CLIMBR

Checklist for Investigating Mechanisms in Behavior-change Research

SOBC | Science Of Behavior Change

Purpose of this checklist:

The goal of developing and optimizing interventions intended to change human behavior may be more effectively realized when researchers study and report on potential mechanisms of behavior change in a standardized way. The NIH Science of Behavior Change (SOBC) is a trans-NIH initiative focused on the mechanisms of behavior change. SOBC embraces five core principles. First, identified mechanisms should be grounded in theory and/or prior empirical work. Second, mechanisms cannot be tested unless they are measured. Third, measures of mechanisms should be valid and reliable ways of measuring the construct of interest (i.e., good psychometric properties are needed). Fourth, transparent sharing of scientific findings—both positive *and* negative—promotes progress in mechanism-focused behavior-change research. Finally, a putative mechanism shows evidence of explaining behavior if all of the following are true: (A) an intervention can affect a measure of the mechanism, (B) the measured mechanism is associated with a behavior-change outcome, and (C) the intervention-related changes in the measured mechanism are associated with changes in the behavior. The Checklist for Investigating Mechanisms in Behavior-change Research (CLIMBR) was created as part of the SOBC initiative to serve as a resource to applied and basic behavioral scientists who study mechanisms of behavior change. CLIMBR is an easy-to-use checklist of guidelines for reporting the findings of behavioral intervention development studies to advance mechanism-focused science. Each item (row) in the checklist reflect one or more of the five SOBC principles noted above, and each of the three columns is applicable to a different behavior-change research design. For ease of use, the sections of CLIMBR reflect the standard organization of a scientific manuscript. For the purposes of this checklist, behavioral outcomes include typical health behaviors (e.g., physical activity, medication adherence, and sleep), but this checklist may also be applied to research on other outcomes of interest to behavioral health researchers (e.g., moods, emotions, cognitions, physical states). Mechanisms include any potentially modifiable and measurable constructs that are hypothesized to drive behavior change. Manipulations and interventions include any procedures designed to change a potential mechanism and/or a behavioral outcome.

To use CLIMBR, identify which column corresponds to the type of study you will report, and follow the instructions for that columns' items only. Some items span all three columns.

- **Column A (X → M)** should be used to report the results of studies that investigate the effect(s) of an intervention or manipulation (X) on a putative mechanism of behavior change (M), *without* measuring a behavior change outcome (Y).
- **Column B (M → Y)** should be used to report the results of studies that investigate the association between a putative mechanism of behavior change (M) and a behavior change outcome (Y), *without* including an intervention or manipulation (M).
- **Column C (X → M → Y)** should be used to report the results of studies that investigate the effect(s) of an intervention or manipulation (X) on a behavior change outcome (Y) and test whether a putative mechanism of behavior change (M) can explain these changes in behavior via a test of mediation.

To facilitate the manuscript review process, the NIH's SOBC recommends that authors include the completed checklist together with their submitted manuscripts (in addition to the CONSORT diagram, if appropriate). If particular items cannot be satisfied, the 'Reported on page #' field should be reported as "N/A," and the authors should briefly explain the reasons for not adhering to the guidelines (e.g., space limitations in the abstract).

