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The Symptoms Self-Management Center (SSMC): Methods for developing and implementing technology-enhanced self-management interventions for pain and fatigue

Shannon Phillips (PhD, RN)[a,*], Julie Barroso (PhD, RN, FAAN)[a], Ronald Acierno (PhD)[b], Teresa Kelechi (PhD, RN, FAAN)[a]

[a] Medical University of South Carolina, College of Nursing, 99 Jonathan Lucas St., Charleston, SC 29425, USA
[b] McGovern Medical School at the University of Texas Health Science Center at Houston, Department of Psychiatry and Behavioral Sciences, 6431 Fannin St., Houston TX, 77030

ABSTRACT

The National Institutes of Nursing Research provides funding via the P20 grant mechanism for research infrastructure and resources to develop nurse scientists with expertise in symptom self-management. The Medical University of South Carolina College of Nursing was awarded a P20 grant in 2016 to build the Symptoms Self-Management Center for technology-enhanced interventions to address pain and fatigue in individuals with chronic health conditions. Resources were derived from three key subcores: bioinformatics, mHealth and eHealth consultative services, and community engagement. This paper describes methods for deriving specific resources within each subcore, the application of subcore resources in two pilot studies, and lessons learned during the early phases of our Symptoms Self-Management Center implementation.

1. Introduction

In 2016, the Medical University of South Carolina (MUSC) College of Nursing was awarded a *Centers in Self-Management of Symptoms: Building Research Teams for the Future (P20)* from the National Institute of Nursing Research (NINR) to build our *Symptoms Self-Management Center (SSMC)*. Per NINR P20 guidelines for this call RFA-NR-001 (National Institute of Nursing Research (NINR), 2015), primary targeted symptom domains were pain and fatigue, two major complaints among patients in the U.S. The goals of NINR P20 Centers are to support teams of interdisciplinary, biobehavioral researchers by providing infrastructure and centralized resources that uniquely facilitate collaboration and mentorship to develop nurse scientists with strong expertise in symptom self-management. P20 Centers provide competitive pilot project funding to initiate or strengthen a program of research specific to symptom and self-management sciences. The long-term goal is to develop independent scientists who are positioned to secure further funding through other specialized or comprehensive grant mechanisms that will significantly advance the field of symptom self-management science, particularly with respect to pain, fatigue, sleep disturbance, and cognitive/affective disorders.

In addition to pilot funding, the SSMC provides pilot principal investigators (PIs) with mentoring, methodological support, collaborative connections, and regulatory guidance in the context of a tripartite set of resources of biomedical informatics, technology-enhanced intervention design, and community-engaged evaluation. The specific purpose of the SSMC is to develop and preliminarily evaluate the feasibility of cutting edge, accessible, scalable and sustainable patient-centered self-management interventions. We define self-management as "the ability of the individual, in conjunction with family, community, and healthcare professionals, to manage symptoms, treatments, lifestyle changes, and psychosocial, cultural, and spiritual consequences associated with a chronic illness or condition" (National Institute of Nursing Research (NINR), 2015, para. 7). The SSMC interventions of the pilot projects cover a spectrum of technology-based strategies (i.e., internet/web-based programs, mHealth applications, devices) that provide patients with information and resources to manage and cope with their health conditions and symptoms of pain and fatigue. The unifying framework of the SSMC is to apply biomedical informatics to identify populations before their problems become tremendously disabling and significantly diminish quality of life; and subsequently deliver technology-enhanced self-management interventions that are evaluated in real world, community contexts. In other words, the framework is built on the concept that the most useful interventions are those that will be used *where they are needed, by whom they are needed, when they are needed.*

Supportive resources for the SSMC derive from three subcores (Table 1). The purpose of the first subcore, Biomedical Informatics Center (BMIC), is to assist pilot PIs with identifying relevant

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* Corresponding author.

E-mail addresses: phillipss@musc.edu (S. Phillips), barroso@musc.edu (J. Barroso), ronald.acierno@uth.tmc.edu (R. Acierno), kelechtj@musc.edu (T. Kelechi).

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Table 1
SSMC subcores.

