TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and Abstract				
Title and Abstract	1	• Information on how unit were allocated to interventions	Page#4; Line 70-71	Abstract / P#2
		• Structured abstract recommended	Page #4; Line 63-84	Abstract / P#1-4
		• Information on target population or study sample	Page#4; Line 77-79	Abastract /P#3
Introduction				
Background	2	• Scientific background and explanation of rationale	Page#5; Line 93-95	Introduction / P#1
		• Theories used in designing behavioral interventions	Page#5; Line 101-106	Introduction/ P#2
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page#7; Line126, 129-137	Study design/ P#2
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page#7; Line 128-129	Study design /P#2
		• Recruitment setting	Page#7; Line 129-130	Study design /P#2
		• Settings and locations where the data were collected	Page#7; Line 138-139	Study design /P#3
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:		
		o Content: what was given?	Page#7; Line 128-127	Study design /P#2
		o Delivery method: how was the content given?	Page#9; Line 174-184	Robotic-Assisted-PCI/P#1
		o Unit of delivery: how were the subjects grouped during delivery?	Page#7; Line 125	Study design/ P#1
		o Deliverer: who delivered the intervention?	Page9; Line 186-189	Training an Education
		o Setting: where was the intervention delivered?	Page7; Line 130	Study Design/P#2
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Page7; Line130-131 / 138-139	Study Design/P#3

		o Time span: how long was it intended to take to deliver the intervention to each unit?	Page 26, Line 528	Table 5
		o Activities to increase compliance or adherence (e.g., incentives)	Page10; Line 211-213	Training and Education
Objectives	5	• Specific objectives and hypotheses	Page11; Line 235-237	Performance goals and
Outcomes	6	• Clearly defined primary and secondary outcome measures	Page 10, Line 216-219 /	Safety primary
		• Methods used to collect data and any methods used to enhance the quality of measurements	Page 7, Line 138-142	Study design / P#3
		• Information on validated instruments such as psychometric and biometric properties	N/A (not used)	N/A (not used)
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Page 11, Line 249-251	Performance goals and
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Page 7,Line 128	Study design/P#2
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Page 12; Line 252-258	Performance goals and statistical considerations/
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	Page 11, 237-240	Performance goals and
Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed.	N/A (not blinded)	N/A (not blinded)
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	Page7; Line 128-129	Study design/ P#2
		• If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)	N/A (not used)	N/A (not used)
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Page12; Line 260-262	Performance goals and statistical considerations/
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Page12; Line 262	Performance goals and
		• Methods for imputing missing data, if used	N/A (not used)	N/A (not used)
		• Statistical software or programs used	Page12; Line 263-265	Performance goals and
Results				
Participant flow	12	• Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)		
		o Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	Page 12; Line 269	Results/P#1

		o Assignment: the numbers of participants assigned to a study condition	Page 12; Line 269	Results/P#1
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	Page 12; Line 269	Results/P#1
		o Follow-up: the number of participants who completed the follow- up or did not complete the follow-up (i.e., lost to follow-up), by study condition	Page 13; Line 292	Results/ P#5
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	Page 25; Line 522	Table4
		• Description of protocol deviations from study as planned, along with reasons	N/A (there is no protocol	deviation)
Recruitment	13	• Dates defining the periods of recruitment and follow-up	Page 12; Line 269-270	Results/P#1
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	Page21; Line 502	Table1
		• Baseline characteristics for each study condition relevant to specific disease prevention research	Page 23; Line 502	Table2
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	N/A (there is no lost of	N/A (there is no lost of
		• Comparison between study population at baseline and target population of interest	Page26; Line527-528	Table5
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	N/A (one group,pre-defined	N/A (one group,pre-defined
Numbers analyzed	16	• Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	Page 12, 25; Line 269, 522	Results/ P#1 Table4
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	N/A (one group,pre-defined	N/A (one group,pre-defined
Outcomes and estimation	17	• For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision	Page12;13 / 20 Line281;288-291 ; 492	Results /P#2;4 Figure 2
		• Inclusion of null and negative findings	Page13; 288-289	Results/ P#4
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	Page12-13 / 20 Line281;288-291; 492	Results /P#2;4 Figure 2
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	Page 13;26 Line 294-297 / 527-528	Results /P#6 ' Table 5
Adverse events	19	• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	Page 13; Line 288-289/ 292-293	Results /P#4-5

DISCUSSION				
Interpretation	20	• Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study	Page 14,15/ Line 299-302/ 316-324	Discussion/ P#1-3
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	Page 15; Line 336-342	Discussion/ P#5
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	Page 15; Line 342-344	Discussion, P#5
		• Discussion of research, programmatic, or policy implications	Page 16; Line 352-355	Discussion; P#6
Generalizability	21	• Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues	Page15; Line 334-336	Discussion; P#5
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	Page 16; Line 357-358	Conclusions /P:1

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: http://www.cdc.gov/trendstatement/

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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.

Materials Design Analysis Reporting (MDAR) Checklist for Authors

The MDAR framework establishes a minimum set of requirements in transparent reporting applicable to studies in the life sciences (see Statement of Task: doi:10.31222/osf.io/9sm4x.). The MDAR checklist is a tool for authors, editors and others seeking to adopt the MDAR framework for transparent reporting in manuscripts and other outputs. Please refer to the MDAR Elaboration Document for additional context for the MDAR framework.

