Statistical Analysis Plan (SAP) components

	Randomised controlled trial	Prospective observational	Retrospective observational
Study title that matches the protocol	X	X	X
Trial registration number	X		
SAP version number with dates	X	X	X
Version of protocol referenced	X	X	X
SAP revision history	X	X	X
Reason for each SAP revision	X	X	X
Timing of SAP revisions relative to interim analyses	X	X	
SAP contributors with roles and responsibilities	X	X	X
Person writing the SAP	X	X	X
Senior statistician	X	X	X
Principle investigator	X	X	X
Background and rationale of study	X	X	X
Objectives and hypotheses	X	X	X
Study type	X	X	X
Randomisation details	X		
Sample size calculation, if applicable	X	X	X
Superiority, equivalence, or non-inferiority hypothesis testing framework	X		
Interim analysis, timing of analysis, and person preforming interim analysis, if applicable	X	X	
Adjustment of the significance level due to interim analysis	X	X	
Guidelines for stopping study early	X	X	
Timing of final analysis	X	X	X
Timing and time interval for assessing each outcome; visit windows	X	X	
Level of statistical significance (P values) and whether one- or two-sided	X	X	X
Plan and rationale for adjustment for multiplicity, if applicable, including how type 1 errors will be controlled	X	X	X

Taken from Gamble et al, JAMA 2017: 318 (23): 2337-43

	Randomised controlled trial	Prospective observational	Retrospective observational
Confidence intervals to be reported and whether one- or two-sided	X	X	X
Definition of intervention adherence and how it will be presented	X		
Definition and summary of protocol deviations	X	X	
Definition of population being analysed	X	X	X
Reporting of screening data to describe representation of study population, if applicable	X	X	X
Inclusion and exclusion criteria	X	X	X
Recruitment strategy	X	X	
Level and timing of withdrawal	X	X	
Presentation of withdrawal and follow-up data	X	X	
Baseline patient characteristics and how they will be descriptively summarised	X	X	X
Definitions of outcomes and sequence of measurement	X	X	X
Specific measurements and units	X	X	X
Calculations or transformations used to derive outcome	X	X	X
Analysis method used	X	X	X
Presentation of treatment effects	X		
Covariates and adjustments	X	X	X
Methods to check for distributional assumptions	X	X	X
Alternative methods if distributional assumptions are false	X	X	X
Sensitivity analysis for each outcome, if applicable	X	X	X
Subgroup definition and analysis, if applicable	X	X	X
Method for handling missing data	X	X	X
Additional statistical analysis, if applicable	X	X	X
Details on summarising safety data	X	X	
Statistical packages used for analysis	X	X	X
Reference to standard operating procedure or additional documents	X	X	X

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