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Original Article

Evaluation of a smartphone application for self-care performance of patients with chronic hepatitis B: A randomized controlled trial

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ABSTRACT

Aim: To verify the usefulness of a smartphone application (App) for facilitating self-care in patients with chronic hepatitis B (CHB).
Background: CHB is a global health problem, and patients with CHB need to routinely perform self-care. Health-related smartphone apps could help users self-manage their disease.
Methods: Fifty-three CHB patients were assessed in this randomized controlled before-and-after experimental study. The patients were randomly and equally assigned to groups that did (n = 26) or did not (n = 27) use the smartphone app for 12 weeks. The experimental and control groups were analyzed for differences in disease knowledge, self-efficacy, and self-care before and after use of the smartphone app.
Results: After intervention, patients who used the app displayed significantly increased disease knowledge compared with the control group ($p = .015$). Self-efficacy and self-care also significantly increased in the experimental group ($p = 0.006$ and 0.001, respectively).
Conclusion: The smartphone app can be useful for increasing self-care in CHB patients.
Abbreviations: App: application, CHB: chronic hepatitis B, CVI: content validity

1. Introduction

The number of patients with chronic hepatitis B (CHB) is estimated at 350–400 million worldwide (Tseng et al., 2012). Every year, around 1 million patients with CHB die from disease-related complications such as cirrhosis, liver failure, and hepatocellular carcinoma and approximately 70% of primary hepatocellular carcinomas are caused by CHB (Tseng et al., 2012). A nationwide assessment of the hepatitis B infection prevalence in Korea, diagnosed by a positive hepatitis B surface antigen test, revealed that approximately 2.5%–3.1% of the population is infected with CHB (Statistics Korea, 2013). If not properly treated and efficiently managed, CHB infection can result in death through its many complications, indicating that CHB is a significant public health issue (Cuenca, Cortés, Cuenca, & Verdugo, 2014).

Moreover, symptoms such as fatigue, body weakness, nausea, vomiting, loss of appetite, dyspepsia, abdominal discomfort, bleeding tendency, swelling, abdominal edema, and jaundice occur as CHB infection progresses (Korean Association for the Study of the Liver, 2011). In addition, CHB can cause psychosocial problems, such as anxiety and withdrawal from interpersonal relationships. Such physical, psychological, and socioeconomic problems will consistently affect the everyday activities and quality of life of patients with CHB (Che et al., 2013).

Accordingly, patients with CHB need to manage the symptoms and prevent severe sequelae (Korean Association for the Study of the Liver, 2011). When a patient with CHB becomes ill, however, clinical symptoms are often not clearly manifested until liver damage has considerably progressed (Korean Association for the Study of the Liver, 2011). Furthermore, many patients do not take disease management seriously and miss regular follow-up appointments or fail to adhere to treatment, potentially due to a low level of disease awareness of the patients (Che et al., 2013).

Thus, it is important for patients with CHB to not only undergo medical treatment but also perform self-care in order to promote their own health and well-being (Orem, 1985). Self-care is an extensive concept that includes activities involved in disease prevention, disease and injury treatment, chronic disease management, rehabilitation, and health promotion (Orem, 1985). Proper and active self-care of patients with chronic health conditions positively affects prognosis (Clark, Gong, & Kaciroti, 2001). Previous reports have indicated that knowledge of a disease (Che et al., 2013) and self-efficacy (Yang, 2012) are the main factors that can improve self-care of these patients.

However, previous studies have revealed low levels of disease knowledge in patients with CHB (Ha et al., 2013), which play a role in the negligence of self-care in these patients, as well as in the transmission of hepatitis B virus (Ha et al., 2013; Soto-Salgado et al., 2011). In order for patients with CHB to effectively perform self-care, in this study, the model of self-regulation for control of chronic disease proposed by Clark et al. (2001) was used as the conceptual framework.

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This model suggests that effective self-care can be achieved through self-regulation using continuous interactive processes.

By 2020, 6.1 billion people, or approximately 70% of the global population, are expected to use smartphones, and at least 50% of smartphone users will use health-related mobile apps (Miller, Cafazzo, & Seto, 2014). Approximately 80% of the Korean population currently uses smartphones (Shin & Lee, 2014). Therefore, smartphones could represent an effective tool for health-related interventions. Specifically, health-related smartphone apps could help users self-manage their disease (Miller et al., 2014). It can be hypothesized that patients with CHB who use a smartphone app focusing on self-care performance would improve their overall self-care performance (Miller et al., 2014). An app search in 2013, however, found 23 hepatitis-related apps in the Google Play and Apple App Stores. Of these, only five apps were specific to hepatitis B (Cuenca et al., 2014), and none were developed in Korea. Moreover, the utilization rate of the already developed hepatitis-related apps was low, likely owing to a lack of evidence-based knowledge and limited functionality. Accordingly, based on user demand, a smartphone app facilitating self-care for patients with CHB was recently developed (Jeon, 2015).

