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Challenges in Tailored Intervention Research

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Summary

Although individuals and nurses value tailored health interventions, incorporating tailored interventions into research is fraught with pitfalls. This manuscript provides guidance on addressing challenges on developing, implementing, and evaluating tailored interventions (TI). The initial step in designing TI involves selecting the individual characteristics on which to tailor the intervention. After selecting critical characteristics for tailoring, researchers must decide how to assess these characteristics. Then researchers can use manuals, algorithms, or computer programs to tailor an intervention and maintain treatment fidelity. If desired outcomes are not achieved, focus groups or individual interviews may be conducted to gather information to improve the intervention for specific individuals/groups. Then, incorporating study arms of TI in intervention studies, investigators may compare TI with standardized interventions statistically and clinically. We believe TI may have better outcomes, promote better adherence, and be more cost efficient.

Keywords

Tailored interventions; individualized interventions; individual centered care

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Introduction

Traditionally, nurses have valued care that incorporates individuals' unique characteristics, including their beliefs, disease state, cognition, race/ethnicity, needs, preferences, and resources.^{1,2} Studies have shown that individuals also value individualized or tailored care and prefer it to standardized health information and care.³⁻⁶ Since both nurses and individuals prefer these types of interventions, it is important that we incorporate them into research so that the findings can contribute to evidence-based practice. However, incorporating individualized or tailored care into research is problematic and fraught with pitfalls. This manuscript provides guidance on addressing the challenges of developing, implementing, and evaluating tailored interventions.

The terms “targeted”, “individual-centered”, “tailored” and “individualized” are often used interchangeably when referring to interventions.⁵ We define targeted interventions as those designed to address a single characteristic *of a group* such as age, gender, diagnosis, or ethnicity, or multiple group characteristics such as cognitive impairment in the elderly. This type of intervention is appropriate when a single characteristic dominates the variables on which individuals may be subdivided into groups with similar responsiveness to interventions. For example, if gender is the key variable affecting individuals responsiveness to a standardized treatment, then an intervention targeted to women or to men might be appropriate.

Lauver et al.² define individual-centered interventions as either 1) addressing salient characteristics or individuals' experiences, or 2) responding to individuals' goals or preferences. Our use of the term tailored incorporates Lauver et al.'s² definition of individual-centered interventions. We define *tailored interventions* (TI) as those designed to address the individual characteristics of persons within a sample, such as personality factors, goals, needs, preferences, and resources. For example, Conrod, Stewart, Comeau and Maclean⁷ identified personality as a risk factor for adolescent alcohol abuse, and then provided personality focused interventions for teens identified as high risk for alcohol abuse. The interventions included psychoeducation and behavioral/cognitive coping skills training that targeted specific personality dimensions.

We may first target an intervention to characteristics of the sample (sex, risk level for alcohol abuse, etc.) and then tailor the intervention to the individual characteristics of participants (e.g., behavioral cognitive skills training). For example, in Tsai's study,⁸⁻¹⁰ she first aggregated cognitively impaired elderly into groups (aggregate sample characteristics), then tailored the intervention to match each individual's unique level of physical endurance, stability, and pain.

To date, most clinical trials have tested standardized or targeted interventions, not individualized or tailored interventions. Many standardized nursing interventions tested in clinical trials have not been highly successful in improving outcomes, as evidenced by small effect sizes or negative findings.² Even standardized or targeted interventions that produce clinically/significant effects may fail in clinical practice, perhaps because they do not address individuals' needs or preferences for care, contributing to non-adherence. Health care providers may also be slow to adopt standardized evidence based practice guidelines because there is no clear understanding of the critical characteristics of aggregate groups among the “responders” and “non-responders.” Health care providers might more readily adopt evidence-based best practice guidelines if they had more options for tailoring them, and thus increasing persons' satisfaction with treatment and improving clinical outcomes.

