Supplementary material. SPIROS checklist

Standardized Protocol Items Recommendations for Observational Studies

Section / Item	Item Number		Description	Page
Part A: General information				
Title	1		Descriptive title Identifying study design in the title	1 (Title page)
Protocol version	2		Version or amendment number with date and summary ofthe changes	1 (Title page)
Protocol summary	3		An informative and balanced summary of the study protocol	2
Sponsor and funder details	4		Name of Sponsor and funder and types of financial, material,and other support	21
Conflict of interest statements	5		Statement about any financial and other competing interestsfor principal or co-investigators for the overall study.	21
Investigators name	6a		Names of the principal and co-investigators	1 (Title page)
Affiliation of investigators	6b		Affiliated institutions of the investigators	1 (Title page)
Principal researcher/s contact detail	6c		Name, e-mail address, affiliation of principal researcher	1 (Title page)
Part B: Introduction				
Background of the study	7a		Description of research question and scientific background ofthe study	Pages 4-6
Review of prior research	7b		Summary of relevant existing research (published orunpublished)	Pages 4-6
Rationale of study	7c		Justification for conducting the study	Pages 4-6
Aim	8a		Broader aims and overall objective	Page 6

Objective /s of the study	8b		Primary and secondary objective/s including any prespecifiedhypothesis (if applicable).	Pages 6-7-8
	8c		Specify whether the intention is to (a) estimate causal effects, (b) predict outcomes, or (c) simple description.	Pages 6-7-8
Part C: Methods				
Study design	9a		Description of study design (case control, cross-sectional orcohort) and type of study (retrospective cohort study, Prospective cohort study etc)	Pages 8-9
Study setting	9b		Description of the study setting (e.g., community-based, hospital based) and detail of precise locations of the study sites	Pages 8-9
Study schedule	10a		Description of the expected schedule of the study including relevant dates, expected periods of recruitment/survey, exposure, follow-up, and data collection.	Pages 8-9, Figure 1
	10b		Figure (Study schematic/flow-chart) or table describing expected time frame for each step including trainings, datacollection, follow-up, analysis and reporting etc.	Pages 8-9, Figure 1
Sample size	11		Estimation of minimum sample size required for the studywith justifications including clinical and statistical assumptions supporting any sample size calculations.	Pages 9-10, Figure 2
Sampling procedure	12		Detailed description of the sampling frame and samplingstrategy (simple random, stratified random, cluster, systematic etc.)	Pages 9-10, Figure 2
Participant selection				
Participant selection for cohort study	13a		Description of inclusion and exclusion criteria, and the sourceand methods of participant selection (exposed and unexposed). For matched cohort studies, give matching criteria and number of exposed and unexposed.	Pages 9-10
Participant selection for case-control study	13b		Description of inclusion and exclusion criteria, and the sourceand methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls. Give diagnostic criteria for identifying cases (if applicable). For matched case-control studies, give matching criteria and thenumber of controls per case.	NA
Participant selection for cross-sectional study	13c		Description of the inclusion and exclusion criteria, and thesource and methods of participant selection.	NA
Variables	14a		Detailed description of all important baseline and outcome variables to be analysed, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	Pages 10-14
Data sources/measurement	14b		For each variable of interest, give sources of data and detailsof assessment /measurement methods. Describe comparability of assessment methods if there is more than one group.	Pages 10-14
Data collection	15a		Plans for assessment and collection of outcomes, baseline,follow up and other study related data.	Pages 10-14

