

Reporting Pragmatic Clinical Trials

Introduction

Transparent reporting of clinical trials is essential for enabling researchers, clinicians, patients, and other stakeholders to understand the validity and reliability of the findings. To promote high-quality trial reporting and to build consensus on the key elements of transparent reporting, a group of clinical trial methodologists and journal editors developed the Consolidated Standards of Reporting Trials ([CONSORT](#)). CONSORT is intended to improve transparency and dissemination of trial findings by providing a checklist and guidance for authors (Moher et al 2010). The original CONSORT statement focused on the reporting of standard, 2-group randomized controlled trials that compare an intervention with a control. CONSORT now includes several extensions to account for variations in trial design, interventions, and data (Appendix A). An extension of CONSORT to pragmatic clinical trials was published in 2008 (Zwarenstein et al 2008).

Pragmatic Clinical Trials

The [NIH Pragmatic Trials Collaboratory](#) supports the design, implementation, and dissemination of several pragmatic clinical trials that address questions of major public health importance. The program is part of an effort to create an infrastructure for collaborative research within healthcare systems. In contrast to traditional randomized controlled trials, which elucidate a mechanical or biological process, pragmatic trials are “designed for the primary purpose of informing decision makers regarding the comparative balance of benefits, burdens and risks of a biomedical or behavioral health intervention at the individual or population level” (Califf and Sugarman 2015). To be clear, pragmatic trials are on a continuum with traditional explanatory trials; aspects of pragmatic trials make the trials either more explanatory or more pragmatic (Appendix B). Generally, a pragmatic trial is more pragmatic if the data are collected during routine clinical care (often through the electronic health record [EHR]); if there is flexibility in the delivery of and adherence to the intervention; if a real-world population is included; and if the outcomes are relevant to patients and other decision-makers.

Purpose of This Template

This template is intended to help authors with transparent reporting of the primary results of their pragmatic clinical trials. While we have looked to the CONSORT guidance and extensions wherever possible, new areas are emerging related to pragmatic trials that the CONSORT checklist does not address. These include reporting on the secondary use of EHR data, wider involvement of research partners and healthcare systems in the conduct of pragmatic trials, and special ethical and regulatory considerations.

Guidance in this template is organized by the recommended reporting elements as presented in the CONSORT checklist, and draws on recent experiences and lessons learned from the NIH Collaboratory Trials. We hope that the resulting template will assist authors in developing the reports of their primary study results for journal publication. We recognize that journals have space limitations, and we encourage authors to use supplements if necessary to report all the recommended elements.

We include the following appendices:

Appendix A contains a table with references to CONSORT and its extensions.

Appendix B provides links to the Pragmatic–Explanatory Continuum Indicator Summary (PRECIS-2) tools and resources.

Appendix C has examples of figures.

Living Textbook of Pragmatic Clinical Trials

Education and training modules, webinar archives, and tools for the design, conduct, and dissemination of pragmatic clinical trials are available on [Rethinking Clinical Trials®: A Living Textbook of Pragmatic Clinical Trials](#), an online resource designed to provide information on how to understand, design, conduct, analyze, and disseminate pragmatic trials. Additional resources for authors can be found after the reference list in this document.

Other Publication Types

Researchers from the NIH Collaboratory Trials make contributions to the peer-reviewed literature on a wide range of topics relating to the design and conduct of pragmatic clinical trials embedded within healthcare systems. Every research team publishes a study design paper and a main outcome paper. Many teams also publish papers in other categories. To help pragmatic trials researchers understand potential opportunities for publication of their work, the NIH Collaboratory created a [publications type handout](#) offering examples of the types of papers commonly published by the NIH Collaboratory Trials study teams.

Note that there are other types of dissemination that may be important for pragmatic clinical trials apart from journal articles; those dissemination approaches are not covered in this template. For more information about dissemination, see the [Dissemination Approaches for Different Stakeholders](#) chapter of the Living Textbook and the discussion by [Simon and colleagues](#) (2020).

Template

Title

Identify the study as a randomized, pragmatic clinical trial or, specifically, a cluster randomized trial, as appropriate. (Optional: Convey the randomization scheme—for example, parallel, stepped-wedge, adaptive). On the title page, include all author names, degrees, and institutional affiliations and give full contact information for the corresponding author. Provide 3 to 5 keywords.