Several reviews and meta-analyses¹¹⁻¹³ provided guidance for the first generation of tailored health behavior change interventions, i.e., the use of tailored health information. There is

increasing literature on developing and testing the more complex second generation of tailored interventions, i.e., clinical trials of tailored biobehavioral interventions.¹⁴⁻²¹ However, when researchers need to develop equivalent biobehavioral interventions based on individual characteristics of participants within the sample, a number of complex issues emerge. Several investigators, for example have identified the challenge of selecting the critical characteristics on which to tailor interventions.^{18,22} Other investigators have raised the issues of standardizing a tailored intervention, measuring the dosage of tailored interventions, and describing the amount of tailoring.^{15,17,23} Finally, there are challenges related to evaluating individualized outcomes. For example, how is power calculated when outcome “measures are included that are not relevant to all individuals’ treatment goals” (p. 801)?²⁴ and how does the researcher determine which interventions are most effective when multimodal tailored interventions are used simultaneously?²⁵

When developing our proposal for a Tailored Biobehavioral Intervention Center, (TBIRC) which was funded by the National Institute of Nursing Research as a P20 Center, we found little guidance in the literature for tackling these complex challenges. To provide guidance to our Center investigators conducting studies of interventions tailored at the level of the person, rather than the sample, we developed the TBIRC Model found in Figure 1. This article describes a process for developing and testing TI based on the TBIRC Model, discusses ways to address some of the challenges in the tailoring process, and provides examples of the various steps in the process, described below.

Selecting of Critical Characteristics

The initial step in designing and testing TI is selecting the individual characteristics on which the intervention will be tailored.²³ Critical individual characteristics might include a) physical health characteristics such as blood pressure or sleep patterns, b) mental health characteristics such as cognition; and c) psychosocial health characteristics such as education, religious orientation, socioeconomic issues, and stressful life events. The selection of the individual characteristics that are of primary importance in tailoring an intervention is driven by the science showing the relationship of these characteristics to intended outcomes and the resources available to design and monitor the tailoring process.

The use of individuals’ physical health characteristics for tailoring an intervention is exemplified in the work of Schnelle, Cruise, Alessi, Al-Samarrai, and Ouslander,²⁶ who sought to improve incontinence care while minimizing sleep disruption in nursing home residents. Initially, the researchers conducted a descriptive study of 118 incontinent nursing home residents. In this study, they found no individualization of incontinence care based on residents’ sleep/wake state or ability to turn independently.²⁷ Subsequently, they developed a nighttime incontinence intervention and tailored it based on three critical characteristics: residents’ sleep/wake patterns, skin health risk, and frequency of body movement. These critical characteristics provided an estimate of the residents’ need for repositioning and incontinence care. The intervention involved assigning residents to a 2-hour incontinence care schedule if they were at high risk for skin problems or a 4-hour incontinence care schedule if they were at low risk for skin problems. Following TI, residents experienced significantly fewer awakenings at night with no adverse changes in skin health.

Similarly, in their studies using Tai Chi (TC) to reduce osteoarthritic knee pain in cognitively impaired elderly, Tsai and colleagues found that because of these elders’ frail physical and cognitive functioning, they could not follow the standardized TC protocol.^{8,28} However, elders with moderate cognitive impairment could learn and practice TC with the TC instructor and they could exercise for 40 minutes by the end of 12 weeks. Therefore, the

researchers identified physical strength and cognitive capacity as critical characteristics to consider in designing a tailored TC intervention for this population.

In some cases, there is insufficient knowledge about the critical characteristics affecting a desired outcome and researchers need to conduct descriptive research to identify these characteristics. For example, in Souder and Mitchell's²⁹ work focused on developing meaningful educational interventions about autopsy, they conducted separate focus groups with Southern Caucasians and African Americans to determine why few persons did not consent for autopsy for a family member with cognitive impairment. The focus groups explored participants' explanatory models (EM), including perceptions, attitudes, and decision-making, of participants in regard to autopsy consent and identified concerns associated with autopsy. An EM is a personal belief that people use to recognize, interpret, and respond to a specific symptom/illness or health related experience, in order to cope with and make sense of these health experiences.^{30,31} Findings from the study suggest that African Americans are particularly concerned that autopsy might delay funeral arrangements, but they are motivated to consent to autopsy by their perception of the need to develop drugs that work effectively in black populations. Findings from this study would be useful in identifying the critical individual characteristics that should be considered in tailoring approaches to increase the autopsy consent rate among African Americans.

