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Intervention Taxonomy (ITAX): Describing Essential Features of Interventions (HMC)

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Abstract

Objectives: To identify key features of interventions that need to be considered in the design, execution, and reporting of interventions. **Methods:** Based on prior work on decomposing psychosocial and clinical interventions, current guidelines for describing interventions, and a review of a broad range of intervention studies, we developed a comprehensive intervention taxonomy. **Results:** Specific recommendations, rationales, and definitions of intervention delivery and content characteristics including mode, materials, location, schedule, scripting, and sensitivity to participant characteristics, interventionist characteristics, adaptability, implementation, content strategies, and mechanisms of action are provided. **Conclusions:** Applying this taxonomy will advance intervention science by (a) improving intervention designs, (b) enhancing replication and follow-up of intervention studies, (c) facilitating systematic exploration of the efficacy and effectiveness of intervention components through cross-study analysis, and (d) informing decisions about the feasibility of implementation in broader community settings.

Key words: randomized trials, intervention taxonomy, intervention delivery, intervention content

Intervention Taxonomy (ITAX): Describing Essential Features of Interventions

Introduction

The scientific community has long endorsed transparency in the conduct of research, insisting on clear rationales for why a study was conducted, concise descriptions of how a study was carried out and how the data were analyzed. Published guidelines and checklists have been developed for both randomized and nonrandomized intervention studies to improve the quality of what is reported so that readers can accurately assess the strength of evidence supporting a particular conclusion of an intervention study.¹⁻⁴ These guidelines, which have been

endorsed by many of the major journals that report intervention studies, cover a broad range of design components and implementation processes. For example, Consolidated Standards of Reporting Trials (CONSORT) recommend that researchers provide “precise details of the intervention intended for each group and how and when they were actually administered” (p. 1989).¹ These recommendations were subsequently elaborated to include information on what was given (content), how it was given (delivery), where the intervention was delivered (setting), and how much was given (dose).⁴ Although useful, these guidelines have gaps that limit the ability of researchers to faithfully replicate studies, and they omit completely some aspects of interventions that may be important to understanding links between treatment and outcomes such as cultural sensitivity, adaptability, and strategies for treatment implementation.

In this paper we present a taxonomy for describing intervention protocols that expands existing guidelines and standards. This taxonomy is designed to help researchers conceptualize needed elements of intervention protocols and to enhance both the internal (eg, understanding the active ingredients of intervention components) and external validity (eg, replicating studies in real world settings) of intervention research.^{5,6} An expanded taxonomy for more fully describing interventions is needed to assure accurate replication and extension of published research and facilitate the translation of controlled efficacy studies into real-world applications to diverse populations and settings.⁵ Providing standardized and detailed descriptions of interventions also expands opportunities for theory testing by enabling researchers to assess the effects of intervention attributes across studies and in different target populations. Ultimately this will facilitate the development of evidence-based guidelines for intervention designers and decrease the risk and inefficiencies of ineffective interventions being adopted.

METHODS

Our interest in developing a taxonomy for characterizing interventions grew out of experience with the Resources for Enhancing Alzheimer's Caregiver Health (REACH) I,⁷⁻¹⁰ a series of multicomponent randomized trials aimed at enhancing the health and well-being of family caregivers of persons with Alzheimer's disease. The basic challenge was to develop a common language that could characterize the several complex, diverse interventions that were being tested across the 6 REACH sites. We sought a strategy that would take full advantage of the diversity and complexity of the various treatment strategies while allowing us to examine relationships between outcomes and intervention components. Initially, we decomposed the REACH I interventions using task analysis.⁹ This analysis revealed that interventions could be described according to 3 dimensions: (a) entity, or entities, targeted by the intervention, which included the caregiver, the care recipient, and the social or physical environment; (b) functional domains targeted by the intervention, which included knowledge, cognitive skills, behavior, and affect; and (c) delivery system characteristics including method of delivery, frequency, duration, and ability to adapt the treatment to the needs of the caregiver.⁹ Using this taxonomy, each of 12 different multicomponent interventions was characterized using a common language that enabled us to assess relationships between outcomes and intervention components.¹⁰ This approach identified caregiver behavioral-skills training as critical to achieving reductions in caregiver depression,¹⁰ a finding not revealed in the individual study-level meta-analyses.⁸ This finding led to the development of a new intervention that was found to be highly successful in improving caregiver well-being.¹¹ Overall, the success of this approach underlined the importance and utility of having detailed information about the content, structure, and delivery methods of interventions and a common language for describing intervention components.