Subcores	Supportive resources
Biomedical Informatics (BMIC)	Discuss and develop predictive algorithms leveraging clinical data warehouse capabilities to identify and target interventions toward high-risk patient groups
Technology Applications for Healthful Lifestyles (TACHL)	Plan and outline development and testing of technology-enhanced patient-centered, scalable and sustainable intervention designs across levels of care
Center for Community Health Partnerships (CCHP)	Engage the community by initiating and fostering partnerships that inform, refine, evaluate and disseminate culturally relevant interventions related to real world settings

populations, both for intervention deployment and for recruiting participants. Following intervention design and evaluation, this subcore 'targets' the interventions to those who need them. BMIC uses Learning Health Systems, natural language processing techniques, and simple text based queries interfaced with the electronic health records (EHR), data warehouses and other databases at MUSC to target and recruit potential research participants. The second subcore, Technology Applications Center for Healthful Lifestyles (TACHL), leverages technological enhancements created for behavioral interventions aimed to optimize symptom management. TACHL is an eHealth and mHealth consultative service that specializes in iterative, patient-centered intervention design. Thus, this subcore works to increase the reach and useability of, and engagement with, existing evidence based intervention components.

The third subcore, Center for Community Health Partnerships (CCHP), facilitates community-engaged research to develop and evaluate interventions in real world settings. CCHP allows the pilot PIs to build upon existing community-based infrastructure for enhanced access to and relationships with community partners, who provide feedback and the evaluation environment for our technology-enhanced interventions.

For this paper, we describe the methods used by two SSMC pilot PIs to develop and implement novel self-management, personalized interventions for groups with high health disparities: children with sickle cell disease (SCD)-related pain and adults with human immunodeficiency virus (HIV)-related fatigue. Specifically, we describe how we leveraged our P20 Center grant to access our 3 subcores to enhance intervention relevance and impact.

2. Case example 1: a family-centered self-management intervention for children and adolescents with SCD experiencing pain

Sickle cell disease (SCD) is a hereditary hemoglobinopathy that affects nearly 100,000 individuals in the U.S., over 90% of whom are African American or Black (Hassell, 2010). An alteration in red blood cell shape leads to blood vessel occlusion, which causes vaso-occlusive crisis and acute pain, though over time, pain often becomes chronic and disabling. Pain and concurrent symptoms, such as fever and fatigue, begin in childhood and continue across the lifespan. Further, chronic organ damage leads to multisystem comorbidities and early mortality (Palermo, Schwartz, Drotar, & McGowan, 2002; Platt, Brambilla, Rosse, et al., 1994; Powars, Chan, Hiti, Ramicone, & Johnson, 2005). Early development of symptom self-management behaviors is needed among children and adolescents with SCD to improve outcomes and reduce ED visits and hospitalizations.

The aim of this pilot project was to develop, refine, and conduct feasibility testing of a mHealth intervention for self-management of pain in children with SCD ages 8 to 17 and their families. Development and testing of the intervention was guided by the Pediatric Self-Management Model (Modi, Pai, Hommel, et al., 2012). According to the Pediatric Self-Management model, improved symptoms and healthcare utilization outcomes result from effective self-management behaviors. The intervention began as an existing mHealth application developed by a member of our study team. The application had not been tested or adapted for use as a self-management intervention for children and their parents. Additional features were added to the application, and consisted of three main components. The first component, designed to enhance disease and treatment knowledge and to facilitate health information-seeking, included educational materials presented so that children/caregivers had continuous access to guideline-based information on SCD pathophysiology, symptom prevention, and home management strategies. The second component was designed to address self- and parent-monitoring, parent supervision, and healthcare needs through pain recordings of intensity, location, characteristics, contributing activities, and actions taken to relieve pain and other symptoms. This component also included a graphical representation of symptoms generated automatically for children/parents and providers to more easily visualize pain history. The third component was designed to facilitate child/parent and provider communication. This component included a health history page and a secure portal for children/parents to send messages to providers to communicate pain and symptoms, and to request guidance.

2.1. Informatics subcore

We engaged with BMIC as an initial step to identify potential research participants and to obtain guidance from BMIC leadership on optimizing resources. To identify potential research participants, we queried the EHR database of individuals who agreed to be contacted for research opportunities and met study inclusion criteria; this query then generated a list potentially eligible participants.

2.2. Technology subcore

Of the subcores, TACHL was the most involved with the initial phase of the project. In the development phase, we conducted key informant interviews with 29 children with SCD – parent dyads and 10 healthcare providers to obtain end-user feedback on the intervention and to inform revisions to the app. We created a detailed matrix of the findings to guide revisions. Revisions were prioritized by the frequency with which participants suggested a revision or stated confusion/dissatisfaction with a particular feature of the app. For example, the majority of participants requested the addition of a medication tracking system, and thus, this was considered a priority addition. In addition, many of the dyads and some of the healthcare providers found the pain descriptors confusing. Using different descriptors that made sense to dyads, such as "sickle cell pain or not sickle cell pain" instead of pain descriptors and adding "usual or new pain," was another priority revision. Once prioritization of revisions was complete, we met weekly with TACHL programmers to refine the app. App revision is somewhat more complex than one might presume, and this experience was particularly valuable in that it yielded an understanding of cost, data security, and feasibility of what often seemed like, but were not, simple revisions. The TACHL team converted the app from native to web-based, created an interfacing application for Android and iOS, and developed a secure, back-end database for data capture, storage, and reporting. Next, we created materials for the app which were translated by the lead programmer into iOS and Android platforms. During weekly meetings, we made additions and changes to the app. For example, at times the materials required corrections or additional revisions for accuracy and visual appeal. Also during these meetings, we reviewed the back-end database and reports built to capture data according to study outcomes. A clinician expert in sickle cell disease was consulted to review the materials for accuracy, and a biostatistician was consulted to assure that automated app-based data reports reflected planned analyses. After revisions were complete, study recruitment and enrollment commenced and during the intervention phase, the TACHL team continued to update the app for bug fixes and addressed ongoing issues identified by study participants.

