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Original article

Development and preliminary validation of the chronic hepatitis B self-management scale

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ABSTRACT

Backgrounds: Chronic hepatitis B (CHB) patients may face many problems resulted from their conditions. To delay the progress of CHB, patients should be responsible for the management of their conditions. There is no dedicated scale for assessing self-management behaviors of CHB patients.
Objectives: This study aimed to develop and validate a self-report measure designed to assess the self-management behaviors for CHB patients (CHBSMS).
Design: A cross-sectional descriptive study design.
Setting: Participants were recruited from the infectious disease department of two hospitals in China.
Participants: A sample of 248 and 346 CHB patients for item analysis and test for validity and reliability, respectively.
Methods: An initial 45-item scale developed based on item generation and a two-round Delphi survey was assessed by CHB patients for item analysis to develop a final scale. Construct validity was evaluated by exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). The Chronic Disease Self-Management Behavior Scale (CDSMBS) was used to test the criterion validity. Internal consistency and test-retest reliability were assessed by Cronbach's α coefficient and intraclass correlation coefficient (ICC), respectively.
Results: A 25-item scale was developed. EFA indicated a four-factor structure (symptom management, lifestyle management, psychosocial coping and disease information management), which accounted for 58.149% of the total variance. CFA indicated appropriate fit of the four-factor model. The total scores of CHBSMS was correlated with that of CDSMBS ($r = 0.634$, $P < 0.01$). The Cronbach's α coefficient ($\alpha = 0.887$) and the test-retest correlation coefficient (ICC = 0.871) showed good internal consistency and stability of the scale.
Conclusions: The 25-item CHBSMS is a reliable and valid measure that can be used to assess the self-management behaviors of CHB patients for improving patient education and health-related outcomes.

What is already known about the topic?

- Chronic hepatitis B (CHB) patients may face physical, psychological, and social problems resulted from their conditions. Self-management is important for CHB patients to delay the progress of the illness.
- There is no specific self-management measure to assess the self-management behaviors for CHB patients.

What does this paper add?

- This is the first study to develop a valid and reliable self-management scale for CHB patients (CHBSMS).
- The CHBSMS can help healthcare providers gain a better understanding of CHB patients' self-management behaviors and develop effective interventions.

1. Introduction

Hepatitis B virus (HBV) infection is a global health concern. According to the World Health Organization, two billion people have been infected with HBV, and among them 248 million are chronically infected (Schweitzer, Horn, Mikolajczyk, Krause, & Ott, 2015). Chronic hepatitis B (CHB) is a serious clinical problem for its high risk to develop into cirrhosis, hepatic decompensation, and hepatocellular carcinoma (HCC) (Fattovich, Bortolotti, & Donato, 2008). In China, the

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prevalence of HBV infection is high. There are 93 million HBV carriers, including 30 million CHB patients (Lu & Zhuang, 2009). CHB-related diseases impose a substantial burden on patients, families, and the society in China (Hu & Chen, 2009). The goal of CHB therapy is to prevent the development of long-term complications. However, current antiviral therapies for CHB are rarely to achieve sustained off-treatment responses and eradicate the infection, resulting long-term treatment to achieve continued clinical benefits (Petersen & Buti, 2012).

CHB is chronic in nature. Living with CHB, patients may face many problems resulted from their conditions, such as declining quality of life, depression, and discrimination, as well as difficulty in following regimens and in changing lifestyles (Keskin, Gumus, & Orgun, 2013; Yang, 2013; Zhuang et al., 2014). To delay the progress or avoid the deterioration of CHB, patients should be responsible for the daily management of their conditions. However, it is reported that CHB patients may have poor skills or knowledge on disease management (Lin, Zhao, Liu, Wang, & Wang, 2015; Yang, 2013).

Self-management is a multidimensional concept that combines biological, psychological, and social activities (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002). Self-management refers to the individual's ability in managing symptoms, treatments, lifestyle alterations, and psychosocial consequences of health conditions (Richard & Shea, 2011). Corbin and Strauss have specified three tasks of self-management for people living with a chronic illness, including medical management, behavioral management, and emotional management (Corbin & Straus, 1988). Previous studies have demonstrated that self-management intervention has positive effect on medication adherence, emotional status, costs of hospitalization, clinical outcomes and quality of life in people with chronic conditions (Grady & Gough, 2014). Self-management has been recognised as a critical component of health care for people with chronic disease (van Grieken, Kirkenier, Koeter, & Schene, 2014).

The concept of self-management is also important for CHB patients because CHB management primarily occurs in the home environment, not clinic settings. CHB patients need behavioral, cognitive and social skills to help them participate more effectively in their disease management process. It has been reported that self-management intervention for CHB patients can improve adherence and quality of life (Shen & Qian, 2012; Yang, 2013). Despite the positive association between self-management and improved health outcomes, there is no dedicated scale for assessing self-management behaviors of CHB patients.

