Deconstructing Interventions: Approaches to studying behavior change techniques across obesity interventions

Deborah F. Tate, PhD^{1,2}; Leslie A. Lytle, PhD¹; Nancy E. Sherwood, PhD³; Debra Haire-Joshu, PhD⁴; Donna Matheson, PhD⁵; Shirley M. Moore, PhD, RN, FAAN⁶; Catherine M. Loria, PhD, MS, MA, FAHA⁷; Charlotte Pratt, PhD, RD, FAHA⁷; Dianne S. Ward, EdD²; Steven H. Belle, PhD, MScHyg⁸; Susan Michie, PhD⁹

¹Department of Health Behavior, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA

²Department of Nutrition, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

³HealthPartners Institute for Education and Research, Bloomington, Minnesota, USA

⁴The Brown School, Washington University, St. Louis, MO, USA

⁵Department of Pediatrics & Stanford Prevention Research Center, Stanford University, Stanford, CA, USA

⁶Frances Payne Bolton School of Nursing, Case Western Reserve University, Cleveland, OH, USA

⁷National Heart, Lung and Blood Institute, NIH, Bethesda, MD, USA

⁸Department of Epidemiology, University of Pittsburgh Graduate School of Public Health, Pittsburgh, Pennsylvania, USA

⁹Centre for Behaviour Change, Department of Clinical, Educational and Health Psychology, University College London, London, UK

Deconstructing Interventions: Approaches to studying behavior change techniques across obesity interventions

Abstract

Background & Purpose

Deconstructing interventions into the specific techniques that are used to change behavior

represents a new frontier in behavioral intervention research.

Methods

This paper considers opportunities and challenges in employing the Behavior Change

Techniques Taxonomy (BCTT1) developed by Michie and colleagues, to code the behavior

change techniques (BCTs) across multiple interventions addressing obesity and capture dose

received at the technique level.

Results

Numerous advantages were recognized for using a shared framework for intervention

description. Coding interventions at levels of the social ecological framework beyond the

individual level, separate coding for behavior change initiation vs. maintenance, fidelity of BCT

delivery, accounting for BCTs mode of delivery, and tailoring BCTs, present both challenges and

opportunities.

Conclusions

Deconstructing interventions and identifying the dose required to positively impact health-related

outcomes could enable important gains in intervention science.

Key words: intervention science, taxonomy, pooled analysis

2

Introduction

An abundance of behavioral intervention studies have been conducted in an attempt to create effective population-based programs that can be disseminated widely in order to reduce the burden of disease in various populations [1-5]. While important advances have been made and successes realized [6, 7], there are numerous examples of carefully designed and well implemented interventions that had small effects or were ineffective [8-14]. Effective interventions have shown diminished effectiveness when disseminated perhaps due to their complex nature and intensive components [15]. Even with careful use of theory and an intervention planning process [16, 17], it is often unclear why interventions have worked or where our approaches have fallen short. New approaches are needed to allow a more thorough understanding of how interventions are or are not changing behaviors.

Population-based interventions are typically multi-component and complex, including numerous components designed to change behavior. Often multiple levels of the social ecological framework including individual, interpersonal and environmental are included as intervention targets, adding to the complexity [4, 18]. Researchers typically represent and test their intervention as one complete and cohesive entity. The total intervention package (sometimes referred to as a 'black box') is delivered to a population group and the success or failure of the intervention as a whole is evaluated [19, 20].

There are many reasons to study interventions as a package, namely research questions and statistical power, though there are important limitations to this approach. Using the 'black box' approach makes it impossible to determine whether all aspects of the intervention were necessary, and which components of an intervention are the most potent in facilitating behavior change. In addition, this approach provides little information on the underlying mechanisms of

action (e.g., mediators) beyond what was initially theorized, and even less on how specific intervention components target theoretical mediators. For interventions that are found efficacious, replication is warranted and dissemination into practice is crucial. However, published descriptions of behavioral interventions are often brief and vague, making replication of successful interventions challenging if restricted to those published descriptions. In addition, dissemination of tested interventions typically involves a modified intervention approach; it is rare that an intervention is replicated or disseminated in its full and original form. Researchers and practitioners are left guessing about the key components that made an intervention successful. It is also possible that interventions that were not successful included some intervention components that were useful, though perhaps not in sufficient dose. Thus, it is difficult to identify what, if any, elements should be retained and examined in another study or become part of evidence-based public health practice. Significant advances could be made in intervention research if methods were available to identify effective behavior change approaches.

Coordinated studies of behavioral interventions provide a unique opportunity to study the components of interventions and their relationships to positive health outcomes. Such studies, often within a consortium, involve a group of coordinated but distinct studies, funded concurrently to test a variety of interventions to ameliorate a health concern. While the intervention packages differ, the targeted outcomes and population groups are similar or the same, allowing several intervention approaches to be evaluated simultaneously in a larger number of participants. Such coordinated studies offer tremendous opportunities to learn more about which components of interventions are effective, for whom, and in what settings, by evaluating the 'active ingredients' found across the varied interventions.

