EMBRACE
Establishing Mechanisms of Benefit to Reinforce the Alzheimer's Care Experience

Emory Roybal Center for Dementia Caregiving Mastery

A guide for conducting rigorous mechanistic research with behavioral interventions:

Introducing the Checklist for Investigating Mechanisms in Behavior-change Research (CLIMBR)

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Columbia | Columbia University Irving Medical Center

SOBC Science Of Behavior Change

Disclosures

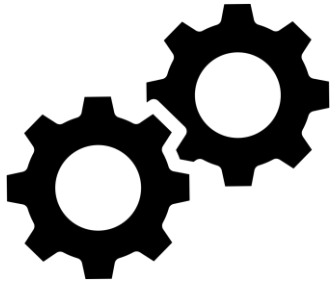
No disclosures

Outline

- Current trends in behavioral intervention research
- The value of rigorous mechanistic research in behavior-change science
  - *Measured mechanisms matter*
- The creation of a new resource: CLIMBR
  - CLIMBR's development process
  - How to use CLIMBR
- How to find measures of mechanisms
  - The SOBC Measures Repository
- How to address some common challenges in mechanism-focused research

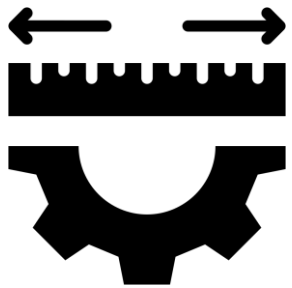
Learning Objectives

1. Understand the importance of **testing mechanisms** in behavior-change research.



2. Learn **how to access and use** the **CLIMBR** resource.

3. Learn **how to access and use** the **SOBC Measures Repository**.



4. Be prepared **to overcome challenges**.

Current trends in behavioral intervention research

- Health behavior intervention research is proliferating in many areas (e.g., medication adherence, sleep, diet, physical activity).

- This research has benefitted greatly from:
  - Identification of behavior change techniques (BCTs) (Michie et al., 2013).
  - Objective measurement of health behaviors (e.g., Diaz et al., 2017; Kronish et al., 2021; Rollo et al., 2016).
  - An explosion of internet-based interventions (e.g., Webb et al., 2010)
  - Adoption of sophisticated and adaptive designs (e.g., MOST, SMART; Collins, Murphy, & Strecher, 2007)

- Additionally, the process of synthesizing intervention research has become more consistently rigorous in practice in recent years (e.g., greater adoption of PRISMA; Page & Moher, 2017).

Intervention development continues to be slowed by a lack of understanding about why health interventions work and why they fail.


HEALTH BEHAVIOR
INTERVENTION
CHANGE IN BEHAVIOR

ELSEVIER

Journal of Psychosomatic Research
Volume 149, October 2021, 110585

Review article

Mindfulness-based interventions for medication adherence: A systematic review and narrative synthesis

William R. Nardi [a], Eric B. Loucks [a b c], Stacey Springs [d], Don Operario [a b], Ian M. Kronish [e], Brandon A. Gaudiano [a f g h], Shufang Sun [a]

Taylor & Francis

Substance Use & Misuse

ISSN: 1082-6084 (Print) 1532-2491 (Online) Journal homepage: https://www.tandfonline.com/loi/isum20

Are Mindfulness-Based Interventions Effective for Substance Use Disorders? A Systematic Review of the Evidence

Alberto Chiesa & Alessandro Serretti

The Journal of Alternative and Complementary Medicine > VOL. 26, NO. 8 | Reviews

normal

Effects of Mindfulness-Based Intervention on the Treatment of Problematic Eating Behaviors: A Systematic Review

Jinyue Yu, Peige Song, Yan Zhang, and Zhuang Wei

Published Online: 30 Jul 2020 | https://doi.org/10.1089/acm.2019.0163

obesity reviews

doi: 10.1111/obr.12795

Behavior/Etiology

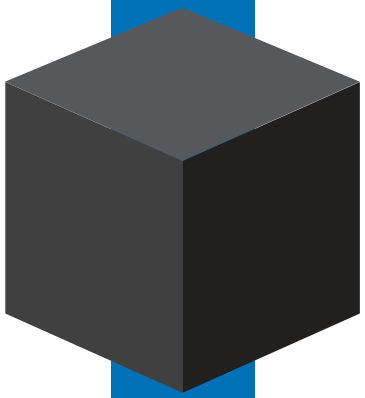
The role of mindfulness in physical activity: a systematic review

J. Schneider[1], P. Malinowski[1], P. M. Watson[2] and P. Lattimore[1]

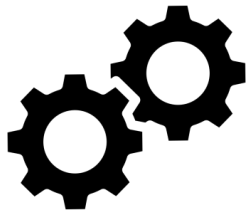

HEALTH BEHAVIOR
INTERVENTION
CHANGE IN BEHAVIOR

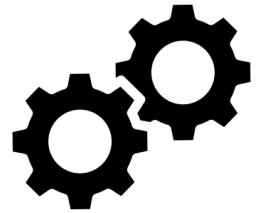
HEALTH BEHAVIOR

INTERVENTION

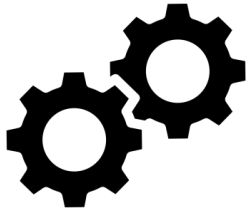


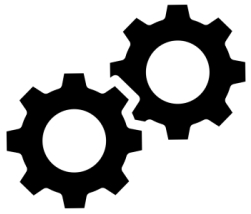
CHANGE IN BEHAVIOR





Just because an intervention is widely and strongly *believed* to target a particular mechanism does not necessarily mean that it *actually engages* that mechanism.





Emotion regulation ability?

Working memory?

Values clarification?

Default mode network connectivity?

But what is the *mechanism*?

Attentional control?

Psychological flexibility?

Sleep quality?

Nardi et al., 2021, *Journal of Psychosomatic Research*.

Shapiro et al., 2006, *Journal of Clinical Psychology*.

Interventions have highly variable effect sizes

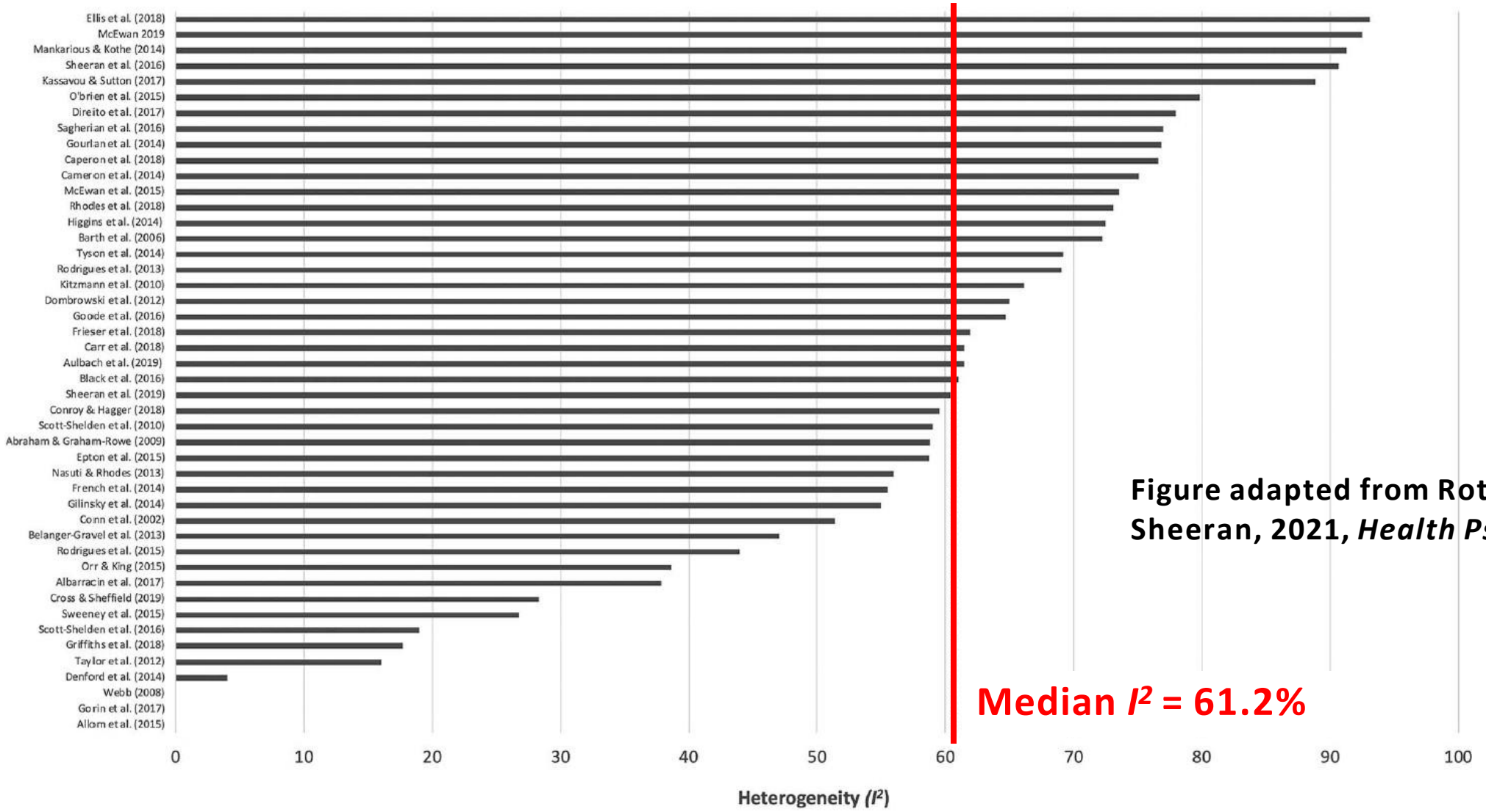


Figure adapted from Rothman & Sheeran, 2021, *Health Psychology*.

Figure 1. Heterogeneity in interventions to change health behaviors: Distribution of I^2 values in 46 meta-analyses.

