

## Checklist for the Approach section of grant submissions to fund a clinical trial (including pilot and feasibility trials)

<b>Preliminary studies (optional and as appropriate):</b>	✓
Describe the study team expertise.	
Describe previous supportive findings from the study team.	
Provide feasibility data (data from previous recruitment, outcome measurement, etc.).	
Describe supportive research infrastructure.	
<b>Methods:</b>	
<b>Study design</b>	
Present key elements of the study design, <b>making sure that it aligns with the specific aims.</b> Specify the type of trial (e.g., pilot and feasibility trial, phase III trial), number and type of study arms (e.g., placebo control); whether the study is randomized and blinded (single or double); type of randomization; details of any restriction (e.g., blocking and block size); methods used to generate and implement the random allocation sequence; and mechanisms used to blind investigators, staff, and participants, and to promote unbiased assessment of the outcome measures.	
<b>Setting</b>	
Describe the setting, locations, and relevant dates, including periods of recruitment, follow-up, and data collection.	
<b>Participants</b>	
Provide the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up, if appropriate.	
<b>Interventions</b>	
Describe the interventions for each group with sufficient detail to allow replication.	
<b>Outcome variable(s)</b>	
Clearly define the outcome variable(s), including primary and secondary outcomes, and feasibility outcomes for feasibility trials (e.g., recruitment rates, consent rates, completion rates, variance estimates, etc.). Describe the data source and/or method and timing of data collection, with estimates of reproducibility and validity, as appropriate. Describe comparability of outcome assessment if there is more than one study arm.	
<b>Correlative study variable(s)</b>	
Describe exposure and outcome variables in similar detail as for the main trial outcomes.	
<b>Covariates</b>	
Briefly describe additional variables used to characterize the study population, potential confounders, and effect modifiers. Include their data source and/or method and timing of data collection.	
<b>Statistical analysis</b>	
Describe all statistical methods, including how quantitative variables will be handled in the analyses (e.g., which groupings and why), interim analyses, and stopping guidelines. Describe any efforts to address potential sources of bias and sensitivity analyses. Describe any methods used to examine subgroups and interactions. Explain how missing data will be addressed. <b>* Make sure that the statistical analysis aligns with the specific aims.</b>	
<b>Power and sample size considerations</b>	
Explain how the study size was derived using power or sample size calculations. This also applies to pilot and feasibility trials, for which a confidence interval approach may be used for the feasibility outcomes. <b>* Do not use the fact that the proposed study is the same size as other studies as justification.</b>	
<b>Limitations</b>	
Discuss limitations of the proposed study, taking into account sources of potential bias, imprecision, and multiplicity of analyses. Discuss both the direction and magnitude of potential biases. Discuss the generalizability (external validity or applicability) of the proposed study results. Discuss steps taken to reduce methodologic limitations and increase generalizability, as appropriate.	

### Adapted from the following two resources:

CONSORT 2010 checklist of information to include when reporting a randomised trial ([www.consort-statement.org](http://www.consort-statement.org)).

STROBE statement – checklist of items that should be included in reports of observational studies ([www.strobe-statement.org](http://www.strobe-statement.org)).

Thabane et al. BMC Medical Research Methodology 2010. 10:1.