Appendix 2: Data extracted

Items	Data extracted	Further information
Descriptives		
Name of first author	Text	
Publication year	Date	The earlier of the print date and electronic date
Journal	Text	
Title	Text	
Country (or countries) in which the trial was set	Text	
Setting where the data were collected	Text	e.g. community, hospital clinic etc.
Pilot trial design	Parallel CRT, factorial CRT, cross-over CRT, other CRT	
What was the cluster?	Text	
Method of cluster randomisation	Text	
Number of clusters randomised	Number	
Number of individuals randomised	Number	
Additional items relating to pilot trial methodology		
Primary objective/ research question of the pilot trial	Text	As specified by the author, else the outcome used in the sample size justification, or else the first objective/ research question mentioned in the abstract or else main text (following a similar method as that used by Diaz-Ordaz et al.[8])
Is the primary objective feasibility?	Yes/No	
Primary objective/ research question measure	Text	
Method used to address primary objective/ research question	Text	Defined as the main method presented for the primary objective/ research question
Main feasibility objective/ research question of the pilot trial	Text	As specified by the author, else the feasibility outcome used in the sample size justification, or else the first feasibility objective/ research question mentioned in the abstract or else main text
Main feasibility objective/ research question measure	Text	
Method used to address main feasibility objective/ research question	Text	Defined as the main method presented for the primary objective/ research question
Is the rationale for numbers in the pilot trial based on formal power calculation for effectiveness (efficacy)?	Yes/no	
Is the paper performing any formal hypothesis testing for effectiveness/ efficacy?	Yes/no	
Is the paper making any statements about effectiveness/ efficacy without a caveat	Yes/no	The caveat must explain that it is an indication of *potential* effectiveness or explain that the study is underpowered
Title and Abstract		
Term 'pilot' or 'feasibility' included in the title	Yes/no	
Identification as a pilot or feasibility randomised trial in the title	Yes/no	Require 'pilot randomised trial' or 'feasibility randomised trial' in the title, or 'pilot study' or 'feasibility study' and 'randomised trial' in the title
Term 'cluster' included in the title	Yes/no	
Identification as a cluster randomised trial in the title	Yes/no	Require 'cluster randomised trial' in the title – don't accept 'clustered' as this can imply correlation rather than cluster randomised
Introduction		
Scientific background and explanation of rationale for future definitive trial reported	Yes/no	
Reasons for randomised pilot trial reported	Yes/no	We specified there needed to be a rationale in the introduction section for the randomised pilot trial, which was not just simply stating the aims/ objectives/outcomes of the pilot trial but gave a clear rationale of why the pilot trial was needed before proceeding to the future definitive trial.

Rationale given for using cluster design	Yes/no	
Methods – Trial design		
Description of pilot trial design	Yes/no	
Definition of cluster	Yes/no	
Reported any changes to methods after pilot trial commencement If yes, reported reasons	Yes/no Yes/no	
Methods – Participants		
Reported eligibility criteria for participants	Yes/no	
Reported eligibility criteria for clusters	Yes/no	
Reported settings and locations where the data were collected	Yes/no	
Reported how participants were identified	Yes/no	We required that the authors describe the exact way the participants were identified (e.g. during consultations/visits to the cluster, or through advertisement requesting volunteers)
Reported how clusters were identified	Yes/no	We required that the authors describe the exact way the clusters were identified (e.g. all clusters in a particular geographical location, or selection from a register/list etc.)
Reported how participants were consented	Yes/no	
Reported how clusters were consented	Yes/no	
Methods – Interventions		
Described the interventions for each group	Yes/no	
Methods – Outcomes		
Reported any changes to pilot trial assessments or measurements after pilot trial commencement If yes, reported reasons	Yes/no Yes/no	
Reported criteria used to judge whether, or how, to proceed with the future definitive trial	Yes/no	
Methods – Sample size		
Reported a rationale for the sample size of the pilot trial	Yes/no	
Cluster design considered during the description of the rationale for numbers in the pilot trial	Yes/no	We required that the authors show some consideration about clustering during the description of their sample size calculation, even if not formally accounting for it currently but describe during their rationale that they e.g. plan to estimate the design effect in the future definitive trial
Reported stopping guidelines	Yes/no	
Methods – Randomisation		
Reported method used to generate the random allocation sequence	Yes/no	e.g. random numbers table, coin tossing, computer generated random list
Reported randomisation method If yes, randomisation method	Yes/no Text	 e.g. simple, stratification, blocking, matching
Reported mechanism used to implement the random allocation sequence	Yes/no	e.g. sequentially numbered containers, sealed envelopes, central telephone
Reported allocation concealment	Yes/no	
Reported who: Generated the random allocation sequence Enrolled clusters Assigned clusters to interventions	 Yes/no Yes/no Yes/no	 Tick yes for last two points if a 'who' is not relevant since done by e.g. post/online
Reported whether consent was sought from participants	Yes/no	
Reported whether consent was sought from clusters	Yes/no	
Reported from whom consent was sought	Yes/no	I.e. reported both whether consent was sought from participants and whether consent was sought from clusters
Reported whether participant consent was sought before or after randomisation	Yes/no	
Methods – Blinding		
Reported on whether there was blinding	Yes/no	

