EXPANDING THE TOOL BOX: USING THE MULTIPHASE OPTIMIZATION STRATEGY TO BUILD EFFECTIVE AND EFFICIENT INTERVENTIONS

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The Methodology Center

PennState

Outline

- Typical development of a behavioral/biobehavioral intervention
- A different scenario
- Introduction to MOST
- Overview of MOST
- Take away messages

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- **Typical development of a behavioral/biobehavioral intervention**
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What is a behavioral/biobehavioral intervention (BBI)?

- BBIs are
  - Programs with the objective of improving and maintaining human health and well-being, broadly defined
  - In individuals, families, schools, organizations, or communities
  - Using a strategy that at least in part aims to modify attitudes, cognitions, or behavior
  - And may include biological, medical, pharmaceutical, or surgical aspects

What is a behavioral/biobehavioral intervention (BBI)?

- BBIs may be aimed at, for example:
  - preventing disease
  - treating disease
  - promoting health
  - preventing violence
  - improving academic achievement

Example of typical development of a BBI

- GOAL: Dr. B wants to develop a BBI to reduce STIs among college students
- Dr. B reviews existing literature, devises a conceptual model, and identifies the following 5 intervention components that are important in reducing alcohol use and sexual risk behaviors that contribute to STI acquisition

Example of typical development of a BBI

- 5 intervention components:
  - Descriptive norms
  - Injunctive norms
  - Expectancies
  - Perceived benefits of using protective behavioral strategies (PBS)
  - Self-efficacy to using PBS

Example of typical development of a BBI

- Pilot test components, possibly revise a little
- Combine components into a BBI
- Evaluate the BBI

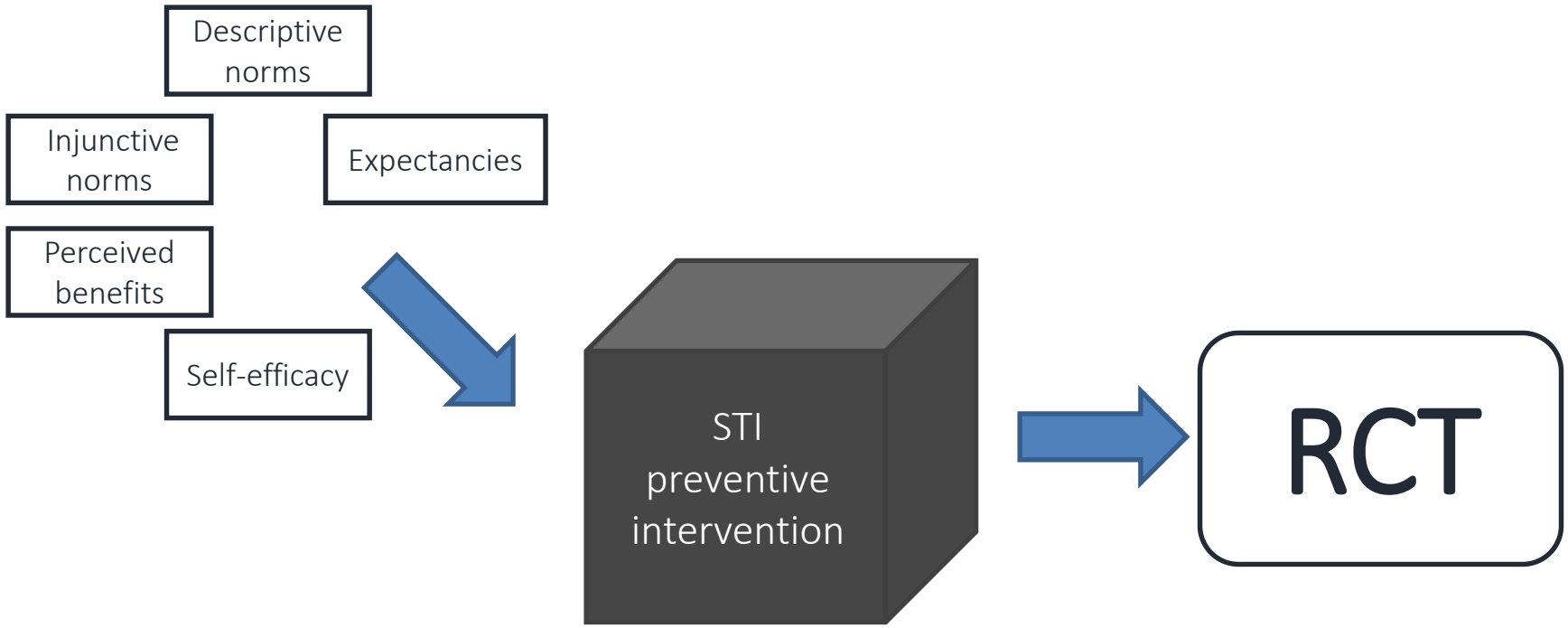
Example of typical development of a BBI

- Evaluation via a randomized control trial (RCT)
- Experiment with two conditions:
  - Treatment (BBI)
    - Descriptive norms, injunctive norms, expectancies, perceived benefits, and self-efficacy to prevent harm
  - Control (standard of care)
    - No descriptive norms, injunctive norms, expectancies, perceived benefits, and self-efficacy to prevent harm

Example of typical development of a BBI

- Subjects are randomly assigned to treatment or control
- Outcome variable: engagement in unprotected sex
- Would typically be analyzed using regression, with a dummy variable representing treatment and perhaps a few covariates
- If treatment group significantly better, SUCCESS!!