Numerous self-management scales have been developed for chronic diseases, such as diabetes mellitus (Lin, Anderson, Chang, Hagerty, & Loveland-Cherry, 2008), asthma (Mancuso, Sayles, & Allegrante, 2009), hypertension (Zhao & Liu, 2012) and COPD (Zhang et al., 2013). To implement a self-management program for CHB patients, it is important to understand their self-management behaviors. Therefore, the goal of the present study was to develop a self-report measure of self-management behaviors for CHB patients (CHBSMS), and to gather evidence of the measure's reliability and validity, which provides an important instrument for assessing and improving the self-management of CHB patients.

2. Methods

2.1. Participants

Using convenience sampling, participants were recruited from infectious disease department of two hospitals in China. Inclusion criteria were: age of 18 years or older, diagnosed with CHB, received antiviral therapy for more than one month, and able to comprehend and communicate using Mandarin, no cognitive impairments and written informed consent. Patients co-infected with hepatitis C, D or human immunodeficiency virus, or having alcohol- or drug-induced hepatitis were excluded. CHB patients who met inclusion criteria were informed about the possibility to participate in a cross-sectional study of questionnaire evaluation.

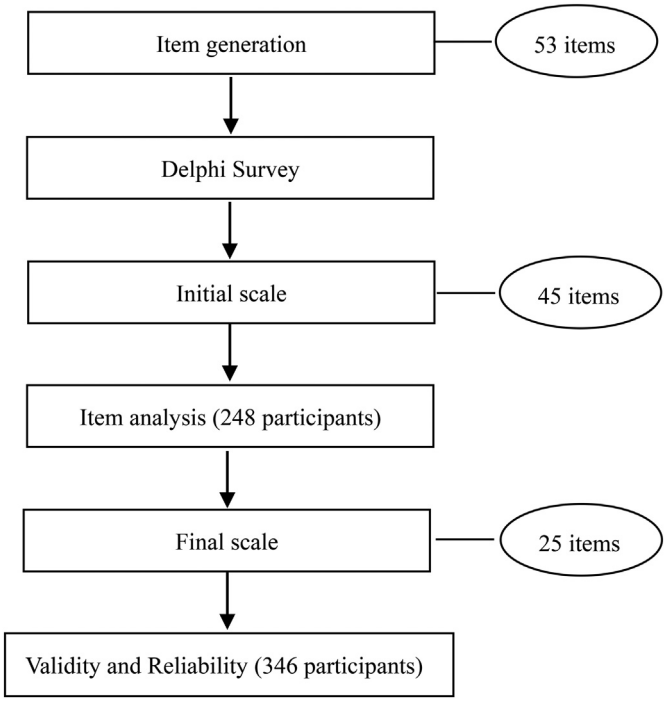

Fig. 1. Summary of development of the CHBSMS.

The minimum sample size for factor analysis should be 5 times the number of items, and should be at least 200 cases (MacCallum, Widaman, Zhang, & Hong, 1999). Thus, a total of 248 participants were included for item reduction (45 items). The psychometric property of the final scale was assessed by 346 new participants (25 items). The study protocol was approved by the ethics committee (2017170). All participants were voluntary to participate in the survey and provided written informed consent.

2.2. Procedures

A cross-sectional descriptive study design was used to develop and validate the CHBSMS in this study. Development of the scale involved three phases: item generation and formation of the initial scale, item analysis and formation of the final scale, and evaluation of reliability and validity of the final scale (Fig. 1).

2.2.1. Phase 1: item generation and formation of the initial scale

CHB self-management was defined as patients' active involvement in the daily activities to control the disease, minimize its impact on functioning, emotions and interpersonal relationships. Based on the self-management framework by Corbin and Straus (Corbin & Straus, 1988) and self-management scale for other chronic conditions (Bonner, Esserman, & Evon, 2012; Xu, Lin, Zheng, & Wang, 2011; Zhang et al., 2013), the 53 candidate items were developed based on a literature review and clinical experience. We conducted a two-round Delphi survey to examine the importance, classification and logicality of the items and provided constructive advice (Kong, Guo, Qin, Peng, & Zhu, 2015). The expert panel was consisted of 30 national experts experienced in CHB care and self-management. Then, we created an initial scale with 45 items with four domains: symptom management (14 items), lifestyle management (10items), psychosocial coping (13 items) and disease information management (8 items). Each item is accompanied by a 5-point Likert scale (1 = never to 5 = always). All participants were asked to give their responses to each item in the questionnaire according to their own situations. The overall score is obtained by summing up the scores of all items. Higher score indicates