The purpose of this manuscript is to describe approaches that are currently being developed to deconstruct behavioral interventions and to describe how these innovative approaches are being used in consortia studies. We report issues that apply in principle to all behavior change interventions with examples drawn from studies that were discussed at a 2013 NHLBI-sponsored workshop on interventions to prevent and reduce obesity

[21] http://www.nhlbi.nih.gov/meetings/workshops/obesity_intervention_taxonomy_pooled_anal_ysis.htm. The consortia represented at the workshop included: Early Adult Reduction of weight through LifestYle intervention (EARLY, 7 trials), Childhood Obesity Prevention and Treatment Research (COPTR, 4 trials), the Obesity Related Behavioral Intervention Trials (ORBIT, 7 studies), and the Lifestyle Interventions in Overweight and Obese Pregnant Women (LIFE-Moms, 7 trials). Details on each consortia are summarized in a paper by Belle, et al [22].

Deconstructing interventions or unpacking the 'black box'

In the past several decades, increasing attention has been paid to specifying and understanding intervention content. Early recognition of the "black box" problem focused on encouraging specification of the underlying theoretical basis for the intervention [17, 23-26], and the constructs targeted by an intervention. Following, methods to systematically plan and develop interventions with links between theory and intervention components were introduced [e.g., 4, 27, 28]. Attention to theory-based interventions and intervention mapping were important efforts to ground intervention design in what is known about behavioral sciences. The focus on theory in intervention development was associated with calls to understand causal mechanisms of change or "how" interventions had their effects, with more thoughtful process evaluation, planned mediational analysis [29] and coding scheme development to delineate the extent to which interventions are based on theory [30-33].

Despite these advances and calls-to-action, there remains a lack of specificity about interventions [30, 34, 35]. Although the CONSORT guidelines [36] for publishing results of clinical trials call for describing the interventions studied, the historical roots for describing interventions are in a medical clinical trials model; describing complex behavioral interventions is quite different. Editors typically require only brief information on the theoretical basis or content of the intervention and space constraints of published papers preclude a thorough description of the intervention. When theoretical constructs are described in manuscripts it is not always clear what specific content or techniques were used to change the construct to change behavior. This limits future replication and development of evidence-based guidance and dissemination and implementation of effective interventions. These limitations result in considerable loss of opportunity to advance behavioral science and its applications.

Examples of approaches for specifying interventions

In recent years, several methods have been used to deconstruct interventions. Some approaches have been developed for specifying dimensions of interventions including characterizing the delivery or entity and the content domain of activities that make up interventions, for example TIDieR [37]. The Template for Intervention Description and Replication (TIDieR) [37] checklist and guide was developed as a supplement to the CONSORT statements to provide additional information on interventions to permit better implementation by clinicians, patients and other researchers. Their guidelines stemmed from a literature review and analysis of interventions in the literature which found descriptions of interventions to be limited; of 137 non-drug interventions reviewed only 39% were described adequately. TIDieR recommends twelve dimensions in the report of interventions including intervention name; theory or rationale; materials used or provided to participants; procedures and activities;

background/ training of interventionists; modes of delivery; locations of interventions and infrastructure needed; frequency, intensity, dose; tailoring or personalization; modifications of the intervention; methods for adherence and fidelity; and actual adherence and fidelity data.

These dimensions provide critical information to permit replication and to expand and enhance learning from published papers.

An Intervention Taxonomy (ITAX) was also proposed to aid investigators in specifying dimensions of interventions including characterizing the delivery and the content domain of activities that make up interventions [38]. The intention of ITAX was to develop a common language that could characterize complex interventions looking at intervention characteristics such as mode, materials, location, schedule, content, goals, and mechanisms of action to permit examination of relationships between outcomes and intervention characteristics [38]. ITAX was used in a consortium called REACH (the Resources Enhancing Alzheimer's Caregiver Health), to combine and examine interventions across multiple studies [39].

In recent years, Michie and colleagues [40] have advanced an international movement toward better specificity in intervention description by attempting to isolate and name the specific behavior change techniques that are used in intervention studies. This approach is complementary to TIDieR and ITAX as it focuses on the content or "what" the intervention is doing to change behavior vs. other aspects of interventions such as dose, delivery, etc. A project involving 400 international experts resulted in a 93-item cross-domain Behaviour Change Technique Taxonomy v1 (BCTTv1) where techniques used to change behavior were grouped by a Delphi process into 16 higher order domains [33]. A behavior change technique, or BCT, is defined as "an observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behavior; that is, a technique is proposed to be an

'active ingredient' (e.g., feedback, self-monitoring, and reinforcement) [33]. The BCTs have well-developed operational definitions to facilitate common dialogue and description (see Table 1 for examples of BCTs) and good reliability and validity have been demonstrated.