Typical development of BBI



Excellent for evaluating whether the packaged intervention performs better than a control or standard of care

If the RCT shows a significant effect, we still do not know

- Which components are making positive contributions to overall effect
- Whether all the components are really needed
- Whether a component's contribution offsets its cost
- How to make the intervention more effective, efficient, scalable and/or sustainable

Or if the RCT shows a non-significant effect, we do not know

- Whether any components are worth retaining
- Whether one component had a negative effect that offset the positive effect of others
- Specifically what went wrong and what the next steps should be

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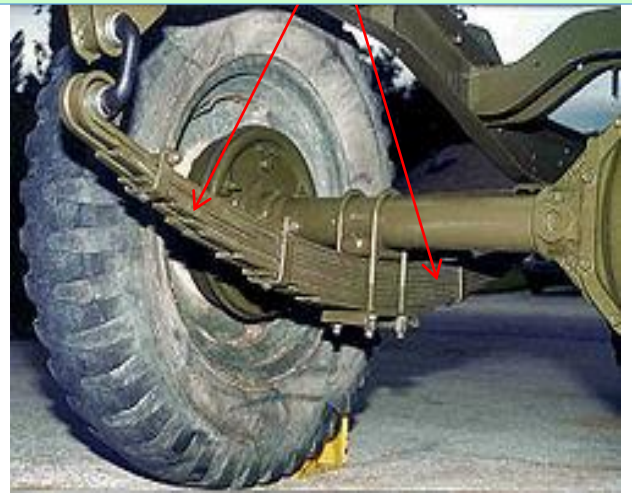
Different scenario: Development of a leaf springs manufacturing process

Leaf Spring:
part of truck suspension system



Development of a leaf springs manufacturing process

- GOAL: An engineer, Dr. E, wants to develop a manufacturing process that will consistently produce leaf springs of the same length

- Dr. E hypothesizes that the following components are important in obtaining leaf springs of uniform length:

Development of a leaf springs manufacturing process

- Furnace temperature
- Heating time
- Time on the conveyor belt
- Time in the high pressure press
- Temperatures over which quench oil ranges

- Each can be low or high. Suppose Dr. E hypothesizes that higher is better.

Development of a leaf springs manufacturing process

- Let's think of this as an intervention on the manufacturing process
- How might Dr. B approach this?
- Create a new manufacturing process:
  - High furnace temp, longer heating time, longer time on conveyor belt, longer time in the press, quench oil ranges over higher temps
- Then compare its performance directly to that of the old process

Development of a leaf springs manufacturing process

- OK, how might Dr. E approach this?
- Dr. E might eventually compare a new process to the old one
- But first, would develop and *optimize* the new manufacturing process
- How?

Development of a leaf springs manufacturing process

- First, Dr. E wants the new process to be implemented as designed
- So, will start by looking at any important constraints
- Example: owners say they must be able to manufacture springs for a cost of < $25

Development of a leaf springs manufacturing process

- Then, Dr. E would assess what resources are available to conduct research
- Carefully select an approach to find out:
- **What is the size and direction of each component's effect?**
- **Is the performance of a component affected by other components?**
- *Why are these questions important?*

Development of a leaf springs manufacturing process

- Don't want to waste resources on components that have very small/null/counterproductive effects
- In selecting components, important to account for how one component may impact the performance of another
- Different components have different resource demands, may want to consider in relation to effect
- Want to be able to improve process further in the future

Development of a leaf springs manufacturing process

- Dr. E cannot obtain the necessary information from an RCT
- Each component must be manipulated individually
- Dr. E will select an experimental design that enables this
- Based on the information, will select the set of components that provides the best process that can be obtained while observing $25 limit

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Can behavioral scientists approach a problem more like Dr. E does?

- The multiphase optimization strategy (MOST) has been developed to enable this
- MOST has been inspired by engineering principles
- Framework for preparation, optimization, and evaluation of BBIs
- What if Dr. B took this approach?

Suppose Dr. B took an engineering-like perspective

- Would not immediately include all five components in BBI; instead, would see them as *candidates*
- Goal: to engineer a BBI that
  - Meets specific criteria for
    - Effectiveness
    - Efficiency
    - Economy and/or
    - Scalability
    - i.e. has been optimized, AND
  - Demonstrates statistical and practical significance

Suppose Dr. B took an engineering-like perspective

- Suppose insurers will pay up to $50 per college student for an STI prevention BBI
- Then Dr. B wants to identify the set of components that produces the most effective STI preventive outcome for < $50 per person
- How can Dr. B identify this set?

