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From Ideas to Interventions: A Review and Comparison of Frameworks Used in Early Phase Behavioral Translation Research

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Developing and testing more effective health-related behavioral interventions is critical to making progress in improving disease prevention and treatment. One way to achieve this goal is to use a systematic and progressive framework that outlines the steps needed to translate theories, findings, and basic understandings about human behavior into risk factor and disease management or mitigation strategies. Although several frameworks and process models have been designed to inform the development and optimization of health-related behavioral interventions, little guidance is available to compare key aspects of these models, clarify their common and unique features, and aid in selecting the best approach for a specific research question. This article describes the major frameworks that focus on early phase translation—that is, approaches that address the design and optimization of behavioral interventions before testing in Phase III efficacy trials. Differences between and common features of these models are described, opportunities for combining frameworks to maximize their impact are noted, and guidance is provided to enable investigators to choose the most useful model(s) when designing and optimizing health-related behavioral interventions. The goal of this article is to promote the consistent use of frameworks that encourage a systematic, progressive approach to behavioral intervention development and testing as one way to encourage the creation of well-characterized, optimized, and potentially more effective health-related behavioral interventions.

Keywords: behavioral intervention development, translational frameworks, early phase translation

Supplemental materials: https://doi.org/10.1037/hea0001095.supp

Designing more effective health-related behavioral interventions to improve disease management and address behavioral risk factors (e.g., tobacco use, adverse diet, sedentary lifestyles, overweight, and obesity) is a critical element in reducing incidence, mitigating progression, and enhancing recovery for chronic diseases such as cancer, cardiovascular disease, and diabetes (Mokdad et al., 2004; Schroeder, 2007). Unfortunately, relatively few behavioral interventions have demonstrated an ability to produce significant and sustainable impacts on either behavioral risk factors or the chronic diseases associated with them. This point has been emphasized in several recent behavioral trial reviews and commentaries that cite a number of problems with behavioral clinical trials and call for new approaches to designing and testing behavioral interventions (Freedland, 2017; Lavoie et al., 2019; Powell et al., in press).

A frequently cited problem with health-related behavioral interventions is that the choice of intervention components, duration, frequency, and modality are typically not based on a progressive, well-delineated research process (Lavoie et al., 2019; Powell et al., in press). In addition, few behavioral intervention studies evaluate health outcomes (e.g., incidence of diabetes or CVD) that are meaningful to patients, providers, health care systems, or payers (Freedland, 2017; Lavoie et al., 2019; Powell et al., in press). Behavioral interventions are also not easily incorporated into medical practice or other health care systems due to complexity, cost or mode of delivery, and a focus on provider and system needs and constraints early in intervention development is an important problem to be addressed (Lavoie et al., 2019). One of the conclusions reached at a conference of the International Behavioural Trials Network—a group of researchers and practitioners "working to improve the quality of clinical trials and behavioural interventions" (see https://www.ibtnetwork.org)—was that, "We need to promote a culture among behavioral trialists that values and encourages the development and rigorous testing of carefully designed, well-described behavioral

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interventions that capture and maintain the attention of medical gatekeepers, health care systems, and third-party payers" (Lavoie et al., 2019).

One promising approach to developing behavioral interventions that have significant clinical impact is illustrated by the over 30 years of foundational and translational research culminating in the development of the highly successful weight loss intervention used in the Diabetes Prevention Program (DPP; Knowler et al., 2002). As outlined by Rena Wing (Wing, 2021), who led the DPP intervention and participated in much of the early research involving its development and preliminary testing, the DPP intervention was based on a long-term, progressive series of research studies. These studies began with basic behavioral and social sciences research (bBSSR) to understand the underlying drivers of obesity, continued through experimental studies evaluating the effects of various weight management strategies and intervention components, and culminated in a large-scale Phase III randomized clinical trial that demonstrated the resulting intervention significantly reduced the incidence of diabetes in prediabetics relative to metformin and a placebo control group and continued to show sustained benefit 15 years later (Diabetes Prevention Program Research Group, 2015; Knowler et al., 2002).

While the development of the DPP weight loss intervention was not guided by a single framework or model, it does exemplify a *translational approach* to intervention development and testing. Translational research has been defined as a multistage process comprised of first, applying discoveries generated during research in the laboratory and in preclinical studies to the development of trials and studies in humans (often referred to as T1 research) and subsequently, research aimed at enhancing the adoption of best practices in the community, or T2 (Rubio et al., 2010). More recently, these two categories of the translational spectrum have been broken down into additional stages and applied to behavioral and social sciences research. Fishbein et al. (2016) provide one example of a more comprehensive translational framework useful for translational behavioral research in which T0 research involves basic discovery science and mechanistic research in both animal models and human subjects; T1 involves early stage intervention development and testing; T2 research is efficacy testing; T3 is effectiveness research; T4 is the dissemination, adoption and implementation of proven interventions in clinical and community settings; and T5 extends this to the global level.

In biomedical research, the translational pathway from basic biological science to clinical research is challenging but benefits from widespread acceptance and use of a well-defined, multiphase regulatory framework that allows drug development to proceed in a standardized, consistent fashion. Translational research progresses from preclinical animal and in vitro research that identifies interventional targets all the way through to effectiveness trials that extend efficacy testing to "real-world" clinical care or community settings (Lipsky & Sharp, 2001). A translational approach to behavioral intervention development is also a powerful vehicle for harnessing new discoveries in the basic behavioral and social sciences in service of building more robust behavioral interventions. We are currently seeing a rapid expansion of knowledge in areas such as the behavioral and cognitive neurosciences, communication science and social marketing, affective, motivational and social processes, choice and decision-making, the psychophysiology of stress, and the dynamics of social systems. Discoveries within these and many other areas of bBSSR are leading to important new insights about behavior and behavior change that hold promise for enhancing the power, reach, and durability of health-related behavioral interventions.

While the systematic and progressive approach to intervention development exemplified by translational research is potentially useful it should be noted that it is not the only avenue through which efficacious behavioral interventions can be designed, optimized, and tested. Approaches using methods derived from engineering have led to the design of effective behavioral interventions in the area of weight management (Savage et al., 2014), and use of systems science and computational modeling approaches (Cipresso, 2015; Luke & Stamatakis, 2012), as well as artificial intelligence and data-mining methods (Robila & Robila, 2020), have led to novel discoveries and the development of innovative interventions for obesity (Gittelsohn et al., 2014) and tobacco control (Luke et al., 2017). Disciplines other than basic behavioral science, such as engineering and agile software development (Hekler et al., 2016) offer examples of other types of frameworks that can be useful in moving an idea from concept to effective application.

Health-related behavioral interventions have been grounded in behavioral theory and basic behavioral science findings since the inception of behavioral medicine as a field, but only recently has early phase behavioral translation research been emphasized as an area of science in its own right. This recognition has been accompanied by an emphasis on developing systematic models or frameworks of the behavioral intervention development process, similar to the "bench to bedside" research phase in biomedical research (Czajkowski et al., 2016). While the biomedical model of translational research may not always be ideally suited to developing and testing complex and multilevel behavioral interventions, it illustrates how a model or framework can be useful in facilitating the translation of novel ideas and findings from discovery to implementation. Following a systematic, progressive framework that guides selection and testing of intervention components, informs modes of delivery, and incorporates end-users' needs can help resolve many of the problems raised in prior critiques of health-related behavioral trial research.

Early models of behavioral intervention development, largely oriented toward public health program planning, focused on theory and methods development in early stages of intervention design. More recently there has been an increase in the number of frameworks that acknowledge and describe in detail the processes and methods useful for translating bBSSR theory and findings into interventions. Notably, unlike in the biomedical arena, there has been a lack of consensus regarding a framework to be used in early phase behavioral translation research. Instead of a standardized, "consensus" model or framework, there now exist several frameworks and process models aimed at translating theory and/or basic behavioral science findings into health-related behavioral interventions. This is also true of later-phase translational research, where some have documented as many as 61 frameworks that have been developed to guide dissemination and implementation (D&I) research (Tabak et al., 2012). However, while some of the models that describe early phase behavioral intervention development also include later-phases of translation, these models are typically distinct from frameworks such as RE-AIM that focus primarily or exclusively on dissemination and implementation research (Glasgow et al., 1999).

