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Original Article

Development and validation of CF-Medication Beliefs Questionnaire: A mixed-methods approach

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Abstract

Background: Beliefs about medication have been associated with adherence in other diseases but there are no existing disease-specific medication beliefs questionnaires for CF. This mixed-methods validated the Cystic Fibrosis Medication Belief Questionnaire (CF-MBQ), based on social cognitive theory.
Methods: Based on previous research, items were developed for five domains: motivation, self-efficacy, perceived importance, and decisional balance to take or miss medications. Cognitive interviews were conducted with 15 adult patients with CF to refine item development. 128 patients with CF completed an online survey and objective medication adherence was measured using pharmacy refill data.
Results: The five subscales demonstrated strong psychometric properties, with adequate-to-good internal consistency scores. More importantly, each domain demonstrated construct validity with adherence.
Conclusions: These theoretically-derived measures may be important for clinical purposes to provide guidance on appropriate interventions to improve adherence and for research to provide enhanced understanding on patient determinants of medication adherence.

Keywords: Social cognitive theory; Medication adherence; Cystic Fibrosis; Medication beliefs

1. Introduction

While cystic fibrosis (CF) was originally considered a pediatric condition, advances in medical care for CF over the past three decades have extended the median predicted survival to nearly 40 years of age [1]. However, the CF treatment regimen has become increasingly complex and demanding [2]. Given the complexity of this regimen, it is not surprising that adherence is consistently suboptimal across treatment components [3]. This poor adherence likely contributes to poor health outcomes, including increased risk of exacerbations and lung function decline, and higher healthcare costs [3,4].

Social cognitive theory (SCT) is a widely used theoretical framework for understanding health behaviors such as medication adherence for chronic conditions [5]. According to SCT, an individual's health beliefs and possession of adequate health management skills both influence the degree to which he or she engages in behavior change. Specific health beliefs associated with SCT, including medication-related self-efficacy, behavioral intention to adhere to medications, and perceived benefits and barriers to medications, consistently emerge as important factors in relation to medication adherence across chronic conditions [6,7,8,9]. Although health beliefs may be key facilitators or

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barriers to medication adherence in other chronic disease populations, there has been limited quantitative research on how SCT health beliefs impact objectively measured medication adherence in CF. This may be attributed to limited available assessments of health beliefs related to CF medications.

Understanding the impact of SCT health beliefs on medication adherence will inform the development and evaluation of clinical interventions to promote adherence. Current assessment methods for medication beliefs are varied. Existing instruments focus may not be disease-specific (e.g., Illness Perception Questionnaire [10]) or on only one SCT construct, such as the Beliefs about Medications Questionnaire which only assesses necessity/concerns about a medication [11]. It is not uncommon for researchers to ask single, un-validated items to assess specific health beliefs [12,13,14]. Only a few surveys target health beliefs for specific conditions or populations (e.g., Self-Efficacy Measure for Sleep Apnea [15]; Beliefs about Dietary Compliance Scale [16]). However, most of these measures are not validated using an objective measure of medication adherence. The only CF-specific health belief measure available was minimally adapted for CF patients, did not objectively measure adherence and does not address all components of SCT available [17].

The purpose of this study was to develop a CF medication beliefs questionnaire (CF-MBQ) focused on the unique, multi-medication CF treatment regimen. For maximum utility and flexibility, the goal was to develop and validate a measurement approach that would allow researchers and clinicians to assess one or more health beliefs using individual modules, or to capture the full range of SCT health beliefs relevant to CF management using the complete instrument, including motivation, importance, self-efficacy and Reasons to Take/Miss medications. These subscales were validated against pharmacy refill records as a measure of objective medication adherence. Furthermore, because depression has been shown to be linked to medication adherence specifically in CF [18] and social support has been shown to be linked in other diseases [19], these measures were included to demonstrate convergent validity.

This study utilized a mixed methods design to develop and validate the measure. Following a review of the literature and qualitative interviews [20] to identify CF-specific medication beliefs, items were developed for the above mentioned SCT health belief domains to create the CF-MBQ. We hypothesized that these SCT health belief measures would be associated with objective measures of adherence (construct validity). We also hypothesized that these measures would be associated with other known determinants of adherence such as depression, self-regulation and social support. Specifically, higher scores on the CF-MBQ would be associated with lower levels of depression and higher levels of self-regulation and social support (convergent validity).

2. Methods

This study used a sequential mixed methods design to develop and validate the CF-MBQ [21]. Phase One included qualitative interviews (previously published [20]) to conceptualize the constructs and inform item development. Then, items were field-tested using cognitive interviewing to obtain more information on patient understanding of the items and feedback regarding the content and wording. Phase Two focused on validation of the measures using quantitative methods. The Johns Hopkins University School of Medicine Institutional Review Board approved this study.

3. Phase One: Item development and field testing

3.1. Participants

Participants were individuals diagnosed with cystic fibrosis (CF) over the age of 16 years treated in the pediatric or adult CF center of a tertiary hospital in the Mid-Atlantic region of the United States. Participants were prescribed at least one of the following: an inhaled mucolytic, inhaled antibiotic therapy, chronic macrolide therapy, and/or hypertonic saline therapy for the previous 12 months. Exclusion criteria included previous lung transplant and diagnosis of *Burkholderia cepacia* complex isolated from the respiratory tract within the previous two years. Potentially eligible patients were mailed an informational letter prior to a clinic visit informing them about the study and giving them the opportunity to opt out of being contacted. Patients who did not opt out were then contacted by phone to assess eligibility and interest in study participation. For those who agreed, a study staff member met with the potential participant prior to the clinic visit and obtained informed consent. For participants below age 18, the study was described to both the parent and teen and both provided consent/assent.

3.2. Item development procedures

The first stage of measurement development was to conceptualize constructs related to health beliefs and to identify the behaviors and beliefs that underlie the constructs. Qualitative interviews with adolescents and young adults with CF [20] were reviewed to categorize beliefs and behaviors that promote medication adherence according to SCT. Beliefs and behaviors were divided into five constructs based on SCT: motivation, importance, decisional balance for taking medications, decisional balance for missing medications, and self-efficacy. The instructions on each measure instructed the participant to answer the questions regarding their pulmonary medications.

A total of 60 items were then developed across these constructs. Patients were asked to answer all self-efficacy, motivation and importance items using a scale from 1 to 10 with 1 being “not at all [sure/motivated/important]” and 10 being “completely sure” or “extremely [motivated/important].” The decisional balance scale was based on a 1 to 5 scale with 1 being “strongly disagree” and 5 being “strongly agree.” Scores for each subscale’s items were summed and divided by the number of items to produce an average score ranging from 1 to 10 (self-efficacy, motivation and importance) or 1 to 5 (decisional balance). Sum scores were not calculated for a participant if greater than 25% of the items on the scale were missing.

The **motivation and importance** subscales both consisted of 3 items each and directly assessed individuals’ motivation to