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Behaviour Research and Therapy

Volume 101, February 2018, Pages 12-19

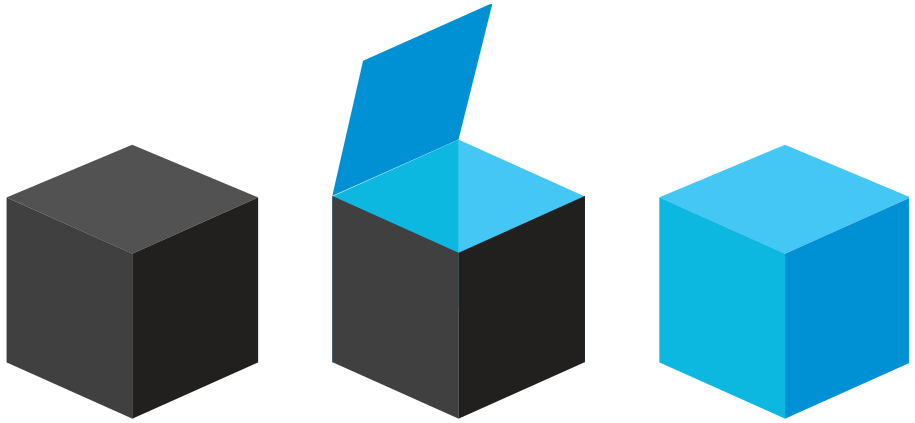
A systematic review of the inclusion of mechanisms of action in NIH-funded intervention trials to improve medication adherence

Donald Edmondson [a], Louise Falzon [a], Kevin J. Sundquist [a], Jacob Julian [a], Laura Meli [a, b], Jennifer A. Sumner [a], Ian M. Kronish [a]

Two of 18 (11%) NIH-funded trials tested a hypothesized mechanism of an intervention's effect on medication adherence. Another 44 studies with medication adherence as a secondary outcome were described in protocol form, and are either ongoing or never published results, but none mentioned mechanism tests. Overall, 3% of NIH-funded trials with adherence as an outcome conducted, or plan to conduct, tests of behavior change mechanisms.

National Institutes of Health

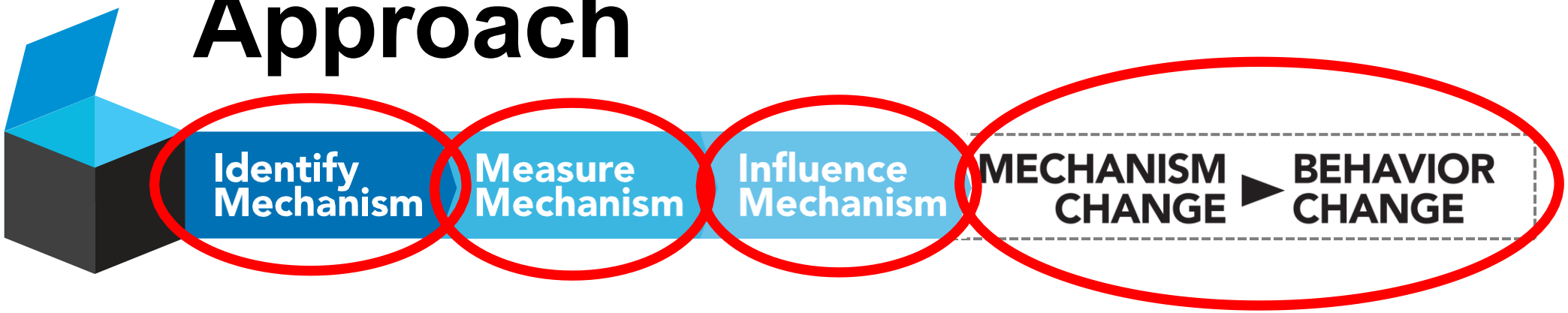
Office of Strategic Coordination - The Common Fund

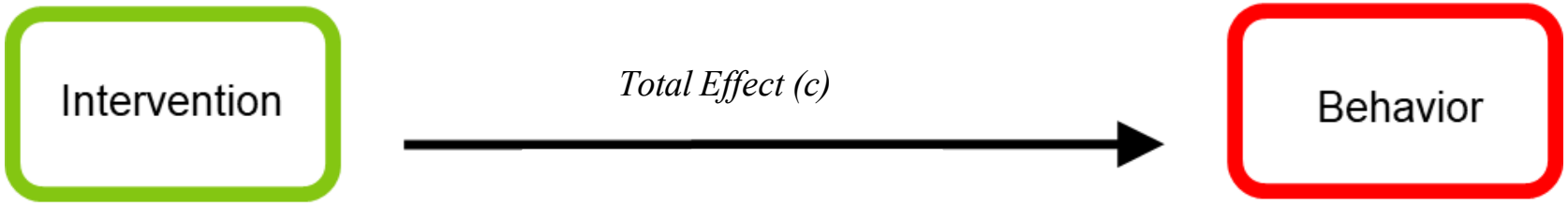


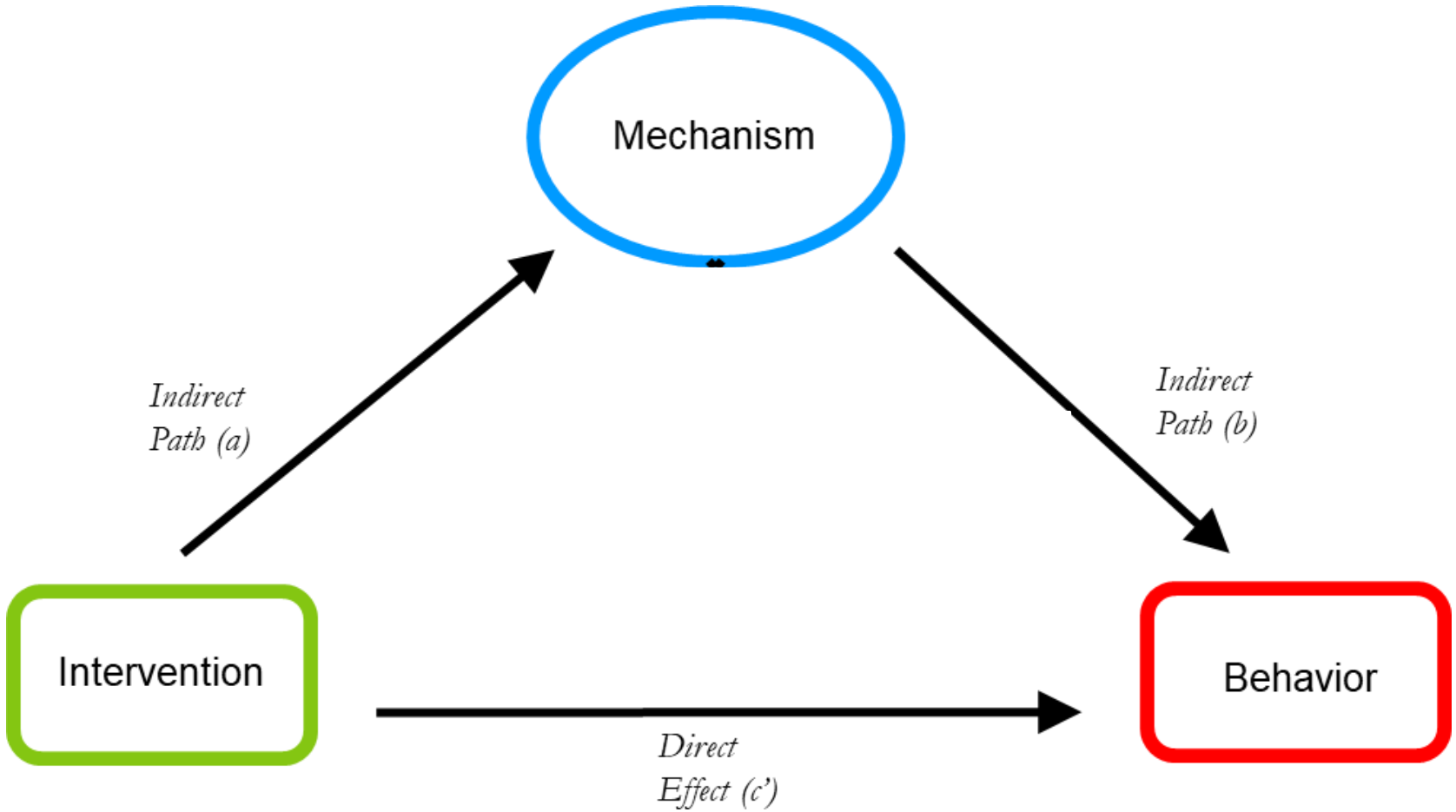
A Common Method

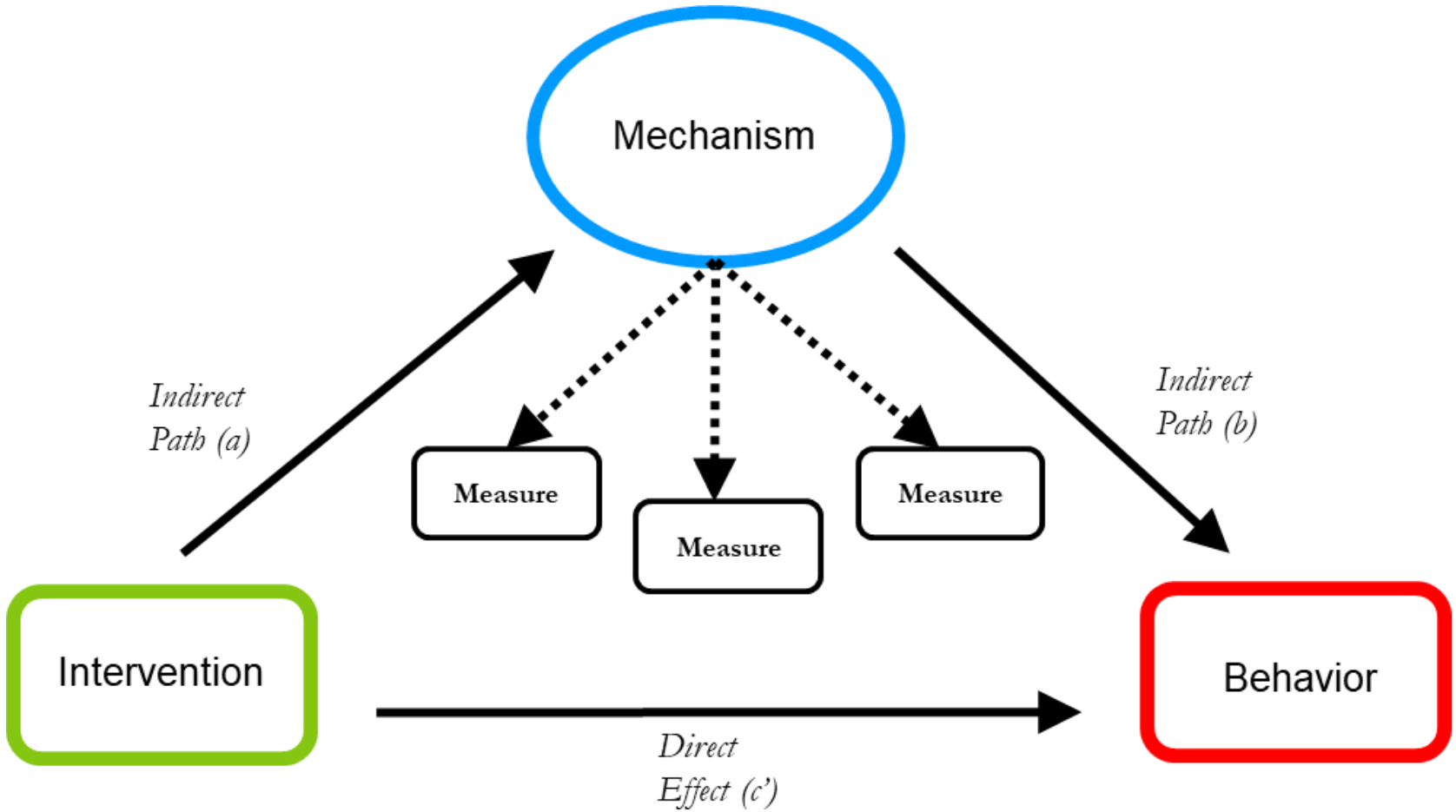
for understanding behavior change.