Although multiple frameworks for behavioral intervention development and preliminary testing exist, little guidance is available that

identifies and compares key aspects of these models, delineates their common and unique features, and informs the selection of the best approach for a specific research question. In this article, several major frameworks are discussed that include behavioral intervention development—that is, approaches that focus on or at least address the design and optimization of behavioral interventions before their testing in Phase III efficacy or Phase IV effectiveness trials. Differences and common features of these frameworks are discussed, as well as how and when some of them can be combined to enhance their impact and scope. Finally, key features of each framework are described, and guidance is provided regarding which frameworks best address specific goals of intervention development research. The intention is to promote greater knowledge about early phase behavioral translational research and the frameworks or approaches that can facilitate it; highlight important commonalities and synergies between the frameworks; and provide guidance to enable investigators to make an informed choice when designing and optimizing health-related behavioral interventions.

Frameworks for Intervention Development

Models That Emerged From Health Promotion Research

Early frameworks involving intervention design and preliminary testing reflect a population health focus—a solutions-oriented approach that emphasizes community involvement and stakeholder engagement, inclusion of policy and the environment as intervention targets, an emphasis not only on the individual but on context, and evaluation of the intervention's impact at the population level rather than individual level.

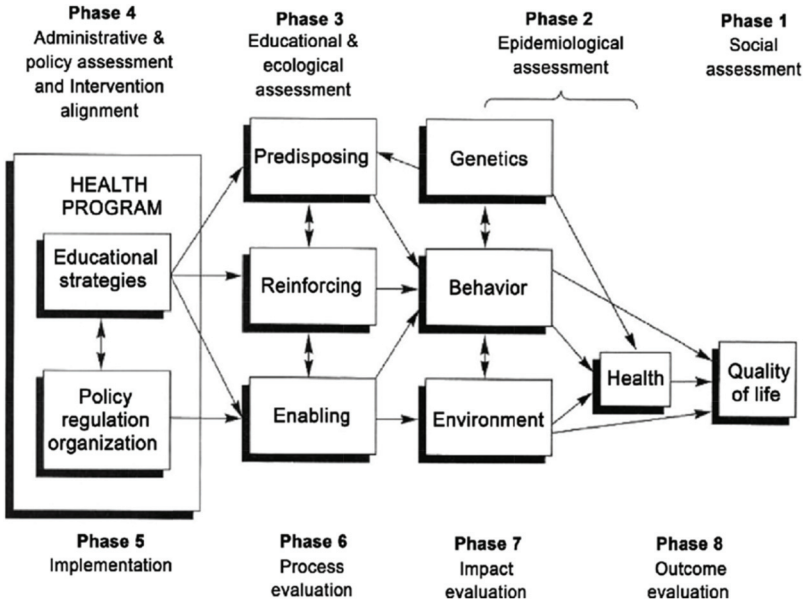
PRECEDE-PROCEED Model

The PRECEDE-PROCEED model (Green, 1974; Green & Kreuter, 2005) represents an ecological approach to health promotion. It is a planning model (Crosby & Noar, 2011) that emphasizes beginning with the desired end point of the intervention and working backward to achieve the specified goal, with community participation featured as a critical aspect of the model. PRECEDE and PROCEED are acronyms. PRECEDE (*Predisposing*, *Reinforcing*, and *Enabling Constructs in Educational/Environmental Diagnosis and Evaluation*) focuses on the processes leading up to a health behavior change intervention. PROCEED (*Policy*, *Regulatory*, and *Organizational Constructs in Educational and Environmental Development*) covers processes inherent in conducting or implementing the intervention (see Figure 1).

PRECEDE-PROCEED encompasses eight phases: four PRECEDE phases (intervention development) and four PROCEED phases (implementing the intervention). Planning the intervention in PRECEDE begins with *Phase 1*, which is aimed at identifying the desired result or end product of the intervention; *Phase 2* involves identifying and prioritizing issues and/or conditions that either act as facilitators or barriers to achieving the desired result, including behavioral, lifestyle, and/or environmental factors that affect them; *Phase 3* focuses on identifying the predisposing, enabling, and reinforcing factors that affect the identified behavioral, lifestyle, and/or environmental factors; and *Phase 4* involves identifying the relevant administrative and policy factors that can influence the process and affect the result.

PROCEED involves four subsequent phases that describe implementation and evaluation of the intervention and its achievement of

Figure 1
PRECEDE-PROCEED Model (Green, 1974)



Note. PRECEDE = Predisposing, Reinforcing, and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation; PROCEED = Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development. From *Health Program Planning: An Educational and Ecological Approach (4th ed.)*, by L. Green and M. Kreuter, 2005, McGraw-Hill. McGraw-Hill has transferred their copyright to co-authors Lawrence Green and Marshall Kreuter, who have given us permission to reproduce the figure in this publication.

the original goal. In *Phase 5*, the intervention is designed and implemented; *Phase 6* involves process evaluation and assesses whether the intervention is being conducted as planned; *Phase 7* involves evaluation of impact (has the intervention achieved the desired impact on the population being targeted); and finally, *Phase 8* involves outcome evaluation (has the intervention achieved the desired outcome outlined at the outset).

The PRECEDE-PROCEED model is extremely flexible and does not specify methods or study designs for use in each of the phases, nor does it define milestones for moving from one phase to the next. Thus, the model lacks guidance about the types of studies most useful for developing an intervention. One of this model's most positive features is its emphasis, at the outset of planning, on incorporating input and involvement from all sectors of a community, from the end-users or stakeholders (the target population), to policymakers, community leaders, community members, and organizations, and all those potentially affected or involved in implementing the program. This framework is also notable for its inclusion of environmental, administrative, and policy factors as key features of the intervention being developed—thus, it is multilevel in nature, focusing not only on the individual, but also on the context (social, policy, and environment) in which the individual resides.

Intervention Mapping

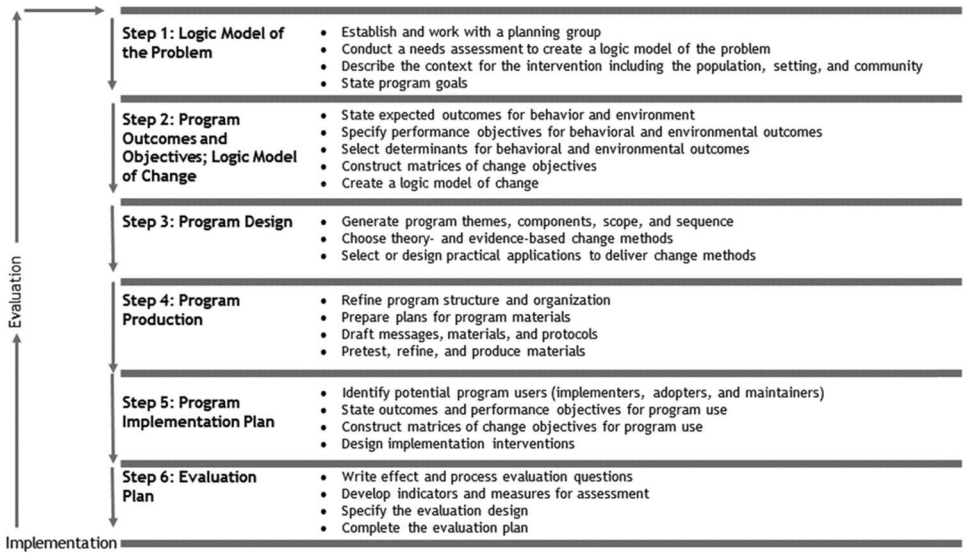
Intervention Mapping (IM) is an intervention development framework (Bartholomew Eldridge et al., 2016) that describes an iterative process that begins with problem identification and proceeds through a series of six steps, each of which involves a set of tasks that provide guidance for the following steps. The series of steps integrate theory and evidence in a framework that encompasses intervention development, implementation, and evaluation (see Figure 2).

The six steps are as follows: *Step 1* involves conducting a needs assessment to identify the problem and what is required to address it; in *Step 2*, one identifies the beliefs and behaviors that should be targeted by the intervention to address the problem; *Step 3* involves identifying theory-based methods that address the behavioral determinants and define practical applications of these methods; in *Step 4*, one combines the methods and applications into an overarching intervention program; *Step 5* aims to identify methods to facilitate the adoption, implementation, and maintenance of the intervention program within a real-world context; *Step 6* involves describing a plan to evaluate process and outcomes of the intervention. It is an iterative, bidirectional model that moves intervention development through a series of phases and permits reversion to earlier steps in the intervention development process, if needed.

