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Cross-cultural Adaptation and Validation of the Arabic Version of Self-Care of Coronary Heart Disease Inventory

A thesis submitted in fulfillment of the requirement for the Master degree in Physical Therapy.

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List of Abbreviations

BMI Body Mass Index

CABG Coronary Artery Bypass Graft

CAD Coronary Artery disease

CAS-R Control Attitude Scale-Revised

CFA confirmatory factor analysis

CHD Coronary heart disease

COSMIN COnsensus Standards for the selection of health Measurement INstruments

CR Cardia Rehabilitation

CSEQ Cardiac Self-Efficacy Questionnaire

CSEQ-A Arabic version of the Cardiac Self-Efficacy Questionnaire

CVD Cardiovascular Disease

CVI Content Validity Index

DMCI Decision Making Competency Inventory

FDS Factor Determinacy Scores

GROC Global rating of change

HMG AL Habib Medical Group

HRQoL Health Related Quality of Life

ICC Interclass correlation coefficient

IRQ Interquartile Range

I-CVI Item- Content Validity Index

KFMC King Fahad Medical City

MDC Minimal detectable change

MI Myocardial infraction

MOS-SAS Medical Outcomes Study- Specific Adherence Scale

PKS-CHD Perceived Knowledge Scale for Coronary Heart Disease

PL- TL Preliminary translated Target langue (Arabic)

SEM Standard Error of Measurement

SEM6S Self-Efficacy for managing chronic disease 6- items

SEM6S-A Arabic version of the Self-Efficacy for managing chronic disease 6- items

SC-CHDI Self-Care of Coronary Heart Disease Inventory

SC-CHDI- Arabic version of the Self-Care of Coronary Heart Disease Inventory

Ar

S-CVI Scale- Content Validity Index

SPSS Statistical Package for the Social Sciences

WHO World Health Organization

Abstract

Background: Measuring self-care is considered a significant outcome in clinics and research. Thus, self-care plays a primary role in patients' daily lifestyle management and helps to impede the progression of coronary heart disease (CHD). The Self- Care of Coronary Heart Disease Inventory (SC-CHDI) is a patient reported outcome measure specifically for patients with CHD. However, no validated Arabic version of the SC-CHDI is available.

Aim: This study aimed to cross-culturally adapt SC-CHDI into the Arabic language and to evaluate its reliability and validity among Arabic-speaking patients with CHD.

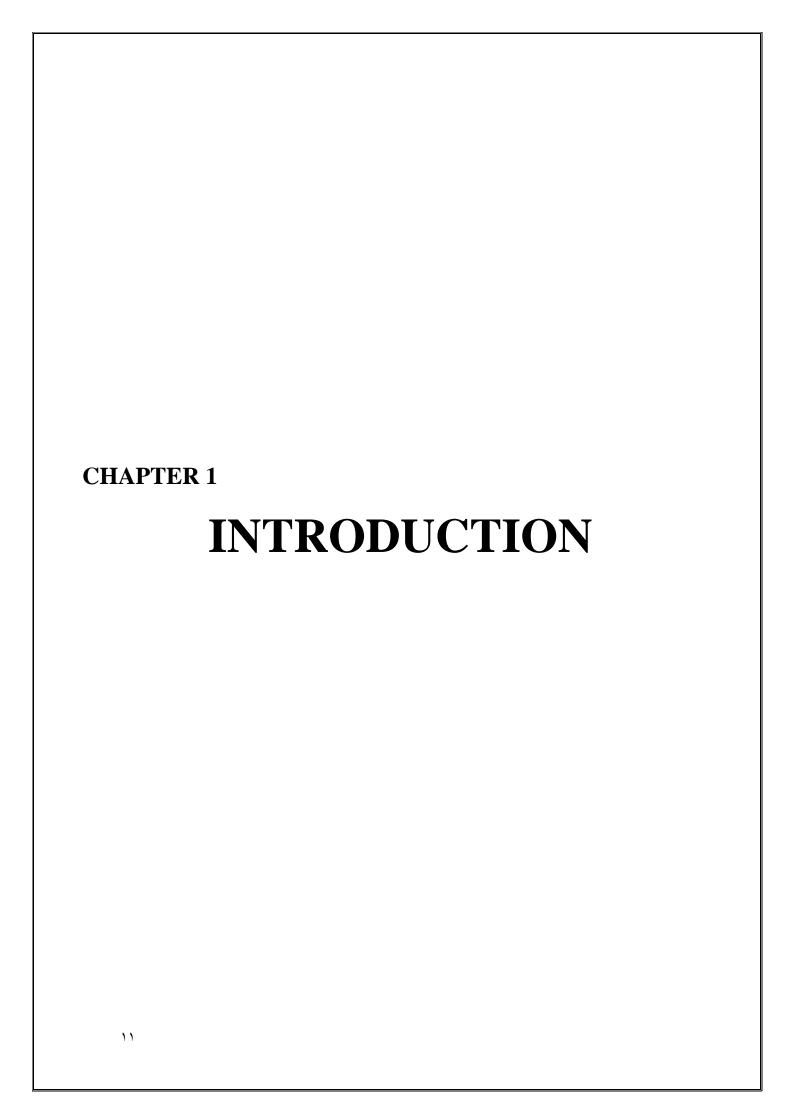
Method: This study followed Sousa's guideline on translation. The psychometric properties were tested among 181 patients with CHD, and a test-retest was carried out on 61 patients at cardiology clinics from three hospitals in Riyadh, Saudi Arabia. In the reliability analysis, internal consistency and test-retest reliability were verified. To determine construct validity the Spearman correlation among the Arabic version of Self Care of Coronary Heart Disease Inventory (SC-CHDI-Ar), Arabic version of Cardiac Self Efficacy Questionnaire (CSEQ-A) and Arabic version of Self Efficacy 6 Items Scale (SEM6S-A) were used.

