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Improving the Rigor of Mechanistic Behavioral Science: The Introduction of the Checklist for Investigating Mechanisms in Behavior-Change Research (CLIMBR)

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Diverse fields rely on the development of effective interventions to change human behaviors, such as following prescribed medical regimens, engaging in recommended levels of physical activity, getting vaccinations that promote individual and public health, and getting a healthy amount of sleep. Despite recent advancements in behavioral intervention development and behavior-change science, systematic progress is stalled by the lack of a systematic approach to identifying and targeting mechanisms of action that underlie successful behavior change. Further progress in behavioral intervention science requires that mechanisms be universally prespecified, measurable, and malleable. We developed the CheckList for Investigating Mechanisms in Behavior-change Research (CLIMBR) to guide basic and applied researchers in the planning and reporting of manipulations and interventions relevant to understanding the underlying active ingredients that do—or do not—drive successful change in behavioral outcomes. We report the rationale for creating CLIMBR and detail the processes of its development and refinement based on feedback from behavior-change experts and NIH officials. The final version of CLIMBR is included in full.

Keywords: reporting guidelines; behavior change; mechanisms of action

Over the past two decades, research on human behavior change has advanced due to the systematic development and coding of behavior change techniques (BCTs; Michie et al., 2013), the continued refinement of new, objective measures of health behaviors (e.g., sedentary behavior, dose-missing medication nonadherence, ingestive behavior; Diaz et al., 2017; Kronish et al., 2021; Rollo et al., 2016), and the rapid expansion of promising internet-based interventions to change human health behaviors (Webb et al., 2010). Despite these notable developments, however, research that aims to understand the mechanisms underlying successful behavior change is currently still not universally conducted or reported in ways that are optimized for allowing a systematic, cumulative advancement of scientific knowledge (Sumner et al., 2018). Indeed, much of behavior change research has been plagued by a failure to reveal exactly which mechanisms make successful interventions effective (Rothman & Sheeran, 2021).

During the last decade, many health behavior researchers have reasoned that investigating mechanisms—whether neural, cognitive, interpersonal, environmental, systemic, etc.—is necessary for developing reliably effective interventions (e.g., group-based health behavior change interventions; Borek et al., 2019; action planning and implementation intention interventions; Hagger & Luszczynska, 2014; social-cognitive mechanisms underlying health behavior change interventions; Schwarzer et al., 2011). First, a mechanistic understanding is crucial for determining whether the theories that motivate selection of specific interventions or intervention components are empirically supported. Relatedly, a mechanistic understanding helps to delineate similarities and differences between theories that support the same intervention for potentially different reasons. Even interventions that are implemented with perfect fidelity will *not* be effective if the assumed theory-driven mechanisms are ultimately irrelevant to changing the outcome of interest (Astbury & Leeuw, 2010). A second reason for focusing on mechanisms throughout intervention development and testing is the high degree of heterogeneity in observed efficacy of behavioral interventions, very little of which is explained by measuring moderators alone (i.e., between-subjects factors responsible for effect modification; see Rothman & Sheeran, 2021, for a review of 46 meta-analyses). Because the field of behavioral medicine research has not yet adopted the proposed mechanistic focus, we rarely know *why* health behavior interventions fail—or even why they work, when they do, and for whom they will work in future trials. Mechanism-focused behavioral science allows us to ask questions such as, Are the observed differences in intervention efficacy due to failure to engage the mechanisms that underlie successful behavior change? Or, conversely, do some mechanisms precipitate behavior change in some samples and not others?

The literature on medication adherence illustrates this deficit and the need for scientists to adopt new practices. Proper medication adherence is reliably associated with prevention of adverse medical outcomes (e.g., major adverse cardiovascular events, mortality) and substantially reduced health care costs (Bitton et al., 2013; Chowdhury et al., 2013). Thus, improving adherence to prescribed medications is a ripe target for improving health outcomes through behavioral intervention. Indeed, by 2018, the National Institutes of Health (NIH) had funded 62 RCTs for which medication adherence was a primary ($n = 18$ studies) or secondary ($n = 44$ studies) outcome. However, only 2 of those trials (~3%) measured a hypothesized mechanism of action (Edmondson et al., 2018).

The NIH Science of Behavior Change (SOBC) program promotes widespread adoption of the experimental medicine approach to identifying mechanisms of behavior change, optimizing intervention development based on their ability to influence identified mechanisms, testing hypothesized mechanistic pathways in subsequent RCTs, and leveraging mechanistic knowledge to efficiently disseminate interventions that are shown to improve human health behaviors through known mechanisms (Nielsen et al., 2018; Riddle & Science of Behavior Change Working Group, 2015). Similar principles apply when designing interventions to improve economic behaviors, social behaviors, and more. Only through broad adoption of the experimental medicine approach, consistent measurement of mechanisms using valid instruments, and consistent reporting of positive and null findings can the field expect to consistently deliver interventions that work and can be deployed at scale.

