

**Supplementary file 1. Checklist for Standard Protocol Items: Recommendations for Interventional Trials 2013 statement**

Reporting Item		Page and Line Number	Reason if not applicable
<b>Administrative information</b>			
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1, line 1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	Page 2, line 26
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	Yes (In trial register PACTR202009822379650)
Protocol version	<a href="#">#3</a>	Date and version identifier	N/A
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	Page 11, line 11
Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	Page 1, lines 6-29 and Page 11, lines 8-10
Roles and responsibilities: sponsor contact information	<a href="#">#5b</a>	Name and contact information for the trial sponsor	N/A
Roles and responsibilities: sponsor and funder	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for	Page 11, lines 13-14

		publication, including whether they will have ultimate authority over any of these activities		
Roles and responsibilities: committees	<a href="#">#5d</a>	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Page 9, lines 28-33	
<b>Introduction</b>				
Background and rationale	<a href="#">#6a</a>	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 4, line 2 to Page 5, line 13	
Background and rationale: choice of comparators	<a href="#">#6b</a>	Explanation for choice of comparators	Page 5, lines 11-13	
Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	Page 5, lines 16-26	
Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	Page 5, line 21-22	
<b>Methods: Participants, interventions, and outcomes</b>				
Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic, academic hospital) and list of countries	Page 5, line 29-32	

		where data will be collected. Reference to where list of study sites can be obtained		
Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 5, line 34-38	
Interventions: description	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 5, line 40-48	
Interventions: modifications	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A	No discontinuations/modifications are planned. Both intention-to-treat and per protocol analyses will be conducted
Interventions: adherence	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	Page 5, lines 43-44 and Page 8, lines 30-32	
Interventions: concomitant care	<a href="#">#11d</a>	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 9, line 47-48	
Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of	Page 6, lines 3-8	

		the clinical relevance of chosen efficacy and harm outcomes is strongly recommended		
Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 6, line 10-15	
Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 7, lines 1-18	
Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment to reach target sample size	Page 7, lines 7-15	
<b>Methods: Assignment of interventions (for controlled trials)</b>				
Allocation: sequence generation	<a href="#">#16a</a>	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 7, line 26-29	
Allocation concealment mechanism	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes),	Page 7, line 28	

		describing any steps to conceal the sequence until interventions are assigned		
Allocation: implementation	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 7, line 31-33	
Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 7, line 35-37	
Blinding (masking): emergency unblinding	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A	
<b>Methods: Data collection, management, and analysis</b>				
Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 7, line 40 to Page 8, line 13, supplementary file 2	
Data collection plan: retention	<a href="#">#18b</a>	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who	N/A	This is a pragmatic trial in which no other interruption to real-life practice will be made – apart from introducing the mobile application at baseline and

		discontinue or deviate from intervention protocols		sending monthly mobile phone short message reminders for 6-months.
Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 8, line 16-32	
Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 8, line 35 to Page 9, line 26	
Statistics: additional analyses	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 9, lines 13-14	
Statistics: analysis population and missing data	<a href="#">#20c</a>	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 8, lines 41, 48	
<b>Methods: Monitoring</b>				
Data monitoring: formal committee	<a href="#">#21a</a>	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 9, line 34	

Data monitoring: interim analysis	<a href="#">#21b</a>	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 9, line 35	
Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A	Introduction of the Med Safety App in the intervention arm is thought to be of very minimal risk.
Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Page 9, line 35	
<b>Ethics and dissemination</b>				
Research ethics approval	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	Page 9, line 41-44]	
Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	Page 10, line 37-41	
Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 9, line 45	
Consent or assent: ancillary studies	<a href="#">#26b</a>	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A	No biological samples will be collected.

Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 7, line 23-28	
Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 11, line 15	
Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 11, line 18	
Ancillary and post trial care	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A	Introduction of the Med Safety App is thought to have very minimal risk for study participants.
Dissemination policy: trial results	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 9 lines 47 to Page 10, line 29	
Dissemination policy: authorship	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of professional writers	Page 11, line 8-10	
Dissemination policy: reproducible research	<a href="#">#31c</a>	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Page 11, line 18-22	



Appendices				
Informed consent materials	<a href="#">#32</a>	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary file 3	
Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A	Biological specimens will not be collected

It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)" license.