



Development and usability testing of a self-management intervention to support individuals with obstructive sleep apnea in accommodating to CPAP treatment

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ABSTRACT

Objective: Development and usability testing of a self-management intervention to promote CPAP adherence.

Background: While CPAP is an effective treatment for OSA, patient adherence is sub-optimal. Qualitative interviews and evidence based approaches were used in development.

Methods: The initial steps in the Campbell (2000) Framework for complex intervention guided development of the intervention in book format. After sleep expert review and modification, CPAP users reviewed the format and content of the intervention and were interviewed by telephone using a “talk-out-loud technique” to determine usability. The interviews transcripts were analyzed thematically.

Results: Ten participants with varying ages, race, education, and CPAP usage, found the intervention contained useful information to understand their diagnosis, to problem-solve, and monitor their progress. Suggestions included minor format changes and the wish that they had access to the intervention when first diagnosed.

Conclusion: This intervention provides a multimodal approach including education, self-management tools, cognitive restructuring, provider communication guides, and peer stories of success that may be helpful in initiating active problem solving to improve self-efficacy to adhere to CPAP. Future research plans include clinical testing in a RCT with new CPAP users.

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Introduction

Continuous positive airway pressure (CPAP) devices worn nightly effectively treat symptoms of obstructive sleep apnea (OSA)¹ resulting in improved sleep and reduced daytime sleepiness. However, treatment adherence has been reported as low as 27% to a high of 54%.^{2,3} Over the years, research studies have focused on factors predicting adherence. In a review of the literature by Olsen et al,⁴ predicting adherence is associated with improvements in daytime sleepiness, severity of disease, lower CPAP pressures, higher body mass index (BMI), and higher level of education; however, these factors account for only 10–15% of the variance in predicting adherence. Thus there is still a need to understand what motivates adherence.

In a recent systematic review of the evidence on adherence by Sawyer et al,⁵ factors that influence adherence were identified: (1) disease severity (airway patency, nasal resistance, and severity level of apnea hypopnea index, oxygen desaturation levels, and daytime sleepiness), (2) patient characteristics (personality type, mood, depression, race and socioeconomic status [SES]), (3) patient experiences with titrating appropriate pressures and use of auto titration devices, (4) device side-effects (mask fit and comfort), and claustrophobia, and (5) psychological (self-efficacy, expectations) and social support factors.⁵ Other factors related to psychological issues include knowledge of treatment and disease which influences risk perception, coping styles which may contribute to active problem solving, as well as, the experience of the bed partners improvement in sleep quality with treatment. This review also suggests proactive coping styles are more likely to increase adherence.^{5,6}

Some of these factors that influence adherence have been used in the design of interventions.⁵ Most of the previous interventions

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included educational approaches that were only effective with the addition of expensive and intensive clinician support in a one-to-one or group format.⁵ The evidence suggests that important components to promote CPAP adherence should include: patient education about OSA, diagnostic information, symptoms, and outcome expectancies for daily management, goals for use (hours per night), anticipatory guidance for trouble-shooting problems, assistance with initial exposure, inclusion of a support person, opportunities to contact others who have used CPAP, resources for problem solving, and follow up with sleep providers,⁵ as well as, self-management approaches that add components of skill development and peer support.⁷ Self-management approaches may include self-monitoring of symptoms or physiologic processes, decision making, and problem solving.⁷ Other research has shown that cognitive behavioral therapy (CBT) and elements of self-efficacy showed some effectiveness.^{3,7–9} The evidence supports a complex multifactorial approach that focuses on improving knowledge of the need for CPAP, improving self-efficacy, evaluation of barriers, and developing behavioral strategies to improve adherence rates which can be cost effective and easy to implement.

