JOHNS HOPKINS
MEDICINE

Common Study Designs in Orthopaedic Surgery Research

Strengths, Limitations, and Real-World Examples

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Why Understanding Study Design Matters

We need to critically evaluate and conduct research that impacts patient care.

Guides methodology selection

The right design addresses your your specific research question question

Determines research validity

Strong designs minimize bias maximize clinical relevance

Impacts clinical practice

Evidence strength influences adoption into clinical guidelines

Evidence Hierarchy in Orthopaedic Research

Observational Studies

- Researcher observes without intervention
- Case reports/series, cross-sectional, sectional, case-control, cohort
- Often more feasible in surgical specialties

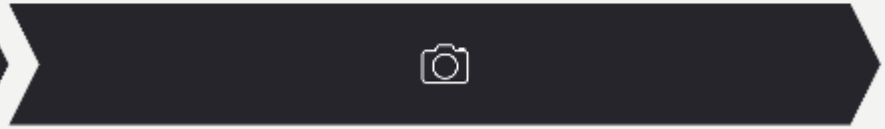
Experimental Studies

- Researcher actively assigns
- Randomized controlled trials, quasi-quasi-experimental
- Stronger for causality but harder to implement

Observational Study Designs

Case Reports & Series

Detailed report of unique or rare phenomena

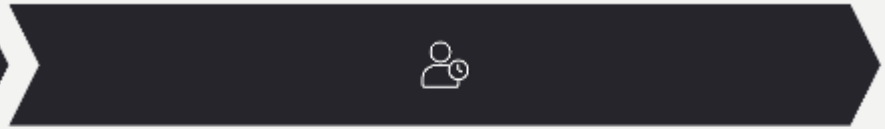


Cross-Sectional

Snapshot of exposures and outcomes

Case-Control

Compares cases with outcome to controls without



Cohort

Follows groups over time to measure outcomes

Observational designs increase in complexity, cost, time-commitment, and typically evidence strength from left to right

Case Reports & Case Series

Detailed account of rare or novel clinical findings, useful for first phenomena

- Strengths
  - *Quick and inexpensive*
  - *Useful for rare findings*
  - *Hypothesis generating*
- Limitations
  - *Cannot establish causality*
  - *Highly susceptible to bias*
  - *Limited generalizability*

Real-World Example: First reports of adverse reactions to metal-on-metal hip replacements led to device warnings and significant changes in clinical practice.

Case-Control & Cross-Sectional Studies

Case-Control Studies

Compares patients with outcome (cases) and those without (controls) to identify risk factors

- *Good for rare outcomes*
- *Relatively efficient*
- *Cannot directly measure incidence*
- *Risk of recall & selection bias*

Example: Risk factors for prosthetic joint infection after replacement (identifying diabetes, obesity as risks)

Cross-Sectional Studies

Takes a “snapshot” measuring exposure and outcomes at a single point in time

- *Time-efficient*
- *Good for prevalence assessment*
- *Cannot determine temporality*
- *Subject to selection bias*

Example: Prevalence of rotator cuff tears in community-community-dwelling older adults

Cohort Studies

Follow groups with/without exposure over time to measure

Prospective - Groups identified and followed forward in time

- *E.g., following smokers vs. nonsmokers after fracture to compare healing rates*
- *Strengths: Less bias, complete data collection*
- *Limitations: Time-consuming, expensive, dropout*

Retrospective - Historical data used to trace backward

- *E.g., Scandinavian Arthroplasty Registry analyzing long-term outcomes*
- *Strengths: Faster, less expensive, good for rare exposures*
- *Limitations: Incomplete data, confounding*

Cohort studies can establish temporality and measure incidence, making them powerful tools for orthopaedic outcomes research

