Title:
A Behavior Change Theory-Based Home-Based mHealth Cardiac Rehabilitation Program for Women

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Innovative Cardiovascular Secondary Prevention Interventions

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Cardiovascular Disease, Mobile health and Secondary Prevention

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Abstract Summary:
Socioeconomically deprived women who face transportation challenges, family obligations, depression or low social support are unable to utilize center-based cardiac rehabilitation (CBCR). We expanded the reach of secondary prevention to women unable to attend CBCR, by developing an innovative, technology-enhanced home-based cardiac rehabilitation intervention.

Content Outline:

1. Benefits of center-based cardiac rehabilitation (CBCR)
2. Under-utilization of center-based cardiac rehabilitation
3. Gender-specific barriers to center-based cardiac rehabilitation
4. Home-based cardiac rehabilitation as a global solution to under-utilization of CBCR
5. Theory-based behavior change techniques
6. Just-in-time adaptive interventions using theory-based behavior change techniques
7. Innovative, technology-enhanced mobile health home-based cardiac rehabilitation
8. Patient-centered development model and repeated cycles of feedback and development
9. Clinical feasibility testing protocol
10. Adherence and engagement outcomes
11. Innovative, mobile home-based cardiac rehabilitation program extends reach with global implications

Topic Selection:
Innovative Cardiovascular Secondary Prevention Interventions (25531)

Abstract Text:

Purpose: The purpose is to describe the development and feasibility testing of the innovative behavior change theory-based, home-based cardiac rehabilitation program for women with coronary heart disease (CHD). Center-based cardiac rehabilitation (CBCR), the gold standard of secondary prevention, (Balady et al., 2007; Smith et al., 2011) provides irrefutable health benefits compared with usual care (Anderson et al., 2016). CBCR referral is a healthcare quality performance metric (Thomas et al., 2018), yet for 3 decades only 10-20% of eligible women have attended CBCR with up to a 56% dropout rate (Lavie, Bennett, & Arena, 2017; Li et al., 2018). CBCR underutilization stems from numerous intrapersonal, interpersonal, logistical, programmatic, and health system barriers (Resurreccion et al., 2017). Socioeconomically deprived women who face transportation challenges, family/work obligations, depression or low social support

are especially unable to utilize CBCR (Beckie & Beckstead, 2010). These limitations have prompted a call to redesign CBCR for women (Balady et al., 2011; Lavie, Arena, & Franklin, 2016; Sandesara et al., 2015). Home-based cardiac rehabilitation (HBCR) offers a potential solution; however, limited evidence is available for HBCR as a means to extend secondary prevention reach for women. We has responded to the call to action to expand the reach of secondary prevention to women unable to attend CBCR, by developing an innovative, technology-enhanced HBCR intervention with global implications. Based on our previous proof-of-concept research, we translated our gender-specific, motivationally-enhanced CBCR program to an innovative mobile health (mHealth) HBCR intervention, called mH-Rehab. mH-Rehab is an innovative, real-time, personalized, adaptive, behavioral intervention using standardized behavior change techniques (Michie et al., 2011) to help women develop and maintain health behaviors in their natural settings via theory-based automated feedback messages, review of health goals, and educational videos. A behavior change technique (BCT) is an observable, and replicable intervention component designed to alter or redirect causal processes that regulate behavior; a technique proposed to be an active ingredient (Michie et al., 2013). Behavior change technique development was guided by the tenants of the most effective behavior change theories including the Transtheoretical Model, Theory of Planned Behavior, Social Cognitive Theory, and Self-determination Theory (Davis, Campbell, Hildon, Hobbs, & Michie, 2015). The BCTs for health behaviors are endorsed by the Society of Behavioral Medicine (Michie et al., 2013) and grounded in the secondary prevention guidelines from the American Association of Cardiovascular and Pulmonary Rehabilitation. Unlike most mHealth interventions that deliver text messages unrelated to recent patient behavior, mH-Rehab implements just-in-time adaptive interventions (JITAI) (Nahum-Shani et al., 2018) comprising gender-specific behavior theory-based BCTs in response to proximal health behaviors while focusing on biopsychosocial vulnerabilities. Theoretically derived BCTs delivered anytime and anywhere, are essential to forming and maintaining health behaviors into lifelong habits. Identifying participant's real-time behavioral patterns and emotions through electronic ecological momentary assessments (EMA) that reflect vulnerable states provides cues for tailored interventions that permit adjustments every few hours or days. The benefit of JITAIs is delivering BCTs that consider moderating or tailoring variables (e.g., mood) and incorporating decision rules for how and when to implement intervention components (Almirall, Nahum-Shani, Sherwood, & Murphy, 2014; Collins, Nahum-Shani, & Almirall, 2014). mH-Rehab comprises automated JITAIs for women by targeting the proximal behaviors of physical activity, healthy eating, medication adherence, tobacco use, and stress management**.**