Section/topic	#	**A: For studies that investigate the effect(s) of an <u>intervention or manipulation</u> (X) on a <u>putative mechanism of behavior change</u> (M), *<u>without</u>* measuring a behavior change outcome (Y)** **X → M** <u>Example</u>: a study of the effects of a mindfulness intervention on self-compassion	**B: For studies that investigate the association between a <u>putative mechanism of behavior change</u> (M) and a <u>behavior change outcome (Y)</u>, *without* including an intervention or manipulation (M)** **M → Y** <u>Example</u>: a study of the relationship between stress reactivity and nicotine use	**C: For studies that investigate the effect(s) of an <u>intervention or manipulation</u> (X) on a <u>behavior-change outcome</u> (Y) and <u>test whether a putative mechanism of behavior change (M) can explain these changes in behavior.</u>** **X → M → Y** <u>Example</u>: a randomized controlled trial of the effects of an episodic future thinking intervention on seatbelt use as mediated by future time perspective	**Reported on page #**
TITLE					
Title	1	If space allows, the title should refer to one or more mechanisms of behavior change as well as the intervention or manipulation. If the journal guidelines allow it, then titles that are informative rather than neutral about the study findings should be considered.	If space allows, the title should refer to one or more mechanisms of behavior change. If the journal guidelines allow it, then titles that are informative rather than neutral about the study findings should be considered.	If space allows, the title should refer to one or more mechanisms of behavior change as well as the intervention or manipulation. If the journal guidelines allow it, then titles that are informative rather than neutral about the study findings should be considered.	
<u>Author action</u>					
ABSTRACT					
Identify mechanism(s) and behavior(s)	2	Specify at least one hypothesized mechanism of behavior change, and specify at least one behavior.			
<u>Author action</u>					

Reporting of intervention-mechanism association	3	Report the degree to which the intervention engaged the mechanism. That is, report the effect size that represents the difference between the intervention and control groups in (1) a post-intervention measure of the mechanism and/or (2) a pre-to-post change in the measure of the mechanism.	*<Not applicable for this study design>*	Report the degree to which the intervention engaged the mechanism. That is, report the effect size that represents the difference between the intervention and control groups in (1) a post-intervention measure of the mechanism and/or (2) a pre-to-post change in the measure of the mechanism.	
Author action					
Reporting of mechanism-behavior change association	4	*<Not applicable for this study design>*	Report the degree to which a measure of an identified mechanism was associated with a behavioral outcome.	For a randomized controlled trial, report the degree to which the intervention-vs-control difference in an identified mechanism was associated with a behavioral outcome. Furthermore, in trials in which a mediation test was conducted to test a potential mechanism's role in an intervention-behavior association, then report the indirect effect (path a*b) for the mediation analysis.	
Author action					

INTRODUCTION					
Identify mechanism(s)	5	Specify *a priori* at least one hypothesized mechanism of behavior change. Describe the causal model implied by the selected mechanism, as well as the level at which the mechanism is thought to operate in this study (e.g., neural, cognitive, behavioral, interpersonal, policy). If relevant, state whether the present mechanism is thought to work in conjunction with the other mechanisms.			
Author action					
Refer to a relevant behavioral outcome	6	Specify a priori at least one behavioral outcome that is relevant to the hypothesized mechanism(s) of behavior change, even though the present study does not measure a change in behavior.	Specify a priori at least one behavioral outcome that is relevant to the hypothesized mechanism(s) of behavior change.	Specify a priori at least one behavioral outcome that is relevant to the hypothesized mechanism(s) of behavior change.	
Author action					
Provide rationale for mechanism(s)	7	Provide clear and appropriate documentation of theory and/or prior evidence that suggests that the mechanism could be engaged by an intervention/manipulation. Mechanism engagement is defined as change in a mechanism that may be attributed to the effects of an intervention/manipulation. If such support is insufficient or if relevant research is currently lacking, then explain the rationale for the selected mechanism(s).	Provide clear and appropriate documentation of theory and/or prior evidence that suggests that the mechanism is associated with a behavioral outcome investigated in the study. If such support is insufficient or if relevant research is currently lacking, then explain the rationale for the selected mechanism(s).	Provide clear and appropriate documentation of theory and/or prior evidence that suggests that (1) the mechanism could be engaged by an intervention and (2) the mechanism is associated with a behavioral outcome investigated in the study. Mechanism engagement is defined as change in a mechanism that may be attributed to the effects of an intervention. If such support is insufficient or if relevant research is currently lacking, then explain the rationale for the selected mechanism(s).	
Author action					