Abstract

Create a structured summary (background, methods, results, discussion) that includes the following information:

- Trial design (eg, cluster randomization, noninferiority)
- Randomization scheme (eg, parallel, stepped-wedge, adaptive)
- Setting (eg, hospitals, community clinics, regional healthcare system)
- Eligibility criteria for the participants or clusters
- Interventions for each group
- Whether the hypothesis pertains to the cluster level, the individual participant level, or both, and whether the primary outcome pertains to the cluster level, the individual participant level, or both
- For cluster randomized trials, how the clusters were allocated to interventions
- Whether participants, caregivers, and those assessing the outcomes were blinded to group assignment
- The number of participants or clusters randomly assigned to each group and the number analyzed in each group
- Results at the individual participant or cluster level as applicable for each primary outcome
- Important adverse events or side effects
- A general interpretation of the results
- The degree of generalizability of the findings
- The trial registration name and number
- If available, where the protocol can be accessed
- The funding source and role of the funder

Introduction

Background and objectives

State:

- The pragmatic question the trial was intended to address. Consider stating the question in the form of a “should” question: “Should hospitals...?” “Should dialysis facilities...?” A question stated in this way can help your readers understand the goals of the study and the rationale for the study design.

Describe:

- The scientific background and rationale
- The health or healthcare system problem the intervention addresses
- The rationale for choosing the specific pragmatic design (includes cluster randomized, stepped-wedge)
- Decisions the trial is intended to inform and in what setting
- Other interventions that are commonly aimed at this problem
- Key features that make the trial feasible in this setting and elsewhere
- Specific objectives, research questions, and hypotheses; for cluster randomized trials, describe whether the objectives pertain to the cluster level, individual participant level, or both

Methods

Stakeholder engagement

Because pragmatic trials are generally conducted as part of routine care and are meant to immediately inform the delivery of care, engagement with relevant stakeholders—patients, delivery system leaders, IT personnel, clinicians, and other frontline providers—is important. Briefly describe the extent to which stakeholders were involved (eg, defining the study question, designing the study, developing workflows, assessing feasibility).

Trial design

Describe the pragmatic aspects of the trial design: decisions related to the real-world healthcare setting, logistical considerations and clinical workflow, and service delivery. Explain the design, such as cluster randomization, stepped-wedge. Indicate if applicable whether this is a population-based study. If possible, include a schematic representation of the study design.

For cluster randomized trials, define the clusters and describe how the design features apply to the clusters. For stepped-wedge, cluster randomized trials, define the timing and randomization of crossover from the control to the intervention.

Describe important changes to the methods after the trial started, and include reasons.

Participants

Frame the eligibility criteria to show the degree to which they include typical participants, providers, institutions, communities, or settings of care. Explain the method of participant recruitment and the attributes of the healthcare system or setting where the data were collected.

Intervention

Readers need a sense of how feasible the intervention would be in their setting. Give a detailed description of the intervention for each group and how it was actually administered; explain the comparator (for example, usual care) in similar detail. If the intervention included multiple components, describe each component in detail. For cluster randomized trials, indicate whether the interventions were applied at the cluster level, individual participant level, or both.

Describe any resources added to or removed from usual care to implement the intervention. Indicate whether delivery of the intervention was allowed to vary between participants, providers, or study sites. For pragmatic trials, efforts that may reduce “natural variation in the intervention and its delivery should be described. However, if reducing variation in a care process or shifting practice patterns is itself the main purpose of the intervention, this should be explicit in the title, abstract, and introduction” (Zwarenstein et al 2008).

When relevant, include details on the experience and training (eg, frequency, intensity) of those who delivered the intervention.

Outcomes

Explain the primary and secondary outcome measures, why they were chosen, and their relevance to participants and key decision-makers. Include whether the outcomes relate to health outcomes for patients or to healthcare system improvements or efficiencies.

Describe any [patient-reported outcome \(PRO\)](#) measures that were used to assess the intervention; include appropriate references in support of the validity and reliability of the measures used. Describe how and when the outcomes were assessed, as well as any changes to the outcomes after the trial started, with reasons. Include the length of follow-up and how it pertains to the decisions the study is designed to inform.

