

Additional file 1: SPIRIT 2013 Checklist

Based on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement (Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 Statement: defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200–7).

Trial: Smartphone and internet-based glucose management system for gestational diabetes: study protocol for a randomised controlled trial (M^oTHer study). ACTRN12625000547448.

Item No	Description	Description or Page addressed	Reviewer notes
Administrative information			
1	Title: Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1	
2a	Trial registration: Trial identifier and registry name; if not yet registered, name of intended registry	p.2 line (Abstract)	
2b	Trial registration: All items from the WHO Trial Registration Data Set	p.2 line 36 ANZCTR record (ACTRN12625000547448); https://anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12625000547448	
3	Protocol version: Date and version identifier	Version 2, 1 Feb 2025	
4	Funding: Sources and types of financial, material, and other support	p.21 (Funding)	
5a	Roles and responsibilities: Names, affiliations, and roles of protocol contributors	p.21 (Author's contributions)	
5b	Roles and responsibilities: Name and contact information for the trial sponsor	Department of Endocrinology and Diabetes, Western Health	

Item No	Description	Description or Page addressed	Reviewer notes
5c	Roles and responsibilities: Role of study sponsor and funders in study design, conduct, analysis, reporting, and decision to submit for publication	p.21 (Funding)	
5d	Roles and responsibilities: 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	N/A	
Introduction			
6a	Background and rationale: Explanation for choice of comparators	p.2–4 (Background)	
6b	Background and rationale: Summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	p.2–4 (Background)	
7	Objectives: Specific objectives or hypotheses	p.5 (Methods/Design)	
Methods: Participants, interventions, and outcomes			
8	Trial design: Description of trial design including type of trial (e.g. parallel, crossover), allocation ratio, and framework (e.g. superiority, equivalence, non-inferiority)	p.5 (Design and setting)	
9	Study setting: Description of study settings and list of countries where data will be collected	p.5-6 (Design and setting; Study population)	

Item No	Description	Description or Page addressed	Reviewer notes
10	Eligibility criteria: Inclusion and exclusion criteria for participants; criteria for study centres/individuals recruiting participants	p.6–7 (Study population; Table 1)	
11a	Interventions: Interventions for each group with sufficient detail to allow replication	p.8–13 (Digital intervention; Intervention arm; Control arm, Figure 1+2)	
11b	Interventions: Criteria for discontinuing or modifying allocated interventions	p.11-13 (Intervention arm; Control arm criteria)	
11c	Interventions: Strategies to improve adherence to protocols	p. 8-13 (Digital intervention; Intervention arm; Control arm)	
11d	Interventions: Relevant concomitant care and interventions permitted/prohibited during the trial	p.13 (Care in both groups)	
12	Outcomes: Primary, secondary, other outcomes, and, when applicable, target-difference, and timepoint(s) for each	p.14-15 (Outcome measures; Table 2)	
13	Participant timeline: Schedule of enrolment, interventions, assessments, and visits (diagram recommended)	Figure 1 (schematic); text p.6–7 (Study population); questionnaire timepoint p.16 (36–38 weeks)	
14	Sample size: Estimated number of participants needed, and how it was determined, including clinical/statistical assumptions	p.15 (Sample size)	
15	Recruitment: Strategies for achieving adequate participant enrolment	p.6 (Study population, recruitment pathway); p.5 (anticipated 12–18 month recruitment period); p.15 (sample size)	
Methods: Assignment of interventions			

Item No	Description	Description or Page addressed	Reviewer notes
16a	Allocation — sequence generation: Method of generating allocation sequence; type of randomisation; details of restriction (e.g. blocking, stratification)	p.6 (Study population)	
16b	Allocation — concealment mechanism: Mechanism to implement allocation sequence, steps to conceal until interventions assigned	p.6 (Study population)	
16c	Allocation — implementation: Who generates the sequence, enrolls participants, and assigns participants to interventions	p.6 (Study population)	
17a	Blinding: Who will be blinded, and how, after assignment (participants, care providers, outcome assessors, data analysts)	p.6 (Blinding of participants not feasible; data analysts not blinded)	
17b	Blinding: If blinded, circumstances under which unblinding is permissible and procedure	p. 5-6 (Not applicable, unblinded, open-label design)	
Methods: Data collection, management, and analysis			
18a	Data collection methods: Plans for assessment and collection of outcome, baseline, and other trial data, including related processes to promote data quality	p.16-18 (Data handling, analysis and result reporting)	
18b	Data collection methods: Plans to promote participant retention and complete follow-up	p.16 (Data handling, analysis and result reporting)	

Item No	Description	Description or Page addressed	Reviewer notes
19	Data management: Plans for data entry, coding, security, and storage, including any related processes to promote data quality	p.16 (Data handling, analysis and result reporting); p.10 (AWS Victorian-health-approved server for platform data)	
20a	Statistical methods: Methods for analysing primary and secondary outcomes	p. 16-18 (Data handling, analysis and result reporting)	
20b	Statistical methods: Methods for additional analyses (e.g. subgroup and adjusted analyses)	p.17 (Model adjustments/covariates of interest)	
20c	Statistical methods: Definition of analysis population, and methods for handling protocol non-adherence and missing data	p.16 (intention-to-treat, per-protocol sensitivity analysis); p.17 (missing data/multiple imputation)	
21a	Data monitoring: Composition of data monitoring committee; whether independent from sponsor/competing interests; description of its role and reporting structure	N/A	
21b	Data monitoring: Stopping guidelines and how they will be implemented	N/A	
22	Harms: Plans for collecting, assessing, reporting, and managing solicited/spontaneously reported adverse events	p.18 (Adverse event reporting to Research Ethics Committee)	
23	Auditing: Frequency and procedures for auditing trial conduct, and whether independent from investigators/sponsor	p.5 (Methods/design)	
<i>Ethics and dissemination</i>			

Item No	Description	Description or Page addressed	Reviewer notes
24	Research ethics approval: Plans for seeking research ethics committee/institutional review board approval	p.18 (Ethics and dissemination)	
25	Protocol amendments: Plans for communicating important protocol modifications to relevant parties	P.18 (Amendments)	
26a	Consent or assent: Who will obtain informed consent, and how	p.6 (Study population, written and verbal consent obtained at recruitment)	
26b	Consent or assent: Additional consent for collection/use of participant data and biological specimens in ancillary studies, if applicable	N/A	
27	Confidentiality: How personal information will be collected, shared, and maintained to protect confidentiality	p.10 (data confidentiality/privacy legislation); p.16 (secure servers, restricted access)	
28	Declaration of interests: Financial and other competing interests for principal investigators for the overall trial and each study site	p.21 (Declarations)	
29	Access to data: Statement of who will have access to the final trial dataset, and disclosure of contractual agreements limiting such access	p.16 (Data handling) p. 21 (Declarations)	
30	Ancillary and post-trial care: Provisions, if any, for ancillary and post-trial care, and compensation for trial-related harm	N/A	

Item No	Description	Description or Page addressed	Reviewer notes
31a	Dissemination policy: Plans for investigators/sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups	p.18-19 (Ethics and dissemination); p.21 (Declarations)	
31b	Dissemination policy: Authorship eligibility guidelines and any intended use of professional writers	N/A	
31c	Dissemination policy: Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	p. 18 (Ethics and dissemination)	
Appendices			
32	Informed consent materials: Model consent form and other related documentation given to participants and authorised surrogates	Participant consent form appendix A attached in related files	
33	Biological specimens: 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	