2.3. Community subcore

The pilot PI had an established relationship with the MUSC Pediatric Sickle Cell Center prior to the study; therefore, consultation to establish processes for recruitment was not needed for this project. However, we consulted with the CCHP mentors to review the protocol and ensure appropriate considerations for underserved populations and their community members were met. For example, we worked with the community engagement subcore to discuss methods to minimize participant burden and maximize reach of the intervention into the underserved local communities most affected by the disease and for whom this self-management mHealth intervention might have the greatest impact. To this end, with the assistance of the P20 administrative core, we designed the study so that data collection could occur via the telephone, in consideration of child care needs, work and school schedules, and transportation barriers. In addition, an eConsent process was implemented so that enrollment could also take place via distance, and rural residing study participants could also participate without commuting to MUSC for the sole reason of signing a paper consent (as the intervention itself did not require visiting the study site).

3. Case example 2: an mHealth cognitive behavioral stress management intervention to ameliorate HIV-related fatigue

Fatigue remains one of the most problematic symptoms for people living with HIV infection (PLWH), with prevalence ranging from 33 to 88% (Jong et al., 2010). Fatigue profoundly and negatively affects one's ability to carry out activities of daily living, and impairs social, vocational, and mental functioning (Barroso, Harmon, Madison, & Pence, 2014). Our data from previous studies indicate that interventions should focus on enhancing skills to cope with current stressful life events and the sequelae of prior traumatic stressors, both of which are associated with increases in HIV-related fatigue (Barroso, Leserman, Harmon, Hammill, & Pence, 2015). Cognitive behavioral stress management (CBSM) therapy has been effective in multiple studies with PLWH to reduce anxiety, distress, and depression, three major correlates of fatigue (Brown & Vanable, 2008; Carrico & Antoni, 2008; Crepaz et al., 2008; Scott-Sheldon, Kalichman, Carey, & Fielder, 2008). To our knowledge, however, CBSM has not been translated to a format for delivery in the community in patient homes via technology-enhanced, self-management interventions such as that which could be achieved through an mHealth design.

To address this need, we adapted the CBSM program developed by Antoni, Ironson, and Schneiderman (2007) and Antoni, Schneiderman, and Ironson (2007) specifically for PLWH to an mHealth format to allow home based symptom self-management targeting fatigue. This CBSM intervention provides stress-related education, relaxation skills, coping strategies, and training developing interpersonal and problem-solving skills. Data from 4 systematic reviews and meta-analyses of the literature on the efficacy of cognitive behavior therapy showed that less expensive, more convenient ways to deliver cognitive behavioral therapies are urgently needed and recommendations for community-based symptom self-management-based treatments would increase reach and reduce barriers to care (Brown & Vanable, 2008; Carrico & Antoni, 2008; Crepaz et al., 2008; Scott-Sheldon et al., 2008).

Evidence suggests that cognitive behavioral interventions reduce fatigue in individuals seeking care at treatment facilities, but there is stigma associated with obtaining mental health care from these facilities. However our mHealth format helps overcome the stigma of presenting at treatment facilities, and resolves logistical issues related to cost and transportation. For this study, we developed a fatigue symptom self-management CBSM program that was delivered through smartphones and tablets (optimized for each). All CBSM content from Antoni's program guide was integrated into the application. It is designed to: a) provide individuals with information on sources of stress, the nature of human stress responses, and coping strategies used to deal with stressors; b) teach anxiety reduction skills, such as progressive muscle relaxation and relaxing imagery; c) modify maladaptive cognitive appraisals using cognitive restructuring; d) enhance interpersonal conflict resolution and communication skills via assertiveness training and anger management; and e) increase the availability and utilization of social support networks through use of improved interpersonal and communication skills. There are five sets of stress management techniques used in this program, and each was adapted for the mHealth format. Thus, the goal of the intervention was to provide PLWH with the tools to self-manage stress, impacting fatigue and other psychosocial outcomes. Our study aimed to assess the feasibility, acceptability, and utility of implementing this low-cost, technologically-enhanced fatigue symptom self-management intervention to enhance coping and manage stress, and to assess initial efficacy on fatigue secondary to stress.