One way of determining critical characteristics is to use subgroup analysis of standardized interventions to determine whether persons at each response level share any characteristics.³² Often, if one intervention has been found more effective than another has, the more effective intervention would most probably work well for most, moderately well for others, and poorly for a few participants. For example, persons with normal cognitive functioning might respond well to a given intervention, while those with severe dementia might respond poorly. For persons with moderate dementia, those with normal hearing might respond well, while those with hearing impairment might respond poorly. Thus, for those with normal functioning, use the intervention in question---it works well; and for those with severe cognitive impairment select an alternative intervention because the one in question does not work. However, for individuals with moderate impairment, one must also consider hearing function.

Statistical methods for recursive partitioning (or classification 'trees') can help identify a hierarchy of variables on which individuals can be subdivided into groups with similar responsiveness to TI.^{33,34} Recursive partitioning first identifies the factor that is most predictive of a response. Then, separately for each subgroup, the next most predictive factor is determined, and so forth, subject to specific statistical properties. This method can identify more complex factor interactions than can be found using interaction terms in a regression analysis. The method has been used in medical settings to classify risk groups that might benefit from targeted medical therapy (particularly in oncology and cardiology), but applications in the biobehavioral arena have been limited. To identify characteristics of individuals for whom tailoring should be considered, recursive partitioning may also be used in combination with more traditional data analytic methods.

Large randomized clinical trials can help address the issue of selecting critical characteristics through subgroup analyses or prediction models, but these require confirmation in further studies. For example, cases with favorable and unfavorable responses to a standardized intervention may be compared for a set of different individual characteristics. If differences in one or more individual characteristics are revealed, this may suggest a subgroup with benefit. However, this finding would need to be confirmed prospectively. Investigators could also evaluate the subgroups of individuals who received the same or similar interventions to assess consistency of outcomes. Alternatively, they

could analyze subgroups of individuals who had similar critical characteristics but received different interventions to determine which, if any, intervention had a superior outcome for participants with these particular characteristics. To create exploratory datasets, investigators could pool data on control groups among studies with similar eligibility criteria, and could then use logistic regression models or chi-square analysis to predict poor responses under usual care.

The choice of approach for addressing the challenge of identifying critical characteristics depends on the state of the science and the nature of the research question. However, it is essential to understand which interventions work for whom and to identify critical individual characteristics that contribute to successful outcomes. The final selection of the number of individual characteristics that may be considered in designing a tailored intervention is based on practicality and resource allocation issues. For instance, Meyer et al.¹⁵ selected three characteristic variables that they determined to be most relevant to the desired outcome and tailored educational messages to these address these characteristics. Similarly, Sedlak, Doheny, Estok et al.³⁵ selected five characteristics, including calcium intake and exercise behaviors, to tailor specific telephone interventions to prevent osteoporosis.

Once an investigator selects the critical characteristics to consider in tailoring the intervention, the next step is to decide how to assess these characteristics. For example, if the researcher is testing a teaching intervention and has determined that an important characteristic is the individual's learning style preference, then it is important to assess learning style. In some cases, appropriate instruments may not be available and the researcher may need to create one to adequately assess the characteristic(s) of interest.

Once the critical characteristics are determined, the researcher may aggregate individuals into groups based on these characteristics, and interventions may be tailored for these subgroups. Thus an investigator does not design a separate intervention for each participant, but tailors to the most important characteristics that are shared by other participants in the sample. Aggregation participants is cost effective and should contribute to easier adoption in clinical practice.

Researchers have reported a variety of mechanisms for assessing critical characteristics-- a necessary precursor to developing TI. For instance, Lusk, Ronis, Kasanis, Eakin, Hong, and Raymond²¹ conducted a study using TI to increase use of protective hearing devices in factory workers. They tailored interventions based on responses from participants to items on a survey, type of protective hearing devices subjects reported using, reported frequency of use of these devices, and perceived hearing ability. These variables were based on selected "theoretically specified predictors of use of HPDs (hearing protective devices)" (pp. 292).

