CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page number/line number	Reported on section/paragraph
Title and abstract				
	1a	Identification as a randomised trial in the title	Page 0/ Line 1	Title page/ Title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Pages 1-2/ Lines 49-73	Abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Page 3/ Lines 75-95	Introduction/ Paragraph 1-2
	2b	Specific objectives or hypotheses	Page 3/ Lines 91-94	Introduction/ Paragraph 2
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 6/ Lines 158-160	Methods/ Recruitment and Participants/ Paragraph 1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable—we did not make changes to methods after trial commencement	
Participants	4a	Eligibility criteria for participants	Page 6/ Lines 148-156	Methods/ Recruitment and Participants/ Paragraph 1
	4b	Settings and locations where the data were collected	Page 6/ Lines 146-148 AND 163-166	Methods/Recruitment and Participants/ Paragraph 1 AND Data Collection/Paragraph 1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pages 4-5/ Lines 119-144 AND Pages 6-7/ Lines 163-175	Methods/EDL Content and Features/Paragraph 1 and 2 AND Methods/Data Collection/Intervention Delivery/Paragraph 1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were	Pages 7-8/ Lines 183-203	Methods/Data Collection/Measures/

		assessed		Paragraphs 1, 2, and 3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable—we did not make changes to the trial outcomes after trial commencement	
Sample size	7a	How sample size was determined	Page 6/ Lines 161-162	Methods/Recruitment and Participants/Paragraph 1
	7b	When applicable, explanation of any interim analyses and stopping guidelines	This was not applicable for this low-risk pilot study.	
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	Page 6/ Lines 158-160	Methods/Recruitment and Participants/Paragraph 1
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Not applicable as we used simple randomisation without any restrictions as part of this pilot study	
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	Page 6/ Lines 158-160	Methods/Recruitment and Participants/Paragraph 1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 6/Lines 145-160	Methods/Recruitment and Participants/Paragraph 1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 7/Lines 175-176	Methods/Data Collection/Intervention and Data Collection Visits/ Paragraph 1
	11b	If relevant, description of the similarity of interventions	Not applicable; the intervention tested is described as noted above.	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Pages 8-9/ Lines 206-217	Methods/Statistical Analysis/Paragraph 1
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable; we did not do additional analyses as part of this pilot study.	
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	Figure 1 and Page 10/Lines 240-249	Results/Paragraph 1

	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 10/Lines 251-252 AND pages 6-7/ Lines 164-181	Results/Study Participants/Paragraph 1 AND Methods/Data Collection/Intervention Delivery and Data Colleciton Visits/Paragraphs 1 and 2
	14b	Why the trial ended or was stopped	Not applicable; this pilot trial was ended after the planned data collection was completed (see above regarding dates of follow up)	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tables 1 and 2 and Page 10/Lines 250-256	Tables 1 and 2 and Results/Study Participants/Paragraph 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 3 and Pages 11-12/ Lines 271-287	Table 3 and Results/Behavior Change/ Paragraphs 1 and 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 3 and Page 11/ Lines 272-278	Table 3 and Results/ Behavior Change/ Paragraph 1
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Because this was a pilot study, we did not calculate or report effect sizes.	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Not applicable; we did not conduct additional analyses.	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable; we did not identify any harms or unintended effects of this behavioral intervention.	
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pages 16-17/ Lines 388-404	Discussion/Paragraph 6
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Pages 14-15/ Lines 346-361	Discussion/Paragraph 3
Interpretation	22	Interpretation consistent with results, balancing benefits and	Pages 14-18/ Lines 330-	Discussion/ Paragraphs 1 - 8

		harms, and considering other relevant evidence	433	
Other information				
Registration	23	Registration number and name of trial registry	This pilot trial was registered with ClinicalTrials.gov (Study ID# 15-2164). Page 2/ Line 74 AND Pages 18-19/ Lines 439-440.	Abstract Footnote/Paragraph 1
Protocol	24	Where the full trial protocol can be accessed, if available	Page 19/ Lines 442-443	Footnote/Paragraph 1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title Page/ Lines 28-32	Title Page/ Acknowledgements

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.