List of candidate items for protocols of observational studies: a scoping review

For consideration of Steering Committee

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Abstract

There are currently no guidelines avalable to define or guide minimum content of protocols of observetional studies. Therefore this scoping review was conducted within the scope of the Standardized Protocol Items: Recommendations for Observational Studies (SPIROS) initiative. SPIROS aims to improve the completeness and use of study protocols of observational studies by producing expert-based recommendations for a minimum set of items to be addressed in those protocols. Through this scoping review we have prepared a long-list of unambiguous candidate items that could be incorporated in the draft reporting guideline.

This list will be further reviewed by steering committee experts and would serve as input for an extensive Delphi study whose objective will be to develop expert-driven criteria for observational study protocols.

This review is based on a systematic selection of 93 protocols of observational studies identified via published protocol papers indexed by Web of Science – Core Collections. The list of items was extended with the STROBE checklist items that are developed as reporting guidelines for the publication of observational studies. Through this review we identified 54 candidate items.

Introduction

The study protocol is a key component of any scientific study. Without it there is no reliable way to assess the occurrence of outcome reporting biases. Particularly in experimental studies, but also in observational research unprotocolized research is often considered a questionable research practice. Anecdotal evedence suggests that a high percentage of observational research still is conducted without a study protocol and existing protocols often lack sufficient detail. This issue becomes more worrying when one realizes there is no formal guidance on what robust observational study protocols should contain.

Standardized Protocol Items: Recommendations for Observational Studies (SPIROS) will develop a reporting guideline for study protocols of observational studies, and by doing so facilitates and encourages scientists to prepare a study protocol of sufficient quality, prior to data collection.

This scoping review was conducted In line with the SPIROS initiative, which aims to develop new standardized Equator (https://www.equator-network.org/) reporting guidelines for protocols of observational studies. The rationale of this scoping review is to generate a detailed list of candidate items for the protocols of observational studies through exhaustively reviewing high quality protocols of published observational studies. This long-list will then be reviewed by an expert steering committee group and ultimately become the baseline of a Delphi consensus survey with the broader aim of preparing draft guidelines for developing protocols for observational studies. Thus the overall objective of this scoping review is to develop a long-list of unambiguous candidate items which could be part of guidelines on protocols of observational studies.

Methods

This is a scoping review of published protocols of observational studies. We reported findings according to PRISMA extension for scoping reviews(PRISMA-ScR) (1). The complete protocol for the SPIROS research initiative is registered on *Open Science Framework (https://osf.io/t6rvj/)* (2).

Eligibility criteria

All protocols of observational studies (cohort studies, case-control studies, cross-sectional studies, and ecological studies) published in indexed journals in the English language were

included in present review. Only articles published between 1st January 2016 and May 2018 were included.

Information sources

Data for this scoping review were identified by searches of Web of Science Core Collection and references from relevant articles using the search terms ´protocol´ PLUS ´observational study´ AND/OR ´cohort study´ AND/OR ´case control study´ AND/OR ´cross sectional study´ AND/OR ´ecological study´ AND/OR ´prevalence study´ AND/OR ´survey´ in advance search mode. Abstracts and reports from meetings were included only when they related directly to previously published work.

The search revealed 450 results. All records were downloaded into Mendeley reference manager. All results were then further screened independently for appropriateness to ensure that they met the inclusion criteria. 203 were excluded on this basis, leaving 247. Corresponding authors of results where full protocols were not openly available were contacted via e-mail to access the full protocol; 8 authors shared full length protocols.

Of these an initial 100 were randomly selected using a random number generator, which were read in detail to develop a long-list of elements to be included with the intention of reaching information threshold saturation. Saturation was considered met after 93 protocols were reviewed. All the key elements present in the subheadings or in the text section of papers were then presented in the form of table.