and managem ent	15b		Description of data collection methods e.g., online survey,Household survey, paper based or electronic data capture etc.	Pages 10-14
	15c		Any related processes to promote data quality during datacollection (e.g., duplicate measurements, training of assessors, validation method)	Pages 10-14
	15d		Description of study instruments (e.g., questionnaires, datacollection forms) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol.	Pages 10-14
	15e		Plans for data entry, coding, security, and storage, includingany related processes to promote data quality (e.g., electronic data capture, double data entry; range checks fordata values, random cross-checking of electronic data with the source documents).	Pages 10-14, 21
	15f		Reference to where details of data management procedurescan be found, if not in the protocol.	Page 22
Blinding procedure (ifblinded study)	16		Description of blinding procedure (if applicable) reporting Who will be blinded (e.g., investigator blinded for disease status when measuring exposure in case-control study) andmethods to ensure blinding and unmasking of blinding if required.	NA
Potential bias	17		Description of any potential biases and plan to minimizethose potential sources of biases.	Pages 9,10,14 15-18
Statistical analysis plan	18		Detailed description of methods for analysing and presentingprimary/secondary outcomes and any additional analysis (e.g. analyses of subgroups and interactions, and sensitivity analyses). Give reference to the where other details of the statistical analysis plan can be found, if not in the protocol.	Pages 15-18
Handling of missing data	19		Detailed description of methods to handle missing data (e.g.multiple imputation).	Page 15
Handling of withdrawals and lost to follow up	20a		Detailed description of the procedures to be followed when a participant ceases participation in the study prematurely or is lost to follow up	Pages 9-10
Replacements	20b		Plans and methods of the replacement or substitution ofwithdrawn participants.	NA
Outcome	21		Definition and description of all primary, secondary and otheroutcomes.	Pages 7-8
Data confidentiality statement	22		A detailed description of process to ensure dataconfidentiality.	Page 21
Follow up	23		A detailed plan of follow up including schedule and methods(telephonic, house based, hospital based etc.) of follow up.	Pages 10-14
Plan of study monitoring	24		Description of plan for study monitoring and whether themonitoring will be independent from investigators or sponsors.	Page 10

Training of surveyors/data collectors	25		Description of how investigators and surveyors will be trained to conduct the research activity.	Pages 10, 13
Quality assurance	26		Plan of quality assurance. back-checking data collection.	Page 10
Part D: Ethical consideration				
Ethical approval	27a		Plan for seeking ethics approval from ethics committees/institutional review boards. If known, give nameof ethical committees.	Page 21
	27b		If ethics approval will not be sought, give justification.	NA
Consent and assent	28a		Description of who will obtain informed consent or assent from potential study participants or authorized surrogates,and how (e.g., written informed consent, verbal consent, video/audio recording of consent procedure etc.)	9, 11
	28b		Give reason if consent or assent not sought.	NA
	28c		Give reference to where informed consent forms and applicable translations plan can be found, if not in the protocol.	Page 22
Risk/harm to participants	29a		A detailed description of potential risks or harms to studyparticipants.	NA
	29b		Plans for collecting, assessing, reporting, and managing any study procedures related adverse events (e.g. adverse eventsdue to blood collection) and other unintended effects of study conduct (e.g. risk to breach confidential and sensitive information of participants)	Page 10
	29c		Give a statement about whether data will be anonymous,pseudonymized, or can be directly linked to participants.	Page 10
	29d		Description of any plan for giving Incentives to the participants	NA
Adverse event and serious adverse event reporting	30		Outline how adverse events and serious adverse eventsinformation will be collected and reported.	Page 10
Involvement of patient/participant representatives in protocol development	31		Patient and Public Involvement (PPI) statement including howpatients or participants involved in the planning of the study. Give statement, if there is no plan to involve of patient/participants and public in designing or any phase of the study	Page 10
Part E. Reporting and dissemination				
Dissemination/	32a		Plans for investigators and sponsor to communicate studyresults to ethical review boards, participants, key stake holders, the public, and other relevant groups.	Page 21

public ation plan	32b	☐	Methods to communicate findings (e.g., via publication (openaccess or closed access), reporting in results databases, or other data-sharing arrangements), including any publication restrictions.	Page 21
	32c	☐	Define authorship eligibility guidelines (e.g., ICMJErecommendations)	Page 21
Part F: Others				
Whether Artificial Intelligence (AI) assisted technology was used in writing the protocol	33	☐	Disclose whether authors used artificial intelligence (AI)-assisted technologies in the production of protocol (e.g., chatbots) or there is planning to use artificial intelligence (AI)-assisted technologies in the production of manuscript or study reports.	NA
	34	☐	Give the name of AI tools (such as ChatGPT). Include a statement if authors did or did not review and edited thecontent created by AI-assisted technologies	NA
References	35	☐	A complete list of references cited in protocol.	Pages 23-32
Funding	36	☐	Source of any funding for the study and the role of thefunders for the study	Page 21
Open science	37a	☐	**Registration of observational study:** Study identifier and registry name (e.g., open science framework, ClinicalTrials.gov, ICTRP or any other national or international study registry platform). If not yet registered, name ofintended registry.	Pages 1 (Title page), 21
	37b	☐	**Data sharing:** Plans, if any, for granting public access to the (1) full protocol and amendments, (2) participant-level data set, (3) Statistical analysis plan, (4) statistical codes and otherstudy material (e.g., case report forms, study questionnaires and Informed consent forms). Give reference to where thesedocuments can be found, if not included as annex in the protocol.	Page 22