The IM approach goes beyond defining these broad steps to describe the specific tasks within each step that must be achieved to move forward to subsequent steps. For example, *Step 1* involves not only description of a health problem to be addressed, but the effect of this problem on the population of interest, identification of behavioral and environmental causes of the problem as well as an understanding of community needs and strengths relative to the problem. In *Step 2*, a set of matrices is constructed consisting of multiple levels at which the intervention applies (i.e., individual through social, policy, and environmental). The matrices define the targets of the intervention and what must be changed by whom at each of the levels.

The specifics of defining components and modes of delivery for an intervention are contained in *Step 3* (program design) while incorporating those methods into a set of plans and program materials, as well as pretesting and refining these materials, are addressed in *Step 4* (program production). However, similar to PRECEDE-PROCEED, there is limited specificity about the ways in which program elements can be developed, delivery modalities tested, and programs optimized—IM relies on the investigator to

Figure 2
Intervention Mapping Framework



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define these details based on the theory used and the context in which the intervention will be applied.

Greenwald and Cullen Model

Greenwald and Cullen (1985) proposed a five-phase model to guide cancer control research (see Figure 3): *Phase I* (Hypothesis development) is aimed at identifying and synthesizing all available scientific evidence about a cancer problem and possible interventions that can be applied, assessing current basic research findings, and developing a testable hypothesis about the effectiveness of applying an intervention; *Phase II* (Methods development) characterizes the variables to be controlled or monitored in subsequent intervention studies and ensures accurate and valid procedures are available for conducting later phase studies. This phase includes pilot testing of feasibility and acceptability of the proposed intervention in a specific population group; development and pilot testing of data collection forms and testing of translations of materials. *Phase III* (Controlled intervention trials) involves testing the hypotheses developed in *Phase I*, with the use of the methodology validated in *Phase II*. The *Phase III* studies test the efficacy of an intervention on a group of individuals who may be selected with the idea to optimize the interpretation of efficacy. In *Phase IV* (Defined population studies), the impact of an efficacious intervention is determined when it is applied in a controlled study of a defined population, and barriers to widespread adoption of the intervention and methods for overcoming these barriers are identified. *Phase V* (Demonstration and implementation) involves applying the proven intervention (from *Phase IV*) in a community at large, with measurement of the public health impact.

While Greenwald and Cullen include phases of research before the Phase III efficacy trial (e.g., hypothesis development, assessment of literature, and feasibility pilot tests), their preefficacy phases do not outline the steps needed nor do they describe any of the possible methods that can be used to define, refine and preliminarily test behavioral interventions. For example, little guidance is provided to the researcher on how to identify treatment targets (either defined as ultimate health outcomes of the eventual intervention or intermediate/proximal treatment targets); how to design and conduct studies to define intervention components; how to refine or optimize interventions; and what the milestones are for moving to later stages of intervention development and testing.

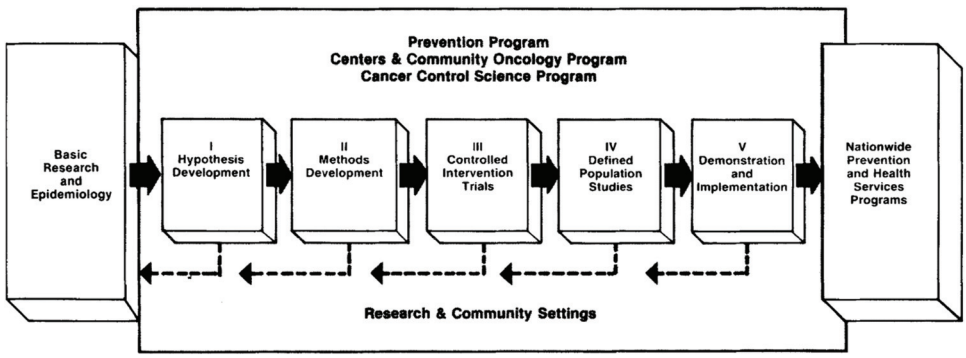
Thus, although Greenwald and Cullen's five-phase model includes phases that precede the Phase III and IV efficacy/effectiveness testing, the description of these early phases omits many details regarding specific processes and procedures through which the ideas and findings from basic science or theory are developed into interventions.

Flay Model

Flay (1986) proposes eight phases of research involved in the development of health promotion programs (see Figure 4): *Phase I* (Basic research) involves conducting research on basic mechanisms (social, psychological, educational, etc.); *Phase II* (Hypothesis development) involves developing hypotheses about new approaches to health promotion for a specific health problem and conducting small-scale pilot tests of intervention components; *Phase III* (Pilot applied research) involves conducting preliminary tests of new approaches using pre- or quasi-experimental designs but on a very small-scale (few individuals or aggregated units per condition); *Phase IV* (Prototype studies) involves conducting smaller-scale tests of refined programs using experimental or quasi-experimental designs and assessing desired behavioral outcomes added at this Phase or *Phase III*; *Phase V* (Efficacy trials) involves conducting experimental (randomized) trials large enough to detect effects on identified behavioral outcomes; *Phase VI* (Treatment effectiveness trials) involves the conduct of trials to determine the effectiveness and acceptability of efficacious programs on a broader population; *Phase VII* (Implementation effectiveness trials) involves the conduct of trials to determine effectiveness of an efficacious and acceptable program under real-world conditions; and *Phase VIII* (Demonstration studies) involves studies to determine effects of an efficacious program on public health on a wider scale (schools, cities, and states).

Flay's eight-phase model builds on and extends the Greenwald and Cullen model. It specifically identifies several early (preefficacy) phases, for example, Phase II–IV (hypothesis development and small-scale pilot studies; pilot applied research; and prototype studies). However, as with Greenwald and Cullen, Flay provides little detail on designs to be applied across this model. Besides stating that these early stages should involve small-scale, experimental or quasi-experimental studies, no specific study methods are discussed, nor are there milestones (treatment targets) for moving forward from one phase to another. In addition, there is no explicit mention of bidirectionality; it is

Figure 3
Greenwald and Cullen's Cancer Control Phases



Note. From "The New Emphasis in Cancer Control," by P. Greenwald and J. W. Cullen, 1985, *Journal of the National Cancer Institute*, *74*, pp. 543–551. Copyright 1985 by Oxford University Press. Reprinted by permission of Oxford University Press.

Figure 4
Flay's Eight-Phase Model

SUGGESTED RESEARCH PHASES FOR THE DEVELOPMENT OF HEALTH PROMOTION PROGRAMS

	Phase	Description	Methods
I	Basic research	Disciplinary-based research on basic mechanisms (e.g., etiology, epidemiology, social psychology, education).	Defined by discipline.
II	Hypothesis development	Development of hypotheses about new approaches to health promotion for a specific health problem.	Review; synthesis of basic research; exploratory research.
III	Pilot applied research	Preliminary tests of new approaches toward using basic research results to achieve specific immediate effects related to specific health promotion goals (and methods development for future research).	Pilot test (pre- or quasi-experimental) of innovative manipulations; very small scale (few individuals or aggregated units per condition).
IV	Prototype studies	Small-scale tests of refined programs using components suggested by Phase III research to be efficacious (and further development of methods for future research).	Experimental or quasi-experimental tests of complete "programs"; small number of aggregated units (e.g., schools) per condition; measurement to include behavioral outcomes.
V	Efficacy trials	Trials to determine the efficacy of programs or approaches suggested to be effective by earlier phases.	Pure experimental trials with random assignment of aggregated units to conditions in sufficient number for practical, significant behavioral effects to be detected.
VI	Treatment effectiveness trials	Trials to determine the effectiveness and acceptability of efficacious programs on a broader population.	Large-scale experimental or quasi-experimental trials in real-world settings, but with delivery/implementation optimized/ standardized as much as possible (and carefully assessed); morbidity/mortality outcomes may be assessed.
VII	Implementation effectiveness trials	Trials to determine the effectiveness of an efficacious and acceptable program under real-world conditions of delivery/implementation.	Large-scale experimental or quasi-experimental trials in real-world settings; delivery/implementation can vary naturally or involve planned comparisons (deliberate variations); careful assessment of delivery/implementation; morbidity/mortality may be assessed.
VIII	Demonstration studies	Studies to determine the effects of an efficacious program on public health when implemented in whole systems (schools, cities, states, nations).	"Naturalistic" quasi-experimental program evaluation; morbidity/ mortality definitely assessed; natural variation in delivery/ implementation may be studied; diffusion patterns may be studied.