Experimental Medicine Approach




Intervention
Total Effect (c)
Behavior


Mechanism
Indirect
Path (a)
Indirect
Path (b)
Intervention
Behavior
Direct
Effect (c')


Mechanism
Indirect
Path (a)
Measure
Measure
Measure
Indirect
Path (b)
Intervention
Behavior
Direct
Effect (c')

CLIMBR

Checklist for Investigating Mechanisms in Behavior-change Research

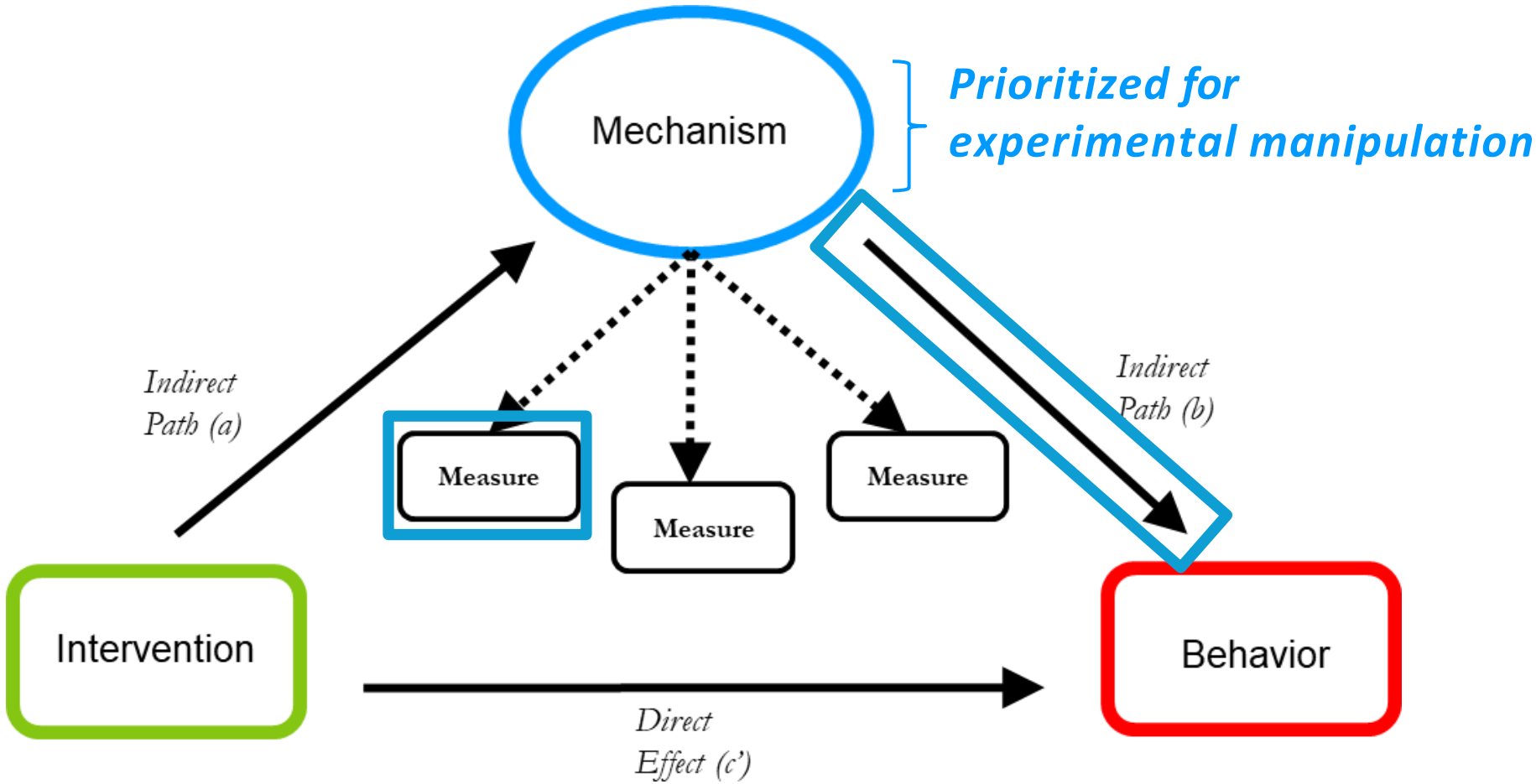
Core Principles

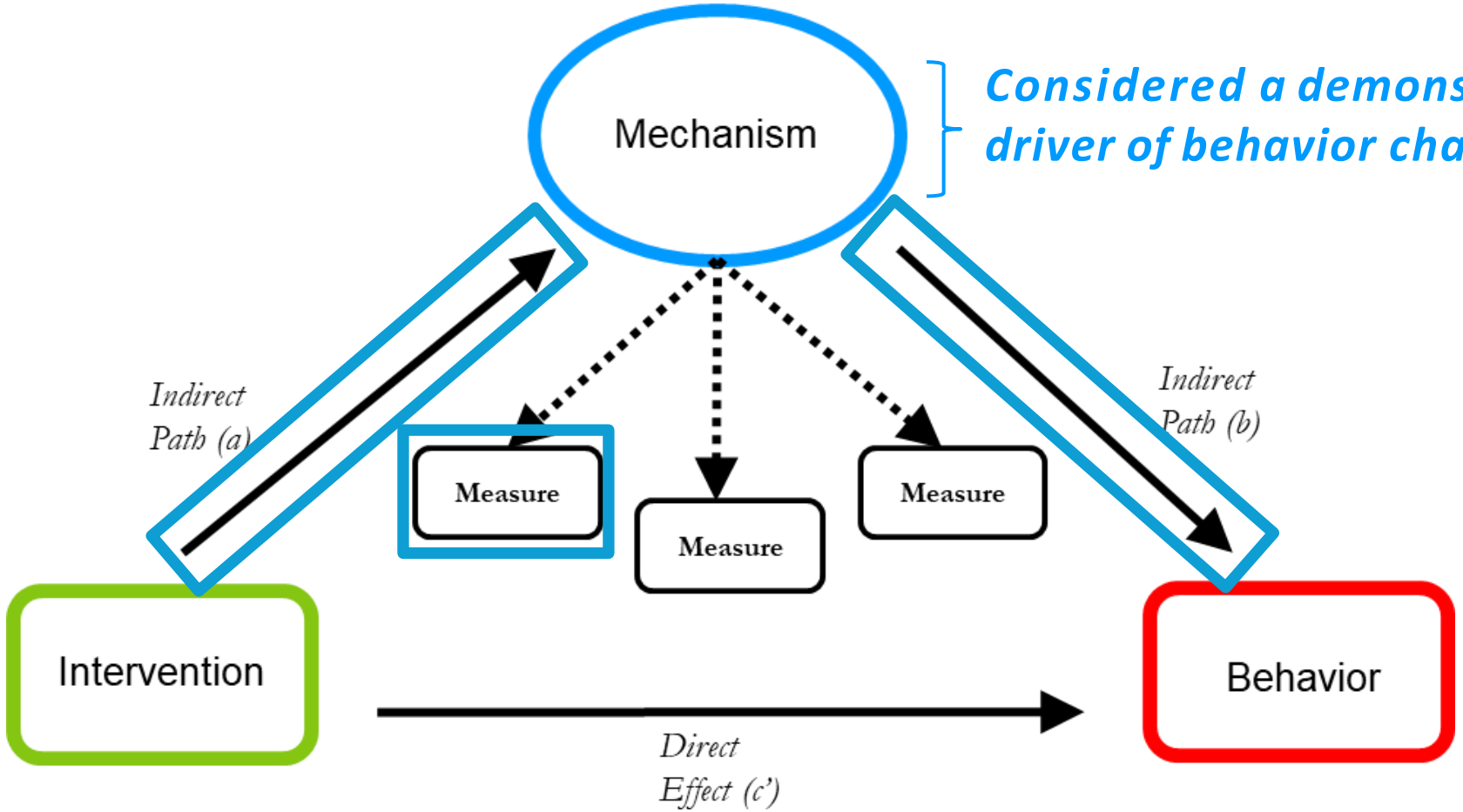
(1) Putative mechanisms of behavior change should be *identified*.

(2) Mechanisms should be *measured*.

(3) Measures of mechanisms should be *psychometrically sound.*

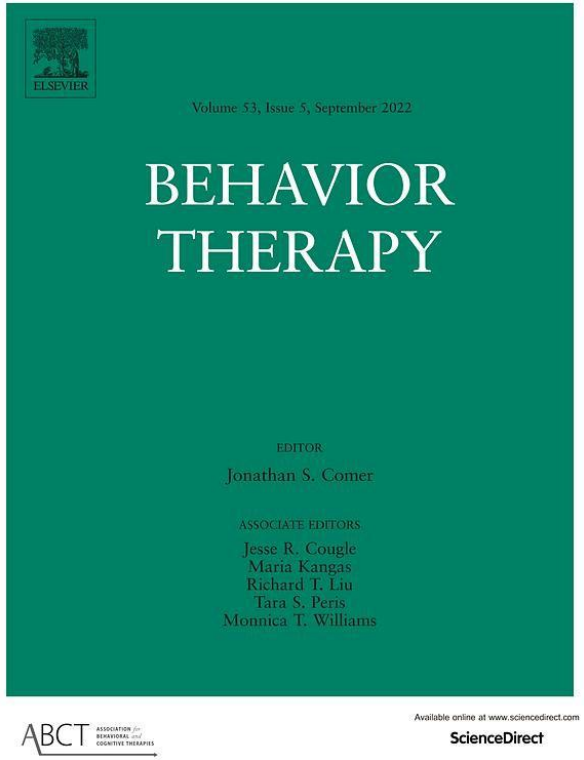
(4) All empirical results related to mechanisms should be *transparently shared with the scientific community.*


Mechanism
Prioritized for
experimental manipulation
Indirect
Path (a)
Measure
Measure
Measure
Indirect
Path (b)
Intervention
Behavior
Direct
Effect (c')


Mechanism
Considered a demonstrated driver of behavior change
Indirect Path (a)
Indirect Path (b)
Measure
Measure
Measure
Intervention
Behavior
Direct Effect (c')

Checklist Development

- **Committee formation**: A CLIMBR executive committee was assembled with five members drawn from SOBC's resource and coordinating center and its multiple working groups.
- **Drafting of checklist**: The committee drafted and revised the checklist in line with initial feedback from NIH officials, including the SOBC program officer.
- **Open-comment period:** Feedback was invited from 18 experts in behavior change research who were selected by the CLIMBR committee. These experts included editors at six relevant journals and members of the Behavioral Medicine Research Council. The open-comment period was extended to the broader research community of behavior-change scientists.
- **NIH feedback:** Specific item-level feedback was provided by NIH officials.
- **Revision:** The CLIMBR committee edited the checklist items and clarified the introductory section in line with all the feedback points suggested by behavior-change researchers and NIH officials.
- **Publication:** CLIMBR was published with its rationale paper in the July 2023 SOBC-themed special section of *Behavior Therapy*.