For cluster randomized trials, indicate whether the outcome measures apply to the cluster level, individual participant level, or both.

Sample size

Explain how sample size was determined, interim analyses, and stopping rules. If sample size was “calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference), then report where this difference was obtained” (Zwarenstein et al 2008). For cluster randomized trials, describe the number of clusters and the cluster size, including whether equal or unequal cluster sizes are assumed. Indicate the intraclass (intracluster) correlation coefficient, as well as an indication of its uncertainty.

Human subjects protection

Describe approval by an ethics committee (eg, an institutional review board) as well as any other oversight bodies from which approvals were obtained. If the pragmatic trial involved a regulated product, indicate whether it was conducted under an investigational new drug (IND) authorization or its equivalent. Delineate who is considered to be a human subject in the research (eg, patients, clinicians, others) as well as indirect subjects of the research. Include details of the type (written, oral) and mode (electronic, mail, in-person) of informed consent used, or explain if a waiver or alteration of informed consent was approved and used. If so, describe what, if any, mechanisms were used to provide information about the research (ie, disclosure) and if participation was specifically authorized by subjects or if an opt-out mechanism was used. If applicable, describe whether notification and/or consent occurred before or after randomization. Describe the method of authorization used for the use of protected health information and the standards for data security. Describe the approach used for data monitoring and, if applicable, the existence of a data monitoring committee. For cluster randomized trials, indicate the nature of engagement with cluster representatives (eg, discussion, consent) and whether consent was obtained from individual cluster members.

Randomization

Sequence generation

Include the method used to generate the random allocation sequence and describe any restriction used (eg, blocking, stratification). Describe the type of randomization (eg, individual, cluster, nonrandomized). For cluster randomized trials, explain if stratification or matching was used.

Allocation concealment mechanism

Describe the method used to implement the random allocation sequence, including any steps to conceal the sequence until after intervention assignment. For cluster randomized trials, specify that allocation was based on clusters. Indicate whether allocation concealment was at the cluster level, individual participant level, or both.

Implementation

Explain who generated the random allocation sequence, who enrolled participants (or clusters), and who assigned participants (or clusters) to the intervention. For cluster randomized trials, describe how individual participants were included in the clusters, such as by random sampling or inclusion of all individuals identified as eligible.

Blinding

Describe whether participants, those administering the intervention, and those assessing the outcomes were blinded to group assignment. If blinding was not done or was not possible, explain why. If relevant, describe the similarity of the interventions.

“In pragmatic trials, as in the real world delivery of care, blinding of participants and clinicians may be impossible.... Authors should speculate on the effect of any suspected modifying factors, such as belief in the intervention, in the discussion [section].... Moreover, in pragmatic trials, it is still desirable and often possible to blind the assessor or obtain an objective source of data for evaluation of outcomes” (Zwarenstein et al 2008).

Monitoring for unanticipated changes in care within study arms

As trials evolve, changes may occur in the care provided within the intervention and/or control arms that could affect the conduct or analysis of the study. For example, some components of the intervention may appear in usual care at some control sites or clusters. Contamination can be due to various reasons: unintentional spillover of intervention effects, other healthcare initiatives that focus on the same problem, or changes in leadership, sites, or healthcare delivery system. Explain how you monitored care provided within all study arms across all sites or clusters and whether you were able to measure treatment fidelity.

Use of data from EHRs or clinical and administrative information systems

If the source of data was from a clinical or billing database instead of one created primarily for research, describe:

- The nature of the data source and data
- The steps used in gaining permission to use the data
- How the population of interest was identified (ie, development of phenotype definitions, use of ICD-10 codes)
 - Reference any specific standards, data elements, or controlled vocabularies used, and provide details of strategies for translating across coding systems where applicable (eg, methods for ICD-9 to ICD-10 translation or assertion of equivalence). If the choice of data collection or methods was informed by a data standards initiative (eg, American College of Cardiology standards), identify the

relevant standard, standards development organization, or professional clinical or research organization that named the standard.

