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Title	Reporting of cohort and routinely collected data in randomised controlled trial protocols (SPIRIT-ROUTINE): extension checklist with explanation and elaboration
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Appendix 1: SPIRIT-ROUTINE Checklist

Section/item	Item No.	SPIRIT-ROUTINE items	Reported on page no.
Administrative Information			
Title and structured summary	1a.1	Specify that a cohort or routinely-collected data will be used to conduct the trial and, if applicable, provide the name of the cohort or the routinely-collected data source(s)	
	1b	Structured summary of trial design and methods, including items from the World Health Organization Trial Registration Data Set	
Protocol version	2	Version date and identifier	
Roles and responsibilities	3a	Names, affiliations, and roles of protocol contributors	
	3b	Name and contact information for the trial sponsor	
	3c	Role of trial sponsor and funders in design, conduct, analysis, and reporting of trial; including any authority over these activities	
	3d	Composition, roles, and responsibilities of the coordinating site, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable	
Open science			
Trial registration	4	Name of trial registry, identifying number (with URL), and date of registration. If not yet registered, name of intended registry	
Protocol and statistical analysis plan	5	Where the trial protocol and statistical analysis plan can be accessed	
Data sharing	6	Where and how the individual de-identified participant data (including data dictionary), statistical code, and any other materials will be accessible	

Funding and conflicts of interest	7a.1	State sources and types of financial, material, and other support for both the trial and the cohort or routinely-collected data	
	7b.1	Financial and other competing interests for principal investigators for the overall trial, each study site, and the data controllers of the cohort or routinely-collected data	
Dissemination policy	8	Plans to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (for example, reporting in trial registry, plain language summary, publication)	
Introduction			
Background and rationale	9a	Scientific background and rationale, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	
	9b	Explanation for choice of comparator	
Objectives	10	Specific objectives related to benefits and harms	
Methods: Patient and public involvement, trial design			
Patient and public involvement	11	Details of, or plans for, patient or public involvement in the design, conduct, and reporting of the trial	
Trial design	12.1	State that a cohort or routinely-collected data was used to conduct the trial (such as electronic health record; registry) and how the data were used within the trial (e.g., identification of potentially eligible trial participants, trial outcomes, or other aspects)	
Methods: Participants, interventions, and outcome			
Trial setting	13	Settings (for example, community, hospital) and locations (for example, countries, sites) where the trial will be conducted	
SPIRIT-ROUTINE: Description of RCD component	SPIRIT-ROUTINE – 1	Name, if applicable, and a description of the cohort or routinely-collected data used to conduct the trial; including the person or role responsible for populating the routinely-collected data, as well as information on the setting (such as primary care), locations, and dates (such as periods of recruitment, follow-up, and data collection)	

SPIRIT-ROUTINE: Eligibility	SPIRIT-ROUTINE – 2	Eligibility criteria for participants in the cohort or routinely-collected data and details of how eligible trial participants will be identified from the source(s) of routine data used to conduct the trial, if applicable	
Eligibility criteria	14a.1	State how to access the list of specific codes (e.g., ICD10; SNOMED) and algorithms used to identify potentially eligible participants; information on accuracy and completeness of data used to ascertain eligibility; and methods used to validate accuracy and completeness (e.g., monitoring; adjudication)	
	14b	If applicable, eligibility criteria for sites and for individuals who will deliver the interventions (for example, surgeons, physiotherapists)	
Intervention and comparator	15a.1	Describe how the data sources will be utilised to deliver the intervention; if relevant, for example, a risk-based intervention where an individual's risk is determined using a cohort or routinely-collected data	
	15b	Criteria for discontinuing or modifying allocated intervention/comparator for a trial participant (for example, drug dose change in response to harms, participant request, or improving/worsening disease)	
	15c	Strategies to improve adherence to intervention/comparator protocols, if applicable, and any procedures for monitoring adherence (for example, drug tablet return, sessions attended)	
	15d	Concomitant care that is permitted or prohibited during the trial	
Outcomes	16.1	Specify how and when outcome details will be determined and identify the cohort or routinely-collected data used to establish each outcome	
SPIRIT-ROUTINE: Codes and algorithms to define or derive the outcome	SPIRIT-ROUTINE – 3	Provide information on how to access the list of codes and algorithms used to define or derive the outcomes from the cohort or routinely-collected data that will be used to conduct the trial; information on the accuracy and completeness of outcome variables; and methods that will be employed to validate their accuracy and completeness (e.g., monitoring adjudication), if applicable	
SPIRIT-ROUTINE: Number of participants in the RCD	SPIRIT-ROUTINE – 4	For each group, specify the number of participants in the cohort or routinely-collected data available to conduct the trial (if applicable), including (if available) the numbers screened for eligibility, randomly assigned, offered, and accepted interventions (e.g., cohort multiple randomised controlled trials), received the intended treatment, and analysed for the primary outcome	
SPIRIT-ROUTINE: Sources of data	SPIRIT-ROUTINE – 5	The sources of data used to conduct the trial should be specified in the methods section	

