Component of trial		**Monitoring methods (exemplars)**	**Amend?**	**Outcomes (exemplars)**
Trial design		Review research protocol especially balance of scientific & practical needs.	Yes/No	Amend trial design & dependent components. Submit amendment to Research Ethics Committee.
Sample size		Test assumptions within protocol on: number of (active) centres; recruitment rates; retention rates; & SD of primary outcomes	Yes/No	Revise if necessary: sample size calculation; trial period; & funding
Interventions	Clinical governance	Assess compliance with: formal training in intervention; Health & Safety regulations; & other clinical governance requirements	Yes/No	Enhance formal training of intervention providers
	Intervention fidelity	Measure & assess adherence to intervention manual by video, observation or audio	Yes/No	Enhance clinical supervision of intervention providers
Participants	Recruitment strategy	Assess: flows of participants; and cost & productivity of each route.	Yes/No	Refine recruitment strategy, generally & locally
	Eligibility criteria	Assess: characteristics of sample; barriers to recruitment; update of intervention	Yes/No	Refine eligibility criteria
Consent procedures	Participant Information Sheets (PIS)	Consult participants & refusers	Yes/No	Refine PIS especially to address frequently asked questions
	Taking informed consent	Audit consent documentation. Measure & assess adherence to consent procedures by video, observation or audio	Yes/No	Enhance training of research team
Randomisation process		Check quality especially: accessibility by researchers; validity of CONSORT flowchart; & accuracy of stratifying variables	Yes/No	Refine: randomisation procedure & parameters; & training of research team
Blinding		Check whether assessors can predict individual allocations. Test whether unblinded researchers can keep other researchers blind.	Yes/No	Refine blinding procedures, e.g. by reallocating responsibilities within research team

Data	Data collection	Assess adherence to interview schedules & fieldwork handbook, including duration of assessments, by video, observation or audio	Yes/No	Refine schedules to reduce assessment burden. Enhance training of research team.
	Data quality	Test missing data procedures within draft analysis plan	Yes/No	Refine data collection tools & missing data procedures
	Data management	Test trial database, related procedures & link to analytical software	Yes/No	Refine trial database & procedures
Research Governance	Research protocol adherence	Enable quality assurance officer (QAO) to test adherence as widely as possible	Yes/No	Refine: protocol; quality assurance plan & training of team
	Adverse events (AE)	QAO to test procedures for: reporting AEs; assessing severity, causality & expectedness monitor at management group; report to DMEC	Yes/No	Refine AE reporting & assessment procedures
	Health & Safety	Test H&S procedures, e.g. for lone working	Yes/No	Refine H&S procedures
Data analysis		Test draft analysis plan on pilot data	Yes/No	Refine analysis plan to address research aims in full.
Trial management		Review role descriptions of research team. Review remits of trial management group, trial research team etc.	Yes/No	Refine roles e.g if workloads vary. Refine remits e.g. if reporting of any component is inadequate.

Note Though some components (e.g. trial design) need brief defined pilot period, other components (e.g. data analysis) benefit from extended pilot period.