- Each clinical phenotype (ie, EHR-based condition definition) used
 - Reference the location where readers can obtain the detailed definitional logic. Use of a national repository for phenotype definitions, such as the [Phenotype Knowledgebase \(PheKB\)](#) or the National Library of Medicine's [Value Set Authority Center \(VSAC\)](#), is preferred. GitHub or another repository for code is valuable as well.
- The process for linking data from different sources, including EHRs, ancillary systems, administrative and billing systems, and external sources, such as the Centers for Medicare and Medicaid Services or regional health information exchange
- The process and results from assessment of the quality of the data. Assessment should be informed by the NIH Pragmatic Trials Collaboratory's [Assessing Fitness-for-Use of Clinical Data](#) handout.
- The data management activities during the study, including a description of different data sources or processes used at different sites
- The plan for archiving or sharing the data after the study, including specific definitions for clinical phenotypes and specifications for the coding system (name and version) for any coded data

Use of a distributed research network (DRN)

If a DRN was used, describe it. For more information and resources about the use of DRNs, refer to the NIH Collaboratory's [Distributed Research Network](#) web page.

Statistical methods

Describe the statistical methods used to compare groups for primary and secondary outcomes. Include methods for subgroup analyses and adjusted analyses. For cluster randomized trials, indicate how clustering was considered.

Results

Participant flow

Describe the flow of participants and/or clusters through the trial and include a diagram if possible (see example in Appendix D). Include the number of participants and/or clusters that were invited to participate, were eligible, were randomly assigned, received the assigned intervention, completed the study protocol, and were analyzed for the primary outcome. Include reasons for nonparticipation of those invited to participate. Also report losses and exclusions of participants (and clusters, if applicable) after randomization, with reasons. For cluster randomized trials, the [CONSORT extension to cluster randomized trials](#) includes helpful examples of participant flow diagrams.

Recruitment

List the dates of recruitment and follow-up. Explain why the trial ended or was stopped.

Baseline data

Include a table showing baseline demographic and clinical characteristics for each group (and cluster, if applicable). If appropriate, give details of [EHR-based phenotyping](#) pertinent to the study.

Unanticipated changes in care within study arms

Report any unanticipated changes in care that occurred in the study arms that could affect the interpretation of the study. Describe any intervention contamination and adjustments made to the analysis to accommodate contamination.

Numbers analyzed

For each group, include the number of participants or clusters (ie, the denominator) included in each analysis.

Outcomes and estimation

For each primary and secondary outcome, present results for each group and estimated effect size and its precision (eg, 95% CI). For binary outcomes, give both absolute and relative effect sizes. For cluster randomized trials, provide results at the individual or cluster level, as applicable, and give the intraclass (intracluster) correlation coefficient for each primary outcome.

Ancillary analyses

Describe results of any other analyses performed. Distinguish between prespecified and exploratory analyses.

Harms

Explain important harms or unintended effects in each group. Clarify how harms data were collected and analyzed. Describe participant withdrawals due to harms and their experiences with the allocated treatment.

Limitations

Discuss limitations of the study, addressing sources of potential bias and imprecision.

Discussion**Generalizability**

Describe key aspects of the setting that determined trial results. Describe possible differences in other settings, where clinical traditions, health service organization, staffing, or resources might vary from those in your study. Keep in mind that “the usefulness of the trial report is critically dependent on how applicable the trial and its results are and how feasible the intervention would be” (Zwarenstein et al 2008).

Interpretation

Discuss the interpretation of results, balancing benefits and harms and considering other relevant evidence. A defining component of a pragmatic trial is that it is intended to inform decision-makers about benefits, burdens, and risks of an intervention. Describe the relevance to decision-makers.

References

Include a full reference list with PubMed IDs, URLs, or DOIs.

Acknowledgments

Include names of contributors who do not qualify as authors, per the guidelines of the [International Committee of Medical Journal Editors](#).

Figures

Potential figures (examples in Appendix D):

- Participant/cluster flow through the trial
- Stepped-wedge cluster intervention timing

Tables

Potential tables:

- Participant/cluster characteristics
- Baseline data and, if applicable, phenotype descriptions

Supplementary Materials

Authors may consider including the URL for the trial website and making available relevant toolkits, participant materials, videos, or other resources.

References Cited

Califf RM, Sugarman J. Exploring the ethical and regulatory issues in pragmatic clinical trials. *Clin Trials*. 2015 Oct;12(5):436-41. doi: 10.1177/1740774515598334. [PMID: 26374676](#).

Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010 Mar 23;340:c869. [PMID: 20332511](#).

Simon GE, Richesson RL, Hernandez AF. Disseminating trial results: We can have both faster and better. *Healthc (Amst)*. 2020 Dec;8(4):100474. doi: 10.1016/j.hjdsi.2020.100474. [PMID: 32992107](#).

Zwarenstein M, Treweek S, Gagnier JJ, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ*. 2008 Nov 11;337:a2390. doi: 10.1136/bmj.a2390. [PMID: 19001484](#).

Additional Resources for Authors

- EQUATOR (Enhancing the Quality and Transparency of Health Research) Network. Library for Health Research Reporting. This website contains a comprehensive searchable database of reporting guidelines and links to other resources relevant to research reporting. Available at: <http://www.equator-network.org/>. Accessed December 26, 2023.
- Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ*. 2015 Feb 6;350:h391. doi: 10.1136/bmj.h391. [PMID:25662947](#).
- Johnson KE, Neta G, Dember LM, et al. Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory. *Trials*. 2016 Jan 16;17:32. doi: 10.1186/s13063-016-1158-y. [PMID: 26772801](#).
- Krist AH, Glenn BA, Glasgow RE, et al. Designing a valid randomized pragmatic primary care implementation trial: the my own health report (MOHR) project. *Implement Sci*. 2013 Jun 25;8:73. doi: 10.1186/1748-5908-8-73. [PMID:23799943](#).

Appendix A. CONSORT Guidance

The Consolidated Standards of Reporting Trials (CONSORT) statement, including the 2008 extension to pragmatic clinical trials, encompasses various initiatives developed by the CONSORT Group to address problems associated with inadequate reporting of randomized controlled trials.

CONSORT resources

Description	Link
Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c869. PMID: 20332511	Moher 2010, PubMed abstract
CONSORT checklist and explanations	https://www.equator-network.org/reporting-guidelines/consort/
CONSORT extensions	
Designs	
	Cluster randomized trials
	Noninferiority and equivalence trials
	Pragmatic trials
	N-of-1 trials
Interventions	
	Herbal medicinal interventions
	Nonpharmacologic treatment interventions
	Acupuncture interventions
Data	
	Patient-reported outcomes
	Harms
	Abstracts

Appendix B. PRECIS-2

The Pragmatic–Explanatory Continuum Indicator Summary (PRECIS-2) tool guides trialists to prospectively consider the design of their trial across 9 domains: eligibility criteria, recruitment, setting, organization, flexibility (delivery), flexibility (adherence), follow-up, primary outcome, and primary analysis (Figure B-1). The rating scale is from 1 (more explanatory) to 5 (more pragmatic).