METHOD					
Construct validity of each mechanism's measure(s)	8	Cite prior research for each of the included measures of the hypothesized mechanism(s) that provides evidence of adequate construct validity. Provide evidence of convergent and divergent validity as available. If evidence of validity is poor or absent for a given measure, then provide a rationale for the inclusion of the particular measure(s) in spite of that limitation.			
Author action					
Reliability of each mechanism's measure(s)	9	Cite prior research for each of the included measures of the hypothesized mechanism(s) that provides evidence of adequate reliability (e.g., good internal consistency).			
Author action					
Expected intervention/ manipulation effects on measured mechanism(s)	10	Describe the intervention or manipulation to be tested, including active components. Specify how the intervention or manipulation was believed to engage the mechanism. Specify why the control condition was believed *not* to engage the mechanism. In the case of multiple studied mechanisms or multiple studied interventions/manipulations, describe which mechanism(s) was/were expected to be engaged by which intervention(s)/manipulation(s).	*<Not applicable for this study design>*	Describe the intervention or manipulation to be tested, including active components. Specify how the intervention or manipulation was believed to engage the mechanism. Specify why the control condition was believed *not* to engage the mechanism. In the case of multiple studied mechanisms or multiple studied interventions/manipulations, describe which mechanism(s) was/were expected to be engaged by which intervention(s)/manipulation(s).	
Author action					

Behavioral outcome measure	11	*<Not applicable for this study design>*	Describe any behavioral outcome measures included and the measurement properties of each.	Describe any behavioral outcome measures included and the measurement properties of each.	
Author action					
RESULTS					
Sample size justification	12	Report the results of an *a priori* power analysis to determine the sample size needed to have sufficient statistical power to detect an intervention effect on the measure of each hypothesized mechanism. Provide an effect size justification for each effect used in the power analysis.	Report the results of an *a priori* power analysis to determine the sample size needed to have sufficient statistical power to detect (1) a meaningful association between an identified mechanism and behavioral outcome and (2) a meaningful association between the degree of change in an identified mechanism and a change in a clinical outcome. Provide an effect size justification for each effect used in the power analysis.	Report the results of an *a priori* power analysis to determine the sample size needed to have sufficient statistical power to detect: (1) a meaningful association between an identified mechanism and behavioral outcome, (2) an intervention effect on the measure of each hypothesized mechanism, and (3) a meaningful association between the degree of change in an identified mechanism and a change in a clinical outcome. Provide an effect size justification for each effect used in the power analysis.	
Author action					

Measured reliability	13	Report the internal consistency reliability using the present study's data for each measure of each mechanism.			
Author action					
Measured construct validity	14	If relevant data were gathered, report findings related to convergent and divergent validity in the present study for each measure of each mechanism.			
Author action					
Observed effect size of intervention or manipulation on measured mechanism(s)*	**15**	Report the effect(s) of the intervention on the measure(s) of each of the hypothesized mechanisms. In the case of a randomized controlled trial, report the standardized effect size (e.g., Cohen's *d*, Hedges' *g*) and its confidence interval comparing the experimental group to the comparison group. If applicable, consider reporting the success rate difference, its confidence interval, and the number-needed-to-treat. If available, also report the within-subjects change in the measured mechanism for each group.	*<Not applicable for this study design>*	Report the effect(s) of the intervention on the measure(s) of each of the hypothesized mechanisms. In the case of a randomized controlled trial, report the standardized effect size (e.g., Cohen's *d*, Hedges' *g*) and its confidence interval comparing the experimental group to the comparison group. If applicable, consider reporting the success rate difference, its confidence interval, and the number-needed-to-treat. If available, also report the within-subjects change in the measured mechanism for each group.	
Author action					