Note. From "Efficacy and Effectiveness Trials (and Other Phases of Research) in the Development of Health Promotion Programs," by B. R. Flay, 1986, *Preventive Medicine*, *15*, pp. 451–474 (https://doi.org/10.1016/0091-7435(86)90024-1). Copyright 1986 by Elsevier Inc. Reprinted with permission from Elsevier.

not clear whether and under what conditions moving backward to earlier developmental stages is encouraged.

Notably, Flay explicitly recognizes the importance of basic behavioral science research and the preliminary testing of behavioral interventions, utilization of nonrandomized (quasi-experimental, small-N) designs in early phases of intervention development, and use of a phased approach to guide this early testing. The following quote reflects his visionary assessment of the state and promise of health-related behavioral intervention research, foreshadowing the emergence of the more recent increased emphasis on health-related basic and early phase translational behavioral and social sciences research:

> Much untapped basic research in the social, educational, medical, and basic sciences provides a wealth of data on which to base new hypothesis development and pilot applied research. The National Institutes of Health (NIH) might be advised to support more such research. This would be more desirable than the current practice of leaving the support of developmental research (Phases II and III) to the few local health agencies who support educational, psychosocial, or behavioral research, while the bulk of federal funds is concentrated in Phases IV and VI–VIII studies. A few well-placed dollars in support of initial tests of new, creative ideas might provide a substantial payoff in the long run. Without such support, younger scientists are not provided the opportunities they deserve to test their ideas, and the future development of the health promotional sciences runs the danger of being thwarted, forever frozen in a cycle of tests of minor variations of current approaches. (Flay, 1986, p. 467)

Models for Basic Science-Informed Behavioral Intervention Research

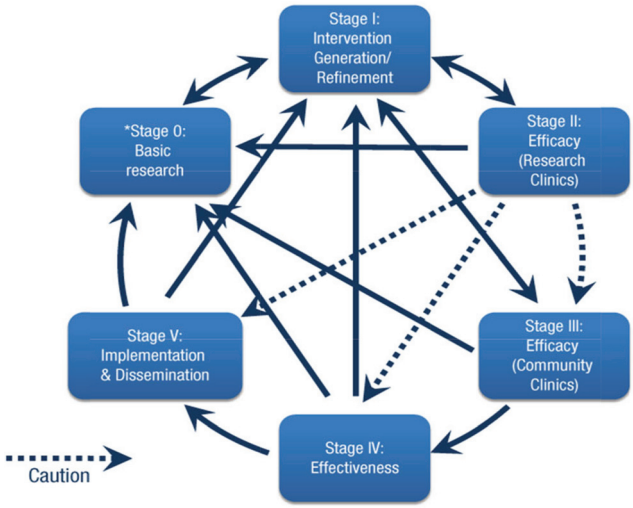
Recently, several frameworks have been developed that focus explicitly on the identification of underlying mechanisms or drivers—biobehavioral, social, or psychological—of an individual's health-related behaviors and the translation of these basic behavioral and social science findings into health-related behavioral interventions.

Stage Model of Behavioral Intervention Development

In the 1990s and 2000s, the National Institute of Mental Health (NIMH) began an effort to explore the disconnect between basic and clinical research and how encouraging increased translation of basic research into clinical applications could yield more effective therapies for mental health conditions. This effort culminated in an NIMH Advisory Council report entitled "Translating behavioral science into action" (DHHS, 2000) that described barriers to and facilitators of basic-to-clinical research in the mental health arena, and that stimulated a series of workshops and publications that elaborated on the need for integrating basic and clinical behavioral research (Muehrer et al., 2002).

During this period, Lisa Onken, Chief of the National Institutes of Drug Abuse's Behavioral Therapies Development Branch, developed a series of workshops that brought together basic behavioral and clinical researchers to explore innovative approaches to address challenging mental health and substance abuse problems. As part of this process, Onken and colleagues identified the need for a model or framework to guide the treatment development process by integrating basic and mechanistic behavioral research with more applied clinical research. Their framework, called the Stage Model of Treatment Development, began as a three-stage model for developing treatments in mental health and substance abuse (Rounsaville et al., 2001) and has since been revised to encompass six stages of intervention development and testing (Onken et al., 2014; see Figure 5).

Figure 5
Stage Model



Note. Dotted arrow indicates the importance of using caution when considering this pathway. From "Reenvisioning Clinical Science: Unifying the Discipline to Improve the Public Health," by L. S. Onken, K. M. Carroll, V. Shoham, B. N. Cuthbert, and M. Riddle, 2014, *Clinical Psychology: Science and Practice*, *2(1)*, pp. 22–34 (https://doi.org/10.1177/2167702613497932), Figure 1, p. 27. Copyright 2014 by SAGE Publications. Reprinted by permission of SAGE Publications, Inc. See the online article for the color version of this figure.

Stage 0 (Basic Research) involves basic science that occurs before intervention development; *Stage I* (Intervention Generation/Refinement) encompasses all activities related to the creation and preliminary testing of a new behavioral intervention, and includes *Stage IA* (generation of new behavioral interventions, modification/adaptation/refinement of existing interventions) and *Stage IB* (feasibility and pilot testing); *Stage II* (Efficacy–Research Clinics) consists of experimental testing of promising behavioral interventions in research settings with research-based providers and patients; *Stage III* (Efficacy–Community Clinics) consists of experimental testing of promising behavioral interventions in community settings with community-based providers but maintains a high level of control over intervention delivery to maximize internal validity; *Stage IV* (Effectiveness) examines empirically supported behavioral interventions in community settings with community-based providers but allows for more adaptation/less control to maximize external validity; *Stage V* (Implementation and Dissemination) examines strategies of implementation and adoption of empirically supported interventions in community settings. Within the model, arrows indicate pathways through which a researcher can move from one stage to another (e.g., one can move from Stage I – "Intervention Generation/Refinement" – to Stage III – "Efficacy in "Real-world" Settings" – and back again from Stage III to Stage I). Dotted arrows indicate pathways meriting "caution" in moving from early (controlled) efficacy research to later stages of efficacy, effectiveness, and implementation research, due to a need to fully characterize mechanisms of action and identify essential and nonessential components of the intervention before moving forward.

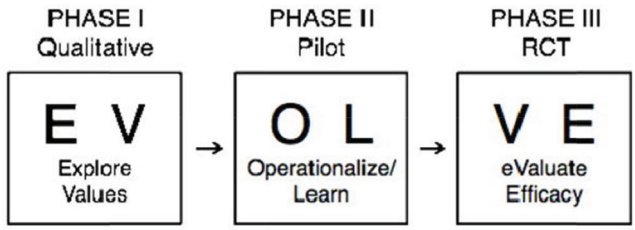
In the Stage Model, treatment development can be based on basic behavioral science theory or findings as well as clinical observation, and the model is iterative in nature—movement back to prior phases of development may be warranted if desired outcomes are not achieved in later phases. It provides more detail about early phases of behavioral intervention development than some of the other models (e.g., either Flay or Greenwald and Cullen), provides milestones for forward movement through its stages, acknowledges use of basic behavioral science findings in treatment development, and proposes a bidirectional treatment development process. It also includes specifics about manual development and training of therapists in early phase treatment development research. The revised (2014) Stage Model encourages research aimed at identifying mechanisms of action at each stage of the behavioral intervention development process and describes behavioral intervention development as incomplete until the intervention is implementable (e.g., includes materials describing how to ensure that community providers administer the intervention with fidelity). Thus, the Stage Model views the entire spectrum of stages, from basic science to implementation research, as part of the intervention development process. However, it does not provide detail in terms of treatment development methods and does not specify the use of clinically significant treatment targets to guide intervention development.

The EVOLVE Mixed-Methods Approach to Behavioral Intervention Development

EVOLVE (Explore Values, Operationalize and Learn, and eValuate Efficacy) is a three-phase, mixed-methods approach to designing and testing health-related behavioral interventions (Peterson et al., 2013) developed as part of the National Heart, Lung, and Blood Institute (NHLBI) initiative entitled "Translational Behavioral Science Research Consortium" (TBSRC), which aimed to translate innovative, cutting-edge findings from basic behavioral and social science research to the prevention and management of heart, lung, blood, and sleep diseases and disorders (National Institutes of Health, 2001). Investigators at the Cornell TBSRC project used the EVOLVE approach to develop and test an intervention involving positive affect and self-affirmation in three different chronic disease populations (Charlson et al., 2007; Mancuso et al., 2012; Ogedegbe et al., 2012; Peterson et al., 2012).