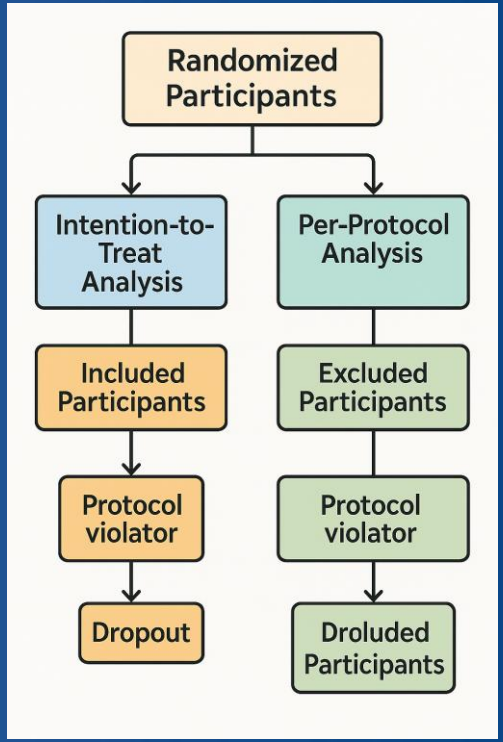
Experimental Designs in Orthopaedic

Randomized Controlled Trials

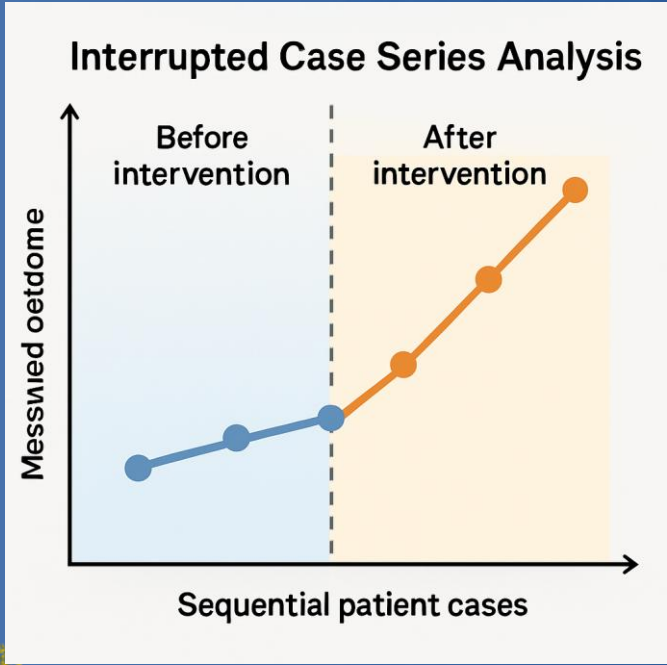
Gold standard for testing efficacy where patients are randomly assigned to interventions

- *Minimizes bias & confounding*
- *Strong causal inference*
- *Often expensive, time-consuming*
- *May lack generalizability*

FAITH Trial Example: RCT comparing sliding hip screws vs. cancellous cancellous screws in femoral neck fracture fixation



Experimental Designs in Orthopaedic



Quasi-Experimental

- Intervention assigned without randomization (e.g., before-after studies)
  - *Practical for quality improvement*
  - *Useful when RCT not feasible*
  - *More prone to bias/confounding*
  - *Weaker evidence than RCT*

Example: Enhanced Recovery After Surgery (ERAS) implementation for joint replacement

Table Summary: Study Design & Statistical Tests

STUDY DESIGNS IN CLINICAL RESEARCH AND THEIR MAIN STATISTICAL TESTS

Study Design	Main Statistical Tests
Case report/series	descriptive stats
Cross-sectional	chi-square, t-test, regression
Case-control	odds ratio, logistic regression
Cohort	risk ratio, survival analysis
RCT	ANOVA, chi-square, regression
Quasi-experimental	paired t-test, ANCOVA, propenity scores

Key terms

Confounding

- Outside factor (“confounder”) associated with both exposure and outcome
- Distorts true relationship between them

Selection bias

- Method of selecting participants leads to a sample that is not representative of the population
- Results could be wrong because they reflect differences in how groups are chosen—not the true effect of the exposure or treatment

Systematic Reviews & Meta-Analysis

Rigorous synthesis of evidence from multiple studies using systematic systematic protocols and statistical methods

Strengths

- *Highest level of evidence*
- *Increases statistical power*
- *Clarifies consistent findings across studies*

Limitations

- *Only as good as included studies*
- *Heterogeneity can limit conclusions*
- *Publication bias may skew results*

Orthopaedic Example

Meta-analysis comparing internal fixation vs. arthroplasty for displaced femoral neck fracture showed no mortality difference rates with arthroplasty

Reporting Standards

Search for reporting guidelines

Use your browser's Back button to return to your search results

CONSORT 2025 Statement: updated guideline for reporting randomised trials

Reporting guideline provided for? (i.e. exactly what the authors state in the paper)