Suppose Dr. B took an engineering-like perspective

- Dr. B needs to gather the following information:
  - How each individual component performs
  - How components perform together, i.e., impact each other's performance
    - Are there synergistic relations?
    - Are there antagonistic relations?
- This information will enable screening out poorly performing components
- Experiment to gather this information is called a *screening experiment*

Suppose Dr. B took an engineering-like perspective

- Let's assume a factorial experiment was conducted
- Dr. B analyzes the data using factorial ANOVA
  - Gets estimates of main effects and interactions
- Uses this information to weed out poor performers and arrive at the *screened set* that can be later evaluated using an RCT

The MOST approach to STI preventive intervention

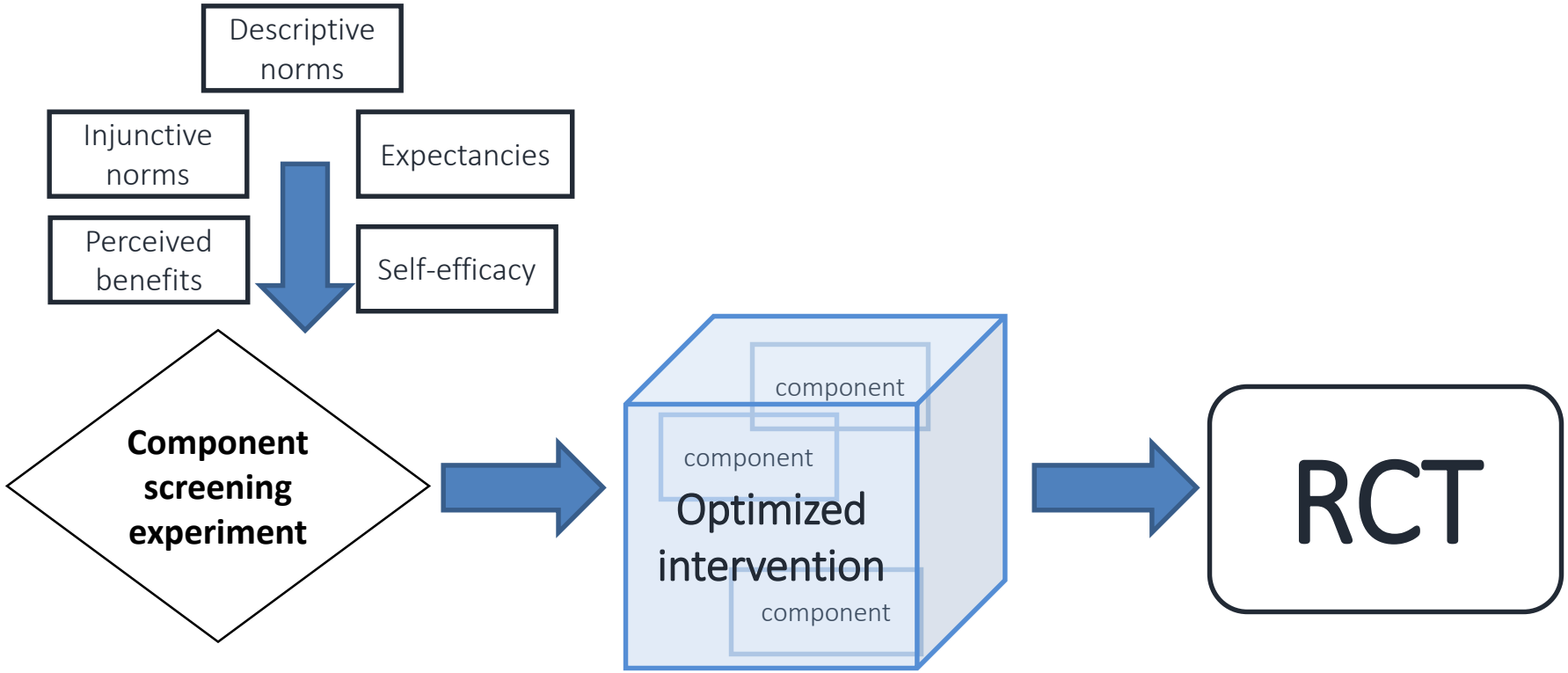

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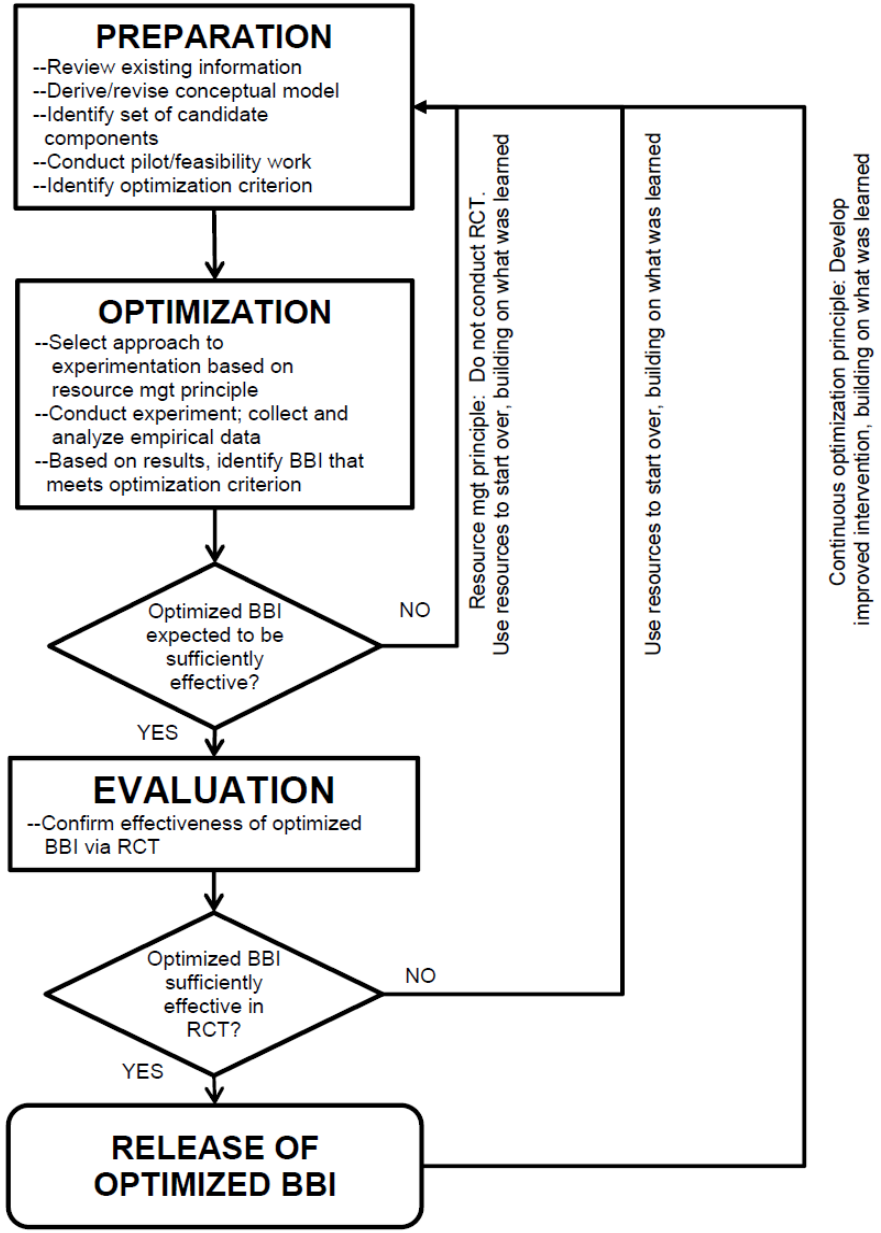
Figure 1.2. Flow chart of one cycle of the multiphase optimization strategy (MOST) to develop, optimize, and evaluate a behavioral or biobehavioral intervention (BBI). Rectangle = action. Diamond = decision. Round-cornered rectangle = the product, which is the new optimized intervention to be released.