Other researchers have used a variety of instruments or patient characteristics to assess the most salient characteristics upon which to tailor interventions^{17,36} As indicated in Figure 1, instruments may need to be modified to assess for the characteristics that have been predetermined based on the literature, pilot findings, clinical observations, or a combination of these. Additionally, once the instruments to assess critical characteristics have been developed or modified, it may be necessary to make changes in measurements of outcomes based on these critical characteristics.

Planning

To address the challenges of planning a tailored intervention based on assessment of the critical individual characteristics, researchers can use manuals, algorithms, or computer programs. Beck et al.³⁷ individualized strategies based on the specific characteristics of

cognitive status, physical abilities, and preferred dressing sequence to improve dressing independence in nursing home residents with dementia. A decision-making algorithm guided the prescription process. The rationale was that the amount of assistance offered should be matched to individuals' cognitive status and physical abilities so as to preserve their remaining abilities for as long as possible. Similarly, the assistance should match the individual's preferred dressing sequence, as much as possible, to support previous routinized behaviors. Offering the lowest level of assistance needed was designed to preserve functioning for as long as possible. For example, if a participant could respond to a verbal prompt, then nursing assistants tried this lower level of assistance before using higher levels of assistance such as touch or physical guidance to start the movements required for dressing. For a participant with ideational apraxia, the algorithm prescribed arranging the clothes in the proper order. When nursing assistants were given information on the abilities and disabilities of their assigned participants, along with a list of prescribed dressing strategies, the result was statistically and clinically significant improvements in dressing independence.

Although some investigators have provided information on the critical characteristics used to make decisions about tailoring,^{15,35,38,39} we found that many investigators provide too little detail about their tailoring process for others to be able to replicate the process.^{21,23} Thus Bakken, Holzemer, Portillo, Grimes, Welch and Wantland¹⁷ suggest that "nurse researchers implementing tailored, multi-faceted interventions might consider incorporating relevant standardized terminologies into study protocols to facilitate documentation of the intervention dose and to determine the amount of individualization in the intervention" (pp. 256-257).

Implementation

In this step, the investigator conducts a clinical trial to test the TI. Intervention fidelity, defined as maintaining standardized delivery of an intervention, is particularly important. Although there are excellent guidelines for maintaining intervention fidelity,⁴⁰ the process is more complex when implementing TIs because the intervention is tailored to critical individual characteristics. Additionally, maintaining intervention fidelity is more complex because one protocol contains several interventions that must be enacted consistently. To address these challenges, interventionists must be trained not only in treatment delivery, but also in the process of tailoring interventions. They need guidance concerning the essential components of an intervention, the components that may be modified in tailoring, and the extent to which modifications can be made. Investigators must also provide guidelines on when and how to record such modifications.

Tsai and colleagues are currently conducting a study using TC to reduce OA knee pain in elders with CI.^{8,9} They are tailoring the TC intervention to the needs of a group of elders to ease the physical and cognitive requirements of TC. Modifications include starting with sitting and high-square posture during the first stage of TC program, providing visual and verbal cues while practicing TC, and modifying teaching strategies. The investigators are thus implementing the tailored intervention based on critical characteristics of participants. Yet, despite these individualized interventions, they are maintaining intervention fidelity.

Evaluation

In most cases, the outcomes assessed in tailored interventions are common across individuals despite the fact that the intervention may differ for different individuals. There are, however, cases in which the outcome may also have to be tailored. For example, if one of the critical characteristics for tailoring the intervention is the individual's cognitive status, the outcome measure may have to be specific to the level of cognitive status. In the study by

Tsai et al^{8,9} discussed above, pain is the primary outcome and the gold standard is verbal report. However, persons with more severe cognitive impairment may have difficulty expressing pain verbally.^{10,41} Thus, Tsai and colleagues are using three pain tools for elders with various level of cognitive functioning- The WOMAC pain scale, the VDS, and Keefes' observational method for OA knee pain.^{8,9}