Interventions can be described in terms of the BCTs they include. Table 2 shows BCTs included in two hypothetical interventions. The interventions have 6 BCTs in common (indicated in black text), but each intervention also includes some BCTs that are unique (shown in red). It is likely that interventions targeting the same behaviors use some similar and some unique BCTs. One of the goals of the taxonomy is to encourage intervention creators and study authors to describe interventions in terms of the BCTs used. Doing so will build collective knowledge about BCTs and their mechanisms of action by synthesizing evidence across behaviors and interventions using common language.

Moving beyond describing interventions to link techniques with outcome

Once interventions are described by their component BCTs, links can then be made between BCTs and outcomes. A goal of this work is to use BCTs as predictor variables in pooled analyses, e.g., involving meta-analytic and meta-regression techniques [31, 41]. At the meta-analytic level, intervention and/or study specific variables that might be associated with study-wide outcomes become control variables (such as population, delivery channel, dose delivered, etc.) and the associations of the specific BCTs, and theoretically-based combinations of BCTs, with respect to dependent variables can be examined. If a meta-analytic approach is applied, intervention-level dose-delivered or planned dose delivered may be used [42]. When a meta-regression approach is applied, participant level data are used so it becomes necessary to determine the dose of BCT received by an individual. In some studies it may be possible to measure actual individual dose of a BCT received by an individual; in others it may not.

The REACH consortium, described earlier, used ITAX as a method to decompose their interventions and identified intervention components used in 16 diverse interventions that targeted family caregivers of people with Alzheimer's Disease or a related disorder [39]. After the components of the interventions were identified, a decision-theory approach, the Analytic Hierarchy Process (AHP) [43], was used to determine the dose of each component in each intervention relative to other components. Time participants spent engaged with each component were then used as independent measures in a regression model with caregiver depression score as the dependent variable. Details of the methodology have been published [44]. As a result of these steps used to identify "active" ingredients across the interventions evaluated by the REACH trials [45], a new, simplified intervention was designed and tested in a subsequent multi-site randomized controlled trial. The new intervention, REACH II, was found to successfully enhance the primary outcome of caregiver quality of life compared to control [46].

The primary advantage of coordinated consortium studies is the opportunity to simultaneously examine a wide range of intervention elements on a targeted public health problem in a large at-risk population. The common foci of such consortia on a similar health problem using different interventions present an opportunity to study intervention differences and their relation to outcome. We believe that such coordinated consortia studies also provide an excellent opportunity to deconstruct interventions with a goal towards identifying, across several interventions, the potentially active ingredients that change behavior.

Application and challenges: Examples from Obesity Consortia Studies

Deconstructing behavioral obesity studies: An example from EARLY

In the EARLY trials [47], NHLBI, NICHD, and OBSSR funded 7 studies to design, implement and evaluate interventions for weight loss or weight gain prevention for young adults

age 18-35. The studies chose what population of young adults they wanted to study (i.e., college students, smokers, pregnant women or the general population) and each designed an intervention or multiple interventions to be evaluated. A primary outcome was agreed upon as were common measurement tools and protocols for data collection and analysis [47]. These common elements across all of the studies allow cross-study analyses of behavior change techniques.

The use of the BCTTv1 as a framework for deconstructing and describing interventions, such as those in EARLY, is appealing as it allows the various complex interventions within the consortia to be compared as to their inclusion of, and emphasis on, specific BCTs. The interventions within EARLY target either weight loss or weight gain prevention through reducing excess calorie intake, promoting greater energy expenditure and using some element of technology as an intervention delivery mode. However, the specifics of how these interventions are designed and delivered vary widely across the studies. In addition to distinguishing the interventions by their delivery modality (e.g., cell phones vs. websites) and content (e. g. weight loss or weight gain prevention), the investigators were also interested in deconstructing each intervention using the BCTTv1 in order to better understand the specific techniques that were used to promote change. Without a process for deconstructing the interventions and the use of a common taxonomy, these interventions are not easily compared in terms of content or techniques being used to change diet and activity behaviors.

EARLY investigators obtained funding (R01HL122144) to deconstruct the interventions using the BCTTv1 and plan to combine it with the process pioneered by REACH, described above, to identify the dose of specific BCTs that is associated with weight change across the interventions. Replication and extension of the process used in REACH with a new health

problem and different taxonomy will also be helpful in identifying its utility as a method for studying intervention differences.

Challenges in Using the Taxonomy Approach to Deconstruct Interventions and Predict Outcome

Using the BCTTv1 or other taxonomy approaches creates the opportunity to advance our

field by unpacking complex interventions into their component techniques, and using engagement with the techniques to predict outcome. However, there are practical and conceptual challenges to this approach.