Results: The content validity index of the three subscales were acceptable. The participants in the current study indicated that SC-CHDI-Ar was clear and understandable. The internal consistency of SC-CHDI-Ar were ranged from ($\alpha = 0.70$)

to 0.95), and the test-retest of the maintenance, management and confidence subscales were acceptable to good ICC_{2,1}= 0.86 (95%CI; .70-0.91), 0.76 (95%CI; 0.59-0.85), and 0.76 (95%CI; 0.56- 0.85), respectively. A positive significant correlation was found among the maintenance subscale of SC-CHDI-Ar, with three domains and the total score of CSEQ-A were (r = .58; .56; .58; .60; p = .000), while the management subscale of SC-CHDI-Ar with two domains of CSEQ-A were (r = .26; .26; p = .000). Additionally, the confidence subscale of SC-CHDI-Ar with one domine of CSEQ-A and total score were (r = .81; .83; p = .000) and with SEM6S-A was (r = .75; p = .000).

Conclusion: The Arabic version of the Self-Care of Coronary Heart Disease Inventory is an understandable, valid, and reliable instrument for determining the self-care needs of patients with CHD in Saudi Arabia.

Keywords: Coronary heart disease, self-care, instrument, psychometric proprieties.



Introduction

The incidence of coronary heart disease (CHD) is growing in developing countries and it is the leading cause of morbidity and mortality (Chen et al., 2021). The main cause of death worldwide is CHD which considered as the most common heart disease (Bayrak & Oğuz, 2021). In 2017, the World Health Organization (WHO) placed CHD first among the ten leading causes of deaths worldwide (WHO, 2017). Additionally, the Gulf Council Countries, including Saudi Arabia, have positioned CHD as a major health concern (Alhabib et al., 2020).

In 2015, 422.7 million people were diagnosed with cardiovascular diseases (CVD) globally (Turk-Adawi et al., 2019). In addition, approximately one - third of all deaths worldwide are caused by CVD (Shajrawi et al., 2020). More people die annually due to CVD than from other diseases. In the Middle East, the associated risk factors and the prevalence of CHD are progressively increasing (Shajrawi et al., 2020). The prevalence of coronary artery disease in Saudi Arabia is 5.5% (Al-Nozha et al., 2004).

Furthermore, CHD results from atherosclerotic changes in the coronary artery (Barham et al., 2019). Atherosclerosis is an inflammatory disease of the arteries associated with lipid and other metabolic alterations and causes CVD. The pathologic process leading to atherosclerosis is complex. It is commonly associated with elevated concentrations of low-density lipoprotein cholesterol that affect the

arterial walls through plaque containing foamy macrophages is present in the inner layer of the vessel and may lead to plaque fissure or rupture that may lead to a fatal thrombosis (Barquera et al., 2015).

The major risk factors that can lead to CHD development include hypertension, diabetes mellitus, obesity, smoking and aggressive response to stress (Barham et al., 2019). Coronary risk factors are likely to increase unless CHD occurrence is reduced through the adoption of a healthy lifestyle and self-care management (Shajrawi et al., 2020).

Self-care is an important component of daily management, prevention, and reduction of CHD rates, with the need to practice behaviors that maintain stability (e.g., adherence to medication, dietary, and exercise regimens), and symptom monitoring and management. However, there is a lack of instruments that can measure self-care in patients with CHD (Dickson et al., 2017). Self-care knowledge in patients with chronic diseases can be evaluated by measuring self-efficacy for self-management (Shajrawi et al., 2020).

Furthermore, self-care is defined as "an individual's decision -making process to maintain health through health-promoting behaviours and to manage the disease" (Ausili et al., 2014). Evidence has showed the positive effect of enhancing self-care among patients with CVD (Barham et al., 2019; Katch & Mead, 2010), while the lower level of self-care can worsen the clinical outcomes. The Katch and

Mead (2010) reported that patients with low levels of self-care do not adhere to the prescribed medications.