Figure B-1. PRECIS-2 Wheel

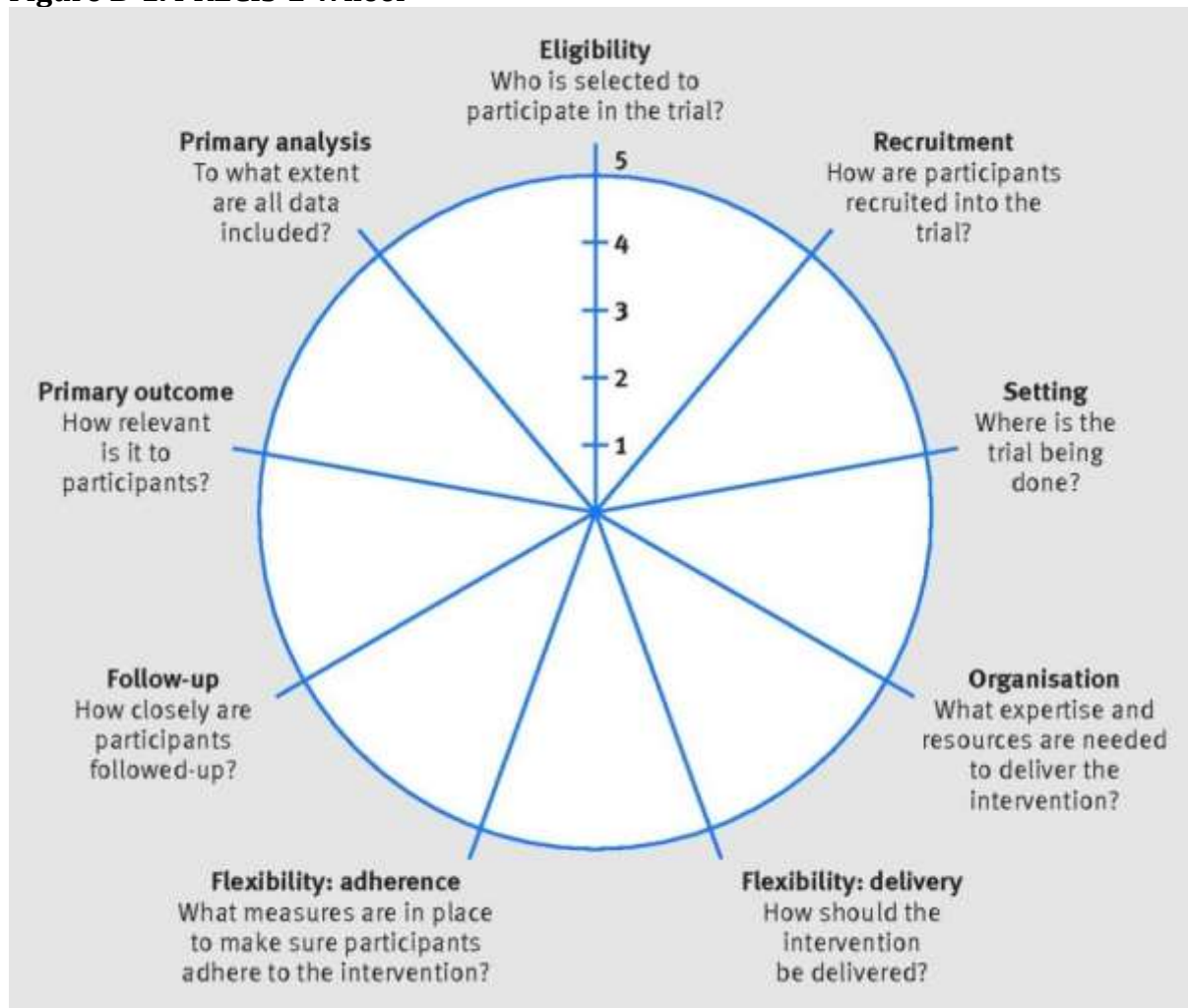


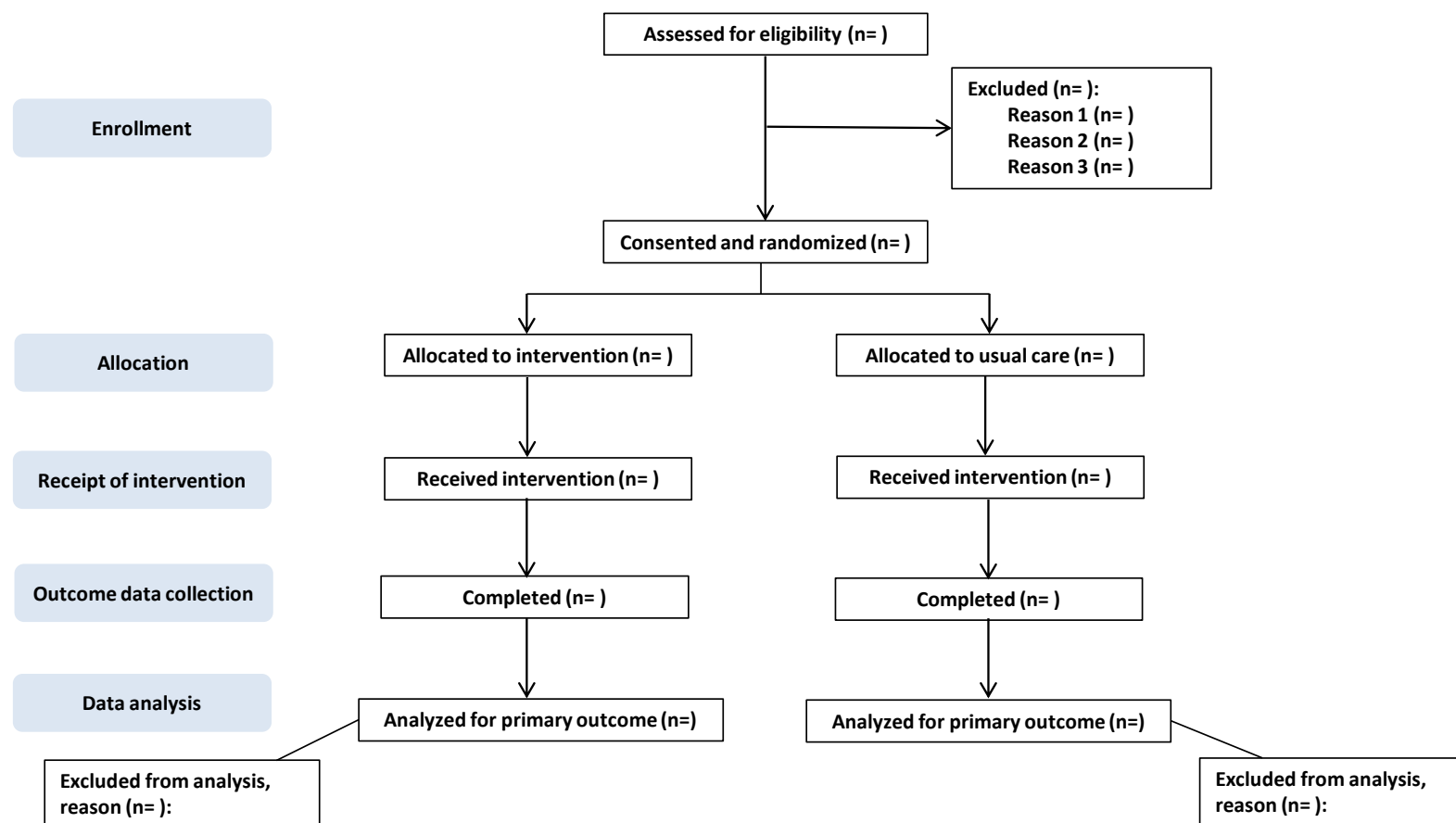
Illustration used with permission. Loudon et al. *BMJ*. 2015;350:bmj.h2147. Copyright 2015 by British Medical Journal Publishing Group.

PRECIS-2 resources

Description	Link
Weinfurt KP. What is a pragmatic clinical trial? Pragmatic elements: an introduction to PRECIS-2. In: <i>Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials</i> . Bethesda, MD: NIH Pragmatic Trials Collaboratory. Updated January 16, 2024. DOI: 10.28929/092.	Living Textbook
Loudon K, Treweek S, Sullivan F, et al. The PRECIS-2 tool: designing trials that are fit for purpose. <i>BMJ</i> 2015;350:h2147. PMID:25956159. doi:10.1136/bmj.h2147.	Loudon 2015, PubMed abstract
Johnson KE, Neta G, Dember LM, et al. Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory. <i>Trials</i> 2016;17(1):32. PMID:26772801. doi:10.1186/s13063-016-1158-y.	Johnson 2016, PubMed abstract
An introductory YouTube video on PRECIS-2 (2:53) by coauthors Kirsty Loudon and Shaun Treweek.	PRECIS-2 video
Health Informatics Centre at the University of Dundee contains information for trialists on using PRECIS-2. The site has a database of trials spanning the pragmatic spectrum. Users can also register their trials at the website	PRECIS-2 website
An index of registered trials showing wheel ratings and other details.	PRECIS-2 wheel examples

