Additional file 2: SPIRIT 2013 Checklist

Section/item	Item No	Included in manuscript (Y/N) or described below
Administrative information		
Title	1	Y
Trial registration	2a	Y
	2b	Y
Protocol version	3	Version 4: 16/09/2015
Funding	4	Y
Roles and responsibilities	5a	Y
	5b	Y
	5c	Y
	5d	The trial steering committee is comprised of the protocol authors. The National Institute for Health Innovation IT team is responsible for the SMS content management system and data management is overseen by the National Institute for Health Innovation data management team.
Introduction		
Background and rationale	6a	Y
	6b	Y
Objectives	7	Y
Trial design	8	Y
Methods: Participants, interventions, and outcomes		
Study setting	9	Y
Eligibility criteria	10	Y
Interventions	11a	Y
	11b	Y
	11c	Y
	11d	Y
Outcomes	12	Y
Participant timeline	13	Y
Sample size	14	Y
Recruitment	15	Y
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Y
Allocation concealment mechanism	16b	Y
Implementation	16c	Y
Blinding (masking)	17a	Y
	17b	Y
Data collection methods	18a	Y – All data collection forms are located in the Trial Master File
	18b	Y

Data management	19	Y – All data collection methods are described in the Manual of Procedures located in the trial master file. All data will be entered into REDCap. At least 10% of data in the electronic system will be checked and validated against the source document (where a hard copy exists).
Statistical methods	20a	Y – The statistical methods are described in full in the Statistical Analysis Plan located in the Trial Master File
	20b	Y
	20c	Y
Methods: Monitoring		
Data monitoring	21a	The study does not meet two or more of the criteria outlined by Ellenburg et al. (2002) and therefore a DMC will not be established for the trial. An independent project monitor will be appointed. The monitor will be trained in GCP. The project is considered to be low risk. The monitor will check primary outcome measures, and TMF and consent forms for completeness and accuracy.
	21b	NA – The trial is low risk and no interim analyses are planned
Harms	22	Y – The trial is low risk
Auditing	23	Y - The trial will be subject to independent auditing.
Ethics and dissemination		
Research ethics approval	24	Y
Protocol amendments	25	Amendments will be communicated to the Trial Steering Committee, ethics boards and trial registry where needed.
Consent or assent	26a	Y
	26b	NA
Confidentiality	27	Y – Confidentiality will be protected by the use of study registration numbers, and only aggregated and anonymous data will be reported. Personal information will be kept confidential and stored securely. Computerised information will be password protected. All reports from the study will be written in a way that no individuals can be identified. Information about study subjects will be kept confidential in keeping with the obligations set out in the Privacy Act 1993, the Health Information Code 1994 and Section 22B to 221

		of the Health Act 1956. Data will be entered, stored and backed-up in a secure manner on a server at the National Institute for Health Innovation.
Declaration of interests	28	Y
Access to data	29	Y
Ancillary and post-trial care	30	Described in the Participant Information Sheet and Consent Form located in the Trial Master File
Dissemination policy	31a	Y – A copy of the trial Publication Plan included in the Trial Master File
	31b	Outlined in the trial Publication Plan included in the Trial Master File. No professional writers will be used.
	31c	Y – There is no plan to make the data set public
Appendices		
Informed consent materials	32	Version 3, (27/02/2015) located in the Trial Master File
Biological specimens	33	NA