Search results

We made a long list of all the elements mentioned more than once using a set format (Table 1). A total of 53 preliminary items were categorized into following thematics, following the structure of the STROBE checklist:

i. General information
ii. Introduction
iii. Methods
iv. Ethical consideration
v. Reporting and dissemination
vi. Others

Table 1: Checklist of preliminary items

Section and topic	Description / sub-categories
i) General Information	
Title	Descriptive title identifying study design
Protocol version	Version or amendment number and date and summary of changes
Protocol summary	Brief summary of protocol research
Sponsor and partner institute name	Name of sponsor and participating institutes (if applicable)
Investigators name	Name of principal and co investigators.
Affiliation of investigators	Affiliated institutions of investigators
Principal researcher contact detail	Name, email address, affiliation of Principal researcher for correspondence.
Table of content	Table of content
Page number	Page number on each page of protocol
List of Abbreviations	A detailed List of all abbreviations used in protocol with full form.
ii) Introduction	
Background of study	Scientific background of study
Review of prior research	Summary of all previous relevant research
Rationale of study	Justification for conducting the study
Aim	Broader aims and specific objectives of the study
Objective of study	Primary and secondry objectives of study
Prespecified hypothesis	Prespecified null or alternative hypothesis

iii) Methods		
Study design	Description of type/design of study	(3–10,12–22,24–95)
Study setting	Description of setting, locations, relevant dates, including periods of recruitment/survey, exposure, follow-up, and data collection. Schedule of study procedure – Figure or table	(3,5–9,12,14–16,18,19,22,24–28,31,32,34,36–40,42,44–49,51,55–57,60–62,64–68,71,72,76,81,83,86–89,91,92,94)
Sample size	Estimated number, calculation and assumptions Power calculation	(3–8,10,12–19,24–32,34–37,39–48,50–67,70–72,75,76,79–81,83–89,91–95)
Sampling procedure	Description of sampling strategy to ensure representativeness and control of potential bias	(5–8,10,12,22,24,27,28,32,34,36,43–45,47,49,55,58–61,64,66,69,70,72,74,76,79,81,83,86,88–90,92,93,95)
Participants	**Cohort study**—eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up. For matched studies, give matching criteria and number of exposed and unexposed **Case-control study**—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls For matched studies, give matching criteria and the number of controls per case **Cross-sectional study**—Give the eligibility criteria, and the sources and methods of selection of participants	(3–19,21,22,24–51,53–72,74–76,78–90,92–95)
Variables	• All outcomes • Exposures- definition of exposure of interest, • Predictors • Potential confounders • Effect modifiers	(3–10,12–19,21,22,24,26,28–34,36–54,57,59–64,66–70,72,74–89,91,92,94,95)
Data Sources/ Measurement	• For each variable of interest, give sources of data and details of methods of assessment (measurement).	(4–6,8–10,13–15,17–19,24–33,35,37,39,41–45,47–49,51,52,54–58,60,62–64,66,67,70–72,74,76–95)

	• Describe comparability of assessment methods if there is more than one group • Data collection points table • Blinding procedure	
Bias	Describe any efforts to address potential sources of bias More specifically- • Information bias • Selection Bias • Control for confounding	(3–7,10,12–15,17,18,22,24,28,30–32,34,36,37,39,40,42,43,47,48,51,52,54,55,57–61,63,65–67,69,71,72,75,76,81–84,86–89,91–93)
Statistical analysis plan	• Method of primary / secondary outcomes and additional analysis • Handling of missing data • Post-hoc analysis	(3–20,22–67,69–72,74–95)
Handling of withdrawals and lost to follow up	Describe the procedures to be followed when a participant ceases participation in the study prematurely or is lost to follow up	(10,31,33,48,55)
Replacements	Provide information on whether or not participants who discontinue the study will be replaced via additional recruitment to maintain the required sample size.	(32)
Outcome	Define and describe all primary and secondary outcome or lost to follow up	(3–10,12–22,24–43,45–61,63–72,74,76–93,95)
Database management	• Detail plan of database management including: • Data collection (electronic or paper based), • Source data • Data entry • Data editing • Coding • Data storage • Record retention • Data confidentiality	(4–6,8–10,13–15,17–19,24–33,35,37,39,41–45,47–49,51,52,54–58,60,62–64,66,67,70–72,74,76–95)
Validation of instrument	Reliability / validity of instrument or plan to establish validation	(4,5,8,9,14,16,19,22,28,30,31,34,39,41,43,47,56,60,64,67,70–72,75,76,78,80,81,84,88–90)