SPIRIT-ROUTINE: Method to select patients within RCD	SPIRIT-ROUTINE – 6	Method for selecting patients within routinely-collected data (e.g., all, random, etc.)	
Harms	17.1	Include implications of using data not collected to answer the specific research question	
Participant timeline	18	Time schedule of enrollment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended	
Sample size	19	How sample size was determined, including all assumptions supporting the sample size calculation	
Recruitment	20	Strategies for achieving adequate participant enrollment to reach target sample size	
Methods: Assignment of interventions			
Randomization:			
Sequence generation	21a.1	Method of generating the allocation sequence (e.g., computer-generated random numbers); including whether this is directly within the cohort or from a routinely-collected healthcare data system.	
	21b	Type of randomization (simple or restricted) and details of any factors for stratification. To reduce predictability of a random sequence, other details of any planned restriction (for example, blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions	
Allocation concealment mechanism	22.1	Mechanism of implementing the allocation sequence (such as embedding the random allocation sequence within; or integrating it with the cohort or routinely-collected data); (including any steps to conceal the sequence until interventions are assigned)	
Implementation	23	Whether the personnel who will enroll and those who will assign participants to the interventions will have access to the random allocation sequence	
Blinding	24a.1	Who will be blinded after assignment to interventions (e.g., trial participants; care providers; outcome assessors; data analysts), how they will be blinded, and, where applicable, outline any precautions taken to reduce the risk of unblinding from the use of routinely-collected data	

	24b	If blinded, how blinding will be achieved and description of the similarity of interventions	
	24c	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	25a.1	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to enhance data quality (e.g., duplicate measurements; training of assessors), and a description of study instruments (e.g., questionnaires; laboratory tests) along with their reliability and validity, if known. Where applicable, outline the role of quality improvement processes implemented for the cohort or routinely-collected data sources. Reference where data collection forms can be found, if not detailed in the protocol	
	25b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	
Data management	26	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (for example, double data entry; range checks for data values). Reference to where details of data management procedures can be accessed, if not in the protocol	
Statistical methods	27a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	
	27b	Definition of who will be included in each analysis (for example, all randomized participants), and in which group	
	27c	How missing data will be handled in the analysis	
	27d	Methods for any additional analyses (for example, subgroup and sensitivity analyses)	
Methods: Monitoring			
Data monitoring	28a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and funder; conflicts of interest and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
	28b	Explanation of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	

Trial monitoring	29	Frequency and procedures for monitoring trial conduct. If there is no monitoring, give explanation	
Ethics			
Research ethics approval	30	Plans for seeking research ethics committee/institutional review board approval	
Protocol amendments	31	Plans for communicating important protocol modifications to relevant parties	
Consent or assent	32a	Who will obtain informed consent or assent from potential trial participants or authorized proxies, and how	
	32b.1	Describe how participants were informed about the potential/planned use of their data in randomised trials	
Confidentiality	33	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	
Ancillary and post-trial care	34	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	