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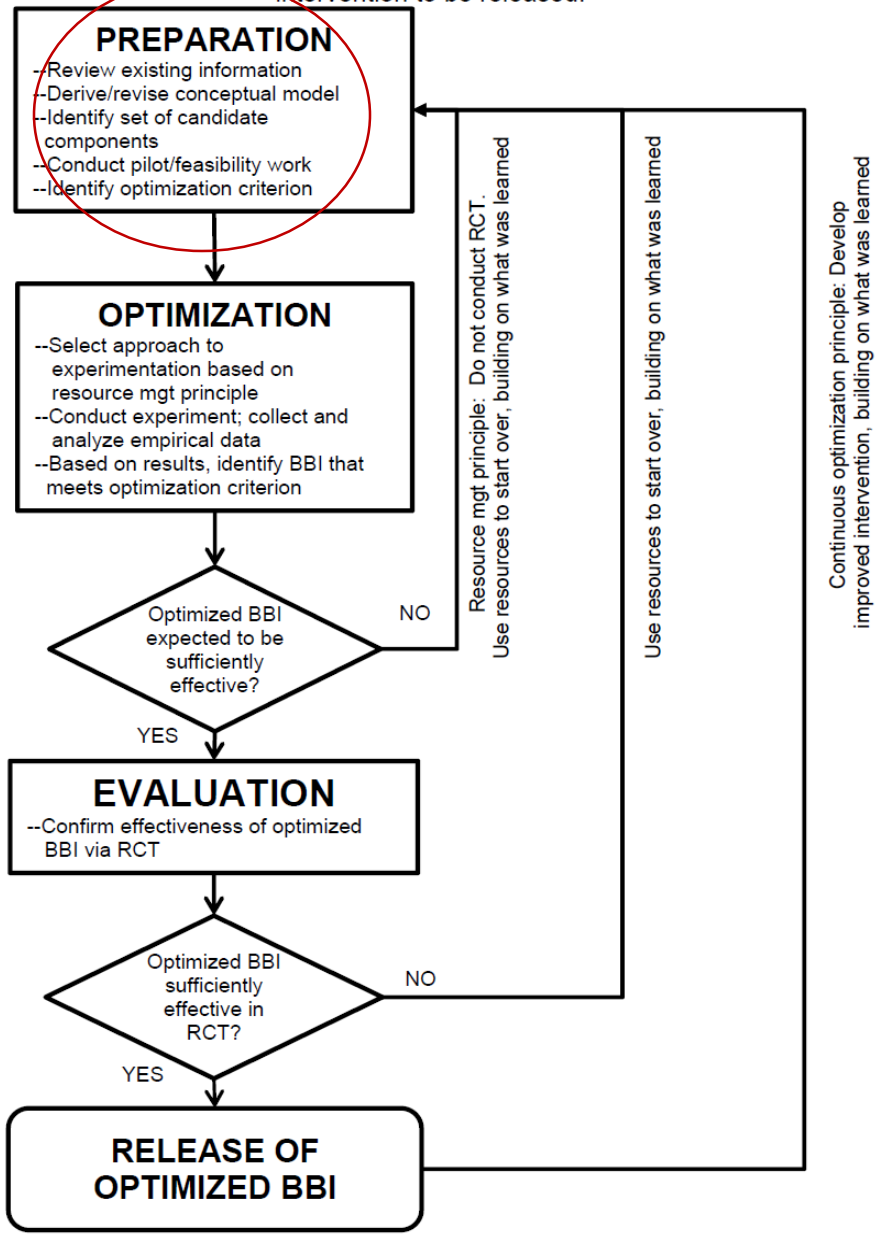


Preparation phase

- Purpose: to lay groundwork for optimization
- Development/revision of conceptual model
- Pilot testing of components
- Identification of optimization criterion

The conceptual model

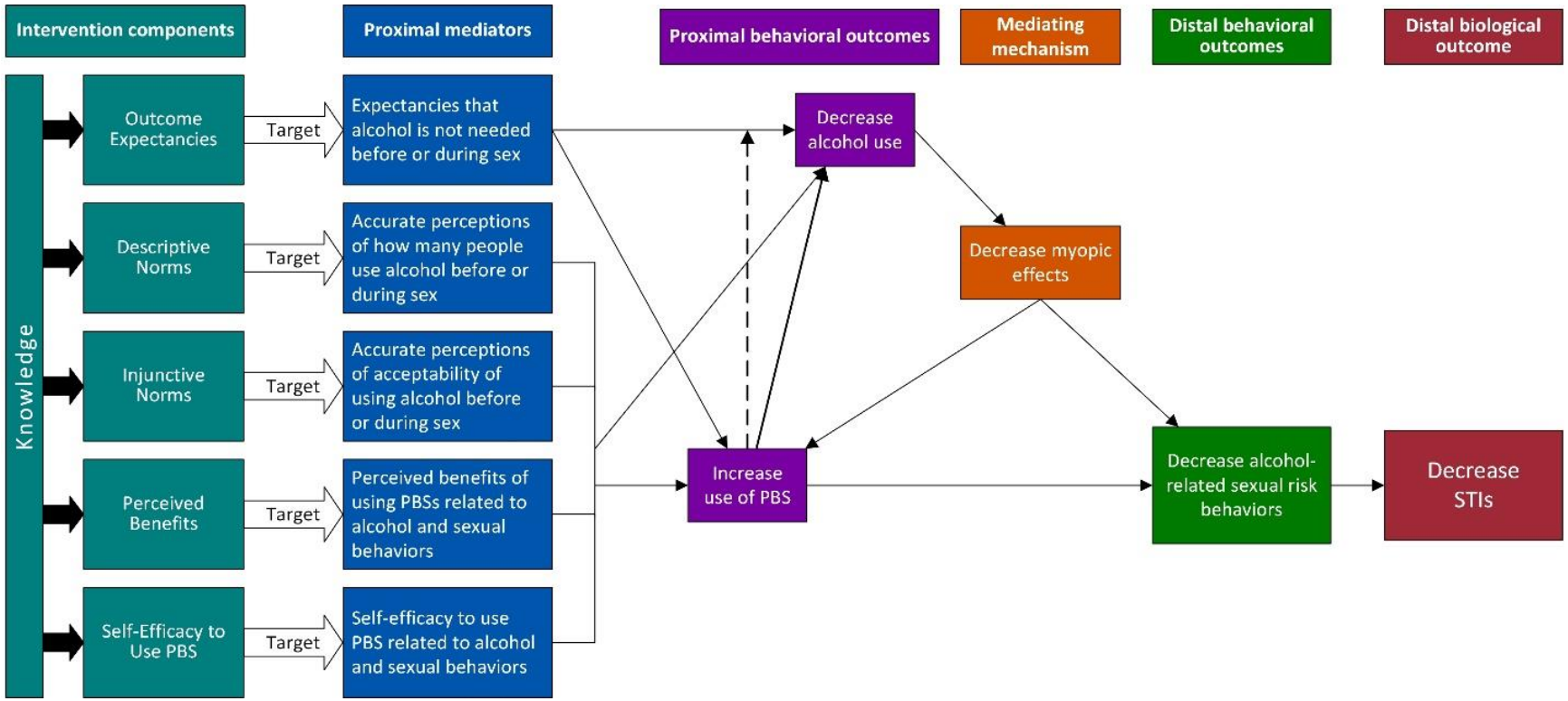
- Expresses how the BBI under development is to intervene on the behavioral or biobehavioral process
  - All of what is known, hypothesized, or conjectured
- Should be explicitly theory-based
  - May be informed by more than one theory, if different theories apply to different aspects of the model.
- Should be directly informed by peer-reviewed empirical literature