To understand the difficulties with adherence from the patient's perspective, a qualitative study of newly diagnosed patients accommodating to CPAP was conducted.⁶ Patients described their need to persevere through the initial tribulation in an attempt to develop a positive mindset to accommodate CPAP use into their lives. The patients who were ultimately successful in adhering to CPAP described their initial troubles and recurring frustrations with getting used to the device. They also described difficulty in recognizing the subtle improvements from using the device that suggested implementing self-monitoring and feedback approaches to help patients recognize improvement. Successful patients learned to access help in problem solving to make CPAP use a part of their daily routine. The patients' stories, while unique, often had common similarities that demonstrated an array of approaches to self-management that assisted in accommodating CPAP use into their daily lives. The patient stories and experiences provided "real life" meanings and practical knowledge of how they managed their CPAP from their lived experiences. Therefore, insight was gained to facilitate development of what we call a qualitatively derived meaning-based intervention that supports using complex and multifactorial contextual patient meanings of CPAP use that emerged from the qualitative interviews.

Thus using the evidence, we proposed targeting patients early in the treatment trajectory with a meaning-based intervention that is contextually appropriate to their experience, which addresses an array of approaches for self-care management to improve

adherence to the CPAP. Therefore, the purpose of this paper is to describe the development of an intervention guided by the Campbell Framework for Design and Evaluation of Complex Interventions,¹⁰ and the initial usability testing of a self-care management intervention in a book format that may provide a cost effective tool to support self-management for individuals with newly diagnosed obstructive sleep apnea who are prescribed CPAP treatment.

Methods

This project took part in two phases: the development of intervention materials and the subsequent evaluation of the intervention first by expert review and subsequently by a usability testing in two groups of CPAP users.

Phase one-development to intervention

Guiding framework

The development of this intervention was guided by the Campbell Framework for Design and Evaluation of Complex Interventions' first two levels of preclinical and modeling phase.^{10–12} This framework has been commonly used in the United Kingdom (UK) to design health related programs to solve complex health problems such as: an online behavioral intervention for individuals with cardiovascular disease; delay of symptomatic patients' presentation to providers for a diagnosis of lung cancer; and case management to reduce emergency hospital admissions.¹¹ Table 1 outlines the Campbell Framework for Development and Evaluation of Complex Interventions, in context with the entire process toward final implementation.

Complexity refers to the number of interacting components, the difficulty of behaviors to be changed, the variability of outcomes and the degree of flexibility needed.¹² CPAP adherence is a multi-dimensional problem that is congruent with this approach that affords the ability to combine interacting components into a complex intervention.

Development of the self-management intervention

The problem of CPAP adherence was defined and quantified during the initial conceptualization of the problem for the intervention. Table 2 summarizes the problem and key tasks. Identification of theoretical and/or empirical evidence of intervention effectiveness is a critical step in developing the self-management program.^{10,12} The initial development of this meaning-based

Table 1
A phased approach to develop a complex intervention to guide the research process toward implementation.

Phases	Tasks
<i>Preclinical phase</i> Identify problem and theoretical approach	<ul style="list-style-type: none"> Identify and quantify the problem, who would benefit from an intervention, how to best approach the problem, and determine expected outcomes. Theory is explored to develop intervention including both qualitative and quantitative evidence.
<i>Phase 1</i> Combine evidence to develop components and outcomes	<ul style="list-style-type: none"> Identify components of the intervention from the evidence based literature. Determine how the components interact, and influence the outcome. Conduct a usability study to evaluate content and form for appropriateness by expert and ultimate user input.
<i>Phase 2</i> Feasibility study	<ul style="list-style-type: none"> Determine efficacy in an exploratory trial of the intervention and protocol.
<i>Phase 3</i> Randomized control trial	<ul style="list-style-type: none"> Determine the effectiveness of the protocol by definitive randomized controlled trials to compare intervention to appropriate alternative.
<i>Phase 4</i> Implementation	<ul style="list-style-type: none"> Determine if intervention is reliably in uncontrolled settings in practice.

Framework for design and evaluation of a complex intervention. Modified from Campbell [2000].¹⁰

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