What is the best way to deconstruct an intervention that has multiple components or phases?

Given the complexity of obesity, it is recognized that multi-level, multi-component interventions are necessary for impacting this intractable problem. Many behavioral interventions target several levels of the social ecological model in their interventions, including community or organizational, family and individual levels. As an example, COPTR, a consortium focused on childhood obesity prevention and treatment includes intervention targeting both parents and children. In COPTR, interventions are being studied in multiple health care, community and school settings. Deconstructing and coding interventions at multiple levels expands the workload substantially. In current form, the BCTTv1 focuses on individual level intervention techniques; coding schemes for levels of the 'social ecological' model beyond the individual level need to be developed to extend version 1 of the Behavior Change Taxonomy. Because BCTTv1 is designed to be an evolving framework with input from the research community, workshop attendees recommended expanding the coding scheme into other ecological levels to make it useful and applicable to a broader range of interventions.

In addition to occurring at multiple levels, interventions often include multiple phases during which different intervention components and dose are delivered. Theorists have questioned

whether separate theories are needed for behavioral initiation vs. maintenance, suggesting different techniques be emphasized at different times [48]. In obesity treatment interventions, which are typically of long duration, different BCTs might occur or be emphasized in weight loss maintenance vs. initial weight loss. It is possible that the while the same BCTs may be used in initial weight loss and maintenance, the emphasis may differ across phases. For example, an intervention might use 2 BCTs – self-monitoring of behavior (dietary intake) and self-monitoring of outcome (weight) but emphasize daily monitoring of dietary intake and weekly monitoring of weight during weight loss and then daily monitoring of weight with only periodic monitoring of dietary intake during maintenance. It is also possible that different BCTs are used over time. The separate coding of BCTs during intervention phases would allow empirical examination of these differences.

Examining different phases in an intervention is particularly relevant when the outcomes during different phases of intervention differ. In the LIFE-Moms consortium, for example, some studies include two distinct intervention phases with different behavioral and outcome goals; one phase during pregnancy (antepartum) when the goal promotes appropriate gestational weight gain, and some also have a separate phase during the postpartum period that encourages healthy behaviors, breastfeeding and/or weight loss. In cases like this, coding BCTs during pregnancy separate from postpartum would be useful.

How can studies train individuals to deconstruct or analyze interventions?

An important challenge in deconstructing and coding interventions relates to training.

Reliable and valid coding requires training and careful attention to the definitions, not just the label, of BCTs. Research staff must be trained to be able to identify the BCTs that were planned, delivered, and/or received by their participants. If the research team and interventionists are not

doing the deconstruction of the intervention, detailed descriptions of all aspects of the intervention must be provided to coders. To facilitate training, definitions of the BCTs are published along with examples of their use in a supplement to the manuscript describing the 93 technique taxonomy [33]. In addition, an online course (http://www.bct-taxonomy.com/) and an app are available for coding BCTTv1; the app is available on both Apple and Googleplay app stores and can be found by searching for 'BCT taxonomy'.

In the NIH- and CDC-funded obesity consortia represented at this workshop, intervention development, and often, full implementation of the interventions, was underway prior to considering coding interventions' components. The level of detailed coding, creation of operations manuals, and training of staff required for the BCT approach was not part of the original scope of these projects. Anticipating the resources (e.g. time, money and expertise) required to conduct the BCT coding and related outcome analyses is an important consideration for behavioral researchers during the planning phases of intervention research.

How does documentation of the extensiveness of focus or quality of BCT delivery occur?

Interventions might be developed that focus on the same BCTs but with different emphasis.

Using the hypothetical example provided in Table 2, for example, Internet-delivered weight loss interventions might use two common BCTs, 'Feedback on Behavior' and 'Feedback on Outcome of Behavior', but differ in the extensiveness of their use. As an extreme example, one intervention might provide automated feedback on dietary behavior and weight at the start of an intervention (baseline only) in the form of a tailored report, yet another provides daily automated feedback on changes in these variables. The interventions both use technology to deliver the same BCTs, but the dose varies from one instance of feedback to ongoing, extensive feedback. Yet another intervention might use the same two BCTs, yet feedback is provided on two

behaviors (diet and activity) and outcome (weight) via weekly email from a live counselor. The same two BCTs are being used by these three intervention examples but the execution of them is different and might be expected to have different effects on the outcome. Thus, technique, dose, manner of delivery, and how those variables might interact are additional dimensions which are likely to be related to efficacy, but are not captured in the BCTs themselves.

Intervention studies are accustomed to tracking the dose delivered and the dose received of many of the major aspects of treatment but less attuned to measuring dose at the BCT level. For example, it is easy to record which treatment sessions were attended by which participants, but less clear which BCTs were used in which session, and engaged with or received by the participants who attended them. In technology-delivered interventions, the dose of specific BCTs might be more easily tracked. There is tremendous opportunity to garner more precise data from our interventions with respect to exactly what BCTs each participant receives, but it is likely to require extensive planning and resource allocation.