The conceptual model

- Should be comprehensive
  - Even if not every aspect of it is to be investigated in a particular study

- Should clearly describe the process to be intervened on
  - Key outcome variables
  - Hypothesized causal influences
  - Mediators and moderators of causal mechanisms

Conceptual model of STI preventive intervention



Kugler, et al. (In press). Using the Multiphase Optimization Strategy (MOST) to Develop an Optimized Online STI Preventive Intervention Aimed at College Students: Description of Conceptual Model and Iterative Approach to Optimization. In L. M. Collins & K. C. Kugler (Eds.), *Optimization of Multicomponent Behavioral, Biobehavioral, and Biomedical Interventions: Advanced Topics* (pp. XXX). New York, NY: Springer.

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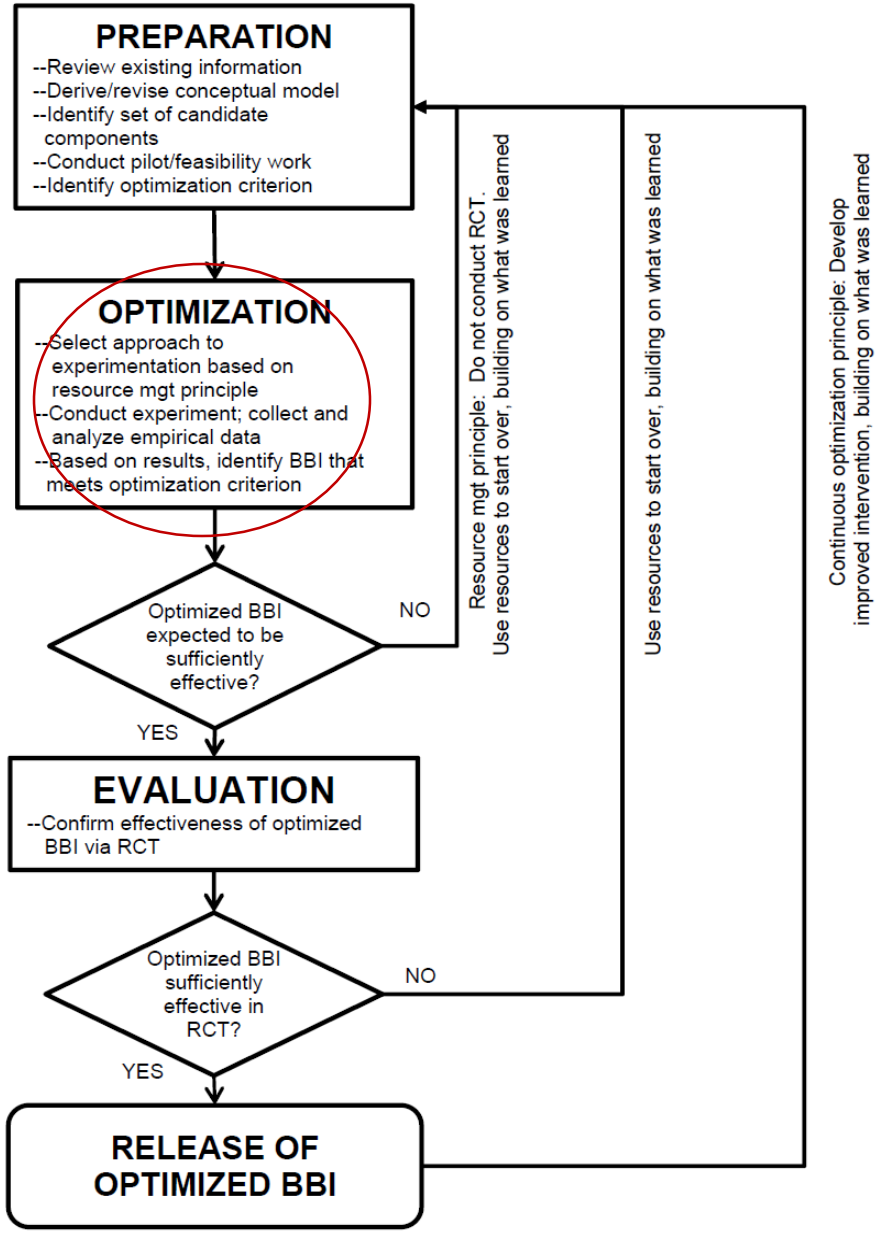