Special Section:

Cognitive Behavioral Treatment Development: An Experimental Therapeutics Focus on Novel Mechanistic Targets

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Available online at www.sciencedirect.com

ScienceDirect

Behavior Therapy 54 (2023) 708–713

Behavior Therapy

www.elsevier.com/locate/bt

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

Jeffrey L. Birk
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Michael W. Otto
Boston University

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Columbia University

Russell A. Poldrack
Stanford University

Donald Edmondson
Columbia University

Highlights

- CLIMBR is a checklist promoting mechanism-focused behavioral intervention science.
- It focuses on modifiable mechanisms that underlie successful behavior change.
- It ensures that research is conducted rigorously and reported transparently.
- The present manuscript describes CLIMBR's rationale and development.

How does CLIMBR work?

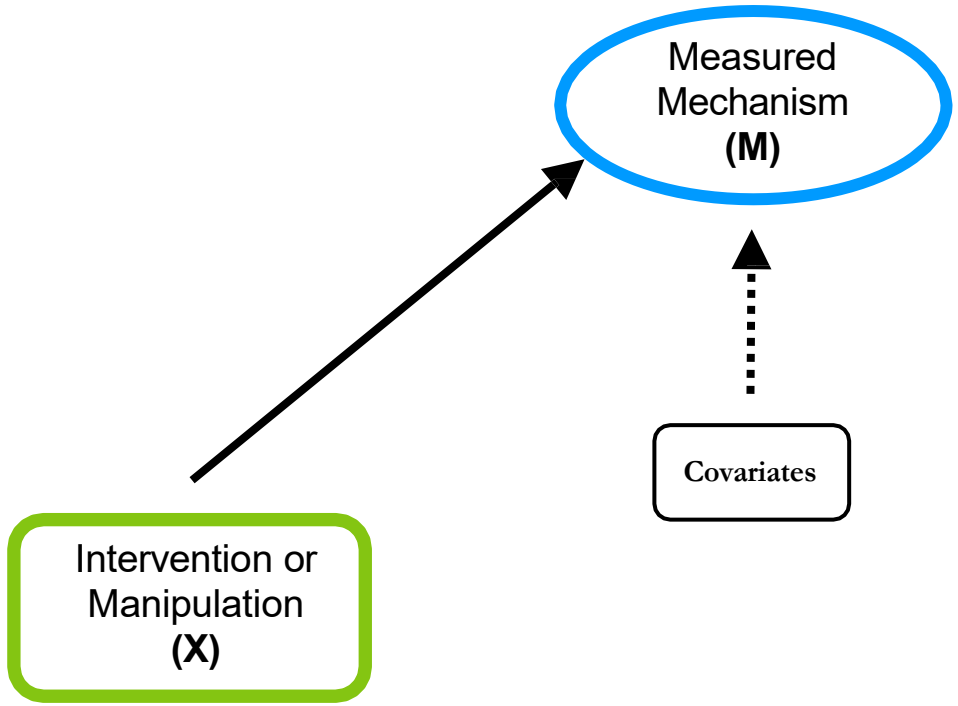
What is SOBC | About | Method | Projects | Repository | CLIMBR Tool | Resources | Climate Change | News

https://scienceofbehaviorchange.org/climbr-tool/

A: For 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)

X → M

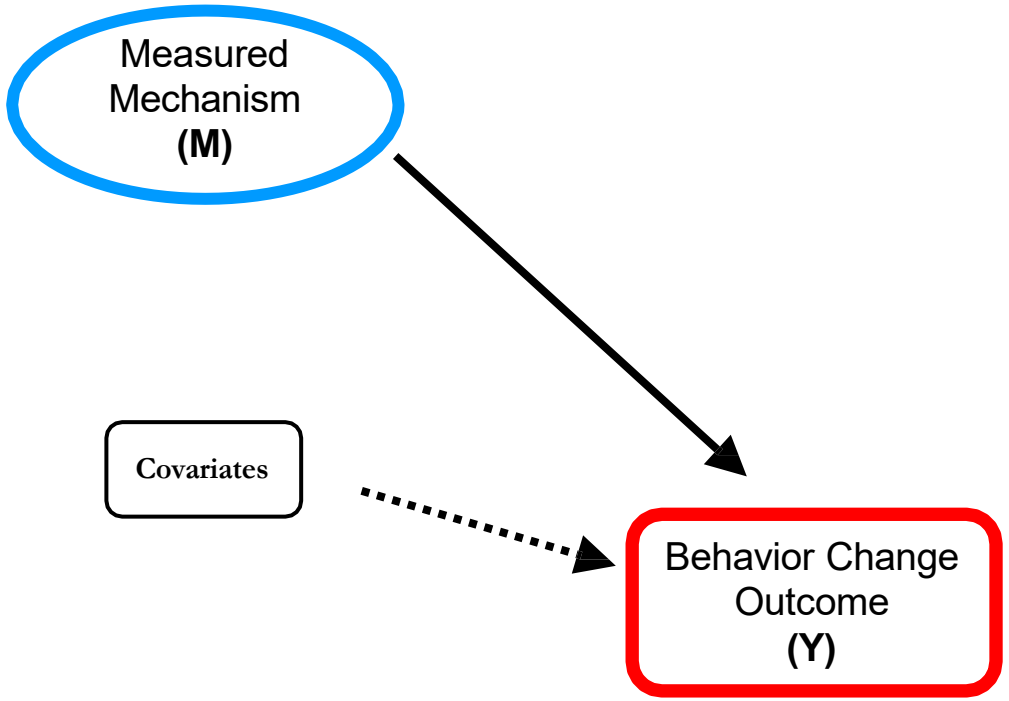
Example: a study of the effects of a mindfulness intervention on self-compassion



B: For 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)

M → Y

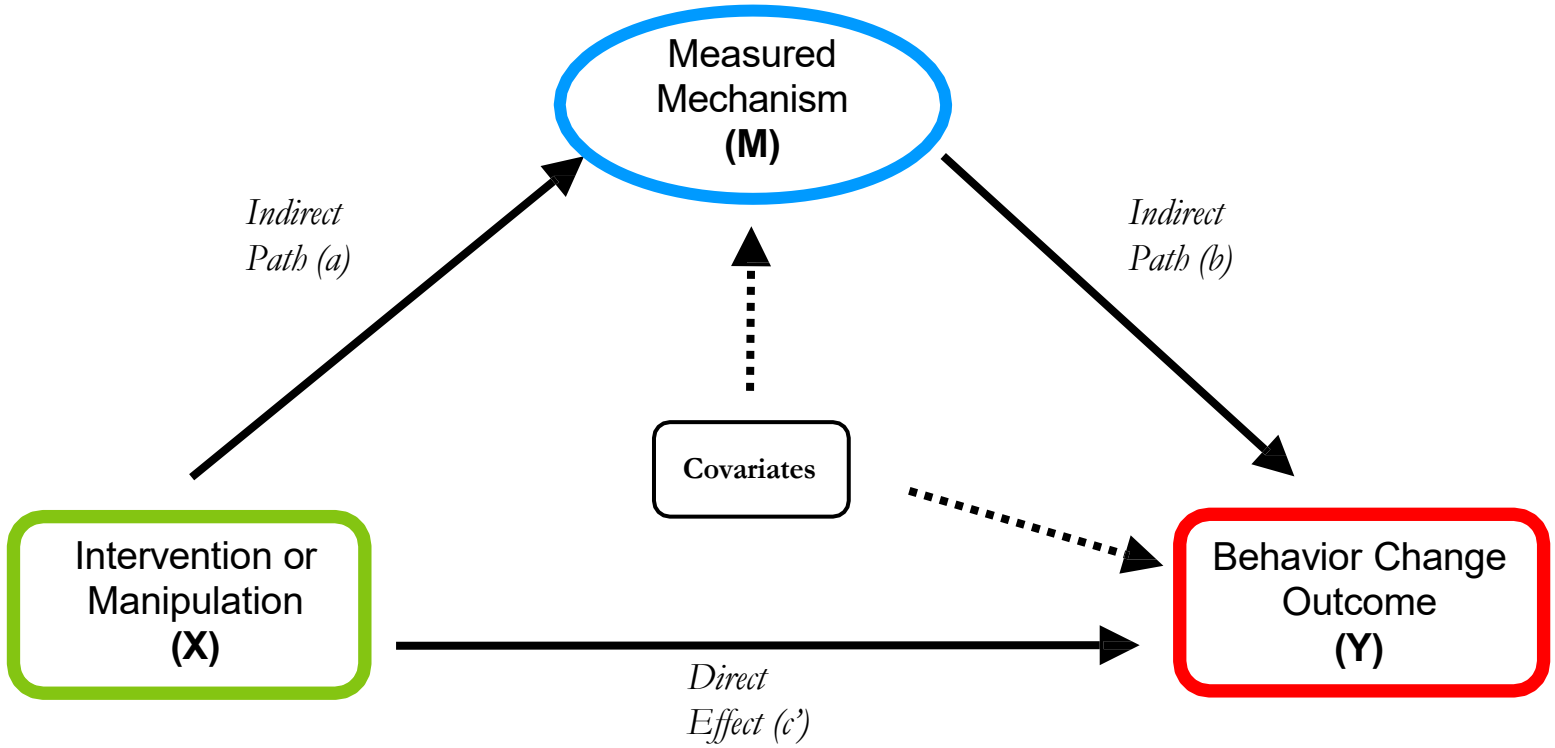
Example: a study of the relationship between stress reactivity and nicotine use



