important to justify the need for piloting
  - ❑The pilot has to be placed in the context of the main study

- ✓**Can I randomize patients in a pilot study?**
  - ❑Yes; to assess how a randomization might work in main study or whether it might be acceptable to patients
  - ❑In general, it is always best for a pilot to maintain the same design as the main study

- ✓**Can I use the pilot to estimate the sample size for the main trial?**
  - ❑Yes, but be cautious
  - ❑Consider supplementing with qualitative discussions
  - ❑Use SS table to capture prevailing uncertainty

- ✓**Can I use the results of pilot study to treat my patients?**
  - ❑Not a good idea!
  - ❑Pilot studies are primarily for assessing feasibility

- ✓**What can I do with a failed or bad pilot study?**
  - ❑No study is a complete failure, it can always be used as bad example!

Should I register a pilot trial/study?

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
Advanced Search | Help | Studies by Topic | Glossary

Comment Period Extended to 3/23/2015 for Notice of Proposed Rulemaking (NPRM) for FDAAA 801 and NIH Draft Reporting Policy for NIH-Funded Trials

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results Text Size

11676 studies found for: pilot
Modify this search | How to Use Search Results

List | By Topic | On a Map | Search Details

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☐ Include only open studies ☐ Exclude studies with unknown status

Rank	Status	Study
1	Unknown †	Pilot Study of the Feasibility of Palm Pilots in Monitoring Smoking Beh Illness **Condition:** Smoking **Intervention:** Device: Palm Pilot
2	Not yet recruiting	ART-3 Pilot - Driving Pressure Limited Ventilation for Patients Without **Conditions:** Mechanical Ventilation; Acute Respiratory D **Interventions:** Other: Driving pressure limited ventilation; C
3	Recruiting	Balloon Palpation vs Loss of Resistance Syringe for Safe Endotrachea Clinical Trial **Condition:** Tracheal Damage **Interventions:** Device: PBP; Device: LOR; Device: Aneroi
4	Enrolling by invitation	Pilot Study Investigating the Feasibility of Determining the Endogenou Hypoglycaemia



ISRCTN registry

Search

View all studies | Why register? | Register your study

Refine your search

440 results within Public title: pilot

Show Results 10 Sort by **Date** / Relevance

Trial Status

- Completed (395)
- Ongoing (26)
- Stopped (19)

Condition Category See all

- Mental and Behavioural Disorders (87)
- Cancer (43)
- Circulatory System (38)

ISRCTN28960271 : Pilot randomised controlled trial of hysteroscopic septal resection

Overall trial status: Ongoing **Recruitment status:** Not yet recruiting

Pilot randomised controlled trial of hysteroscopic septal resection

ISRCTN14861313 : PRO-REHAB - The development and pilot trial of two programmes of rehabilitation for cancer patients

Overall trial status: Ongoing **Recruitment status:** Recruiting

PRO-REHAB - The development and pilot trial of two programmes of rehabilitation for cancer patients

Key messages

- Pilot study provides a good opportunity to assess feasibility of large full-scale evaluation studies
- It can enhance the success probability of the main study
- It is about exploring uncertainties before undertaking a main study and has objectives and outcomes to match

- ✓Pilot studies should be well designed
  - ❑Clear feasibility objectives
  - ❑Clear rationale for piloting – needs to be linked to main study
  - ❑Clear analytic plans
  - ❑Clear criteria for determining success of feasibility
- ✓Pilot studies should be used cautiously for determining
  - ❑Treatment effects
  - ❑Power/sample size calculations
- ✓They should be scrutinized the same way as full scale studies/RCTs
  - ❑Require registration
  - ❑They should also be published/reported in peer-review journals

Remember that a pilot study is NOT

- A small single centre study undertaken because there were no/insufficient resources for a larger multi-centre study!
- A small study that is similar in size as someone else's published study so it must be alright
- A study to demonstrate effectiveness of an intervention

African Proverb (Ashanti, Ghana)

You never test the depth of a river with both feet




thank you
danke
謝謝
ngiyabonga
شكراً جزيلاً
рахмат
teşekkür ederim
Баярлалаа
спасибо
gracias
dank je
tapadh leat
faafetai lava
vinaka
спасибі
blagodaram
misaotra
matondo
paldies
grazzi
mahalo
хвала
asante
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