Expansion of the REACH Taxonomy

To generalize to intervention studies beyond one set of clinical trials, we chose the Health Maintenance Consortium (HMC) studies as they represented a wide range of intervention approaches and target behaviors. The goal of HMC, a trans-NIH collaborative effort initially funded in 2004, is to conduct both process and intervention studies to test different theoretical models for achieving long-term health-related behavioral change.¹³ The behaviors targeted in the HMC studies include lifestyle behaviors associated with chronic illness (eg, tobacco cessation, exercise, nutrition) as well as the prevention of more risky behaviors (eg, substance abuse, HIV-related sexual behaviors).

Using a consensus process, we (RS, SC, JM, SB) reviewed the protocols of the 18 HMC intervention studies to capture elements of the interventions, not captured in our original taxonomy, which were important to subsequent replication efforts. On the basis of this review, the taxonomy was revised to include expanded operational definitions of treatment delivery characteristics, treatment content strategies, and mechanisms of treatment action.

Pilot Testing and Refinement

The expanded taxonomy was pilot tested by having 4 HMC investigators not involved in the taxonomy development process evaluate and apply the taxonomy to their studies. A detailed structured survey instrument, which included the categories in the taxonomy, was used to rate the interventions. Based on feedback from the pilot testing, the taxonomy was further refined. The refinement included clarification of instructions and expansion of options for mode of treatment delivery (eg, Internet contact), treatment strategies, target behaviors, and location of treatment delivery.

Testing the Taxonomy

The refined intervention taxonomy was then tested by having 18 HMC investigators not involved in the previous pilot test each apply the taxonomy to their interventions being tested in the HMC consortium. Investigators were given a structured survey instrument to assess each study. The investigators concurred that the taxonomy comprehensively captured key intervention components of all studies.

To further establish the generalizability of the taxonomy to studies not included in the HMC, we asked 3 additional non-HMC researchers at the University of Pittsburgh and the University of Miami to apply the taxonomy to diverse studies ranging from clinical medical trials (pharmacologic and psychotherapeutic intervention for lower back pain) to psychosocial/behavioral interventions (treatments for chronic fatigue syndrome and for depressed caregivers of persons with spinal cord injury). These researchers concurred that use of the taxonomy was feasible and that it adequately captured components of their heterogeneous intervention approaches.

RESULTS

Components of this final taxonomy, their definitions, and the rationale for including them are presented below. Our discussion is organized into 2 broad categories: delivery characteristics (Table 1) and intervention content (Table 2).

Treatment Delivery Characteristics

How a treatment is delivered has multiple dimensions, such as mode of delivery, materials used, location, and dose, many of which are routinely reported in descriptions of intervention studies. For example, across the HMC interventions the most common mode of delivery was face to face (84%); the most common locations for delivering interventions were

clinical research space (41%), participant's home (31%), and participant's work site (25%).

These delivery characteristics are included in the taxonomy along with less commonly described delivery attributes, including sensitivity to participant characteristics, intervention adaptability (ie, the extent to which the intervention can be modified), interventionist selection and training, and treatment implementation. Our discussion focuses on these additional attributes because they have received little attention in the literature and represent important elements of an intervention protocol.³

Sensitivity to Participant Characteristics

The attitudes, behaviors, and cultural competence of health care providers, who are predominantly white, have been identified as possible contributing factors to health disparities between blacks and whites and other racial/ethnic groups. For example, research suggests that African Americans prefer to receive health care from physicians of the same race¹³⁻¹⁷ and report receiving better health care from physicians of the same race.^{16,18} Although there are no randomized trials that systematically test the effects of racial matching in intervention studies, there is some evidence that such matching may be important. For example, a study on youth and their families in multisystematic therapy found that adherence ratings were higher when caregiver and therapist were ethnically matched.¹⁹ A post hoc analysis of the REACH I trials, which included white, Hispanic, and African American family caregivers of dementia patients, showed that African American caregivers with an interventionist of the same race had greater decreases in depression than did African American caregivers with interventionists of a different race or ethnicity.²⁰ These data suggest that one should consider issues of racial concordance in designing and reporting studies including interventionists.

Other important issues to consider include whether (a) interventionists and assessors were knowledgeable about and received special training in the perspectives and values of the

target population, (b) the design of treatment strategies included layperson or community input, and (c) the intervention was delivered in the participant's preferred language. Related issues include the extent to which the interventions were adapted to accommodate other participant characteristics, such as literacy or vision and hearing impairments.²¹ (Table 1). In the context of medical treatment trials, participant characteristics such as weight or concomitant medical conditions could affect dosage.

Adaptability

Adapting or tailoring an intervention to the unique needs and preferences of each participant has become a commonplace strategy for many interventions²²⁻²⁵ and is increasingly becoming a feature of health care delivery in general.²⁶ The rationale underlying this approach is that adherence and effectiveness will be greater if the intervention accommodates to individual variability in needs, preferences, and response to treatment. There is substantial range in the degree to which and how an intervention can be adapted.