EVOLVE involves a qualitative phase, a pilot phase and a randomized controlled trial (RCT) phase (see Figure 6). *Phase I*

Figure 6
The EVOLVE Mixed-Methods Approach to Behavioral Intervention Development



Note. EVOLVE = Explore Values, Operationalize and Learn, and eValuate Efficacy. From "Translating Basic Behavioral and Social Science Research to Clinical Application: The EVOLVE Mixed Methods Approach," by J. C. Peterson, S. Czajkowski, M. E. Charlson, A. R. Link, M. T. Wells, A. M. Isen, C. A. Mancuso, J. P. Allegrante, C. Boutin-Foster, G. Ogedegbe, and J. B. Jobe, 2013, *Journal of Consulting and Clinical Psychology, 81(2)*, pp. 217–230 (https://doi.org/10.1037/a0029909). Copyright 2013 by the American Psychological Association.

(Qualitative study to Explore Values) involves qualitative methods that can include focus groups, ethnographic interviews, and/or other qualitative methods (Boutin-Foster et al., 2007) that are used to explore the values, attitudes, and beliefs of individuals who are the targets of the intervention, as well as the facilitators of and barriers to adopting the behavior(s) being promoted in the intervention. Participant responses during this phase are used to shape the intervention's components and mode of delivery and to tailor the intervention to the particular patient population being targeted. *Phase II* (Pilot study to Operationalize and Learn) involves pilot testing of the intervention's components and delivery approach. In this phase, the intervention and how it is delivered are iteratively refined to achieve an optimized intervention package and delivery mode. *Phase III* (Randomized Controlled trial to "eValuate" Efficacy) involves conduct of an adequately powered RCT to evaluate the effects of the optimized intervention on clinical or behavioral endpoints of interest.

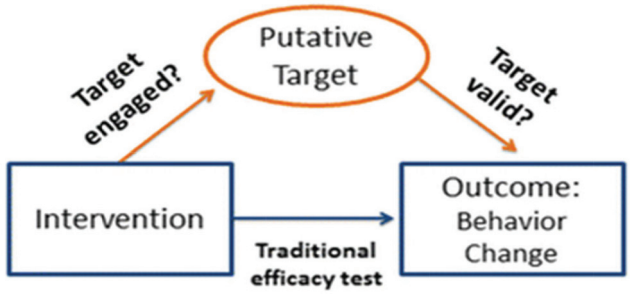
EVOLVE is notable for its explicit inclusion of qualitative methods to identify and incorporate the perspectives, values, and beliefs of individuals who will be the end-users of the intervention being developed into both the intervention's content and mode of delivery. It also highlights the importance and value of utilizing basic behavioral science theory and findings in health-related behavioral interventions and of iteratively refining the intervention's content and delivery modality in pilot studies to maximize the intervention's effects before more rigorous testing in a randomized trial design. Furthermore, it is one of few examples in which use of a behavioral intervention development framework produced an intervention that significantly improved clinically meaningful endpoints in randomized efficacy trials (Ogedegbe et al., 2012; Peterson et al., 2012).

Science of Behavior Change (SOBC) Experimental Medicine Approach

The NIH Common Fund Science of Behavior Change Program (SOBC, https://commonfund.nih.gov/behaviorchange/index) supports the application of an "experimental medicine approach" to the development of mechanistically based interventions for preventing and treating unhealthy behaviors that promote development of disease (see Figure 7). This approach includes four main steps: *Step 1* involves identifying a set of putative targets within a psychological or behavioral domain that is implicated in health behavior; *Step 2* involves leveraging existing or developing new experimental or intervention approaches to engage the targets; *Step 3* involves identifying or developing appropriate assays (measures) to permit verification of target engagement; and *Step 4* involves testing the degree to which engaging the targets produces a desired change in health behaviors that lead to clinically significant outcomes or endpoints (Nielsen et al., 2018).

The experimental medicine approach provides a well-delineated "roadmap" for identifying, assessing, and validating targets of behavior change interventions to maximize the impact of the intervention on the behavioral risk factor and ultimately, the health outcome of interest. The model emphasizes that intervention development should only move forward once there is clear evidence about what works to change behavior and why it works. While the SOBC approach is not explicit about what methods to use, it emphasizes clear milestones for advancement. The approach also uses biomedical terminology, such as identifying and validating the engagement of putative "targets" of an intervention and measurements as "assays" of target engagement. The congruence with biomedical terminology may enhance the acceptance and uptake of this approach by biomedical scientists and clinicians.

Figure 7
SOBC's Experimental Medicine Approach



Note. SOBC = Science of Behavior Change Program. From "The NIH Science of Behavior Change Program: Transforming the Science Through a Focus on Mechanisms of Change," by L. Nielsen, M. Riddle, J. W. King, W. M. Aklin, W. Chen, D. Clark, E. Collier, S. Czajkowski, L. Esposito, R. Ferrer, P., Green, C. Hunter, K. Kehl, R. King, L. Onken, J. M. Simmons, L. Stoeckel, . . . W. T. Weber and NIH Science of Behavior Change Implementation Team, *Behaviour Research and Therapy, 101*, pp. 3–11 (https://doi.org/10.1016/j.brat.2017.07.002). Copyright 2017. Published by Elsevier Ltd. Reprinted with permission from Elsevier. See the online article for the color version of this figure.

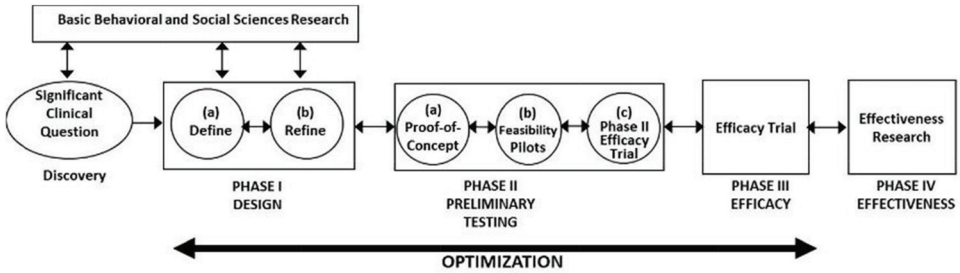
Obesity-Related Behavioral Intervention Trials (ORBIT) Model

The ORBIT model was developed as part of a trans-NIH Consortium funded in 2009 to support the translation of basic behavioral and social science findings into innovative interventions to reduce obesity and improve obesity-related behaviors. Although designed by members of a consortium focused on obesity, the model is intended to apply more broadly to the early phase (preefficacy) development of behavioral treatments for a wide range of chronic physical diseases and their risk factors (Czajkowski et al., 2015). The ORBIT framework encompasses two overarching phases of intervention development, entitled "Phase I" (Intervention Design) and "Phase II" (Preliminary Testing), each of which includes distinct subphases. The original ORBIT model (Czajkowski et al., 2015) included two phases with two subphases in each; it has been revised (Powell et al., in press) to expand the second phase to incorporate three distinct subphases (see Figure 8).

The ORBIT model begins with identification of a significant clinical or public health problem for which findings from bBSSR can be used to determine the drivers of the problem and define intervention strategies to address the problem. Once these bBSSR drivers or mechanisms are identified, one moves through a series of phases designed to target these behavioral drivers and ultimately the behavioral and health outcomes in question.

Phase 1. (Design) includes two subphases. In *Phase Ia* (Define the Intervention) treatment targets and components are initially defined. Tasks include identifying the behavioral risk factor target and clinically significant/meaningful milestones, providing the basic behavioral and social science research basis for treatment

Figure 8
ORBIT Model for Development of Behavioral Treatments



Note. ORBIT = Obesity-Related Behavioral Intervention Trials. From "*Behavioral Clinical Trials for Chronic Diseases: Scientific Foundations*," by L. H. Powell, K. Freedland, and P. G. Kaufmann, in press, Springer International. Copyright with permission from Springer.

components and targets, describing the pathways through which treatment can affect outcomes, and identifying candidate intervention components. Approaches might include systematic reviews to determine treatment targets and potential intervention elements; laboratory and field experiments to identify behavioral and biological mechanisms of action; observational studies to identify key intervention targets and points of "entry;" and qualitative and mixed methods research to assess acceptability of the proposed approach to end-users (e.g., "user-centered" research).

In *Phase Ib* (Refine the Intervention), intervention components are tested and refined for strength and efficiency to identify an essential set of treatment components; determine aspects of delivery (mode, frequency, duration, dose, and intensity); and determine the need for tailoring (e.g., for subgroups). Here, methods can include single-case designs and/or experimental studies that test effects of varying an intervention's content, timing, frequency, duration, intensity, and mode of delivery; dose-finding studies; factorial or fractional factorial experiments (Collins, 2018); system identification modeling (Timms et al., 2012); adaptive trial designs including sequential, multiple assignment, randomized trials, or SMARTs (Collins et al., 2014), and microrandomized trials or MRTs (Klasnja et al., 2015).