Conducting in-depth qualitative interviews with individuals who have not had a successful outcome despite tailoring of an intervention is one way to evaluate why the interventions are not effective. These interviews could assess not only individuals view of why they did not achieve the desired outcome, but also their recommendations for how to develop TI that would be more useful to them in attaining their goals. Additionally, if one subgroup of individuals achieves the desired outcomes while another subgroup does not, researchers could conduct interviews with members of both groups or conduct focus groups composed of members from each group to assess why the groups responded differently to the TI. The qualitative data could provide key information on the tailoring process that would increase the likelihood of positive outcomes.

Discussion

Both individuals and nurses highly value interventions that incorporate each individual's unique characteristics, but most previous research has tested only standardized interventions or tailored educational interventions. We recommend that researchers incorporate study arms of TI in biobehavioral intervention studies, so that tailored interventions can be compared to standardized interventions for both statistical and clinical significance. Even if a standardized intervention is effective, a tailored intervention may promote better adherence, have better outcomes, and/or be more cost efficient.

We have reviewed some of the challenges in the process of conducting research on TI and suggested approaches for addressing these challenges. We believe that interventions tailored to scientifically identified and personally meaningful individual characteristics will have greater efficacy than standardized interventions, and thus will have the potential to result in greater adherence, improved health outcomes, and cost savings. As health care moves to "designer drugs" based on an individual's genetic make-up or biomarkers, it is important to evaluate a similar level of individualization in biobehavioral interventions.

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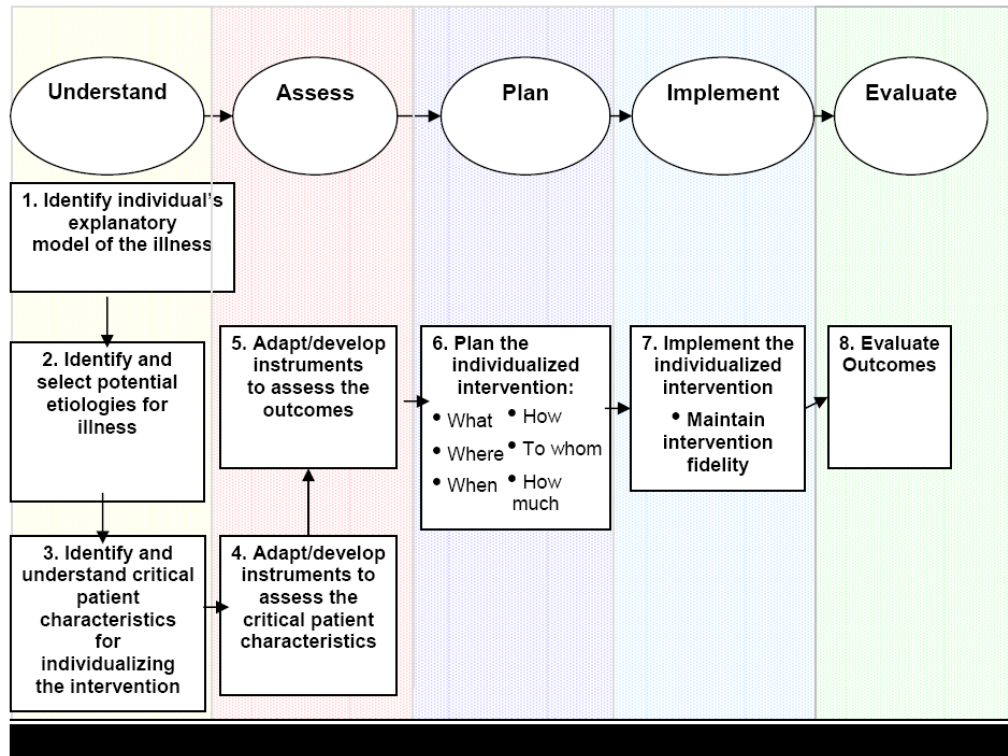


Figure 1.
Model for Tailoring Biobehavioral Interventions