Appendix 2: Template data collection form for extracting study characteristics and study design items for risk of bias assessment

This form should be adapted for the collection of study characteristics in line with the methods outlined in the protocol of the review.

Part 1: **Administrative details**
Extractor name:
Date:
Study ID:
Citation(s):

Part 2: Study methods, participants, interventions and outcomes (intended to be entered in section 'Characteristics of included studies')

Methods

STUDY DESIGN (parallel, crossover):

LOCATION, NUMBER OF CENTRES:

DURATION OF STUDY:

Participants

N SCREENED:

N RANDOMISED:

N COMPLETED:

M=

F=

AGE:

BASELINE DETAILS:

INCLUSION CRITERIA:

EXCLUSION CRITERIA:

Interventions

INTERVENTION:

CONTROL:

RUN-IN PERIOD:

TREATMENT PERIOD:

FOLLOW-UP PERIOD:

CO-INTERVENTIONS:

Outcomes:

Coding for subgroup analysis (e.g. adults/children; mild/moderate/severe etc):

Coding for sensitivity analysis (e.g. blinding; etc):

Part 3: Risk of bias items, notes for other extractors and correspondence

Risk of bias assessment (amend as per stated risk of bias items in protocol):

Item	Question	Judgement (delete as appropriate)	Description (provide summary or paste from trial report/correspondence)

Adequate allocation generation?	Was the allocation sequence adequately generated?	Yes/No/Unclear	
Allocation concealment?	Was allocation adequately concealed?	Yes/No/Unclear	
Blinding?	Was knowledge of the allocated interventions adequately prevented during the study? (the importance of this may depend on the outcome(s) being measured)	Yes/No/Unclear	
Incomplete data addressed?	Were incomplete data adequately addressed?	Yes/No/Unclear	
Free of selective reporting?	Are reports of the study free of suggestion of selective reporting bias?	Yes/No/Unclear	
Free of other bias?	(Use additional rows if further risk of bias items are required)	Yes/No/Unclear	
(Add items as appropriate)		Yes/No/Unclear	

Notes:

Requirement for further correspondence (see sheets with extracted data to see whether numerical outcome data are also required):

Yes/No

What information regarding the design of the study is needed from investigators/study sponsors?

What information regarding the results of the study is required from investigators/study sponsors