Planning to employ BCTs in an intervention does not insure if or how well they are delivered [49]. Where possible, it is important to describe and evaluate the fidelity of an intervention using the BCT framework. BCTs can be specified in a protocol and then measures of actual delivery of BCTs can be collected, resulting in an estimate of the proportion of planned BCTs that were actually delivered [see 50 for exemplar]. Studies using BCTs to examine fidelity have shown that in telephone delivered behavioral support for smoking cessation, an average of only 41% of BCTs specified in treatment manuals were delivered [50] and 42% in an intervention to increase physical activity [51, 52]. If these interventions were effective with fewer BCTs, evolution of treatment approaches might occur with this knowledge. Without this analysis, the interventions would likely be repeated in their entirety.

How can adaptive or tailored interventions be coded?

Researchers might also wish to capture the way in which a BCT was delivered and the degree of tailoring involved in use of a BCT. Tailoring is an important aspect of interventions as articulated in the ITAX [38]. For example, two interventions might both include the BCT "Goal Setting (Behavior)." In one intervention, an "app" is used to enable participants to set SMART goals, yet in another, goals are set during telephone counseling. Many behavioral interventions are highly tailored to the individual, including certain BCTs, only when participants require it. For example, telephone coaches may be trained to employ problem-solving only with those who are struggling with reaching behavioral goals. The tailored use of BCTs adds complexity in determining how much dose of a BCT was associated with success, particularly if the criterion for using a BCT is lack of progress. Since tailoring has been shown to support behavior change [53], it may be necessary to add a cross-cutting measure of the extent of tailoring when evaluating the BCTs in tailored interventions. In digital interventions, participants are offered a variety of BCTs and select whether or not to use them. Although this can be assessed and participants can be encouraged or nudged to use certain BCTs, intervention developers cannot control their use. The delivery mode and the degree of tailoring are potential moderators, or at least control variables, that will likely be important when exploring the impact of BCTs on outcome.

Recommendations for Characterizing Intervention Techniques and Examining Efficacy of the Techniques in Consortia Studies

Attendees at the 2013 NHLBI-sponsored workshop on interventions to prevent and reduce obesity identified numerous opportunities and outlined key research recommendations.

<u>Recommendation 1:</u> Describe interventions with enough specificity to allow coding for BCTs.

- Plan for development of intervention manuals of operations and a manuscript describing
 intervention details. Detailed protocol manuals may be developed and made available for
 coding purposes, though it is preferred that descriptive papers about how behavior change
 was targeted with an intervention be considered valid for publication.
- Where possible, intervention studies should plan to decompose (or specify during intervention development) the content of each intervention utilizing established theory, and preferably a published taxonomy. Examples of taxonomies include behavior change techniques (BCCTv1), intervention taxonomy (ITax), and other checklists like TIDieR to be sure important elements are included in descriptions of interventions.
- An amendment or expansion of BCCTv1 to include BCTs used to change environmental or
 other levels of the social ecological framework is needed. If an established theory or
 taxonomy is adopted but amended, there should be appropriate scientific rigor to justify and
 document the change(s).

<u>Recommendation 2:</u> Include measures to examine fidelity to delivery of specific components, and if possible at the BCT level, in interventions.

- Determine the intervention components and dose intended to be delivered (according to protocol) per each intervention component (e.g., BCT).
- Determine differences in how and what aspects of the intervention are delivered compared
 with what was intended to be delivered (BCT fidelity). When possible, examine the influence
 of mode of delivery/setting/environment on BCT fidelity.
- Rating the competence with intervention components, and where possible BCTs, are
 delivered is an added dimension beyond dose delivered and received that should be
 considered in intervention fidelity evaluations.

<u>Recommendation 3:</u> Measure dose received by participants of specific intervention components and, where possible, behavior change techniques.

- Measurement of overall intervention dose delivered and reporting of average dose received by participants is fairly routine and we recommend that studies strive to determine the dose of specific intervention components (e.g., BCTs) received by participants.
- Careful process evaluation and tracking of dose received by participants is essential to accomplish the above goals and requires careful planning and adequate budget.
- Engagement with components of the intervention that are specifically designed utilizing
 BCTs should be tracked for eHealth and mHealth interventions.
- Characterization of dose-received in eHealth/mHealth interventions requires additional thought and attention, as it involves sequencing as well as quantity.

Recommendation 4: Create a website for dissemination of methods and papers on this topic.

- Create a website or repository that includes methods and papers on key learnings, how these approaches are implemented, steps used in decomposition, links to taxonomy resources and training, and results of decomposition studies that examine the BCTs linked to outcome.
- Provide sample manuals of operations describing interventions and coding templates so developers have the detail necessary to inform their interventions.