Reporting of randomised trials

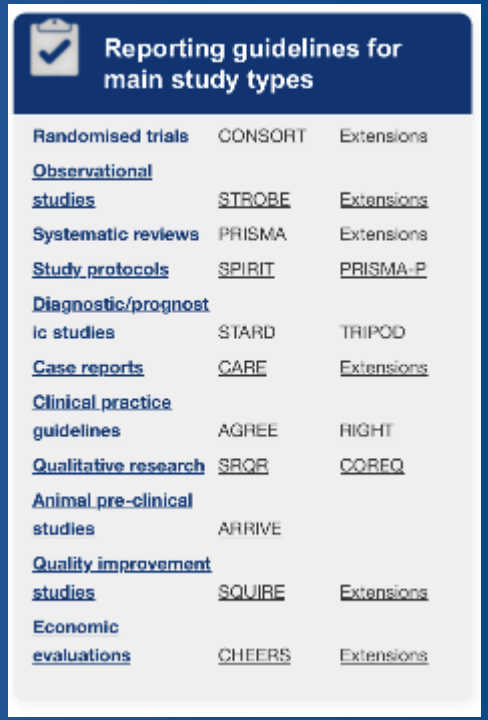
CONSORT 2025 Checklist (Downloaded from CONSORT-SPIRIT website)

Full bibliographic reference

Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, Tunn R, Aggarwal R, Berkwits M, Berlin JA, Bhandari N, Butcher NJ, Campbell MK, Chidebe RCW, Elbourne D, Farmer A, Ferguson DA, Golub RM, Goodman SN, Hoffmann TC, Ioannidis JPA, Kahan BC, Knowles RL, Lamb SE, Lewis S, Loder E, Offringa M, Ravaud P, Richards DP, Rockhold FW, Schriger DL, Siegfried N, Staniszewska S, Taylor RS, Thabane L, Torgerson D, Vohra S, White IR, Boutron I. CONSORT 2025 statement: updated guideline for reporting randomised trials.

This guideline was published simultaneously in 6 journals. You can read the guideline in any of these journals using the links below.

BMJ. 2025; 388:e081123. PMID: 40228833
JAMA. 2025. PMID: 40228499
Lancet. 2025. PMID: 40246801
Nat Med. 2025. PMID: 40229553
PLoS Med. 2025; 22(4): e1004587. PMID: 40228477

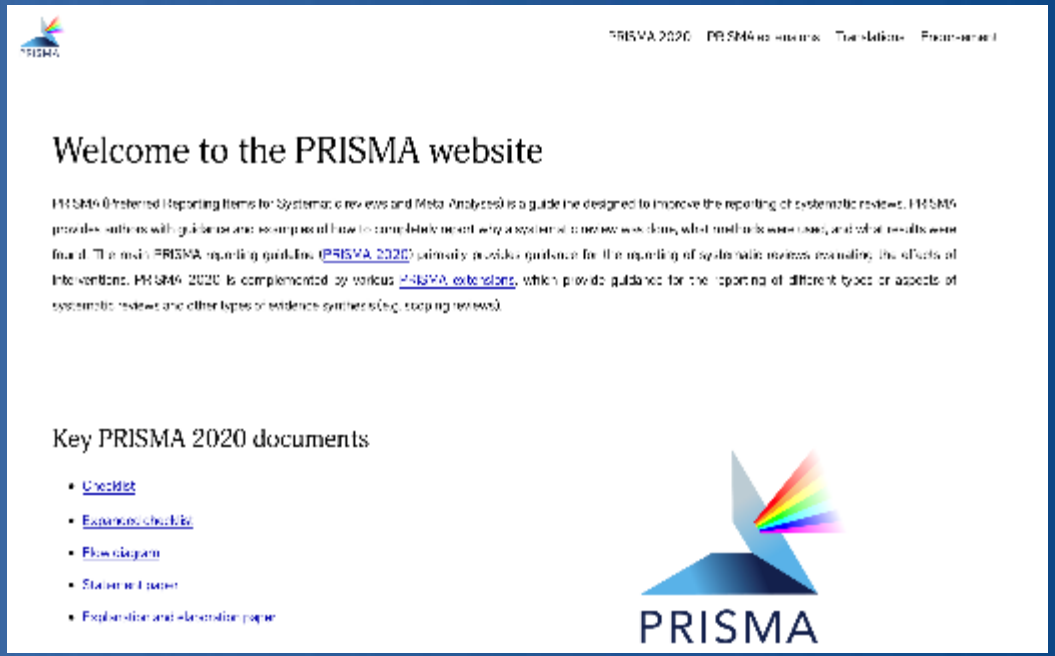


Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical studies	ARRIVE	
Quality improvement studies	SQUIRE	Extensions
Economic evaluations	CHEERS	Extensions