Materials

Antibodies	**Yes (indicate where provided: section/paragraph)**	**n/a**
For commercial reagents, provide supplier name, catalogue number and RRID, if available.		X

Cell materials	**Yes (indicate where provided: section/paragraph)**	**n/a**
Cell lines: Provide species information, strain. Provide accession number in repository **OR** supplier name, catalog number, clone number, **OR** RRID		X
Primary cultures: Provide species, strain, sex of origin, genetic modification status.		X

Experimental animals	**Yes (indicate where provided: section/paragraph)**	**n/a**
Laboratory animals: Provide species, strain, sex, age, genetic modification status. Provide accession number in repository **OR** supplier name, catalog number, clone number, **OR** RRID		X
Animal observed in or captured from the field: Provide species, sex and age where possible		X
Model organisms: Provide Accession number in repository (where relevant) **OR** RRID		X

Plants and microbes	**Yes (indicate where provided: section/paragraph)**	**n/a**
Plants: provide species and strain, unique accession number if available, and source (including location for collected wild specimens)		X
Microbes: provide species and strain, unique accession number if available, and source		X

Human research participants	**Yes (indicate where provided: section/paragraph)**	**n/a**
Identify authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.	Yes (Methods / Study design and Patient population/ Page 7, Paragraph#3, Line 139-141) - National Commission of Ethics in Research (CAAE: 96392318.4.0000.0071), Brasília-DF, Brazil	
Provide statement confirming informed consent obtained from study participants.	Yes (Methods / Study design and Patient population/ Page 7, Paragraph#3, Line 142-143)	
Report on age and sex for all study participants.	Yes (Table1, Page 21, Line 502)	

Design

Study protocol	Yes (indicate where provided: section/paragraph)	n/a
For clinical trials, provide the trial registration number **OR** cite DOI in manuscript.	NCT03927560 (https://clinicaltrials.gov/ct2/show/NCT03927560)	

Laboratory protocol	Yes (indicate where provided: section/paragraph)	n/a
Provide DOI or other citation details if detailed step-by-step protocols are available.		X

Experimental study design (statistics details)	Yes (indicate where provided: section/paragraph)	n/a
State whether and how the following have been done**, or** if they were not carried out.		
Sample size determination		X
Randomisation		X
Blinding		X
Inclusion/exclusion criteria		X

Sample definition and in-laboratory replication	Yes (indicate where provided: section/paragraph)	n/a
State number of times the experiment was replicated in laboratory		X
Define whether data describe technical or biological replicates		X

Ethics	Yes (indicate where provided: section/paragraph)	n/a
Studies involving human participants: State details of authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.	Yes (Methods / Study design and Patient population/ Page 7, Paragraph#3, Line 140-141) - National Commission of Ethics in Research (CAAE: 96392318.4.0000.0071), Brasília-DF, Brazil	
Studies involving experimental animals: State details of authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.		X
Studies involving specimen and field samples: State if relevant permits obtained, provide details of authority approving study; if none were required, explain why.		X

Dual Use Research of Concern (DURC)	Yes (indicate where provided: section/paragraph)	n/a
If study is subject to dual use research of concern, state the authority granting approval and reference number for the regulatory approval		X

Analysis

Attrition	Yes (indicate where provided: section/paragraph)	n/a
State if sample or data point from the analysis is excluded, and whether the criteria for exclusion were determined and specified in advance.		X

Statistics	Yes (indicate where provided: section/paragraph)	n/a
Describe statistical tests used and justify choice of tests.	Yes (Methods/ Performance goals statistical considerations section; Page 12, Paragraph #4, line 259-266)	

Data Availability	Yes (indicate where provided: section/paragraph)	n/a
State whether newly created datasets are available, including protocols for access or restriction on access.	(Methods / Study design and Patient population/ Page 7, Paragraph#3, Line 139-141) Institutional review board of Hospital Israelita Albert Einstein, Sao Paulo-SP, Brazil and by the National Commission of Ethics in Research (CAAE: 96392318.4.0000.0071), Brasília-DF, Brazil	
If data are publicly available, provide accession number in repository or DOI or URL.		X
If publicly available data are reused, provide accession number in repository or DOI or URL, where possible.		X

Code Availability	Yes (indicate where provided: section/paragraph)	n/a
For all newly generated code and software essential for replicating the main findings of the study:		
State whether the code or software is available.		X
If code is publicly available, provide accession number in repository, or DOI or URL.		X

Reporting

Adherence to community standards	Yes (indicate where provided: section/paragraph)	n/a
MDAR framework recommends adoption of discipline-specific guidelines, established and endorsed through community initiatives. Journals have their own policy about requiring specific guidelines and recommendations to complement MDAR.		
State if relevant guidelines (eg., ICMJE, MIBBI, ARRIVE) have been followed, and whether a checklist (eg., CONSORT, PRISMA, ARRIVE) is provided with the manuscript.	Yes, ICMJE, and TREND (Transparent Reporting of Evaluations with Nonrandomized Designs) reporting checklist.	

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