TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported? ✓	Reported? Pg #
Title and Abstract				
Title and Abstract	1	• Information on how unit were allocated to interventions	V	Abstract
		• Structured abstract recommended	V	Abstract
		• Information on target population or study sample	V	Abstract
Introduction				
Background	2	• Scientific background and explanation of rationale	V	Introduction
		• Theories used in designing behavioral interventions		
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	V	Eligibility, recruitment and follow up
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	V	Eligibility, recruitment and follow up
		• Recruitment setting	V	Methods
		• Settings and locations where the data were collected	V	Methods
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	V	Tissue collection, isolation and culture of cancer cells; Immunofluorescence characterization of spheres; In vitro sensitivity assay
		○ Content: what was given?	V	(same for all bullets in item#4)
		○ Delivery method: how was the content given?	V	
		○ Unit of delivery: how were the subjects grouped during delivery?	V	
		○ Deliverer: who delivered the intervention?	V	
		○ Setting: where was the intervention delivered?	V	
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	V	
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	V	
		○ Activities to increase compliance or adherence (e.g., incentives)		
Objectives	5	• Specific objectives and hypotheses	V	Eligibility, recruitment and follow up
Outcomes	6	• Clearly defined primary and secondary outcome measures	V	
		• Methods used to collect data and any methods used to enhance the quality of measurements		
		• Information on validated instruments such as psychometric and biometric properties		
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	V	Eligibility, recruitment and follow up
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	V	Tissue collection, isolation and cultu of cancer cells
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)		
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)		

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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.	v	Eligibility, recruitment and follow up
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	v	Statistical analysis
		• 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)		
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	v	Statistical analysis
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis		
		• Methods for imputing missing data, if used		
		• Statistical software or programs used		
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)	v	Patient characteristics
		○ Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	v	Patient characteristics
		○ Assignment: the numbers of participants assigned to a study condition	v	Patient characteristics
		○ Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	v	Patient characteristics CSC isolation and sensitivity
		○ 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	v	Patient characteristics
		○ Analysis: the number of participants included in or excluded from the main analysis, by study condition	v	Patient characteristics
		• Description of protocol deviations from study as planned, along with reasons	v	Eligibility, recruitment and follow up
Recruitment	13	• Dates defining the periods of recruitment and follow-up	v	Patient characteristics
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	v	Patient characteristics
		• Baseline characteristics for each study condition relevant to specific disease prevention research	v	Patient characteristics; CSC isolation and sensitivity assay
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition		
		• Comparison between study population at baseline and target population of interest	v	Patient characteristics; CSC isolation and sensitivity assay
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences		

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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	V	Statistical analysis; Patient characteristics; CSC isolation and sensitivity assay
		• Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses	V	Statistical analysis
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	V	Statistical analysis; Patient characteristics; CSC isolation and sensitivity assay
		• Inclusion of null and negative findings		
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any		
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	V	Patient characteristics; CSC isolation and sensitivity assay; Patient treatment
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)	V	Cancer stem cells isolation and sensitivity assay
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	V	Discussion
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	V	Discussion
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	V	Discussion
		• Discussion of research, programmatic, or policy implications		
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	V	Discussion
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	V	Discussion

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