Follow up	Plan of follow up and addressing lost to follow up	(10,18,60,71,84)
Quality control	• Method of quality control • Monitoring (internal and external) • Training of surveyors	(8,44)
Quality assurance	Plan of quality assurance	(87)
Expected outcome /results	A brief description of expected outcome or results	(3–6,8–10,12–19,21,22,24–37,39–52,54–95)
iv) Ethical consideration		
Ethical approval	Weather it has been obtained and name of ethical committees. If approval not sought , Reason	(3–37,39–50,52–95)
Agreement and consent	Method of taking consent. Reason if consent not sought	(3–19,22,24–37,39–68,70–76,78–86,88–90,92–95)
Risk / Harm to participants	Any potential risk or harm to study participants	(55)
Adverse event and Severe adverse event reporting	Outline how Adverse Event and Severe adverse event information will be collected.	(4,5,7,8,10,12,13,16,22,25–27,29–33,35–37,40–42,44–46,48,50,54,55,57,60,62,67,71,75,82,84–88,90–93,95)
v) Reporting and dissemination		
Protocol amendments	Methods of communicating to investigators/IRBs and documenting	(27,37,64,79)
Dissemination	How results will be disseminated to participants, practitioners, public	(3–5,10–20,22–28,31–34,36,37,40–43,45,46,49,50,54,55,59–65,67,69–71,73,75,77–79,85–87,89–93,95)
Publication Plan	Who has right to publish; restrictions; authorship guidelines Open Access	(3–5,7–10,12,13,15,16,18,28,30–32,34,36,37,39,40,43,44,47,49,50,53–55,57–60,62–65,67,68,70–75,77,78,80–86,89–92,94)
Reporting of early stopping	Dissemination of results if trial is stopped early (for any reason)	
vi) Others		
Limitations	Limitations of proposed study, including risk of bias	(3–5,9,10,12–18,21,22,24–28,30,32–37,41–52,54,55,57–67,69–72,75–79,81–87,89–93)
Strength of study	Highlight strengths of proposed study	(4,12,31,42,46,64,70,76,80,82,84,91,95)
References	List of references cited in protocol	(3–95)

Data collection forms	Summary table of all forms used for data collection at each point of study	
Informed consent forms	Sample of informed consent form, translated into local language	
Funding	Source of funding and the role of the funders for the present study	(3–10,12–19,22,25–34,36,37,39–47,50,51,54–64,67–72,74,76–78,80,81,83–86,88,89,91–95)
Acknowledgement for protocol development	Acknowledgement of persons involved in protocol preparation	(5,7,8,10,12–15,18,19,27,28,31,37,39,40,44,46,47,51,53,59–61,64,70,72,74,76,78,80,84,87,89,90,92,94)
Data sharing policy	To describe how data will be made available in public domain.	(3,18,91)
Contributions of authors to protocol	Listed authors should have participated sufficiently in prepartion of protocol with details of their contribution.	
Trial registry	For observational studies also registered as trial	(4,5,10,12–15,25,27,29,30,33–39,41–43,47–50,56,61–63,65–67,72,77,79,84,87,88,93,95)
Annexures	Data collection form /instruments Informed consent form Standard operating procedures (SOPs) Detailed Statistical analysis plan (SAP)	

Discussion

To our knowledge there are no standard guidelines available for protocol of observational studies, without which it is nearly impossible to track reporting bias of observational studies. Our scoping review was a first step to identify content and current practices within published protocols. We identified all possible candidate items available in these protocols and added it to STROBE checklist (96). The analysis found a large disparity among protocols in regards to standardised structure of protocols.

We considered the STROBE checklist as baseline because it is the standard reporting guideline for observational studies, hence should be already built into study protocols. Our scoping review has a limitation of majorly selecting published protocols. Very few journals are publishing protocols as it is a relatively new concept in research, and even more so for observational studies.

The scope of this review was limited to identification of potential candidates of for inclusion into guidance protocols of observational study. This list will be further review by a group of steering committee experts before making a final list for Delphi survey.

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