A key distinction in the context of intervention studies is between adaptability within interventions (ie, variability in treatment as the treatment is being delivered) versus adaptive designs that focus on decision rules for assigning participants to treatments. We do not discuss further adaptive designs (eg, sequential, enrichment)^{22-25,27} but rather focus on adaptability as an intervention characteristic as described below.

Our taxonomy (Table 1) includes 3 dimensions of adaptability: (a) what aspects of the intervention can be adapted, (b) who or what determines that an adaptation should be made, and (c) when in the course of the intervention such adaptations can be made. With respect to what can be adapted, this could potentially be any aspect of intervention delivery and content. For example, it might include flexibility in the number of sessions devoted to a particular treatment module²⁸ or the specific content of a treatment module or patient support aid.^{29,30} The

intervention may also allow changes in the number, duration, or scheduling of sessions (eg, across the HMC treatment conditions, 28% allowed changes in the number of session, 23% in the scheduling of sessions, and 19% in the duration of sessions), the dosage intensity (eg, due to side effects), or the treatment delivery mode (eg, in person vs telephone). It is important, for the purposes of replication and translation, to have precise decision rules about what can and cannot be changed and to carefully record what was altered.

The second dimension of adaptability concerns the decision rules for making changes and requires defining who makes decisions and the criteria used to make them. An intervention may be adapted in response to a spontaneous request from a participant or on the basis of formal decision rules specified as part of the intervention protocol.²³

The third dimension of adaptability relates to when, in the course of treatment, an adaptation can be made. An intervention may include a baseline needs or risk assessment of the participant that is used to guide the content of the intervention such that high need or risk areas receive more attention than low need/risk areas as was the case in the REACH II trial.¹¹ Interventions can also be adapted to the participants' progress or status during treatment on the basis of clinical judgments. The degree of latitude varies substantially, ranging from, for example, "standard of care" to a detailed algorithm that must be followed for any treatment change. For example, in one of the HMC studies, a brief assessment of current risk and protective factors for alcohol relapse was done at the start of every clinical contact and used to determine whether treatment should be intensified, stepped down, or kept at the same level. Additionally, intervention studies must be responsive to unanticipated secular events that might affect intervention response and outcomes, and ethics of continuation. These events may include reports of promising new treatments related to the goals of an intervention or new knowledge about adverse effects of treatment.

Treatment Implementation

It is important to measure the extent to which treatment was implemented as intended, which, if low, could threaten internal validity³¹ and ultimately external validity. Multiple measurement strategies are available to assess treatment implementation, and there is broad consensus that there are 3 key components of treatment implementation: (a) treatment delivery, the extent to which the appropriate quantity and content of intervention was delivered as intended; (b) treatment receipt, the degree to which the participant received and understood the intended treatment, as indicated by mastery of concepts or skills targeted by the intervention; and (c) treatment enactment, the degree to which the participant demonstrates changes in behaviors related to the intervention beyond the intervention context.^{32,33}

With respect to treatment delivery, a minimum requirement is an accurate record of the frequency, duration, and types of contact between interventionist and participant. A more challenging task is monitoring the content of interventions, particularly those with multiple components. This can be achieved by using highly scripted intervention protocols and reviewing intervention sessions through notes or audio-recordings.

Treatment receipt is designed to assess the extent to which the participant “gets” or “buys into” the intervention. This might include increased knowledge, skills, and motivation, enhanced self-efficacy, greater social integration, or changes in pathophysiology. From an intervention-design perspective, it is important to both articulate what these mechanisms are and develop a measurement strategy for capturing them.

Treatment enactment involves the generalization of processes and goals to situations outside the therapeutic session. To what extent is the client able and motivated to appropriately use newly acquired knowledge or skills in his or her everyday environments?³⁴ Strategies for assessing enactment might include directly observing the participant or obtaining self-reports from the participant or reports from other observers of the participant. It is important to note that

enactment is not the same as outcome. Enactment focuses on the application of skills and knowledge imparted by the intervention, not whether or not the desired outcome is attained.

Intervention Content

There is no standard taxonomy for describing the content of interventions, even though there is strong consensus that one is needed.³⁵⁻³⁷ With the exception of one study specifically designed to develop a taxonomy of behavior change techniques,³⁵ most efforts in this arena are implicit rather than explicit. Meta-analyses of intervention studies typically involve characterizing intervention content along one or several dimensions that are thought to be related to outcomes. For example, a recent meta-analysis of behavioral interventions to prevent childhood obesity assessed the efficacy of 4 different strategies for interventions aimed at changing lifestyle behaviors—increased physical activity, decreased sedentary activity, increased healthy dietary habits, and decreased unhealthy dietary habits.³⁸ Another common approach is to evaluate the efficacy of a specific strategy such as computer technology-based HIV prevention interventions.³⁹ However, combining information across studies without a standard taxonomy has a number of limitations. First, interventions included in meta-analyses are typically tailored to the content area of the intervention and may not easily be generalized to other research domains. Second, because meta-analyses are based on completed studies, they reflect what has been done as opposed to what might be done. Third, the extent to which multicomponent interventions can be decomposed into subcategories is constrained by the competing demand to maximize the number of studies that can be included in a meta-analysis. These limitations argue for a taxonomic system that is generic enough to apply to a wide range of studies, yet specific enough to generate meaningful categories of intervention content.