https://www.equator-network.org/reporting-guidelines/consort/

Reporting Standards



Welcome to the PRISMA website

Key PRISMA 2020 documents

- Checklist
- Extension checklist
- Flow diagram
- Statement paper
- Explanation and elaboration paper

PRISMA

https://www.prisma-statement.org

Key Takeaways & Best Practices

Match design to question

Consider your research question, resources, and feasibility when selecting a study design

1

Understand limitations

Every design has inherent strengths and limitations – acknowledge these in your research

2

Follow reporting guidelines

Use STROBE for observational studies and CONSORT of RCTs to ensure transparent, complete reporting

3

Build on evidence

Use case reports to generate hypotheses; observational studies to explore associations; and experimental designs to test interventions

4

Understanding study design is crucial for both conducting meaningful research and critically appraising the orthopaedic literature to improve patient care

Example 1

- *“used hospital chart data from patients treated for infections of total joint arthroplasties or internal fracture fixation devices at three academic referral institutions. Subjects with recurrence of an implant-related infection within 1 year after the last surgical procedure were defined as case group, and patients without recurrence of an implant-related infection as control group. We placed a distinct focus on infection of open reduction and internal fixation (ORIF) constructs.”*

Spitzmüller R, Gümbel D, Güthoff C, Zaatreh S, Klinder A, Napp M, Bader R, Mittelmeier W, Ekkernkamp A, Kramer A, Stengel D. Duration of antibiotic treatment and risk of recurrence after surgical management of orthopaedic device infections: a multicenter case-control study. BMC Musculoskelet Disord. 2019 May 1;20(1):184. doi: 10.1186/s12891-019-2574-4. PMID: 31043177; PMCID: PMC6495646.s

Example 2

- *“study of consecutive emergency department (ED) referrals to the Department of Orthopaedic Surgery was conducted comparing outcomes prior to (November 2015-February 2017) and after (March 2017-June 2018) implementation of a VFC. The primary outcome measures assessed were the proportion of referrals virtually discharged and unplanned 30-day ED re-attendance rates.”*

Cavka B, Cross E, Montvida O, Plunkett G, Oppy A, Bucknill A, Treseder T. Retrospective cohort study evaluating the efficacy and safety of an orthopaedic consultant-led virtual fracture clinic in an Australian level 1 trauma centre. ANZ J Surg. 2021 Jul;91(7-8):1441-1446. doi: 10.1111/ans.16574. Epub 2021 Jan 18. PMID: 33459513.

Example 3

- “This 3-month, single-blind randomized clinical trial with a 12-month follow-up period was performed from September 10, 2018, to March 12, 2019, and the trial follow-up was completed March 17, 2020. A total of 113 people with chronic low back pain were included in the experiment.

  Participants were randomized to either the therapeutic aquatic exercise or the physical therapy modalities group. The therapeutic aquatic exercise group received aquatic exercise, whereas the physical therapy modalities group received transcutaneous electrical nerve stimulation and infrared ray thermal therapy. Both interventions were performed for 60 minutes twice a week for 3 months.”

Peng MS, Wang R, Wang YZ, Chen CC, Wang J, Liu XC, Song G, Guo JB, Chen PJ, Wang XQ. Efficacy of Therapeutic Aquatic Exercise vs Physical Therapy Modalities for Patients With Chronic Low Back Pain: A Randomized Clinical Trial. JAMA Netw Open. 2022 Jan 4;5(1):e2142069. doi: 10.1001/jamanetworkopen.2021.42069. Erratum in: JAMA Netw Open. 2024 Mar 4;7(3):e249399. doi: 10.1001/jamanetworkopen.2024.9399. PMID: 34994794; PMCID: PMC8742191.

Example 4

- “This 3-month, single-blind randomized clinical trial with a 12-month follow-up period was performed from September 10, 2018, to March 12, 2019, and the trial follow-up was completed March 17, 2020. A total of 113 people with chronic low back pain were included in the experiment.

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