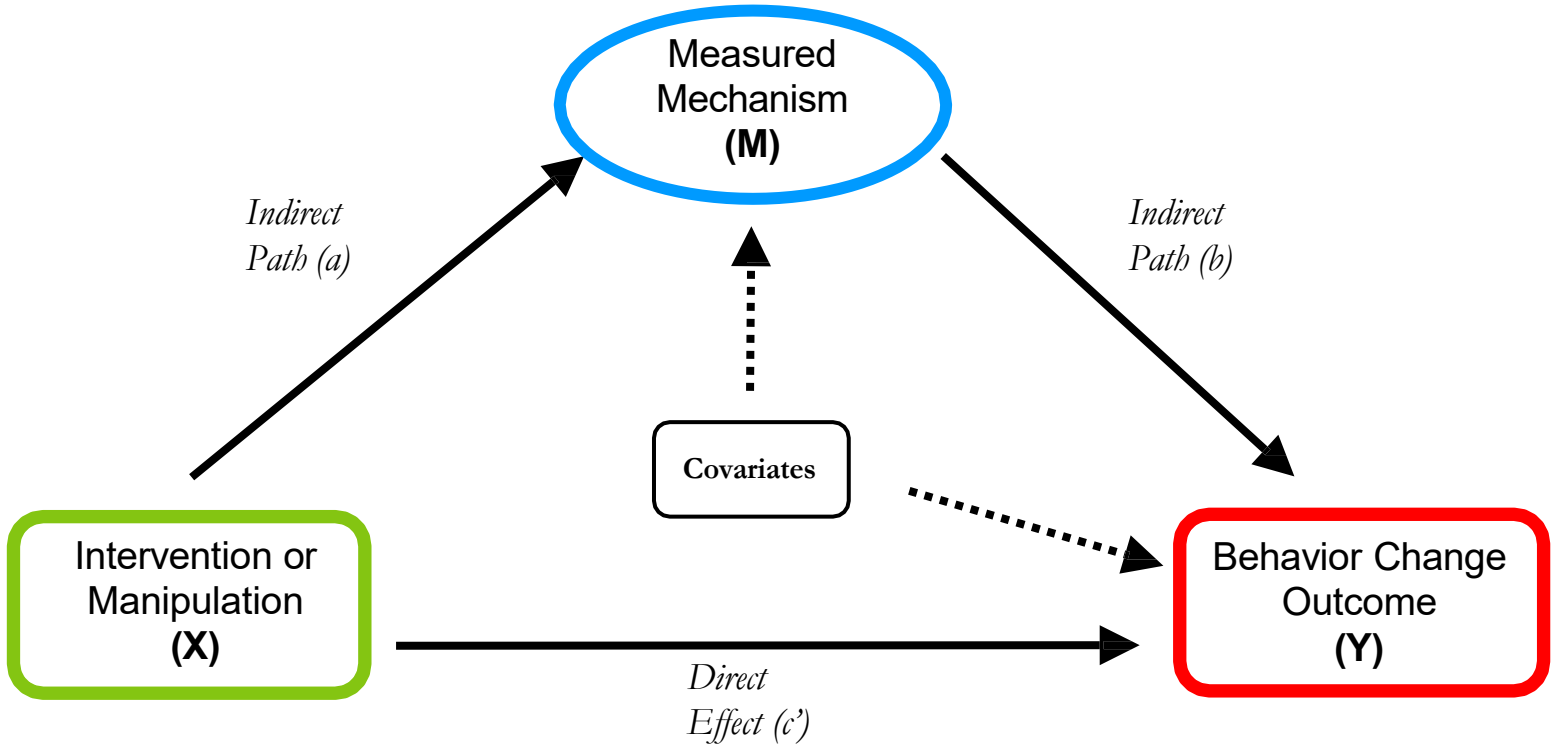
C: For studies that investigate the effect(s) of an intervention or manipulation (X) on a behavior change outcome (Y) and test *associations* with a putative mechanism of behavior change (M)

X → M → Y

Example: a randomized controlled trial of the effects of an episodic future thinking intervention on seatbelt use as mediated by future time perspective



A: For 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)	B: For 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)	C: For studies that investigate the effect(s) of an intervention or manipulation (X) on a behavior change outcome (Y) and test *associations* with a putative mechanism of behavior change (M)
X → M	M → Y	X → M → Y
Example: a study of the effects of a mindfulness intervention on self-compassion	Example: a study of the relationship between stress reactivity and nicotine use	Example: a randomized controlled trial of the effects of an episodic future thinking intervention on seatbelt use as mediated by future time perspective



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).

Overarching Goal

Guiding principles & scope

Instructions

Section/topic	#	A: For 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) X → M Example: a study of the effects of a mindfulness intervention on self-compassion	B: For 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) M → Y Example: a study of the relationship between stress reactivity and nicotine use	C: For 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. X → M → Y Example: 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.	
ABSTRACT					
Identify mechanism(s) and behavior(s)	2	Specify at least one hypothesized mechanism of behavior change, and specify at least one behavior.			
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.	

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.	
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.			
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.	
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).	

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.			
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).			
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).	
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.	

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.	
Measured reliability	13	Report the internal consistency reliability using the present study's data for each measure of each mechanism.			
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.			

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.	
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.	
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.	

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.	

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.	
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.	
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.	
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.			

A Real-World Research Example

Available online at www.sciencedirect.com
ScienceDirect
Behavior Therapy 54 (2023) 623–636
Behavior Therapy
www.elsevier.com/locate/bt

Pain Catastrophizing and Clinical Outcomes Among Patients Receiving a Novel Cognitive-Behavioral Therapy for Irritable Bowel Syndrome: An Experimental Therapeutics Approach

Andrew H. Rogers
University of Houston

Gregory D. Gudleski
Brian M. Quigley
University at Buffalo

Michael J. Zvolensky
University of Houston and the University of Texas MD Anderson Cancer Center

Jeffrey M. Lackner
University at Buffalo

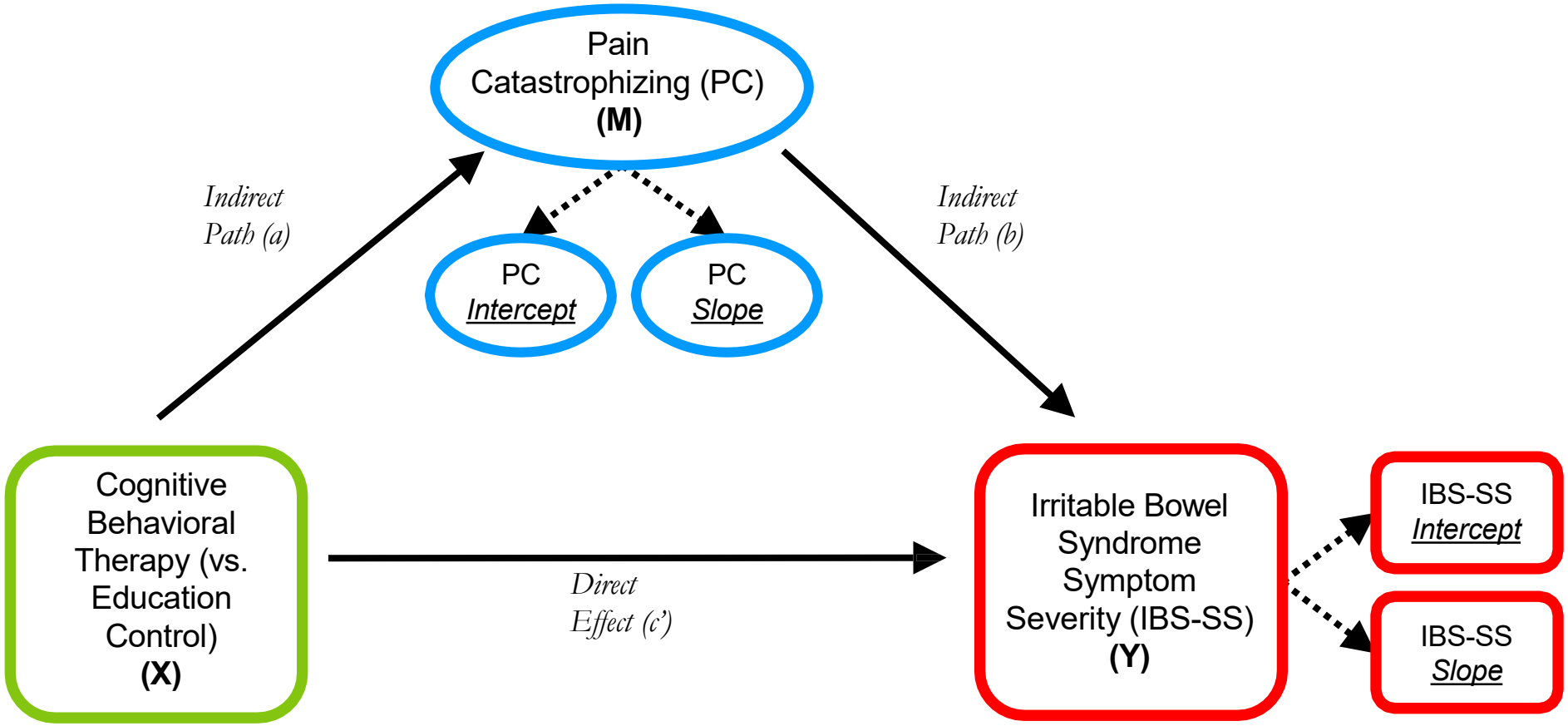
A Real-World Research Example

Cognitive Behavioral Therapy (vs. Education Control) **(X)**

Irritable Bowel Syndrome Symptom Severity **(Y)**

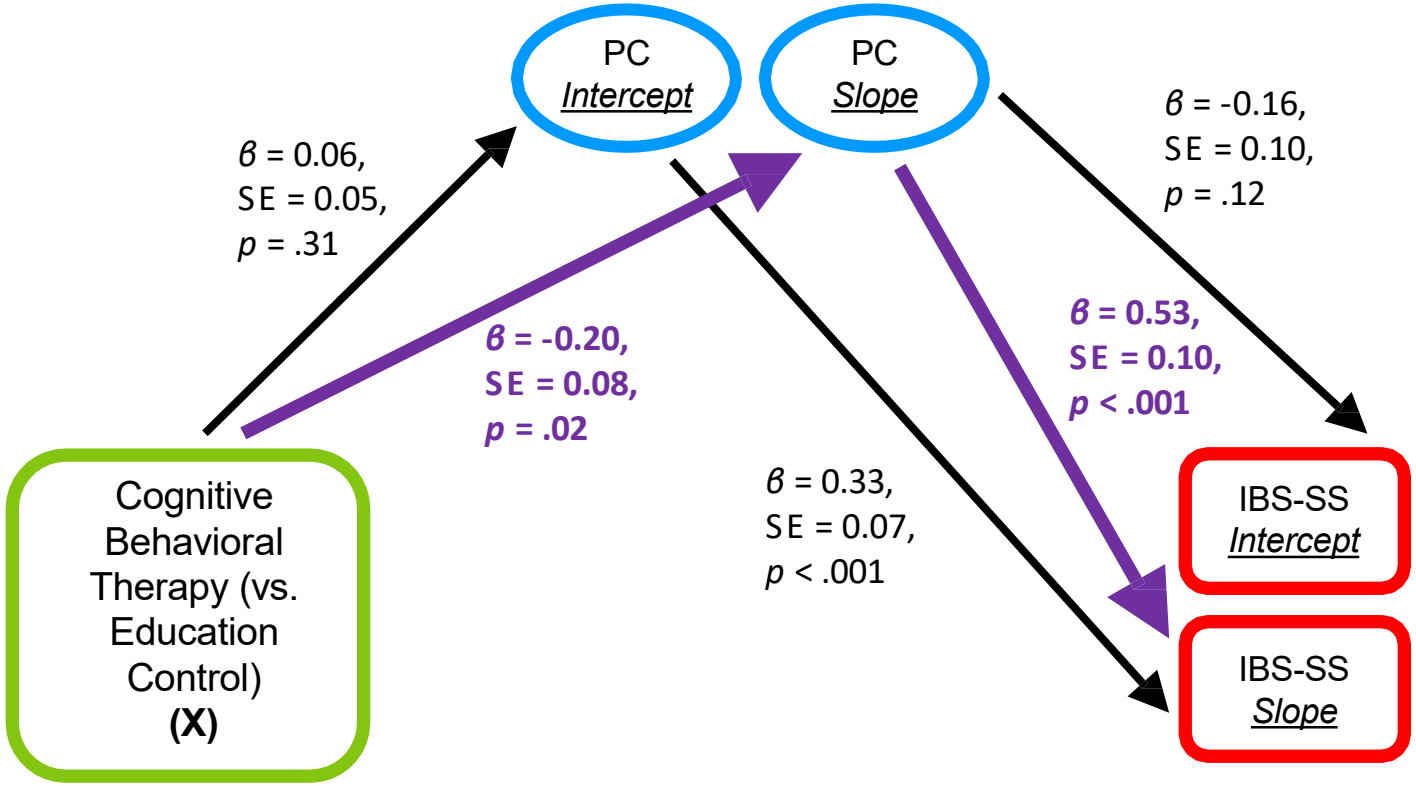
Rogers, Gudleski, Quigley, Zvolensky, and Lackner, 2023, *Behavior Therapy*