Phase II. (Preliminary testing) includes three subphases. *Phase IIa* (Proof-of-Concept) involves testing aimed at demonstrating plausibility of the intervention's ability to alter the treatment target in a prespecified, clinically significant way. The typical designs for this phase are nonrandomized, uncontrolled, small-N, or single-case design studies (e.g., Dallery & Raiff, 2014; Ridenour et al., 2013).

Phase IIb (Pilot and Feasibility Testing) involves pilot and feasibility tests to determine feasibility and acceptability, including the ability to implement the protocol and recruit and retain patients. Study designs used in this phase may be randomized or nonrandomized, and usually involve assessment of the numbers available for screening and recruitment, estimates of yield (screening to enrollment ratio), drop-out rate, crossovers, and adherence to treatment, among other practical issues regarding the intervention and study protocol.

Phase IIc (Phase II Efficacy) determines whether the intervention influences a behavioral or intermediate outcome of interest that is typically in the mechanistic pathway and/or related to the ultimate clinical or physical health outcome of interest. These studies are usually randomized and may or may not precede a larger Phase III trial.

Key features of the ORBIT model include: (1) ***beginning with the end in mind***, with the goal being to produce behavioral interventions that can show meaningful clinical and/or public health impact, not just small though statistically significant changes in behavior, with the process guided by significant clinical questions from end users (e.g., patients, providers, public health researchers and practitioners, and health care systems); (2) ***progression from basic to more clinical/applied stages***, which addresses the problem that many behavioral interventions are stuck in preefficacy phases, testing how to achieve small changes in behavior without moving to Phase III and IV RCTs with clinically important endpoints; the ORBIT model pushes toward the efficacy trial and beyond, emphasizing the importance of developing a long-term, systematic program of intervention development, culminating in Phase II/IV trials; (3) ***each phase includes clinically meaningful milestones***, specifying a priori criteria for moving to next phase of the intervention development process, with an emphasis on achieving clinically significant (not just statistically significant) change in behavioral targets.

Similar to other frameworks, the ORBIT model is flexible in terms of the number and types of studies within phases, the duration of each phase, and movement from one phase to the next (e.g., one can "skip" a phase if necessary); provides guidance regarding specific study designs and methods for use at each phase; is bidirectional, allowing for "failure" at any stage and return to earlier phases as needed; and like the SOBC approach, the ORBIT model mirrors the biomedical framework, using Phase I–IV terminology.

Models for Testing Complex, Multicomponent, and/or Multilevel Interventions

Medical Research Council (MRC) Framework

The Medical Research Council (MRC) framework is intended to guide the design and testing of complex interventions (Craig et al., 2008). It deviates from some of the other intervention development frameworks in its explicit focus on the development and testing of interventions in the context of the broader social, environmental and policy levels of influence on human behavior. The MRC framework defines a complex intervention as encompassing not

just multiple interventional components, but the number and difficulty of behaviors required in delivering and engaging in the intervention, the number of levels (individual, group, and organization) being targeted by the intervention, and the number of outcomes and degree of intervention tailoring allowed (Craig et al., 2008). The MRC Framework involves a cyclical framework with four steps (see Figure 9).

Step 1 (Development) involves identifying the evidence base, identifying/developing appropriate theory, and modeling process and outcomes; *Step 2* (Feasibility/Pilot Testing) involves testing procedures, estimating recruitment/retention, and determining sample size; *Step 3* (Evaluation) involves assessing effectiveness, understanding change processes, and assessing cost-effectiveness (e.g., causal modeling and economic evaluation); *Step 4* (Implementation) involves dissemination, surveillance and monitoring, and long-term follow-up.

The MRC guidance provides a framework that allows researchers "to develop interventions systematically, using the best available evidence and appropriate theory, then to test them using a carefully phased approach, starting with a series of pilot studies targeted at each of the key uncertainties in the design, and moving on to an exploratory and then a definitive evaluation." This framework also involves bidirectional movement across stages and includes two preefficacy phases.

The MRC framework is one of the few intervention development frameworks that focuses exclusively on complex interventions. It explicitly acknowledges the importance of the early phases of behavioral intervention development and proposes a bidirectional model that includes developmental and early testing, citing "*. . . the need for greater investment in developmental studies prior to large scale evaluations, and in implementation research*" (Craig et al., 2008). The MRC framework does not describe specific study designs, methods, or analyses to be used but rather identifies issues and questions to be addressed across the stages of behavioral intervention development, evaluation, and implementation. However, it does provide a series of case studies that illustrate approaches that can be taken at each stage of the framework.

Similar to other approaches that emphasize the importance of identifying mechanisms of action as targets of the intervention, the MRC framework promotes theoretical specification of the process through which the intervention is thought to achieve behavioral change to identify and strengthen links in the causal chain. Finally, this framework is different in several other respects from other intervention development models. For example, it encourages use of multiple outcome measures to assess potential unintended consequences of an intervention. The MRC framework also promotes flexibility of procedures rather than strict standardization in intervention protocols to allow for adaptation to local settings.

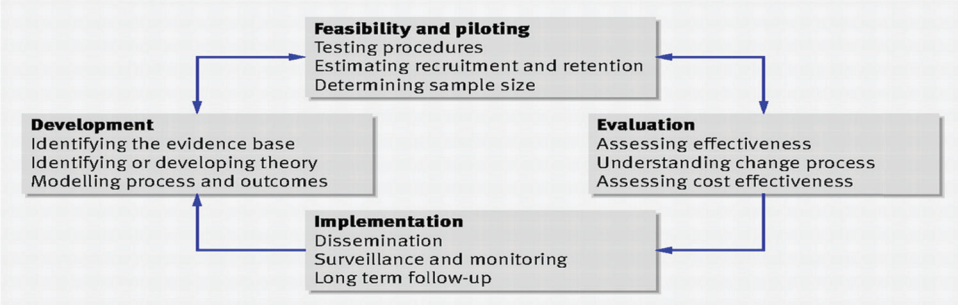
COM-B and Behavior Change Wheel

Susan Michie and colleagues have developed a behavioral intervention classification and intervention development framework that is based on a comprehensive review of 19 frameworks that classified behavior change interventions (Michie et al., 2011). This effort to define a comprehensive and coherent framework for designing and testing behavioral interventions is based on several tenets. First, behavioral intervention components are often poorly described and there exist no systematic, comprehensive systems for organizing and classifying interventions and their components, limiting progress in the science of behavior change and reducing generalizability of findings. Second, the lack of emphasis in behavioral science on identifying and testing mechanisms of action results in inability to identify why successful interventions work and how they can be replicated, and if ineffective, why and how this can be redressed in future studies.

Key to this framework is the classification system with standardized definitions of interventional components, known as Behavior Change Techniques (BCTs). A BCT is defined as "an observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behavior." BCTs are the active ingredients of behavior change interventions (Abraham & Michie, 2008) and use of the common standardized vocabulary to define behavior change intervention components supports transparency and reproducibility.

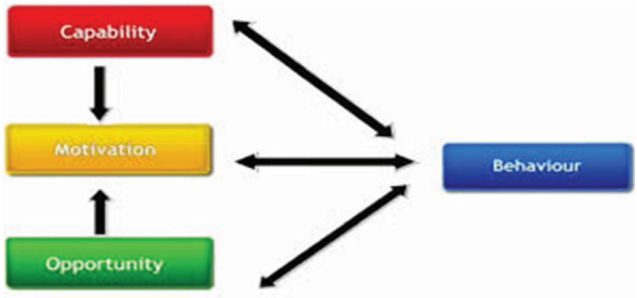
Additionally, Michie and her team described nine functions of interventions and seven conditions or policies that could enable those interventions. The result was the COM-B system (see Figure 10), which outlines the interactions between three Factors. *Factor 1* (Capability) defines a person's psychological and physical capacity

Figure 9
Medical Research Council Framework



Note. Republished with permission of from "Developing and Evaluating Complex Interventions:The New Medical Research Council guidance," by P. Craig, P. Dieppe, S. Macintyre, S. Michie, I. Nazareth, M. Petticrew, and The Medical Research Council Guidance, 2008, *BMJ, 337*, p. a1655 (https://doi.org/10.1136/bmj.a1655). Copyright 2008 by BMJ Publishing Group Ltd. Copyright permission conveyed through Copyright Clearance Center, Inc. See the online article for the color version of this figure.