<u>Recommendation 5</u>: Plan appropriate resources to code interventions for BCTs.

- Grant planning should include resources (e.g., time and personnel) for disaggregating interventions. To include this as a requirement post hoc or post award is very difficult.
- In the future, researchers should plan to define their interventions as they develop them using BCTs and publish these descriptions. Planning for this step in intervention development is essential as this requires coding during development and the availability of the necessary

resources, including personnel time. In the absence of such a priori coding by the developers of an intervention, we recommend that intervention studies publish intervention development papers in peer reviewed journals that include descriptions of the intervention with sufficient detail to allow coding at the level of the behavior change techniques.

Summary

Deconstructing interventions into the specific techniques that are used to change behavior represent a new frontier in behavioral intervention research and with that new frontier are both opportunities and challenges. Successful interventions may include a combination of elements that are effective and ineffective, and potentially, harmful. Including ineffective elements adds to the cost or intensity of the intervention or, worse, weakens the action of other components by distracting or diluting their effects. To optimize behavioral interventions and make them more potent and cost-effective, it is critical to unpack the black box and specify interventions in terms of their elements. Greater specificity of the techniques used to change behavior, when they are used, the dose intended, dose delivered, and dose received at the technique level are new questions that can help us advance our science of intervention implementation by linking them with theory and outcomes. To make important gains in the intervention science field, appropriate methods and resources are needed for synthesizing the information gleaned from the unpacking of the 'black box' to examine the elements of interventions and dose that impact health-related outcomes.

Table 1: Names and definitions of 5 BCTs (taken from Michie et al. 2013, supplemental material)

Behavior Change	Definition	Example
Technique (BCT)		
Goal setting (behavior)	Set or agree on a goal defined in terms of the behavior to be achieved	Agree on a daily walking goal (e.g. 3 miles) with the person and reach agreement about the goal
Problem	Analyze, or prompt the person to	Prompt the patient to identify barriers
solving	analyze, factors influencing the	preventing them from starting a new
	behavior and generate or select	exercise regime e.g., lack of
	strategies that include overcoming	motivation, and discuss ways in
	barriers and/or increasing facilitators	which they could help overcome them
		e.g., going to the gym with a buddy
Prompts/cues	Introduce or define environmental or	Put a sticker on the bathroom mirror
	social stimulus with the purpose of	to remind people to brush their teeth
	prompting or cueing the behavior.	
	The prompt or cue would normally	
	occur at the time or place of	
	performance	
Behavior	Prompt substitution of the unwanted	Suggest that the person goes for a
substitution	behavior with a wanted or neutral	walk rather than watches television
	behavior	
Restructuring	Change, or advise to change the	Arrange to move vending machine out
the physical	physical environment in order to	of the school
environment	facilitate performance of the wanted	
	behavior or create barriers to the	
	unwanted behavior (other than	
	prompts/cues, rewards and	
	punishments)	

Table 2: Example of two hypothetical interventions with some overlapping (indicated in black text) and some unique (red text) BCTs

Intervention A

- Problem solving
- · Feedback on Behavior
- Feedback on Outcome of Behavior
- Self-monitoring of behavior
- Instruction on how to perform the behavior
- Social support (emotional)
- Avoidance/reducing exposure to cues for the behavior
- Goal setting (behavior)
- Goal setting (outcome)
- Incentive (outcome)
- Reward (outcome)

Intervention B

- Problem solving
- Feedback on Behavior
- Feedback on Outcome of Behavior
- Self-monitoring of behavior
- Instruction on how to perform the behavior
- Social support (emotional)
- Information about health consequences
- Information about social and environmental consequences
- Social comparison

ADHERENCE TO ETHICAL PRINCIPLES

This paper reflects discussions and recommendations from a 2013 NHLBI-sponsored workshop on obesity intervention taxonomy and pooled analysis with more broad application to all behavior change interventions. There were no human subjects involved.

ACKNOWLEDGEMENTS

Funding for this work comes from the National Heart, Lung, and Blood Institute, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institutes of Health (NIH) Office of Behavioral and Social Science Research, the NIH Office of Disease Prevention, National Institute of Digestive, Diabetes, and Kidney Diseases, National Center for Complementary and Integrative Health, National Cancer Institute, Office of Research on Women's Health, and the Centers for Disease Control and Prevention (CDC).

CONFLICTS OF INTEREST

Dr. Tate reports being a member of the Scientific Advisory Board for Weight Watcher's International. No other authors report any conflicts of interest.