A Real-World Research Example



Rogers, Gudleski, Quigley, Zvolensky, and Lackner, 2023, *Behavior Therapy*

A Real-World Research Example



Indirect Effect (*ab*):

***β* = –.11,**
***SE* = .05,**
95% CI [–0.23, –0.02]

Rogers, Gudleski, Quigley, Zvolensky, and Lackner, 2023, *Behavior Therapy*

A Real-World Research Example

"[I]ndirect effect analyses provide evidence that the mediating effect of PC on IBS symptom severity… was specific to the CBT condition...."

Rogers, Gudleski, Quigley, Zvolensky, and Lackner, 2023, *Behavior Therapy*

Moderation in a Mediational Model

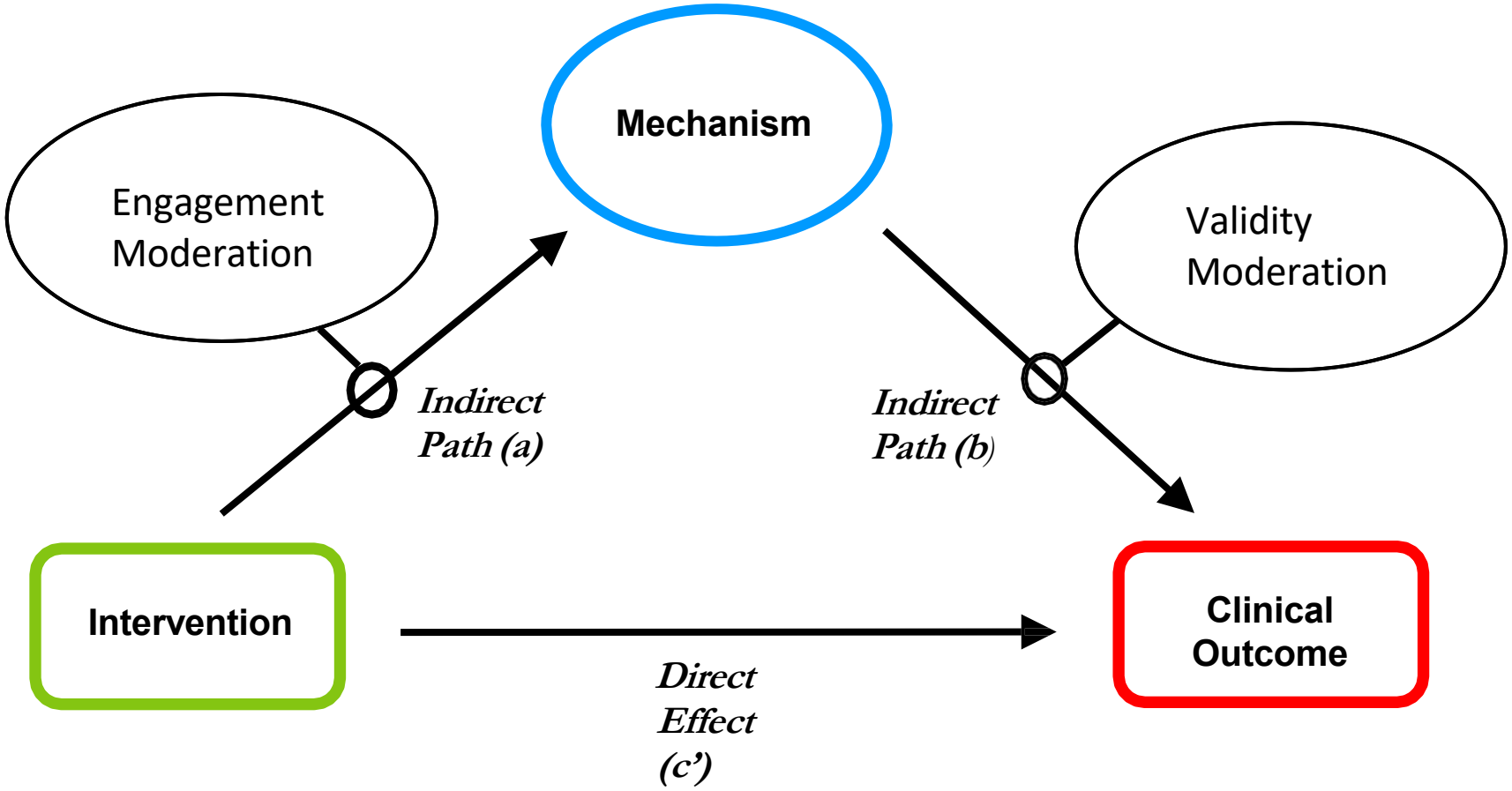


Figure adapted from Rothman & Sheeran, 2021, *Health Psychology*

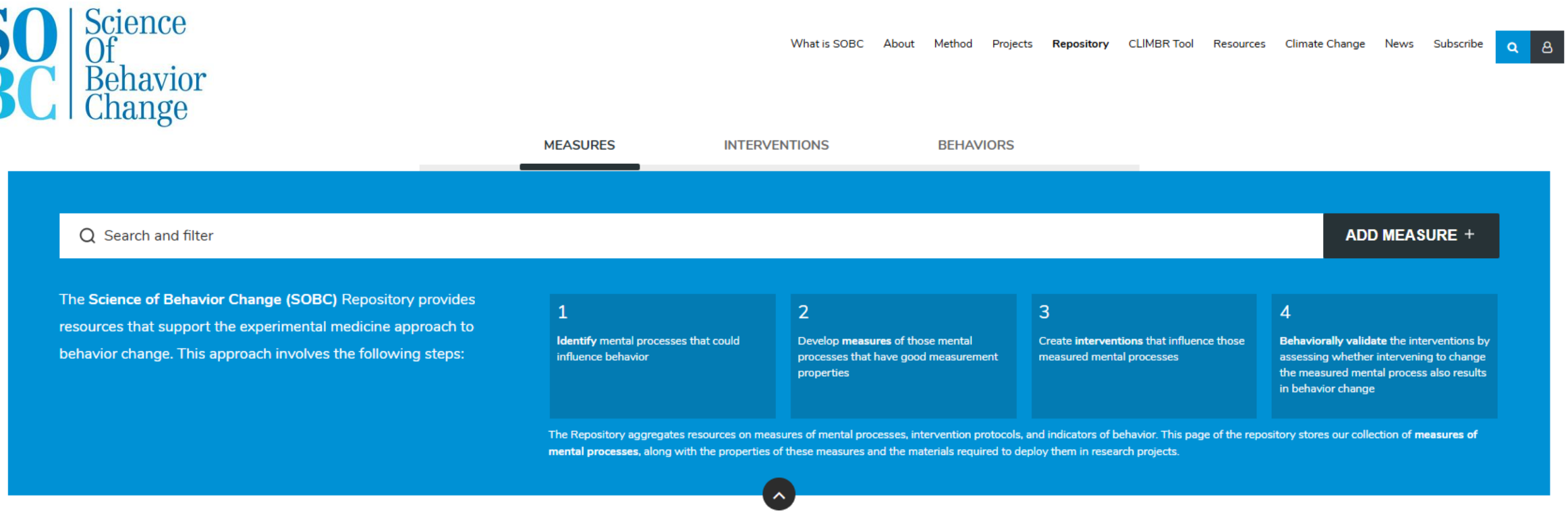
SOBC Measures Repository

SOBC | Science Of Behavior Change

- 331 total measures (and growing)
- Google Scholar integration
- Open Science Framework (OSF) documentation for a subset of measures

https://measures.scienceofbehaviorchange.org/

SOBC Measures Repository



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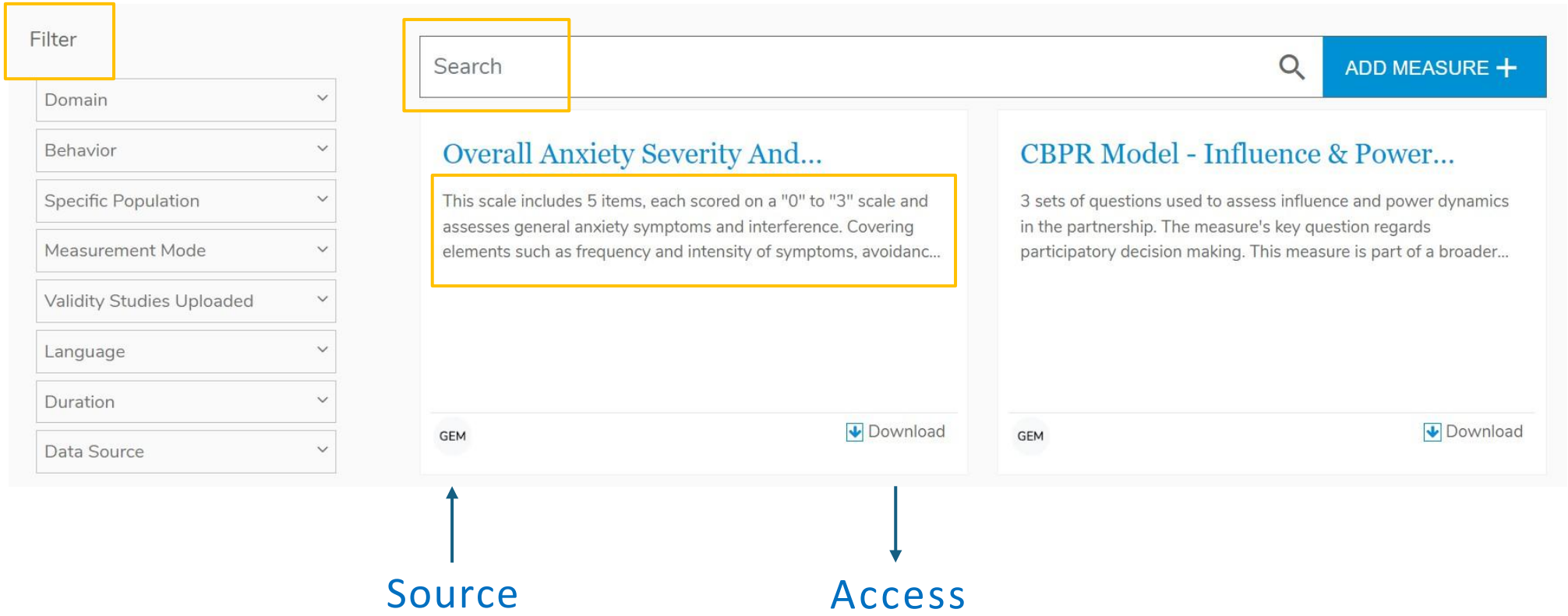
Measures Repository Functions & Usability



