Intervention Manuscript Preparation Guide

Track your progress by checking the box for each suggested field that is presented with a detailed description in your study. Refer to the Research Road Map for manuscript submission criteria regarding journal specific requirements.

Title

Author(s)/Affiliation

Date

Title
- ☐ Relevant title

Author & Details
- ☐ Last name, first initial, credentials of all authors (e.g. degree, job title, department, and location)

Abstract
- ☐ Background
- ☐ Goals/objectives
- ☐ Study Design (e.g. randomized controlled trial)
- ☐ Population
- ☐ Sample group descriptions
- ☐ Disease status (e.g. suspects, diagnosed, healthy)
- ☐ Methods
- ☐ Results (Key findings and statistical data)
- ☐ Conclusion (Take-home message, implications, etc.)

Keywords
- ☐ Search terms (Ex. Disease name or abbreviation, instrument name or abbreviation, main intervention, key anatomy, etc.)

Introduction
- ☐ Background
- ☐ Rationale
- ☐ Main objectives
- ☐ Applicability

Methods and Materials
- ☐ Informed consent/study approval
- ☐ Number and description of study centers
- ☐ Number and description of sample groups
- ☐ Duration of study
- ☐ Instruments/tools used
- ☐ Validity of measurement tools
- ☐ If random, randomization process (described and at low risk)
- ☐ Recruitment method
- ☐ Consecutive enrollment (e.g. enrolling all participants fitting criteria without selection bias)
- ☐ Inclusion and exclusion criteria
- ☐ Allocation concealment method (described and at low risk)
- ☐ Blinding (described and at low risk for participants and examiners)
- ☐ Credibility of examiner background and training
- ☐ Baseline patient characteristics (noted significant differences)
- ☐ Process details (including rescue medication if applicable)
- ☐ Outcomes of interest and measurement methods (described and identical for all groups)
- ☐ Threshold/cutoff values used
- ☐ Time between interventions
- ☐ Follow-up times (described and identical for all groups)
- ☐ Intended comparisons

Statistical Analysis/Data Management
- ☐Statistical software
- ☐Statistical models
- ☐Calculations
- ☐Data organization strategies

Results
- ☐Final examined patient count
- ☐Study duration
- ☐Follow-up times
- ☐Scale Directionality of all outcome measurement tools
- ☐Data evaluated at each follow-up time for each group
- ☐If Continuous Outcomes: raw means and standard deviations (SD) AND at least one of the following: Univariate Analysis (mean differences and SD of mean differences between groups and all confidence limits), Univariate Regression (parameter estimate/slope and p-values), and/or Multivariate Regression- parameter estimates and p-values)
- ☐If Dichotomous Outcomes: raw events and non-events AND one of the following statistics for variable or regression analysis: odds ratios (OR), risk ratios, (RR), risk differences (RD), log odds, or hazard ratios (HR) along with the confidence limits of the chosen statistics
- ☐Group comparison data
- ☐Explanation of data tables
- ☐Rate and details of patients lost to follow-up
- ☐Selective reporting avoided (main outcomes pre-specified)
- ☐If any, explanation of missing data
- ☐Intent to treat population (if applicable)
- ☐Rescue medication consumed (if applicable with significant differences noted)
- ☐Patient adverse events, benefits, or harms (if documented/analyzed)

Discussion
- ☐Strengths
- ☐Limitations
- ☐Author interpretations
- ☐Clinical implications

Conclusions
- ☐Summary statement of main findings and/or interesting results

Acknowledgements
- ☐Recognition for those involved in any aspect of the study

Disclosures/Conflicts of Interest
- ☐Disclosure of any author conflicts of interest, funding, or influence risks

Ethics, Quality, or Safety Concerns
- ☐Any risks, harms, or ethical concerns with this study or implications of this study

Funding Sources
- ☐Any organizations, groups, or individuals associated with the funding of this study

References
- ☐All references used/cited in development of this study
- ☐Study protocol contact location, and/or accessibility

Appendix
- ☐Any forms, charts, and/or tables used but not included in the content

ADDITIONAL DETAILS

Patient Recruitment

Standard (Low risk of bias)

- Patients should be recruited and examined prospectively at one location or similar locations (e.g. multi-center study in three county hospitals in Southern Illinois)
- All patients presenting with diagnosis of the target condition, or a random sample of that population, should be considered for inclusion
- Patients should be recruited following a pre-defined criteria for how, when, and why they will be recruited.
- A complete count of patients that were included should be reported as well as the patient count for any groups or categories of patients
- Baseline patient characteristics and disease status (e.g. diagnosis, comorbidities, demographics, etc.) should be reported and described for all patients and groups
- Matching techniques or statistical control for possible confounders (e.g. comorbidities, demographics, etc.) should be done upon inclusion

Discouraged (High risk of bias)

- Healthy or undiagnosed patients included in the recruitment or analysis
- Patients or groups with unspecified or unclear patient counts, recruitment strategies, or uncontrolled potential confounders

Patient Enrollment

Standard (Low risk of bias)

- The study should be approved with informed consent to meet safety, ethics, and regulation standards
- Patients should be consecutively enrolled by including all patients that fit the criteria and agree to participate (e.g. avoiding "cherry picking")
- A description should be provided of how, and within what population, enrollment will be conducted
- A detailed list of criteria should be set for patients to be included or excluded from the study

Discouraged (High risk of bias)

- Unapproved or unorganized studies with uninformed patients
- Enrollment of patients by convenience sampling, non-consecutive enrollment, or other unrandomized methods
- Including or excluding patients with limited details or rationale
- Including patients with possible confounders (e.g. comorbidities, variant patient characteristics) with no statistical method for control or matching technique