Each discovery of an underlying mechanism that, when intervened upon successfully, yields observable behavior change must be reported consistently by researchers so that other scientists can build upon that discovery. In a field that prioritizes mechanisms, each study contributes to a cumulative science that promotes incremental improvement in the speed of effective intervention development by better exploiting established mechanistic pathways or expanding the intervention's influence to concurrently activate multiple

mechanistic pathways. The present paper outlines the development of a resource designed to address this need: the CheckList for Investigating Mechanisms in Behavior-change Research (CLIMBR).

CLIMBR was created to explicate and formalize the necessary steps for rigorously applying the experimental medicine approach to behavior change research, according to the NIH SOBC program's guiding principles. The overarching goal of this effort was to provide a helpful resource to guide the conduct and reporting of mechanism-focused research and to maximize precision, consistency, and transparency in results reporting. The development of the checklist was informed by six core SOBC principles: (1) putative mechanisms of behavior change should be identified (i.e., hypothesized *a priori*) explicitly and logically; (2) mechanisms should be measured (not simply invoked as likely or assumed drivers of change); (3) assays (i.e., measures) of mechanisms should be psychometrically sound; (4) all empirical results related to mechanisms (including null findings) should be shared with the scientific community; (5) a putative mechanism should be prioritized for experimental manipulation to engage it once (a) a valid measure of the mechanism that could reasonably be changed by manipulation/intervention is identified and (b) observed change in the valid measure of that mechanism has been reliably associated with change in a valid measure(s) of behavior in observational studies; and (6) a putative mechanism of behavior change will be considered a demonstrated driver of behavior change if (a) a valid measure of that mechanism can be reliably engaged (i.e., changed in the predicted direction) by an intervention component and (b) change in the measured mechanism subsequently and reliably leads to observable change in the predicted direction on a valid measure of behavior, in at least one population.

The CLIMBR checklist is designed to improve the quality of scientific research and its dissemination, similar to other checklists. For example, the Consolidated Standards of Reporting Trials (CONSORT; Altman et al., 2001; Schulz et al., 2010), the Strengthening the Reporting of Observational Studies in Epidemiology checklist (STROBE; Von Elm et al., 2007), and the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA; Page et al., 2021) are widely used checklists that address, respectively, the reporting of randomized trials (CONSORT), observational studies (STROBE), and systematic reviews and meta-analyses (PRISMA). These existing checklists have improved research by significantly increasing the completeness of reported information (Liu et al., 2019; Turner et al., 2012), as well as standardizing study designs and formalizing best practices. It is our hope that CLIMBR will similarly increase the rigor and reporting of mechanism-focused behavior change research.

Checklist Development

The checklist was developed in three stages. First, a CLIMBR executive committee was assembled with five members drawn from the NIH SOBC Resource and Coordinating Center and its multiple working groups. The CLIMBR executive committee (the authors of the present manuscript) drafted the initial version of the checklist according to the SOBC principles outlined above. It was determined at the outset of development that the checklist should be compatible with the NIH Stage Model for intervention development (Onken, 2019), due to the core emphasis on incorporating basic science questions about mechanisms into every stage of clinical science research in the stage model. However, it was also decided that the checklist items should not dictate exactly how the stage model must be mapped onto mechanistic research, because not all mechanistic behavioral research is explicitly intervention-focused at inception, and to prioritize ease of use for all researchers who use CLIMBR.

Second, the CLIMBR committee revised and expanded the checklist based on feedback from discussions with SOBC's NIH program officer and other NIH officials associated with the initiative. The checklist was expanded to encompass not only RCTs, but also experimental study designs relevant to modulating potential mechanisms of behavior change and observational or correlational study designs. During this phase, CLIMBR acquired a multiple-column structure to accommodate basic and applied researchers from a wide variety of disciplines. The first column corresponds to "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)." This category could pertain to psychological scientists who conduct manipulations intended to influence psychological outcomes that may be considered potential mechanisms of behavior change (e.g., mindfulness training intended to increase self-compassion). The second column corresponds to "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)" (e.g., examining the relationship between stress

reactivity and nicotine use). The third and final column corresponds to "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" (e.g., a randomized controlled trial of the effects of an episodic future thinking intervention on seatbelt use as mediated by future time perspective).

The third stage of development for the checklist began with an open-comment period. The initial open-comment phase lasted from June 10, 2022 to July 8, 2022. A link to the checklist and an open-comment portal (hosted at Boston University via REDCap) was distributed directly via email to 18 experts in behavior change research to invite their written feedback. These invited experts included editors at six relevant journals (in alphabetical order: *Annals of Behavioral Medicine*, *Behavior Therapy*, *General Hospital Psychiatry*, *Health Psychology*, *Social Science & Medicine*, and *Translational Behavioral Medicine*) and members of the Behavioral Medicine Research Council. (Note that only a subset of the invited experts at the organizations listed above chose to provide feedback.) An invitation to a second open-comment period from July 8, 2022 to July 29, 2022 was extended to researchers via Twitter (SOBC account and shared by SOBC affiliates) and via the SOBC website to capture a broader range of stakeholder feedback. All commentors who offered feedback and suggestions via the open-comment portal were given the option to respond anonymously or to provide their names. The executive committee discussed the feedback point by point and revised the checklist in line with submitted suggestions. The content of the feedback and its incorporation in the finalized checklist are described below.