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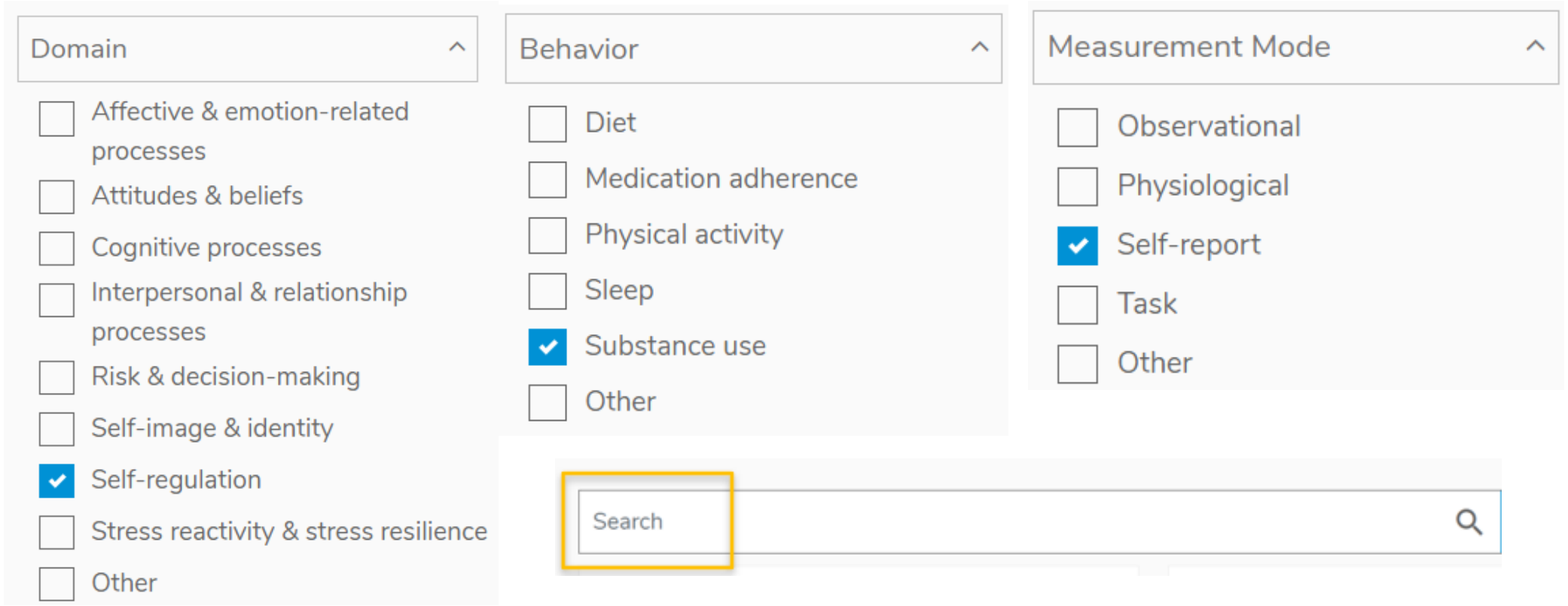
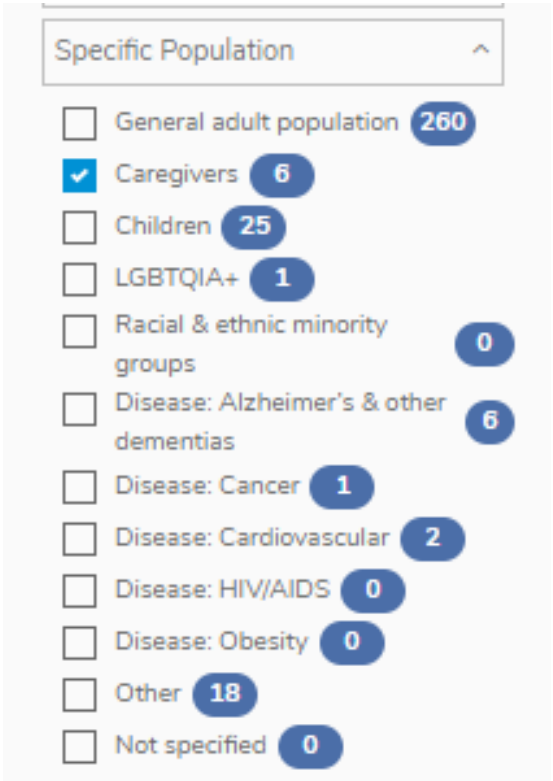
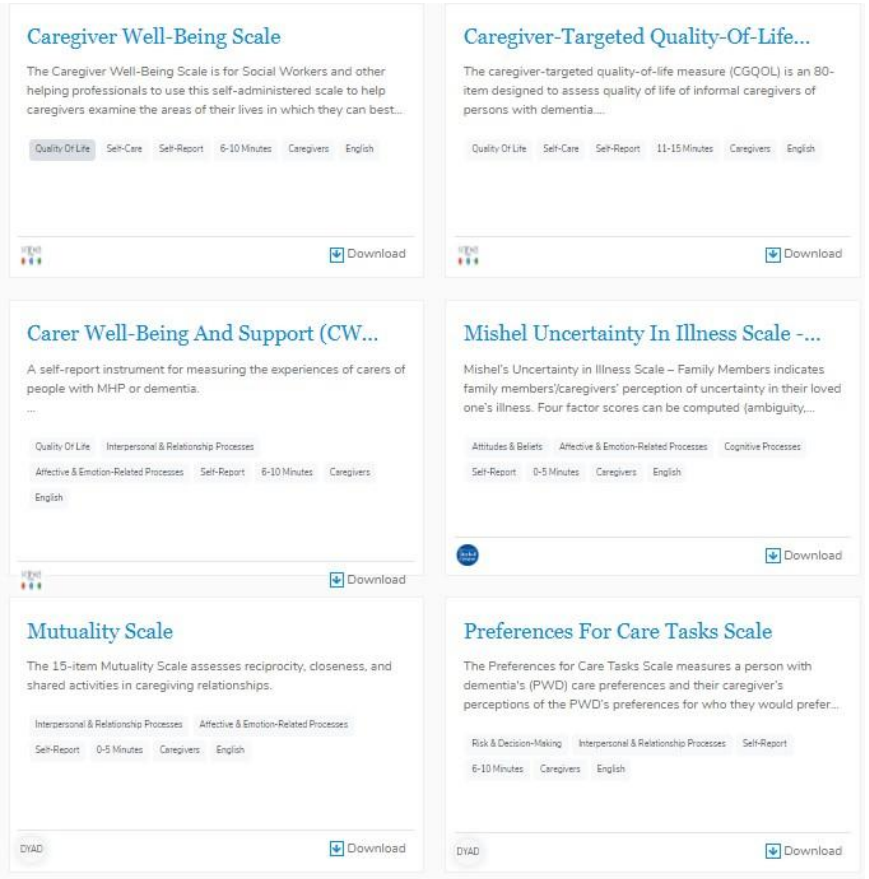
Measures Repository Filtering & Searching



SO BC | Science Of Behavior Change

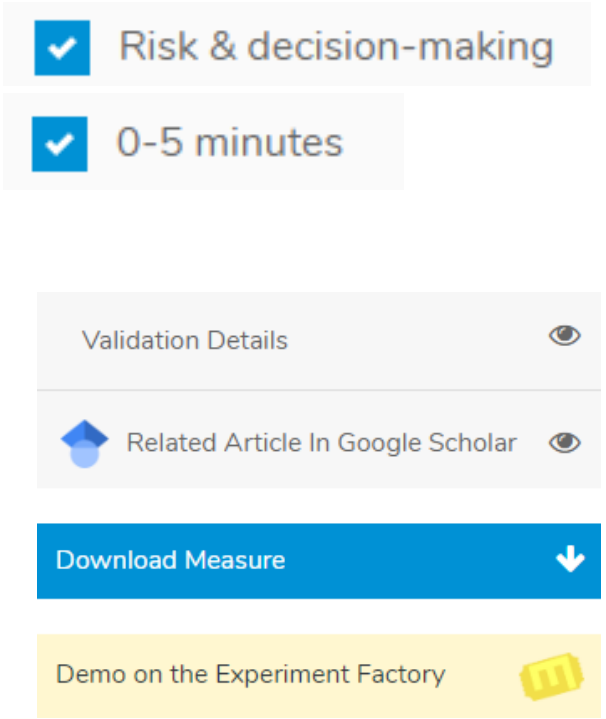
Measures Repository Filtering & Searching