Materials

Standard (Low risk of bias)

- Describe the details (range, direction, source, etc.) and reference the validity and/or reliability of any scales, questionnaires, categorization techniques, medical devices, etc. that will be used at any stage of the study duration

Discouraged (High risk of bias)

- Use of invalidated or unapproved scales, questionnaires, devices, etc. to categorize and measure patient outcomes

General Methods

Standard (Low risk of bias)

- Determine and report the duration of the recruitment and study periods
- Duration of study follow-up times should reflect the intervention (e.g. common duration mins: 3mo post-op, 1mo conservative, 1day peri-op, etc.)
- Organize a blinding strategy for examiners and patients through techniques such as: medication concealment, draped administration, sham control, third party review, etc.
- Ensure examiner credentials are provided with proper certification to administer, analyze, and/or interpret patient procedures and outcomes
- Describe pre-defined primary and secondary outcomes of interest
- Define any necessary steps needed to understand/recreate the administration methods and outcome measurements
- Randomization method including: computer generate random number tables, coin tossing, lottery drawing, shuffling cards, or other completely randomized method
- Allocated patients to groups without patients or administering clinicians being aware of the groups through use of sealed and opaque envelopes, central allocation by telephone, blister packs, or other blinding technique at the allocation level

Discouraged (High risk of bias)

- Patients or examiners that are unblinded or have the ability to discover the results of any of the examinations used in the interpretation of results or analysis
- Examiners that are not trained, credentialed, and/or approved to use or interpret any aspect of their function in the study
- Examiners of the patients or results that are credentialed to use materials, devices, and/or procedures, but they are not properly trained on one or more aspects of those materials or procedures used in the study
- Investigating outcomes that are not predefined and described
- Quazi-randomized or unrandomized method of allocation including: randomization by admission date, odd or even birth date, hospital number, or other high risk technique
- Allocation not fully concealed at risk of a patient or investigator being able to discover the assigned intervention group including: posting assignments on a board, non-opaque envelopes, treatments of different appearance, or other unconcealed method

Details and Procedures

Standard (Low risk of bias)

- Describe how each intervention will be administered and measured including a process description that permits replication and predetermined threshold/cutoff values for diagnosis
- Choose valid and referenced threshold/cutoff values for diagnosis confirmation, inclusion, and/or outcome response
- Choose time-points for follow-up that are clinically relevant and do not fall outside the scope of the effect of the intervention
- Ensure each patient will be measured in the same way and at the same time-points across all groups being directly compared
- Describe all groups and measures that will be compared and how they will be compared in the analysis of the results
- Describe the rescue medication allowed with dosage and administration limits if applicable

Discouraged (High risk of bias)

- Lack of description of any of the intervention procedures or comparisons of interest
- Use of inapplicable or invalidated devices or outcome measures used for the condition of interest
- Threshold/cutoff values for diagnosis or outcome measurement that are unlisted or clinically irrelevant
- Unlimited allowance of rescue medication or rescue medication that may have confounding effects on the intervention or outcome of interest
- Patients measured differently within individual groups or across comparator groups

Statistical Modeling and Analysis

Standard (Low risk of bias)

- Reference the statistical software packages that will be used to calculate target outcome data
- Describe how, and by whom, the data was documented and organized to prepare for analysis
- Describe any equations that will be used in preparation and analysis including: power analysis, variance, significance, dichotomous events/non-events, etc.
- Create data tables (e.g. raw means with standard deviations at each follow-up time) and statistical models (e.g. univariate or multivariate analysis) that will assist with comparisons, control for possible confounding or baseline differences, and interpretation of the results for desired conclusions

Discouraged (High risk of bias)

- Insufficient data or calculations that will not allow the reader to clearly observe significance or evaluate the raw continuous means and standard deviations or dichotomous events and non-events
- Invalidated equations or statistical methods used for interpretation of results
- Means, change scores, or totals without evaluation of variance through standard deviation or confidence limits

General Results

Standard (Low risk of bias)

- All patient/group data needed to analyze all target comparisons is organized in a way that allows complete analysis of all necessary calculations
- All outcome measurements are made on validated tools or scales with range and direction indicated (e.g. VAS pain scale: 0-100 where 100 is best)
- Observed patient/group numbers from recruitment and intervention are listed as well as the data for those included in final analysis
- Any missing data or observations are described in detail with rationale provided for those patients/groups
- Intent-to-treat (ITT or LOCF) analysis is provided for studies with missing patients/data after baseline measurements
- Differences and significance of rescue medication consumption between intervention groups if applicable

Discouraged (High risk of bias)

- Data presented at recruitment, during follow-up, or in the final analysis that is not presented, lacks agreement, and/or lacks appropriate rationale for missing data, observations, or patients/groups
- Inconsistent data measurements or follow-up times among intervention groups
- Outcomes presented in analysis that are not predefined and listed in the study protocol/methods
- Lack of intent-to-treat analysis when accompanied by large loss to follow-up

Data Comparisons

Standard (Low risk of bias)

- All patient/group data are evaluated at the same time-points and are organized in a way that allows for all target comparisons and calculations (e.g. continuous mean difference, standard deviation, or dichotomous events/non-events and odds/risk ratios) including confidence limits and determination of significance for each calculation
- Rationale for the structure of the data tables and for the target comparisons and data chosen is provided

Discouraged (High risk of bias)

- Data presented supports conclusions but is insufficient for necessary continuous or dichotomous calculations, and the structured data tables do not allow for target comparisons and conclusions to be made
- Group data not presented individually and/or target time-points that do not include consistent reporting with all other time-points