

Table 1: CONSORT 2010 checklist of information to include when reporting a within-person randomised trial. For within-person trials, a group is the set of participants' body sites that was allocated a particular intervention.

Section/Topic	Item no.	Standard CONSORT Checklist item	Extension for within-person trials	Page no.
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a within-person randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts[3])	Specify a within-person design and report all information outlined in table 2	2-3
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale		4-5
	2b	Specific objectives or hypotheses		4-5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Rationale for using a within-person design and identification of body sites	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		not applicable
Participants	4a	Eligibility criteria for participants	Eligibility criteria for body sites	6
	4b	Settings and locations where the data were collected		6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions were given sequentially or concurrently	6
Outcomes	6a	Completely defined pre-specified primary and	Outcomes should be clearly defined as per-site or per-	7-12

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		secondary outcome measures, including how and when they were assessed	person	
	6b	Any changes to trial outcomes after the trial commenced, with reasons		not applicable
Sample size	7a	How sample size was determined	Report the correlation between body sites	12-13
	7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		6-7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Methods used to determine the allocation sequence of body sites and treatments within an individual (e.g. how first site to be treated was decided)	6-7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		6-7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replaced by 10a	6-7
	10a		Who generated the random allocation sequence, who enrolled participants, and who assigned body sites to interventions	
Blinding (masking)	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		not appl.

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	11b	If relevant, description of the similarity of interventions		not appl.
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Statistical methods appropriate for within-person design	12-14
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		12-14
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Number of participants and number of body sites at each stage [See Figure 1]	14-15 Fig 1; (Flow chart)
	13b	For each group, losses and exclusions after randomisation, together with reasons	Number of participants and number of body sites lost or excluded at each stage, with reasons	7, 14-15
Recruitment	14a	Dates defining the periods of recruitment and follow-up		6
	14b	Why the trial ended or was stopped		not appl.
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for site and individual participants as applicable	15-16 Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Number of randomised body sites in each group included in each analysis	18-23 Table 2-5
Outcomes and	17a	For each primary and secondary outcome, results for	Observed correlation between body sites for continuous	18-23

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estimation		each group, and the estimated effect size and its precision (such as 95% confidence interval)	outcomes and tabulation of paired results for binary outcomes	Table 2-5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		20 Table 3
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		not appl.
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Harms or unintended effects reported by participant and by body site	not appl.
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		28-29
Generalisability	21	Generalisability (external validity, applicability) of the trial findings		28-29
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		24-28
Other information				
Registration	23	Registration number and name of trial registry		3
Protocol	24	Where the full trial protocol can be accessed, if available		5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		31

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