REFERENCES

- 1. Carr, A.B., Ebbert, J., *Interventions for tobacco cessation in the dental setting*. Cochrane Database Syst Rev, 2012. **6**: p. CD005084.
- 2. Everett, T., Bryant, A., Griffin, M.F., Martin-Hirsch, P.P., Forbes, C.A., Jepson, R.G., Interventions targeted at women to encourage the uptake of cervical screening. Cochrane Database Syst Rev, 2011(5): p. CD002834.
- 3. Rice, V.H., J. Hartmann-Boyce, and L.F. Stead, *Nursing interventions for smoking cessation*. Cochrane Database Syst Rev, 2013. **8**: p. Cd001188.
- 4. Excellence, N.I.o.H.a.C., Behaviour change at population, community and individual levels (Public Health Guidance 6). 2007.
- 5. Excellence, N.I.o.H.a.C., Behaviour change: individual approaches (Public Health Guidance 49). 2014.
- 6. Diabetes Prevention Program Research Group, *The Diabetes Prevention Program (DPP):*description of lifestyle intervention. Diabetes Care, 2002. **25**(12): p. 2165-71.
- 7. Lemmens, V., et al., *Effectiveness of smoking cessation interventions among adults: a systematic review of reviews.* Eur J Cancer Prev, 2008. **17**(6): p. 535-44.
- 8. Booth, H.P., et al., Effectiveness of behavioural weight loss interventions delivered in a primary care setting: a systematic review and meta-analysis. Fam Pract, 2014. **31**(6): p. 643-53.
- 9. Brown, T., et al., Systematic review of long-term lifestyle interventions to prevent weight gain and morbidity in adults. Obes Rev, 2009. **10**(6): p. 627-38.

- 10. Hutchesson, M.J., et al., eHealth interventions for the prevention and treatment of overweight and obesity in adults: a systematic review with meta-analysis. Obes Rev, 2015.
- 11. Lin, J.S., et al., Behavioral counseling to promote a healthy lifestyle in persons with cardiovascular risk factors: a systematic review for the U.S. Preventive Services Task Force.

 Ann Intern Med, 2014. **161**(8): p. 568-78.
- 12. Safron, M., et al., Effects of school-based interventions targeting obesity-related behaviors and body weight change: a systematic umbrella review. Behav Med, 2011. **37**(1): p. 15-25.
- 13. Schwingshackl, L., S. Dias, and G. Hoffmann, *Impact of long-term lifestyle programmes on weight loss and cardiovascular risk factors in overweight/obese participants: a systematic review and network meta-analysis*. Syst Rev, 2014. **3**: p. 130.
- 14. Terranova, C.O., et al., *Effectiveness of lifestyle-based weight loss interventions for adults with type 2 diabetes: a systematic review and meta-analysis.* Diabetes Obes Metab, 2015. **17**(4): p. 371-8.
- 15. Glasgow, R.E., et al., *National Institutes of Health approaches to dissemination and implementation science: current and future directions.* Am J Public Health, 2012. **102**(7): p. 1274-81.
- 16. Michie S, A.L., West R., *The Behaviour Change Wheel: A Guide to Designing Interventions*. 2014, London: Silverback Publishing.
- 17. Glanz K., R.B., Viswanath K. (Eds), ed. *Health Behavior and Health Education: Theory, Research, and Practice.* 4th ed. 2008, Jossey-Bass: San Francisco, CA.
- 18. Stokols, D., *Translating social ecological theory into guidelines for community health promotion*. Am J Health Promot, 1996. **10**(4): p. 282-98.

- 19. Pearson, T.A., et al., Dissecting the "black box" of community intervention: lessons from community-wide cardiovascular disease prevention programs in the US and Sweden. Scand J Public Health Suppl, 2001. **56**: p. 69-78.
- 20. Levesque, L., et al., Unpacking the black box: a deconstruction of the programming approach and physical activity interventions implemented in the Kahnawake Schools Diabetes Prevention Project. Health Promot Pract, 2005. **6**(1): p. 64-71.
- 21. National Heart Lung and Blood Institute. *NHLBI and the NIH Office of Disease Prevention Working Group On Obesity Intervention Taxonomy and Pooled Analysis Working Group Meeting*. 2013 [cited 2015; August 29-30, 2013 Executive Summary]. Available from:

 http://www.nhlbi.nih.gov/meetings/workshops/obesity_intervention_taxonomy_pooled_analysis.htm.
- 22. Belle SH, S.J., Cella D, Foltz J, Loria C, Murray D, Thom E, Arteaga S, Czajkowski S, Pratt C, Overview of the Obesity Intervention Taxonomy and Pooled Analysis Working Group.

 2015.
- 23. Glanz, K. and D.B. Bishop, *The role of behavioral science theory in development and implementation of public health interventions*. Annu Rev Public Health, 2010. **31**: p. 399-418.
- 24. Craig, P., et al., *Developing and evaluating complex interventions: the new Medical Research Council guidance.* Int J Nurs Stud, 2013. **50**(5): p. 587-92.
- 25. Campbell, M., et al., Framework for design and evaluation of complex interventions to improve health. Bmj, 2000. **321**(7262): p. 694-6.
- 26. Campbell, N.C., et al., *Designing and evaluating complex interventions to improve health care.* Bmj, 2007. **334**(7591): p. 455-9.