Methods: mH-Rehab was developed from 2016-2018 collaboratively by a multidisciplinary team and with extensive input from 130 women with CHD. To clarify stakeholder needs, we completed over 600 interviews with women with CHD, healthcare system and health insurance executives, and cardiovascular professional organizations that set policy for secondary prevention and women's cardiovascular health. We employed an iterative scrum agile methodology to develop mH-Rehab, while minimizing user cognitive load. We designed and rigorously tested the graphic user interfaces with minimal required functionalities based on participant feedback. To enhance engagement we used principles of gamification, contingency management,

and behavioral economics. Repeated cycles of development and clinical testing resulted in a robust, stable product with superior functionality for user engagement. Additional feasibility testing was conducted in 2018 with 10 women with CHD using a mixed-methods design. The study was approved by the Institutional Review Board and informed consent was obtained from all participants. Participants enrolled in the 12-week feasibility study were provided a smartwatch and a smartphone with the mH-Rehab app loaded on both. At baseline and immediately after the 12-week feasibility study, depressive symptoms were measured with the Patient Health Questionnaire-9 and self-efficacy for managing their chronic condition was measured with the Self-Efficacy for Managing Chronic Disease Questionnaire. Semi-structured interviews were conducted at 12-weeks.

Results: The resulting key innovations of mH-Rehab include: (1) age-specific machine learning algorithms for physical activity (PA) assessment encoded in the mH-Rehab application on a smartwatch exclusively designed for women; (2) multiple daily electronic ecological momentary assessments (EMA) via the mH-Rehab application on a smartphone evaluating physical activity, eating behavior, mood, location, and social context; (3) up to 30 behavior change techniques (ecological momentary interventions, EMI) automatically delivered to the smartphone each day depending on their EMA responses and the health goals set for physical activity, healthy eating, stress management, medication adherence, and, if relevant, smoking cessation; (4) a web portal dashboard monitored by a health coach and accessible to participants; (5) a chat function for peer support; and (6) 30 educational videos on the smart phone developed specifically for women with heart disease. Physical activity detected by the algorithm and heart rate from the smartwatch are streamed via Bluetooth to a local smartphone and exported via Wi-Fi to a secure, HIPAA-compliant Microsoft Azure server, that are accessible by the health coach on a visually engaging web portal dashboard to deliver personalized interventions and for trend analyses. A password-protected portal allows participants to view their data. Results from our feasibility study and continuous participant feedback through the dashboard revealed few issues with the functionality or design. Adherence to all components of mH-Rehab over 12-week trial was 93%. Participants who began the study with high step counts, sustained this behavior throughout the study. Participants with low functional capacity achieved substantial gains in step count by the end of the study. The mean heart rate decreased over the 12-week study. However, blood pressure remained unchanged from baseline values. Although underpowered for rigorous statistical analyses, after 12-weeks engagement with mH-Rehab, we found a trend for improvements in depressive symptoms (5.6 vs 2.3, p=.06), and self-efficacy for managing chronic disease (7.47 to 8.13). Qualitative data revealed several common themes including increased engagement with randomly deployed motivational messages received after completing an EMA surveys. They also valued the repetition of various motivational messages. The most valuable component of mH-Rehab from the patient perspective was that the health coach was monitoring their activity, heart rate, goal setting, and EMA responses and they perceived an accountability as a result.

Conclusion: Over the 12-week feasibility study, engagement with mH-Rehab was high and there was no attrition. There were no adverse events associated with this feasibility study and there was a trend for positive behavioral and psychological improvements.

Cochrane reviews ascertained that HBCR and CBCR exhibit equivalent clinical outcomes, quality of life, safety, costs, and infrequent adverse events primarily among men (Buckingham et al., 2016). CBCR-eligible patients given the choice between HBCR and CBCR, are up to 4 times more likely to participate in HBCR (Beatty et al., 2018; Tang et al., 2017). HBCR, compared to CBCR, overcomes logistical barriers to access, the need for expensive facilities, specialized exercise equipment, high personnel costs, and provides education, coaching and monitoring by a health coach through wearable sensors and smartphones that are available 24 hours/day, 7 days/week. Higher levels of self-monitoring/management and unsupervised exercise inherent in HBCR versus CBCR can aid transition from active intervention to lifelong self-management seamlessly. HBCR using mHealth technology provides numerous patient touchpoints for enhanced engagement via wearable sensors, continuously available peer support, and communication with, and monitoring by, a health coach. This research is intended to support a paradigm shift away from a reactionary, logistically-demanding, visit-based healthcare model toward a more proactive, personalized model that is accessible anytime and anywhere, and seamlessly integrated into the daily lives of women.