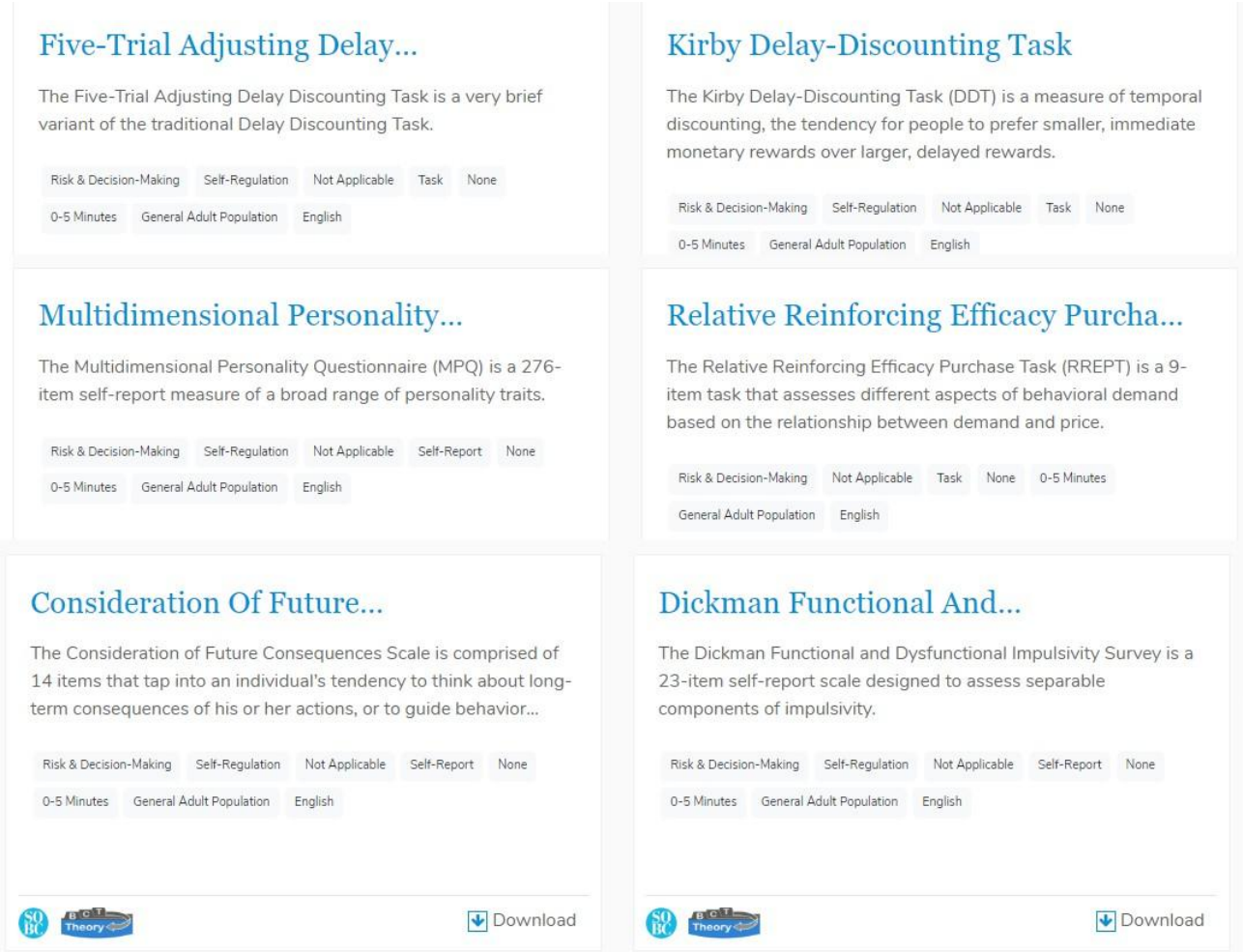




SO BC | Science Of Behavior Change

Measures Repository Choosing & Using

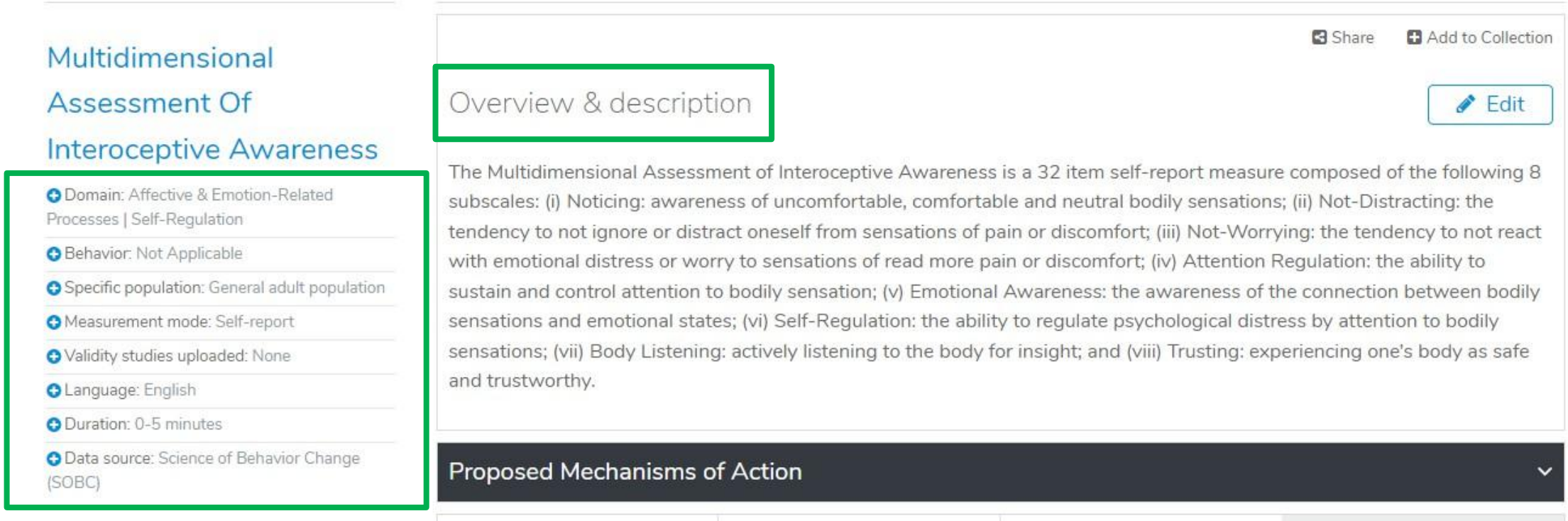




Emory Roybal Center for Dementia Caregiving Mastery

eMBRACE

Measures Repository Functions & Usability



Addressing Some Common Challenges

1. How do I ensure that each chosen measure is **valid**, **reliable**, *and* **appropriate** for my research context?

   - If possible, use tested assays with good psychometric characteristics.
     - In particular, good convergent validity, good discriminant validity, and high internal consistency reliability (Cronbach's alpha ≥ .80) are important.

   - If *not* possible, then modification of existing assays *can* be appropriate.
     - Modify wording of scale items as little as possible.
     - Report all modifications transparently in published reports.

   - Development of entirely new assays can also be appropriate, but it should *not* be the first option you consider.
     - If you choose this route, collaborate with researchers who have experience with scale development (e.g., exploratory and confirmatory factor analysis for new self-report measures).

Addressing Some Common Challenges

2. How do I handle a potential **mechanism** that is itself a **behavior**?

- It *is* acceptable for the assay of a *mechanism* to be operationalized as a *behavioral* measure.
  - E.g., Attentional control can be measured behaviorally using a response-time metric from a laboratory task.

- It is even acceptable a mechanism to be a *behavior* at the conceptual level.
  - E.g., Increased disclosure of HIV status as a result of an educational intervention.
    - In that case, however, note that you will likely want to assess at least one additional mechanism that may explain the effect of the intervention on disclosure.

- The key is to ensure that your mechanism and behavior are *conceptually distinct*.
  - E.g., A mechanism and a behavioral outcome should *not* be performance on the 6-minute walk test at an earlier and a later time point.

Addressing Some Common Challenges

3. Must I test mediation using a particular **time-ordered relationship** among variables?

- If possible, the mediator should occur in time between the predictor and outcome.
  - Consider the relevant timescales for your research design in terms of expected effects as well as practical considerations.

- You might consider measuring *changes* in M and *changes* in Y.
  - However, a well powered randomized controlled trial does *not* require measurement of M or Y at baseline.

- Entirely cross-sectional research is relatively easy to conduct. However, it may have less utility than a thoughtfully sequenced research design in which the progression of X➔M➔Y is evaluated over time.

Addressing Some Common Challenges

4. How do I make sense of **multiple** tested mechanisms of interest?

- Example: A small initial efficacy trial tests three potential mechanisms: a *primary* mechanism of perceived social support and two *secondary* mechanisms of positive affect and self-efficacy.
    - Scenario 1: The intervention engages just one of three tested mechanisms but *not* one that has been previously shown to be most strongly associated with the health behavior of interest.
        - Your intervention may be missing key ingredients. Knowing that points clearly to next steps.
    - Scenario 2: The intervention *does* engage the key hypothesized mechanism as well as one of the two secondary mechanisms.
        - Your intervention could be tested in a larger randomized trial as a next step.

Addressing Some Common Challenges

5. What if I find only **weak evidence for partial mediation** and/or just a small and **not clinically significant effect** of the intervention/manipulation on the behavioral outcome?

   - A weakly successful trial with mechanistic support is *more* valuable than a powerfully successful trial in which no putative mechanisms were measured.

     - The findings are **more informative** and **useful** to *you*.

     - *Other researchers'* **confidence in your positive findings can be bolstered.** This is especially true if it can be shown that not only does an intervention "work" (X➔Y), but you have some evidence about *why* it works (X➔M➔Y).

Health Behavior Researchers

Embrace Team Science and Become an MBRC Member

https://www.mbrc-sobc.org/

The Mechanistic Behavioral Research Consortium (MBRC) is designed to **promote the SOBC approach** and to **enhance the productivity of member researchers** by facilitating cutting-edge investigations **without the need for independent funding**.

MBRC

Mechanistic Behavioral Research Consortium

Better Science Faster

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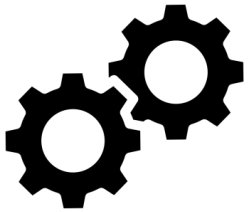
Summary of Key Points



- *Measured* mechanisms matter!
  - Please visit the **Measures Repository**: https://measures.scienceofbehaviorchange.org/

- CLIMBR provides steps to ensure that the experimental medicine approach is applied with rigor to your own behavior-change research.
  - Watch a brief explainer video and download **CLIMBR** here: https://scienceofbehaviorchange.org/climbr-tool/

- Achieving successful behavior change proceeds more quickly when researchers participate in cumulative, transparent science.
  - Create a page on the **Open Science Framework**: https://osf.io/

Key References

Learn more about CLIMBR:

- Birk, J. L., Otto, M. W., Cornelius, T., Poldrack, R. A., & Edmondson, D. (2023). Improving the rigor of mechanistic behavioral science: The introduction of the Checklist for Investigating Mechanisms in Behavior-change Research (CLIMBR). *Behavior Therapy, 54*(4), 708–713. https://doi.org/10.1016/j.beth.2022.12.008

Read about the principles underlying SOBC:

- Nielsen, L., Riddle, M., King, J. W., Aklin, W. M., Chen, W., Clark, D., Collier, E., Czajkowski, S., Esposito, L., Ferrer, R., Green, P., Hunter, C., Kehl, K., King, R., Onken, L., Simmons, J. M., Stoeckel, L., Stoney, C., Tully, L., & Weber, W. (2018). The NIH Science of Behavior Change Program: Transforming the science through a focus on mechanisms of change. *Behaviour Research & Therapy, 101*, 3-11. https://doi.org/10.1016/j.brat.2017.07.002

Read a published real-world research example:

- Rogers, A. H., Gudleski, G. D., Quigley, B. M., Zvolensky, M. J., & Lackner, J. M. (2023). Pain catastrophizing and clinical outcomes among patients receiving a novel cognitive-behavioral therapy for irritable bowel syndrome: An experimental therapeutics approach. *Behavior Therapy, 54*(4), 623-636. https://doi.org/10.1016/j.beth.2023.01.004

Thank You!

Q & A

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Resource and Coordinating Center

NIH National Institute on Aging
U24AG052175

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https://embraceroybal.wisc.edu

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