Figure 10
COM-B Model



Note. From "The Behaviour Change Wheel: A New Method for Characterising and Designing Behaviour Change Interventions," by S. Michie, M. M. van Stralen, and R. West, 2011, *Implementation Science, 6*, p. 42 (https://doi.org/10.1186/1748-5908-6-42). CC-BY. See the online article for the color version of this figure.

for engaging in the required activity; *Factor 2* (Opportunity) describes the external factors that enable or allow the behavior to occur; and *Factor 3* (Motivation) identifies the processes that direct and energize the behavior, including both conscious processes such as goal-setting and decision-making, and nonconscious processes, such as habits and emotional factors.

This COM-B "behavioral system" forms the hub or center of a "behavior change wheel" (BCW), which is encircled by the nine identified intervention functions that address deficits in one or more of these conditions. These functions are themselves surrounded by seven categories of policy or external conditions that prompt, enable, or promote the intervention (see Figure 11).

The BCW incorporates concepts from another framework—the Theoretical Domains Framework (TDF)—that was originally used to evaluate the behavior of health professionals implementing practice-based recommendations but has been extended for use in characterizing the determinants of behavior more generally. In the TDF, 33 theories of behavior and behavior change were synthesized into 12 domains (Michie et al., 2005) and in a subsequent version, 14 domains (Cane et al., 2012). The TDF has since been used in behavior change research including the design of interventions using the BCW (Michie et al., 2011).

Notable features of the BCW and COM-B model include the ability to precisely specify target behavior, the use of behavioral theory to develop interventions systematically, the description of mechanisms through which the intervention works, and the ability to specify behavior change techniques and to link them to theories. The advantages of the COM-B and BCW systems are that they support the reporting of behavior change interventions using standardized and widely shared and understood terminology, they focus on defining mechanisms of action to provide more clarity about how and why an intervention might (or might not) work, and they recognize that multilevel influences, from the individual level through interpersonal and policy levels, are drivers of behavior and behavior change.

The Multiphase Optimization Strategy (MOST)

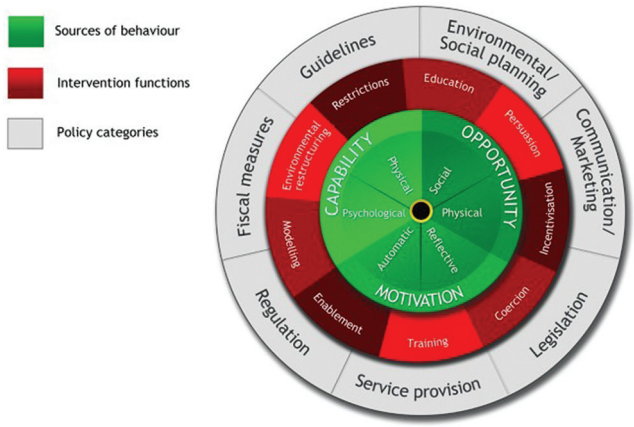
MOST is an intervention development framework based on engineering principles that aims to optimize multicomponent behavioral interventions (Collins, 2018). The goal of MOST is to identify the most effective and efficient set of components before more rigorous testing in a randomized controlled trial. Thus, the ultimate goal of the optimization process is to balance effectiveness and efficiency (i.e., money, participants, time, equipment, staff, and patient burden; Collins, 2018). MOST consists of three phases: Preparation, Optimization, and Evaluation (see Figure 12).

In the *Preparation* phase, the groundwork is laid for intervention optimization through mining of behavioral theories, review of literature, and secondary data analyses. This leads to delineation of a theoretical model that guides decisions that are required for optimization such as the selection of intervention components based on specific optimization criterion (e.g., a specific level of effectiveness taking into account cost, burden, and other contextual elements).

During *Optimization*, intervention components are tested using the optimization criterion. The methods used can include factorial or fractional factorial experiments (Collins, 2018), or adaptive trial designs including sequential, multiple assignment, randomized trials or SMARTs (Collins et al., 2014), and micro-randomized trials or MRTs (Klasnja et al., 2015). The *Evaluation* phase involves an RCT to confirm the effectiveness of an optimized intervention.

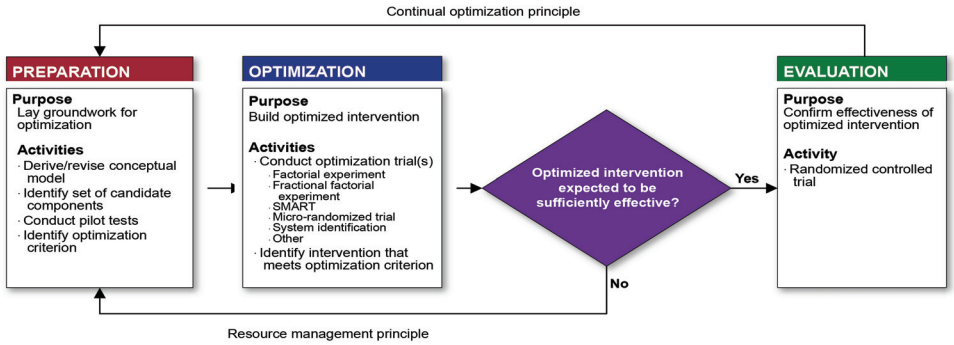
Following the Optimization phase, and based on effect size estimates obtained, a decision is made to either evaluate the intervention in an RCT; to move back to the Preparation or Optimization phase for further refinement of the concepts or components of the intervention, or in some cases (e.g., if one intervention component emerges from the optimization phase as clearly superior in meeting the optimization criterion), to move the intervention into application in clinical or public health practice. If a decision is made to move to the Evaluation phase, the intervention is tested in an RCT against a control or comparison condition. If the intervention is not found to be effective, movement back to the Preparation phase may be warranted.

Figure 11
Behavior Change Wheel



Note. From "The Behaviour Change Wheel: A New Method for Characterising and Designing Behaviour Change Interventions," by S. Michie, M. M. van Stralen, and R. West, 2011, *Implementation Science, 6*, p. 42 (https://doi.org/10.1186/1748-5908-6-42). CC-BY. See the online article for the color version of this figure.

Figure 12
The Multiphase Optimization Strategy (MOST)



Note. From "*Optimization of Behavioral, Biobehavioral, and Biomedical Interventions: The Multiphase Optimization Strategy (MOST)*," by L. M. Collins, 2018, Springer. Copyright 2018 by Springer International Publishing. Reprinted with permission. See the online article for the color version of this figure.

Two fundamental principles underlie MOST. First, the resource management principle, which specifies the strategic management of research resources such as money, participants, time, equipment, staff, and patient burden to move intervention science forward in a timely manner. Second, the continuous optimization principle, which recognizes optimization as an ongoing process, resulting in continuous improvement to an intervention to enhance its effectiveness and/or efficiency. Designing and testing interventions based on these fundamental principles is intended to improve the uptake and implementability of behavioral interventions.

Comparison of Intervention Development Frameworks: Common and Unique Elements

Each of the models, frameworks, and approaches discussed in this article focuses on promoting a systematic, rigorous, and thoughtful approach to intervention development. Increased use of one or more of these models has the potential to advance behavioral intervention development research and accelerate progression across the translational continuum. Table 1 (see online supplementary materials) provides an overview of some of the key features of each model.

These models and frameworks share a number of common elements that are essential features of any intervention development program, and also have unique features that recommend their use for particular research questions. These common and defining features are described below.

Common Elements Among Frameworks

All of the frameworks discussed describe a *systematic intervention development process* that links one or more sources of ideas, theories, findings, and concepts on which to base an intervention (e.g., basic behavioral research findings and theory, clinical or public health observations, epidemiologic research, and prior systematic reviews) to clinical and public health applications. In addition, all of these frameworks highlight the importance of *identifying the processes that drive behavior change* and can serve as appropriate targets of behavior change interventions. These drivers of behavior change vary from underlying psychological mechanisms to broader features of the social, cultural, behavioral, and policy environment, but an essential aspect of all intervention development models or frameworks is the precise identification of drivers of behavior and behavior change.

