

CONSORT 2025 checklist of information to include when reporting a randomised trial*

Section / Topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	P3-4-Abstract
	1b	Structured summary of the trial design, methods, results, and conclusions	P3-4-Abstract
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	P4-5-Introduction
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	"Protocol of cluster-randomized controlled trial of MSM, En", "Protocol of evaluation".
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	P21- Availability of data and materials
Funding and conflicts of interest	5a	Sources of funding and other support (e.g., supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	P3-4-Abstract P22-Acknowledgement
	5b	Financial and other conflicts of interest of the manuscript authors	P21-Competing Interests
Introduction			
Background and rationale	6	Scientific background and rationale	P4-5-Introduction
Objectives	7	Specific objectives related to benefits and harms	P4-5-Introduction
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	P5-8-Method
Trial design	9	Description of trial design including type of trial (e.g., parallel group, crossover), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory)	P5-8-Method, Supplementary appendix
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	None
Trial setting	11	Settings (e.g., community, hospital) and locations (e.g., countries, sites) where the trial was conducted	P5-8-Method, P32-Figure 2

Eligibility criteria	12a	Eligibility criteria for participants	P5-8-Method, Supplementary appendix P2
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (e.g., surgeons, physiotherapists)	"Protocol of cluster-randomized controlled trial of MSM, En"- IV. Study Site Selection and randomization
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (e.g., intervention manual) can be accessed	"Protocol of cluster-randomized controlled trial of MSM, En"
Outcomes	14	Pre-specified primary and secondary outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome	P9-13-Result
Harms	15	How harms were defined and assessed (e.g., systematically, non-systematically)	Given the nature of the interventions as established routine practices, this study did not prespecify operational definitions for adverse events (AEs) or harms, nor did it employ systematic active surveillance to assess their occurrence. Harms were monitored through non-systematic/passive surveillance-. At each study visit, participants were asked a non-directive, open-ended question: "Have you experienced any new health issues or discomfort since your last visit?" All spontaneously reported events and any observed

			adverse medical occurrences were documented.
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	"Protocol of cluster-randomized controlled trial of MSM, En"-VI. Intervention Implementation-Task 8
	16b	Explanation of any interim analyses and stopping guidelines	P7-8-Statistical analysis. No formal interim analyses were pre-specified in the trial protocol, and no interim analyses were conducted during the study period. Accordingly, no stopping guidelines for early trial termination were established. The trial was designed to continue until the scheduled completion of follow-up for all participants, with no planned early stopping rules based on efficacy or safety.
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	"Protocol of cluster-randomized controlled trial of MSM, En"- III. Study Design Study design; IV. Study Site Selection and randomization
	17b	Type of randomisation and details of any restriction (e.g., stratification, blocking and block size)	"Protocol of cluster-randomized controlled trial of MSM, En"- IV. Study Site Selection and randomization

Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (e.g., central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	P5-8-Method; “Protocol of cluster-randomized controlled trial of MSM, En”- III. Study design.
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	Randomization was performed at the cluster level by the central research team, which generated and concealed the allocation sequence. The field staff responsible for participant recruitment and enrollment did not have access to the random allocation sequence at any time during the study. However, because the intervention was cluster-based, field workers in the intervention clusters were naturally aware of their cluster’s allocation status (i.e., intervention group) after randomization, as they were required to deliver the specific intervention components. The allocation sequence itself, including future or unallocated assignments, remained concealed from all field staff involved in enrollment and data collection.

Blinding	20a	Who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors, data analysts)	All the cohort participants in the both intervention and control regions were blinded.
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	"Protocol of evaluation"- Appendix 1. Informed Consent Form for MSM Population Health Survey (For Dating App Appointment-Based Testing Platform); After the regions were randomly assigned, all eligible individuals were notified through the online platform to attend testing, following the same procedure as routine voluntary counselling services in both intervention and control regions. No additional recruitment incentives were provided, ensuring a naturalistic enrolment process.
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	P7-8- Method-Statistical analysis
	21b	Definition of who is included in each analysis (e.g., all randomised participants), and in which group	P9-13; Result
	21c	How missing data were handled in the analysis	P7-8-Method-Statistical analysis; Missing data was imputed using random forest.
	21d	Methods for any additional analyses (e.g., subgroup and sensitivity analyses), distinguishing prespecified from post-hoc	P6-7 - Statistical analysis. We conducted sensitivity analyses by repeating the modeling procedures using the original

			un-imputed dataset which contained complete information of all variables to assess the robustness of our findings.
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	P31-Figure 1: The framework of the cohort follow-up study.; Supplementary Appendix P4-Supplementary figure 1: The process of online and offline surveys.
	22b	For each group, losses and exclusions after randomisation, together with reasons	In this open cohort, all enrolled participants were included in the analysis with no exclusion.
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	P9-13;Results
	23b	If relevant, why the trial ended or was stopped	Not relevant
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (e.g., where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended [fidelity])	“Protocol of cluster-randomized controlled trial of MSM, En”; Supplementary Appendix P2-5
	24b	Concomitant care received during the trial for each group	“Protocol of cluster-randomized controlled trial of MSM, En”-V. Rationale of intervention package development
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	P27-28-Table1
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: - the number of participants included in the analysis - the number of participants with available data at the outcome time point	P9-13- Result; P27-30-Table 1-2, Figure 1-4

		● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size	
Harms	27	All harms or unintended events in each group	None were reported
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post-hoc	P9-13-Result; Supplementary Appendix P10-12, 14, 16, 19-20, 22.
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	P14-18-Discussion
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	P14-18-Discussion

*We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.

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