Optimization phase

- Purpose: to build an optimized intervention
- Select approach to experimentation
- Conduct fully powered experiment
- Based on results, identify optimized BBI

Definition of optimization of a BBI

- *Optimization of a BBI is the process of identifying the BBI that provides the highest expected level of effectiveness obtainable within key constraints imposed by the need for efficiency, economy, and/or scalability.*
- Note:
  - Process
  - Key constraints
  - Highest expected level obtainable

Optimization phase

- What kind of approach?
  - For fixed, multicomponent interventions → Factorial experiments (or fractional factorial experiments)
  - Adaptive interventions → SMART (Sequential Multiple Assignment Randomized Trial)
  - Just-in-time adaptive intervention → mRT (Microrandomized Trial) or systems identification

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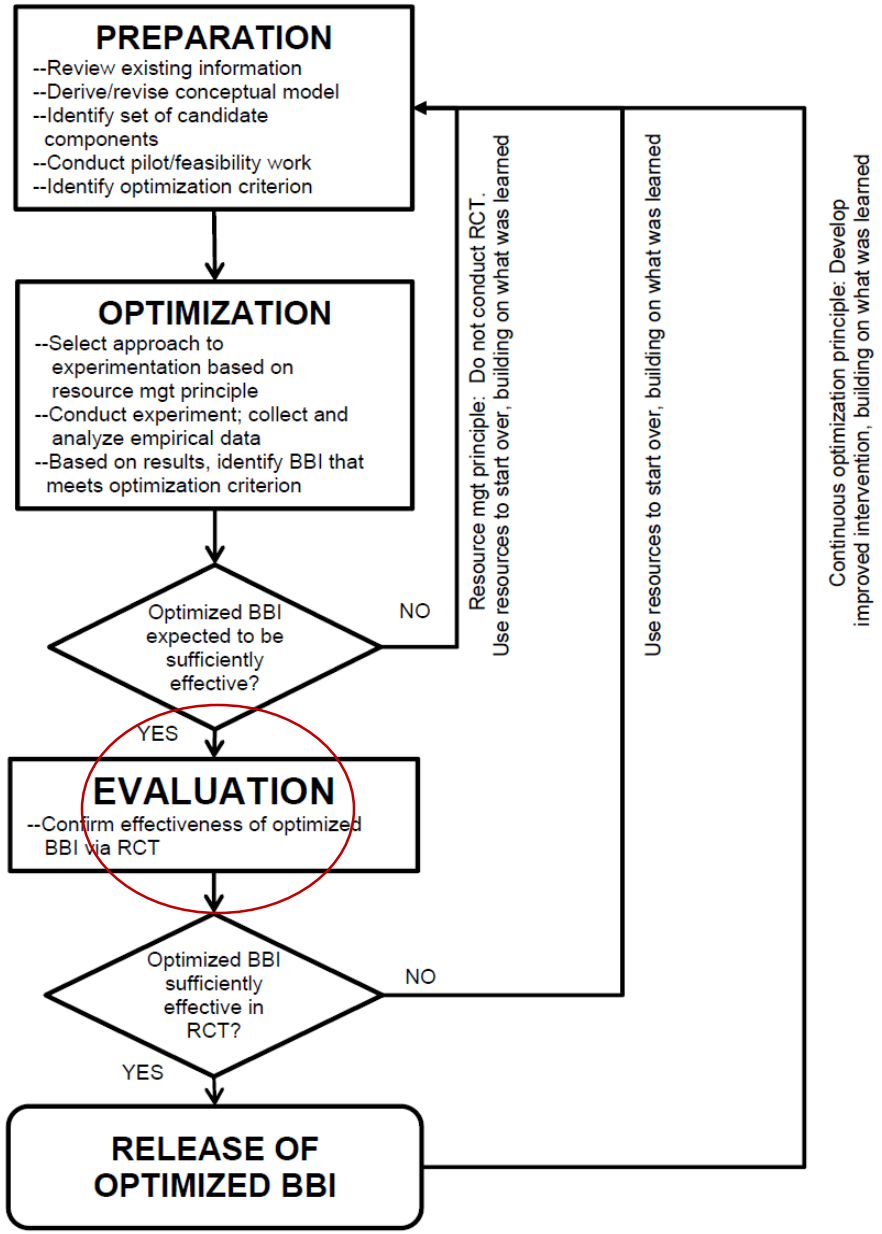

Evaluation phase

- Evaluate optimized intervention in RCT compared to a control or standard of care