Reported who was blinded	Yes/no	tick yes if they report anyone who was blinded, even if they don't report on everyone
Reported how they were blinded	Yes/no	tick yes if they report on how anyone was blinded, even if they don't report on how everyone who was blinded was blinded
Methods – Analytical methods		
Reports clustering accounted for in any of the methods used to address pilot trial objectives/ research questions	Yes/no	
Results – Participant flow		
Reports a diagram with flow of individuals through the trial	Yes/no	
Reports a diagram with flow of clusters through the trial	Yes/no	
Reported number of: Individuals approached and/or assessed for eligibility Individuals randomly assigned Individuals that received intended treatment Losses for individuals after randomisation Exclusions for individuals after randomisation Individuals that were assessed for primary objective	 Yes/no Yes/no Yes/no Yes/no Yes/no Yes/no	
Reported number of: Clusters approached and/or assessed for eligibility Clusters randomly assigned Clusters that received intended treatment Losses for clusters after randomisation Exclusions for clusters after randomisation Clusters that were assessed for primary objective	 Yes/no Yes/no Yes/no Yes/no Yes/no Yes/no	
Results – Recruitment		
Reported on dates defining the periods of recruitment	Yes/no	
Reported on dates defining the periods of follow up	Yes/no	
Reported the pilot trial ended/stopped	Yes/no	
Results – Baseline data		
Reported a table showing baseline characteristics for the individual level If yes, by group	Yes/no Yes/no	
Reported a table showing baseline characteristics for the cluster level If yes, by group	Yes/no Yes/no	
Results – Outcomes and estimation		
Reported results for main feasibility objective (quantitative or qualitative)	Yes/no	
Results – Harms		
Reported on harms or unintended effects	Yes/no	Tick yes even if reported that there were no harms
Reported other unintended consequences	Yes/no	An unintended consequence would be an unexpected result/finding that was not one of the objectives to explore and where the result would have consequences on the future definitive trial, such as a change in design/population etc.
Discussion		
Reported limitations of pilot trial	Yes/no	
Reported sources of potential bias	Yes/no	
Reported remaining uncertainty	Yes/no	
Reported generalisability of pilot trial methods/findings to future definitive trial or other studies	Yes/no	To be reporting on the generalisability of the pilot trial methods/findings to the future definitive trial, we deemed it sufficient for the paper to be discussing whether the methods/findings of the pilot study can be applied to the future definitive trial. To be reporting on the generalisability of the pilot trial methods/findings to other future trials, we deemed it sufficient for the paper to be discussing whether the methods/findings of the pilot study can be applied to other future trials.
Interpretation of feasibility consistent with main feasibility objectives and findings	Yes/no	

Reported implications for progression from the pilot to the future definitive trial If yes, what were the implications?	Yes/no Proceed/ proceed with changes/ Further research or piloting needed first/ Don't go ahead	
Other information		
Reported registration number for pilot trial	Yes/no	
Reported name of registry for pilot trial	Yes/no	
Reported where the pilot trial protocol can be accessed	Yes/no	
Reported source of funding	Yes/no	
Reported ethical approval/research review committee approval If yes, reported reference number	Yes/no Yes/no	