3.1. Informatics subcore

We recruited individuals who received healthcare services at MUSC, provided authorized research contact through the MUSC electronic ‘opt in’ designation, and were identified by the BMIC subcore with HIV infection and suffering from fatigue (1200 individuals). We contacted local patients to determine if they were interested in participating in the study; however, most were not immediately receptive. Many had forgotten about agreeing to be contacted for study participation, and many were concerned that the PI knew they were HIV-infected.

3.2. Technology subcore

In the development phase, we worked with our TACHL programmers to convert Antoni's CBSM program guide into 10 modules based on the 10-week program used for group meetings. Each module has a “learn” section, which provides information about stress management techniques. There are numerous embedded worksheets in modules for the participant to learn more about themselves and how they deal with stress; each module concludes with a “relax” section, where a video of a stress reduction technique is shown and participants are encouraged to practice it. We enrolled 5 PLWH in this development phase to obtain feedback on the content, delivery modes, and structure of the modules. We met twice with the 5 participants during the development of the modules over a period of 8 weeks, and asked questions to obtain feedback on the CBSM app. Participants made useful suggestions and helped us make needed changes prior to the intervention phase in which pilot randomized controlled trial (RCT) was conducted.

3.3. Community subcore

Because of challenges we encountered to recruitment, we turned to our community partners, the local AIDS service organization and healthcare providers, to publicize the study. This strategy was successful for recruiting the targeted sample size. The pilot PI has been working with PLWH for 30 years, as a researcher, nurse practitioner and community activist, and was aware of the issues inherent in working with this vulnerable and underserved group, particularly stigmatization.

4. Discussion/lessons learned

The P20 center mechanism provides funding for institutions to develop infrastructure in the form of subcores to support the institution's research endeavors. However, as illustrated by our case examples, each subcore may not be needed in full by every investigator. Support offered by subcores should be flexible so that investigators can access the services that best fit the project and the population. In addition, the mechanism provides mentorship to new researchers to determine the subcores and services that are most needed and appropriate.

In our case examples, both investigators recruited participants using community-based approaches rather than solely via the informatics subcore. The informatics subcore was useful in the second case example by specifying the number of patients available for recruitment, but the pilot PI's awareness of the experiences of the population allowed her to act accordingly and recruit participants via community-based methods. Similarly, the pilot PI in the first case example did not recruit her participants using the informatics subcore because EHR research 'opt in' processes were not in place for child and adolescent participants. Nonetheless, the PI had established community and clinical connections that led to recruitment success, meeting 100% of recruitment targets (30 child/parent dyads).

In both cases, the pilot PIs relied on prior experience and knowledge of relevant literature to construct end-user-based approaches for obtaining feedback on interventions during the conceptualization and development stage. The pilot PI in the first case example recognized a gap in the literature on methods to inform app revisions for child/parent dyads. Therefore, existing end-user designs were merged and adapted with a focus on revisions to existing apps for child/parent dyads (Phillips et al., 2019). Both PIs have strong qualitative backgrounds and exhaustive knowledge of the literature by which to create an end-user design for obtaining feedback on the intervention. In addition, the Barriers to Treatment Participation Scale (Kazdin, Holland, Crowley, & Breton, 1997) and the Credibility and Expectancy Evaluation Scale (Devilly & Borkovec, 2000) were administered to determine barriers to treatment and to better understand participant expectations of the intervention and perceptions of credibility. However, whereas pilot PIs may have deep knowledge of the population for whom the intervention is intended, many may not have a skill set for mHealth development and programming. In both pilot project cases, the PIs had to learn how to translate knowledge of the intervention and end-user perceptions and feedback to programmers. This required frequent, iterative meetings with open knowledge-sharing between the PIs and the programmers. Further, funding for programmers should be budgeted for the entire project and not solely for the development phase; programmer involvement must continue through the project period to address issues that arise during feasibility testing. Sustainability of the app after feasibility or pilot testing is completed, including funding sources for maintenance and/or commercialization are important considerations.

Whether a new or established investigator, each PI has unique experiences and backgrounds that require individual evaluation of existing knowledge and resources in order to customize the use of subcores. Importantly, centers that are establishing subcore resources should conduct a detailed analysis of the benefits and challenges to subcore use for pilot PIs in the early phases of center funding to inform processes for subsequent projects.

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Declaration of competing interest

The authors declare no conflicts of interest.

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