- 27. Bartholomew K, P.G., Kok G, Gottlieb N., *Intervention Mapping: Developing theory and evidence-based health education programs*. 2001, Mountain View, CA: Mayfield.
- 28. Perry, C., Creating Health Behavior Change: How to Develop Community-wide Programs for Youth. 1999, Thousand Oaks, CA: Sage Publications.
- 29. Baranowski, T., C. Anderson, and C. Carmack, *Mediating variable framework in physical activity interventions. How are we doing? How might we do better?* Am J Prev Med, 1998. **15**(4): p. 266-97.
- 30. Michie, S. and A. Prestwich, *Are interventions theory-based? Development of a theory coding scheme*. Health Psychol, 2010. **29**(1): p. 1-8.
- 31. Michie, S., et al., A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. Psychol Health, 2011. **26**(11): p. 1479-98.
- 32. Abraham, C. and S. Michie, *A taxonomy of behavior change techniques used in interventions*. Health Psychol, 2008. **27**(3): p. 379-87.
- 33. Michie, S., et al., The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med, 2013. **46**(1): p. 81-95.
- 34. Prestwich, A., et al., *Does theory influence the effectiveness of health behavior interventions?*Meta-analysis. Health Psychol, 2014. **33**(5): p. 465-74.
- 35. Davis, R., et al., *Theories of behaviour and behaviour change across the social and behavioural sciences: a scoping review.* Health Psychol Rev, 2014: p. 1-22.
- 36. Begg, C., et al., *Improving the quality of reporting of randomized controlled trials. The CONSORT statement.* Jama, 1996. **276**(8): p. 637-9.

- 37. Hoffmann, T.C., et al., *Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide*. Bmj, 2014. **348**: p. g1687.
- 38. Schulz, R., et al., *Intervention taxonomy (ITAX): describing essential features of interventions*. Am J Health Behav, 2010. **34**(6): p. 811-21.
- 39. Schulz, R., et al., Introduction to the special section on Resources for Enhancing Alzheimer's Caregiver Health (REACH). Psychol Aging, 2003. **18**(3): p. 357-60.
- 40. Michie, S., et al., Strengthening evaluation and implementation by specifying components of behaviour change interventions: a study protocol. Implement Sci, 2011. **6**: p. 10.
- 41. Bangdiwala, S.I., et al., Statistical methods for designing and assessing the effectiveness of community-based interventions with small numbers. Int J Inj Contr Saf Promot, 2012. **19**(3): p. 242-8.
- 42. Voils, C.I., et al., *Approaches for informing optimal dose of behavioral interventions*. Ann Behav Med, 2014. **48**(3): p. 392-401.
- 43. Saaty T, V.L., *Decision making in economic, political, social and technological environments with the Analytic Hierarchy Process.* Vol. II. 1994: RWS Publications.
- 44. Czaja, S.J., et al., A methodology for describing and decomposing complex psychosocial and behavioral interventions. Psychol Aging, 2003. **18**(3): p. 385-95.
- 45. Belle, S.H., et al., *Using a new taxonomy to combine the uncombinable: integrating results across diverse interventions.* Psychol Aging, 2003. **18**(3): p. 396-405.
- 46. Belle, S.H., et al., Enhancing the quality of life of dementia caregivers from different ethnic or racial groups: a randomized, controlled trial. Ann Intern Med, 2006. **145**(10): p. 727-38.
- 47. Lytle, L.A., et al., *The EARLY trials: a consortium of studies targeting weight control in young adults.* Transl Behav Med, 2014. **4**(3): p. 304-13.

- 48. Rothman, A.J., *Toward a theory-based analysis of behavioral maintenance*. Health Psychol, 2000. **19**(1 Suppl): p. 64-9.
- 49. Borrelli, B., *The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials.* J Public Health Dent, 2011. **71 Suppl 1**: p. S52-63.
- 50. Lorencatto, F., et al., A method for assessing fidelity of delivery of telephone behavioral support for smoking cessation. J Consult Clin Psychol, 2014. **82**(3): p. 482-91.
- 51. Hardeman, W., et al., *Fidelity of delivery of a physical activity intervention: predictors and consequences*. Psychol Health, 2008. **23**(1): p. 11-24.
- 52. Michie, S., et al., *Investigating theoretical explanations for behaviour change: the case study of ProActive*. Psychol Health, 2008. **23**(1): p. 25-39.
- 53. Noar, S.M., et al., *Tailored Health Communication to Change Lifestyle Behaviors*. American Journal of Lifestyle Medicine, 2011. **5**(2): p. 112-122.