Expert Feedback

The open-comment period yielded a total of 26 comments, including 18 comments from invited experts and 8 comments from NIH program officials. In addition to positive comments supporting the mission of CLIMBR and selected details of the approach, commenters highlighted the following concerns and suggestions for revision. These suggestions can be grouped in three broad categories. First, suggestions were made about how to use the checklist, and these suggestions affected the content of the preamble to the checklist or the column headings. Examples under this category include adding the labels "X" (intervention or manipulation), "M" (mechanism), and "Y" (behavioral outcome) to the checklist columns, clarifying whether a mechanism can itself be a behavior, clarifying the wide scope of potential behavioral outcomes, defining the meaning of "interventions" and "manipulations" in the context of the checklist, and encouraging researchers to submit their completed CLIMBR and CONSORT checklists together during the review process of a manuscript, if appropriate. A second group of comments referred to elements to be ideally included either in the analytic design or the reported findings. These types of comments affected the items in the checklist's results section, for example, the recommended use of random-effects models, reporting not only between-group effects but also within-subject changes, reporting the success rate difference when appropriate, and reporting not only mediation effects but also treatment-by-mediator interaction effects. A third category of comments included miscellaneous suggestions that affected checklist items *not* in the results section. Examples included specifying a potential behavioral outcome of interest in a manuscript's introduction even if the reported study did not measure any behaviors, explicitly considering (e.g., in a manuscript's discussion section) whether one or more unmeasured constructs may have been partially responsible for any observed effects, and a recommendation for manuscript titles to be informative about results.

Finalization of the Checklist

The members of the CLIMBR executive committee drafted and circulated suggestions for changes based on the assembled comments, along with a written rationale for the wording of each suggested addition or edit, internally. The committee reached consensus via sharing revised versions of the document and via electronic discussions of the suggested edits. Twenty-five of the 26 comments (96%) resulted in edits to the checklist. The only comment that did not result in an edit to the checklist was a concern from one reviewer that CLIMBR may cause manuscript or grant reviewers, or scientists themselves, to view other (i.e., non-CLIMBR) approaches to behavior-change research negatively. Although we appreciate this potential concern, we believe that the checklist does not merit a special notice of caution in this regard. If research pertains to proposed mechanisms that are *not* modifiable, then the experimental medicine approach—and thus the checklist—would not apply. However, it is our hope that any research on putatively changeable mechanisms would benefit from the application of this framework because the goal of CLIMBR is to improve behavior change research on potentially modifiable mechanisms. The full version of

the final checklist is provided in Appendix A. The checklist is also available on the SOBC website (https://scienceofbehaviorchange.org/resources/).

Future Directions

An important focus for the future will be to ensure that journal editors, grant reviewers, and behavior-change researchers working in diverse disciplines are aware of CLIMBR, its rationale, and its use cases. To achieve this goal, partnerships between SOBC and relevant research organizations (e.g., behavioral medicine research groups, journals) may be established to encourage the use of the checklist by scientists writing grant applications, designing studies, and disseminating findings relevant to understanding the drivers of behavior change. We plan to share an instructional how-to video to demonstrate how basic scientists and applied researchers can apply CLIMBR to their own research domains using a variety of study designs (e.g., lab-based experiments intended to modulate psychological constructs, randomized controlled trials targeting mechanisms and the real-world health behaviors they drive). CLIMBR will also be disseminated via conference presentations and workshops to reach broad audiences.

Conclusions

CLIMBR is an easy-to-use, comprehensive checklist that details the necessary components researchers should include to conduct mechanism-focused behavioral intervention science that advances the field. It includes the items to be reported in manuscripts to demonstrate that behavior-change research has been conducted rigorously and transparently in line with a focus on understanding the modifiable mechanisms that underlie behavior change. Applying CLIMBR is also useful for enhancing the rigor and competitiveness of grant applications that address behavior-change research questions, as it can ensure that grant writers describe all necessary features of impactful mechanistic research designs. If broadly employed, CLIMBR will accomplish the fundamental goal of the NIH-funded Science of Behavior Change (SOBC; https://scienceofbehaviorchange.org; https://www.nia.nih.gov/research/dbsr/science-behavior-change-sobc) to bring about a generational boost to the rigor, reproducibility, and cumulative impact of behavioral science through the field's adoption of research practices that reveal the underlying mechanisms of behavior change in ways that allow for steady accumulation of knowledge, easy harmonization of data, and growing efficiency, efficacy, and scalability of interventions.

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