All of these models exhibit some degree of flexibility, with most emphasizing *bidirectional, iterative movement* through phases or stages in progressive fashion, but with an ability to move backward to earlier phases if warranted. The concept of "fail early, fail fast," a principle that underlies many if not most of these frameworks, acknowledges that moving prematurely to larger, randomized study designs can result in less robust interventions and inability to demonstrate effects in expensive randomized clinical trials. By using study methods and designs in early phases that allow more rapid participant accrual, intervention and data collection, early "signals" of *plausible* efficacy that can allow an intervention to move forward to more rigorous testing can be identified and "failure" to find an effect is de-stigmatized and redefined as an opportunity to optimize an intervention. Failure in this context does not lead to premature abandonment of a promising intervention but provides an opportunity to move backward to earlier phases to better define and refine the intervention, potentially producing a more effective intervention.

The flexibility required in early phase intervention development research has resulted in the inclusion of *new, more nimble designs and methods, especially in early phases of these frameworks,* rather than reliance on traditional, parallel-group RCTs. The iterative nature of early intervention design includes the use of nonrandomized, small-N studies as well as optimization designs based on engineering and computer science models. Whether or not to use a control or comparison group(s), and the choice of an appropriate control/comparison group if one is used, is an important consideration in behavioral intervention development research and these considerations have been thoroughly discussed elsewhere (Freedland et al., 2019). Several of the study designs and methods used in early phases of intervention development to characterize an intervention's features, define optimal dosing, and optimize the intervention for effectiveness and efficiency are described in the online supplemental materials.

Finally, many of the frameworks described here are *complementary and can be integrated or used in combination*. For example, the SOBC experimental medicine approach can be used in early

phases of many of the frameworks, such as the Stage Model, ORBIT, MOST, and the COM-B model, to define mechanisms of action and experimentally evaluate their appropriateness as intervention targets. The BCW and COM-B model can be integrated with Stage I in the Stage Model or ORBIT's Phase Ia to identify potential intervention components to be tested and refined. The factorial and adaptive designs that are often used in MOST's optimization phase can be used in ORBIT Phase Ib to refine the intervention and/or choose essential intervention components for further testing. An example of the latter is the testing of an adaptive intervention (SMART) in an ORBIT Phase Ib study designed to identify tailoring variables for use in weight loss interventions for African American adolescents (Naar-King et al., 2016).

Unique and Defining Features

Since multiple options are available to guide the early phases of behavioral intervention development and testing, researchers wishing to use a framework to inform their work face the task of choosing one of the existing models for their specific research objectives. Table 2 (see the online supplementary materials) describes whether and how each model addresses several unique or defining features that may help guide an investigator's decision to use a particular framework.

Choosing a Framework

The choice of which model or models to use should be based on the type of intervention being developed and the specific research questions that need to be addressed. Below are some examples of how the models and frameworks apply to various types of interventions and research goals.

Developing a Broadly Defined, Community-Based, Public Health Intervention With the Need for Maximum Stakeholder Engagement

Both the PRECEDE-PROCEED and IM frameworks are particularly useful for developing a public health or health promotion intervention where there are multiple stakeholders and the need for a high degree of community input. These frameworks define their goals very broadly—they may be health-related, but may also involve other aspects of individual or community well-being, and can be used in contexts other than health-related behavioral interventions. If the primary outcomes of interest are at the community or implementation strategy level, these frameworks are useful because they emphasize the importance of incorporating input from and involvement of all sectors of a community *at the outset of planning*, including not only end users or stakeholders (the target population), but also policymakers, community leaders, community members, organizations, and all those potentially affected or involved in implementing the program.

Developing Complex, Multicomponent, Multilevel Interventions

When interventions involve multiple levels of influence (the individual, family unit, community, and policy) and are highly complex, the MRC and BCW/COM-B frameworks may be most useful. These frameworks also include strategies that can be useful in designing and testing interventions with policy related outcomes as well as individual level outcomes. While the BCW/COM-B frameworks are not as specific in terms of study designs and methods, they use a standardized set of behavior change techniques and advance the field by improving reproducibility of the interventions developed.

Developing Interventions That Maximize Mechanistic Evidence About the Drivers of Human Behavior

Several of the frameworks—the Stage Model, EVOLVE, SOBC experimental medicine approach, and ORBIT—explicitly incorporate the contributions of basic behavioral and social sciences research, arguing that only by identifying and targeting the drivers of human behavior can we design the most effective interventions to alter human behavior. These models are less often used in a multilevel context, and focus primarily on identifying and experimentally manipulating individual-level drivers of human behavior. Of these, EVOLVE, SOBC, and ORBIT focus primarily on maximizing the effect or impact of the intervention on behavioral risk factors and ultimately, on disease outcomes, focusing less on implementability or scalability of the intervention. However, the Stage Model emphasizes implementation of the intervention, and states that behavioral intervention development is complete only when the intervention is successfully implemented.

Developing Interventions That Take Into Account Environmental/Contextual Constraints

The MOST framework is the approach that is most amenable to addressing situational or environmental constraints in developing an intervention. With MOST, an intervention's criteria for success incorporates environmental or situational constraints (cost, burden, and time) and balances these against effectiveness criteria to determine not only whether the intervention has an effect on a desired outcome, but also examines outcomes given a particular set of constraints that are specified in advance by the investigator.

Conclusion

Using a well-defined, systematic framework or approach when developing a health-related behavioral intervention has several advantages. Use of a framework for designing and optimizing behavioral interventions can encourage the systematic linkage of new discoveries about human behavior with clinical and public health applications, potentially leading to greater innovation in behavior change interventions. Use of one (or more) of the models described above also promotes the development of behavioral interventions that are well-characterized, appropriately tested and optimized before testing in larger efficacy trials, potentially leading to better, more powerful behavioral interventions. This systematic approach can also lead to the identification of "failures" earlier in the process, allowing more refinement of interventions and reducing the premature testing of "weak" behavioral interventions in larger, more expensive trials.

A number of examples exist documenting the value of a framework in developing an optimized behavioral intervention for obesity (Spring et al., 2020), behavioral treatments that have significant effects on clinically related behavioral outcomes such as physical activity and medication adherence (Ogedegbe et al., 2012; Peterson et al., 2012), or show promise in favorably altering a clinical outcome such as the metabolic syndrome (Powell et al., 2018). However, there is no definitive empirical evidence showing

the benefits of using a framework compared with not using one in developing either biomedical or behavioral treatments; in fact, a systematic examination of the benefits, costs, and feasibility of using a framework in intervention development, while outside the scope of this article, would be a valuable contribution to the literature. Nevertheless, the use of a framework to guide treatment development and testing provides a more standardized approach to judging progress and identifying the next steps to be addressed through research. It stands to reason that use of any of the systematic, progressive and well-defined frameworks discussed here should lead to better characterized, optimized, and potentially more robust interventions that have a greater chance of success in large-scale randomized efficacy trials.

All of the intervention development frameworks require a long-term, programmatic approach to intervention design and testing which may well require many years, multiple studies, and a team composed of investigators with diverse research backgrounds and skills. This is true of intervention research development that is not model or framework driven but the use of a systematic and progressive framework or model allows for more transparent identification of the needed next steps, gaps, and research questions to be addressed. Support for the integration of multiple, diverse disciplines, and a long-term programmatic vision in developing and testing behavioral interventions is evidenced by organizations such as the Behavioral Medicine Research Council (BMRC), which have as their goal the progressive, long-term, strategic development, and testing of interventions for behavioral risk factors for disease (Freedland, 2019). Translational behavioral science efforts and use of these frameworks is also supported by funding agencies such as the NIH, which has emphasized the integration of basic and applied behavioral research as a goal of the Office of Behavioral and Social Sciences Research (OBSSR) Strategic Plan (see https://obssr.od.nih.gov/wp-content/uploads/2016/12/OBSSR-SP-2017-2021.pdf). The NIH also emphasizes the use of these frameworks in intervention development research; for example, Czajkowski et al. (2016) provides multiple examples of NIH support for transdisciplinary translational behavioral research, and specific funding opportunity announcements that promote the use of intervention development frameworks are included in a recent NIH Notice of Special Interest (see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-106.html).

Because the field of behavioral medicine has multiple frameworks to guide health-related behavioral intervention development and testing, an investigator should choose a framework based on how well its key or defining features address the goals of their research program. These frameworks are useful heuristics—"roadmaps" that can direct an investigator's or field's long-term program of research beginning with identifying a health-related problem through defining, optimizing, and evaluating an effective behavioral solution to the problem. In the end, like using a map to navigate one's journey to a new place, carefully choosing and following any one or more of these frameworks will maximize the chances of reaching one's destination while minimizing the possibility of getting lost on the way.

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