In this study, this smartphone app, used as a self-regulation strategy for patients with CHB to perform self-care, is presented, and its effects and utility with respect to disease knowledge, self-efficacy, and self-care performance of patients with CHB are analyzed.

2. Materials and methods

2.1. Theoretical basis

This study is based on the conceptual framework model of self-regulation for control of chronic disease (Clark et al., 2001). Self-regulation is an interactive feedback in which decisions are made based on observations, followed by appropriate responses (Clark et al., 2001). A self-regulation model is a process in which the ultimate goal is achieved through self-regulation based on continuous interaction and feedback (Bandura, 1986). In other words, individuals can change their behavior to manage chronic disease by self-regulation as a result of continuous interaction and feedback via observations, judgments, and reactions (Clark et al., 2001).

For patients with CHB, such a self-regulation model consists of intrapersonal and external factors, observations, judgments, reactions, a self-regulation strategy, and a purpose. The intrapersonal factors in this study are the knowledge of the disease and attitudes and beliefs about using a smartphone app for CHB self-care. The external factors are the healthcare services for health management provided through the smartphone app. Responses occurring during the interaction feedback of observations and judgments are defined as the outcome expectations and expected values of a resource. Accordingly, during the development of this smartphone app, the attitudes, beliefs, outcome expectations, and the expected value of the app were assessed and considered (Jeon, 2015).

A self-regulation model strategy is a method that individuals use to control their current disease. Individuals establish a strategy based on observations, judgments, and reactions to intrapersonal or external factors and consequently utilize that strategy during the self-regulation process (Clark et al., 2001). In this study, the self-regulation strategy was used for the smartphone app for self-care, and the reaction thereof was considered the outcome measurement of such use (e.g. the app utilization rate).

The conceptual framework of the study is shown in Fig. 1. In a self-regulation model, the purpose is achieved through a positive feedback loop. The smartphone app, provided as an external factor for patients with CHB, helps the patients acquire disease knowledge and improve self-efficacy through self-regulation that occurs during continuous interaction and feedback of observations, judgments, and reactions in order to ultimately improve self-care performance.

2.2. Study design and participants

This study was designed as a randomized controlled trial. Pre-tests, interventions, and post-tests were conducted between April 1 and August 20, 2015. The participants were outpatients treated in the Department of Gastroenterology of the university hospital where the author works, which has 800 in-patient beds and an online support group for patients with CHB with approximately 20,000 members.

For inclusion in the study, participants had to understand the study objectives, voluntarily agree to participate, and sign a written consent form. The specific inclusion criteria were: (1) patients diagnosed with CHB by a physician and with positive hepatitis B surface antigen test results during the prior 6 months and no CHB comorbidity, such as cirrhosis, hepatocellular carcinoma, or liver failure; (2) patients aged between 19 and 60 years and capable of survey self-administration; (3) patients who were using an Android smartphone at the time; and (4) patients who understood the study objectives and provided written consent for study participation.

The sample size was estimated in the following manner: the expected effect sizes of disease knowledge, self-efficacy, and self-care performance were calculated by using a program for patients with CHB based on previous studies by Yang (2012). In Yang's (2012) study, the estimated effect sizes were 2.00 for knowledge, 0.83 for self-efficacy, and 0.88 for self-care performance. Hence, with the assumption of a two-tailed test, an α of 0.05, power $(1-\beta)$ of 0.80, and a large effect size of 0.8, the minimum required sample size per group was estimated to be 26 (Cohen, 1992). With an expected dropout rate of 20%, the required sample size was thus determined to be 31 per group, for a total of 62 patients.

2.3. Ethical considerations

This study was approved by the Institutional Review Board of the hospital where the author works (C2014188 (1385)), and conducted with permission of the chief of the hospital, the chief of the nursing department, and a liver specialist in the gastroenterology department. Additionally, permission was received from the manager of the online support group for patients with CHB. All study participants provided written consent for participation. The study data were stored in a locked area and will be destroyed 3 years post-study. For ethical purposes, the control group was provided with the same smartphone app as the one used by the experimental group after the study was completed, and all participants were offered a small payment for participating. Permission was also obtained from the original authors to use the previously developed instruments in the study.

2.4. Randomization

Participants were assigned to experimental and control groups by a research assistant using a block randomization method (http://www.r-bloggers.com/example-2014-2-block-randomization/) (Kleinman, 2014). Specifically, group assignments were made so that 31 patients each were allocated to the experimental and control groups in the order of enrollment (Fig. 2). The allocation was concealed from the participants until the end of the experiment.

2.5. Intervention

2.5.1. Smartphone app

The smartphone app used consists of 8 screens: Self-Care, Disease Knowledge, Statistics, Record of Liver Lab Data, My Information, Alarms, Role Practices, and App Information. In the "Self-Care" menu, the user can check the daily progress by answering 8 questions regarding 6 topic areas (regular follow-up, medicine, meals, drinking, exercise, and body weight). The results can be viewed as daily, weekly, and monthly statistics. "Disease knowledge" delivers theoretical knowledge based on