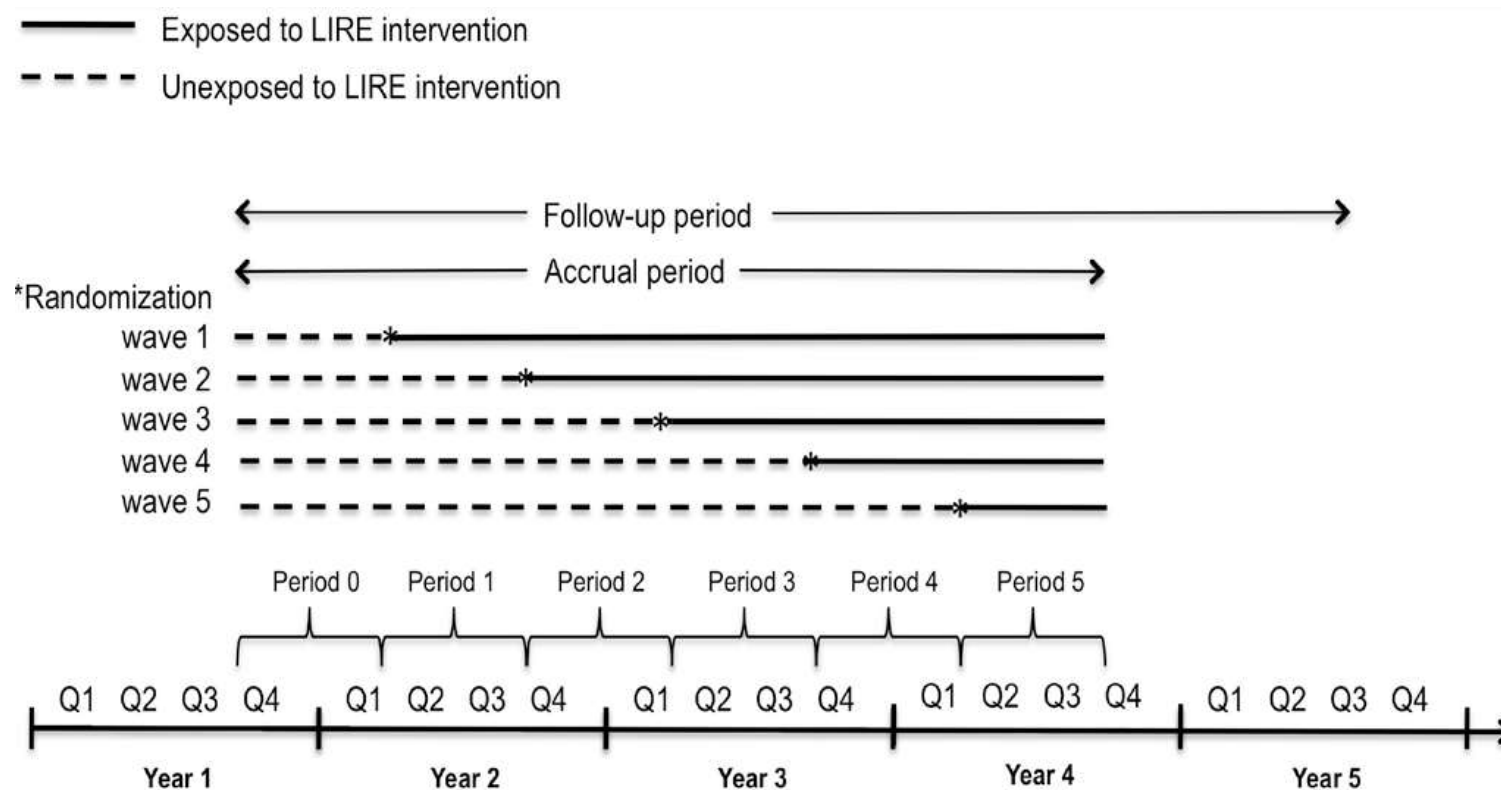
Appendix C. Sample Figures

Figure D-1. Example of participant flow diagram*



* For another example, see the STOP CRC trial's publication (Coronado GD, Vollmer WM, Petrik A, et al. Strategies and opportunities to STOP colon cancer in priority populations: pragmatic pilot study design and outcomes. *BMC Cancer*. 2014 Feb 26;14:55. doi: 10.1186/1471-2407-14-55. [PMID: 24571550](#)). More examples are in the [CONSORT](#) guidance documents and extensions.

Figure D-2. Example of stepped-wedge cluster intervention timing



In each wave, 20 new clinics have the LIRE intervention (inserting epidemiologic benchmarks into imaging reports) until all 100 are exposed to the intervention. Figure is from NIH Pragmatic Trials Collaboratory Grand Rounds slide presentation, November 6, 2015: Lumbar Imaging with Reporting of Epidemiology (LIRE): Lessons Learned. Available at: <https://dcricollab.dcri.duke.edu/sites/NIHKR/KR/GR-Slides-11-06-15.pdf>.