Observed effect size of measured mechanism(s) on target behavior*	**16**	*<Not applicable for this study design>*	Report the association(s) between the measure(s) of each of the hypothesized mechanisms and the target behavior. Report the results of the association, including the effect size (e.g., standardized coefficient) and its 95% confidence interval.	Report the association(s) between the measure(s) of each of the hypothesized mechanisms and the target behavior. Report the results of the association, including the effect size (e.g., standardized coefficient) and its 95% confidence interval.	
Author action					
Observed extent of behavior change associated with mechanism change*	**17**	*<Not applicable for this study design>*	Report the association between *changes* in measure(s) of the identified mechanism(s) and *changes* in at least one behavioral outcome. This test can take multiple forms (e.g., a simple zero-order correlation, an association in a regression model). It should include assessments of change over time (e.g., not measures of the two constructs at a single time point). If appropriate, consider the use of random-effects models to tease apart within-person changes from between-person differences.	Report the association between *changes* in measure(s) of the identified mechanism(s) and *changes* in at least one behavioral outcome. This test can take multiple forms (e.g., a simple zero-order correlation, an association in a regression model). It should include assessments of change over time (e.g., not measures of the two constructs at a single time point). If appropriate, consider the use of random-effects models to tease apart within-person changes from between-person differences.	
Author action					

Evidence for mediation by the measured mechanism(s)	18	*<Not applicable for this study design>*	*<Not applicable for this study design>*	Conduct and report the results of a mediation test to assess the standardized effect size of the indirect effect of each measured mechanism. That is, report the extent to which the intervention's effect on a target behavior was mediated by the measured mechanism of action. Ideally, the mediation test should model the proposed mediator as *change* in the measured mechanism and model the outcome as *change* in the behavior. If a mediation test of change is not possible due to the study design, then a cross- sectional mediation analysis should be reported instead. Proper care should be taken to conduct and interpret the mediation results properly, including accounting for potential confounders using covariates, as appropriate, and assessing possible treatment-by-mediator interactions.	
Author action					

DISCUSSION					
Consider the intervention's effect on the mechanism(s)	19	Provide an interpretation of the findings that address the extent to which the intervention/manipulation in question may have shifted one or more hypothesized mechanisms of interest that are relevant to a target behavioral outcome. Consider the intervention's characteristics (e.g., dose, frequency, duration). Consider also the time elapsed between the conclusion of the intervention/manipulation and the subsequent assessment time of the measured mechanism (i.e., short- vs. long-term change). Consider and discuss the possibility that one or more *unmeasured* constructs that may have been correlated with the measured mechanism may have been partially responsible for any observed effects.	*<Not applicable for this study design>*	Provide an interpretation of the findings that address the extent to which the intervention/manipulation in question may have shifted one or more hypothesized mechanisms of action that are relevant to a target behavior. Consider the intervention's characteristics (e.g., dose, frequency, duration). Consider also the time elapsed between the conclusion of the intervention/manipulation and the subsequent assessment time of the measured mechanism (i.e., short- vs. long-term change). Consider and discuss the possibility that one or more *unmeasured* constructs that may have been correlated with the measured mechanism may have been partially responsible for any observed effects.	
Author action					

Consider the association(s) of the mechanism(s) with behavior change	20	*<Not applicable for this study design>*	Provide an interpretation of the findings that address the extent to which one or more hypothesized mechanisms of interest were associated with change in a target behavior. Consider whether the measured mechanism and the behavior were each assessed via self-report or via differing methodologies.	Provide an interpretation of the findings that address the extent to which one or more hypothesized mechanisms of interest were associated with change in a target behavior. Consider whether the measured mechanism and the behavior were each assessed via self-report or via differing methodologies.	
Author action					
Consider the evidence for mediation	21	*<Not applicable for this study design>*	*<Not applicable for this study design>*	Discuss the strength of evidence (or lack thereof) that each of the measured mechanisms may underlie changes in behavior resulting from effects of the intervention.	
Author action					
OTHER INFORMATION					
Study protocol	22	If a protocol for the study exists (e.g., clinicaltrials.gov, Open Science Framework), then provide the relevant information in the manuscript. Similarly, if a protocol paper has been published, that should also be cited.			
Author action					

Note. The bolded items that are accompanied by the * symbol are the essential components that should be included to report on findings that investigate potential mechanisms in behavioral research.