Evaluation and optimization: Both important, not the same thing

Optimization: Is the intervention the most effective obtainable within key constraints?	**Evaluation: Is the intervention's effect statistically significant?** No	Yes
No	Identify stronger set of components via screening experiment	Intervention can probably be improved
Yes	Identify stronger components or optimize using different criterion	What we should be aiming for

The resource management principle

- Investigator using MOST must strive to make the best and most efficient use of available resources
  - Available = what the investigator has or can reasonably obtain
- Greatest amount and most appropriate scientific information for money and other resources spent
- MOST does not require an increase in research resources
  - But possibly a realignment

The continuous optimization principle

- Optimization is a process, not an end point
- Think about engineering of consumer products
- Ongoing quest for incrementally better BBIs

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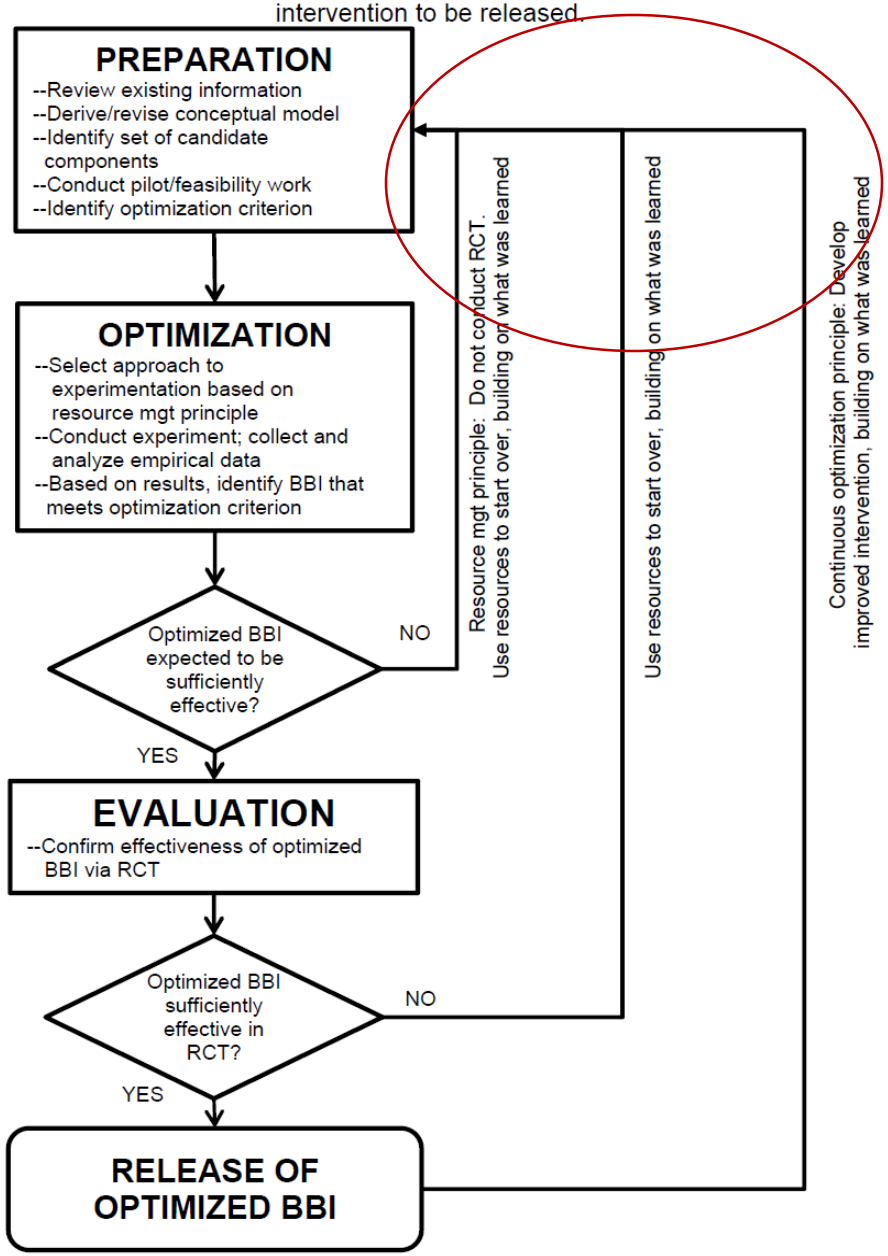

Returning to the preparation phase

- Three return arrows on figure
- If optimized BBI is not expected to be sufficiently effective
  - Resource management principle
- If optimized BBI turns out not to have a statistically significant effect
- After release of BBI
  - Continuous optimization principle

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Take away messages

- MOST is an engineering-inspired framework for building more effective and efficient BBIs
  - Requires an additional phase of optimization
- Resource management principle guides study design
- Using MOST can help move science forward faster
  - As constraints are lifted, new research questions can be asked

Thank you!

- Questions or comments, please contact me
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- Visit Methodology Center website:
- http://methodology.psu.edu