The taxonomy presented here distinguishes between strategies and mechanisms of action (Table 2), related aspects that address how intervention is delivered to the client and how

it works. Examples of intervention strategies found in the behavioral change literature include providing information, using incentives or reinforcements for desired behaviors, tracking and monitoring behavior, teaching problem solving, skill building, using stress-management techniques, and providing social support.

Strategies of delivering interventions can affect outcomes through multiple actions. For example, information provision is thought to enhance knowledge, the ability to assess risks/goals, as well as improve behavioral and problem-solving skills. Problem solving and skill-building strategies are thought to enhance not only specific skills but also self-efficacy and motivation.

Although most intervention studies identify the treatment strategies used, not all studies specify the mechanisms thought to affect treatment outcomes, and even fewer studies collect data assessing mediators of treatment effect. We emphasize mechanisms of action because of their importance in theory development and testing. Understanding mechanisms of action also helps elucidate pathways through which the content of interventions affect desired changes in behavior. This helps to identify aspects of an intervention that are successful and those that need to be eliminated or modified.

CONCLUSION

Our goal is to expand existing taxonomies for characterizing interventions by identifying elements that might be related to outcomes and thus are crucial for replication and extension of intervention science. To be sure, our taxonomy is likely to be most useful for characterizing complex, multicomponent behavioral studies of the type carried out by the Health Maintenance consortium, but the taxonomy has utility as well for simpler randomized clinical trials. Having comprehensive and standardized taxonomies for characterizing interventions is important for several reasons.

First, taxonomies serve as useful tools in developing interventions and alerting the researcher to elements of interventions that should be addressed prior to study implementation. Our taxonomy goes beyond existing classification systems by including issues such as cultural sensitivity; intervention adaptability; measures of treatment delivery, receipt, and enactment; treatment content strategies; and mechanisms of action. A good taxonomy should lead to improved intervention design and execution and foster cross-study similarities.

Second, consistent and comprehensive descriptions of interventions facilitate systematic exploration of the efficacy of intervention components through post hoc and cross-study analyses. The availability of comprehensive standardized descriptions of intervention studies expands the range of questions that might be tested through meta-analysis. For example, one reason hypotheses such as the effects of racial matching have not been extensively explored in the literature is the lack of attention paid to this variable in both the design and description of studies. In addition, the availability of information on dose, delivery method, content strategy, and participant characteristics enables researchers to explore complex interactions among these attributes. Although various categories of these attributes and their combinations could be systematically tested in randomized trials, this is not feasible. The cost and time to evaluate the efficacy of individual components of complex interventions would be prohibitive. An alternative strategy is to articulate clearly a detailed conceptual framework and explore the role of variables defining that framework across multiple studies. This strategy, successfully implemented in REACH,¹⁰ can help to identify critical components of interventions for future studies. Detailed descriptions of intervention studies can also facilitate decisions about the feasibility of implementing an intervention in broader community settings.⁴⁰

Another benefit of a good intervention taxonomy is that it can improve the quality of intervention science. There is broad consensus in the scientific community about what constitutes a good study.⁴¹ For example, well-implemented randomized experiments are better

than well-implemented studies using matching strategies to equate groups. Other quality criteria include fit between concepts and operations (eg, treatment delivered vs treatment intended); validity of comparisons (eg, the extent to which participants in multiple treatment arms were comparable); generality of findings (eg, representativeness of participants, ability to replicate treatments in various settings); and accuracy, precision, and relevance of outcome estimation (eg, whether the outcomes are appropriate to the intervention and the extent to which they can be measured in a general setting). Knowing the delivery characteristics and content of an intervention is critical to making judgments about the quality of a study.

The stimulus to develop this taxonomy was to shed light on how interventions are thought about and described in the research literature. The added value is to aid in intervention design, replication, and cross-study evaluations. We provide specific recommendations about key features of interventions that need to be considered in the design, execution, and reporting of intervention studies. Although it may not be feasible to include this level of detail in published manuscripts, the level of detail may be more practically posted on Web sites linked to the published article. Although trying to be exhaustive in generating this taxonomy, we anticipate that additional attributes may come to light as this taxonomy is applied to future studies. When carefully considered to avoid redundancy or overcomplication, such additions would serve to further expand the utility and applicability of this system.

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