The treatment outcomes of CVD are influenced by the patients' belief in their ability to improve their health status through medications adherence and following a healthy lifestyle. According to the literature, insufficient self-care can hinder patients' ability to change their lifestyle despite their physical capability (Barham et al., 2019; Katch & Mead, 2010). In addition, a previous study investigated the factors associated with quality of life among patients with CHD, and reported that lower levels of self-care and poor patient-physician interactions predict lower health-related quality of life, which can negatively impact clinical outcomes (Barham et al., 2019).

The self-care of coronary heart disease inventory (SC-CHDI) is an instrument that measures self-care among patients with CHD. It investigates how patients maintain and adhere to common healthy behaviors, and recognize and respond to their symptoms. In addition, self-care includes a confidence scale that reflects self-efficacy, which can aid in direct individualized counseling (Dickson et al., 2017).

The original form of this scale is available in English and is valid and reliable (Dickson et al., 2017; Appendix 1). This scale has been culturally adapted to many languages such as; Portuguese, Lithuanian, Chinese, Turkish, Russian and Italian Self-Care of Coronary Heart Disease Inventory | Self Care Measures (self-

<u>care-measures.com</u>); Bayrak & Oğuz, 2021; Chen et al., 2021; Kabargina & Lopatin, 2020).

This is the first study to have applied SC-CHDI to meet the needs of Arabic-speaking patients. Cross-cultural adaptation entails maintaining the content validity of the instrument at a conceptual level when it is used in other cultures. As this new culture has dissimilar ways of accomplishing tasks, this makes it somewhat difficult for the participants to perform the tasks in comparison to participants from the original culture (Sousa & Rojjanasrirat, 2011).

Healthcare providers and researchers can use the Arabic version of SC-CHDI to evaluate self-care skills among Arabic-speaking patients, as well as to apply secondary prevention intervention measures and promote cardiac rehabilitation programs in Arabic-speaking countries. Therefore, this study aims to translate and cross culturally adapt the SC-CHDI into Arabic and evaluate the psychometric properties of the Arabic version of SC-CHDI.

1.1 Objectives of the study

- 1- To translate and cross-culturally adapt the Self-Care of Coronary Heart Disease Inventory (SC-CHDI) into the Arabic language.
- 2- To evaluate the reliability and validity of the Arabic version of the SC-CHDI (SC-CHDI-Ar) among patients with CHD.

1.2 Research questions

- 1- Does the Arabic version of SC-CHDI match with the original English version in terms of language, component construction and cultural accuracy?
- 2- Is the Arabic version of the SC-CHDI a valid and reliable self-care measure for coronary heart disease patients?

1.3 Hypothesis

- 1- The Arabic version of the SC-CHDI will be matched with the original English version in terms of language, component construction, and cultural accuracy.
- 2- The Arabic version of the SC-CHDI would have acceptable for internal consistency and test-retest reliability.
- 3- The Arabic version of the SC-CHDI demonstrates evidence of construct validity as a self-care measure in patients with CHD.

1.4 Significance of the study

Using SC-CHDI as a clinic and research instrument can help recognize how patients with CHD deal with and respond to their symptoms. This knowledge can help clinicians and researchers promote the interventions to improve self-care management skills among patients with CHD in Arabic- speaking countries (Dickson et al., 2017).

In addition, SC-CHDI can be used to enhance cardiac rehabilitation programs, which are considered secondary prevention, by educating the patients with CHD about how to promote self-care management and assess self-care skills (Ausili et al., 2014; Shajrawi et al., 2020). This support patients with CHD and their families and reduces health service utilization (Katch & Mead, 2010).

Self-care plays an important role in clinical outcomes. In addition, it mediates the positive effect of support on mental health and is directly associated with positive health outcomes (Eller et al., 2018).

Self-care requires a significant effort by patients, because they spend an average of 0.01% of their time (i.e., 66 minutes) yearly with healthcare providers. In addition, the previous studies have encouraged healthcare providers to empower patients with chronic conditions, such as CHD, to perform self-care, which can improve patient well-being, decrease morbidity and mortality, and reduce healthcare costs (Riegel et al., 2017).

Previous studies have highly recommended the implementation of self-care assessment in clinics to detect the level of self-care skills for guiding a specific intervention. However, a valid and reliable instrument that can measure self-care among patients with CHD is lacking, such a tool has only been developed in English. Therefore, translating this tool into the Arabic language is needed for effective use by Arabic-speaking populations while maintaining their validity and reliability.

1.5 Definition of terms

Cardiac Rehabilitation: "as a comprehensive long-term program involving medical evaluation, prescribed exercise, cardiac risk factor modification, education and counseling" (Halliday, 2011).

Coronary artery disease: coronary arteries are vessels that supply blood to the heart, and coronary artery disease (CAD) is caused by the narrowing of the large blood vessels (Hillegass, 2017).

Coronary Heart Disease: "Coronary Heart Disease (CHD) results from CAD includes the diagnoses of angina pectoris, myocardial infraction and silent myocardial ischemia" (Sanchis-Gomar et al., 2016).

Cross cultural adapation: The term "cross-cultural adaptation" encompasses a process that adresses both language translation and cultural adaptation issues in the process of preparing a questionnaire for use in another setting (Beaton et al., 2000).

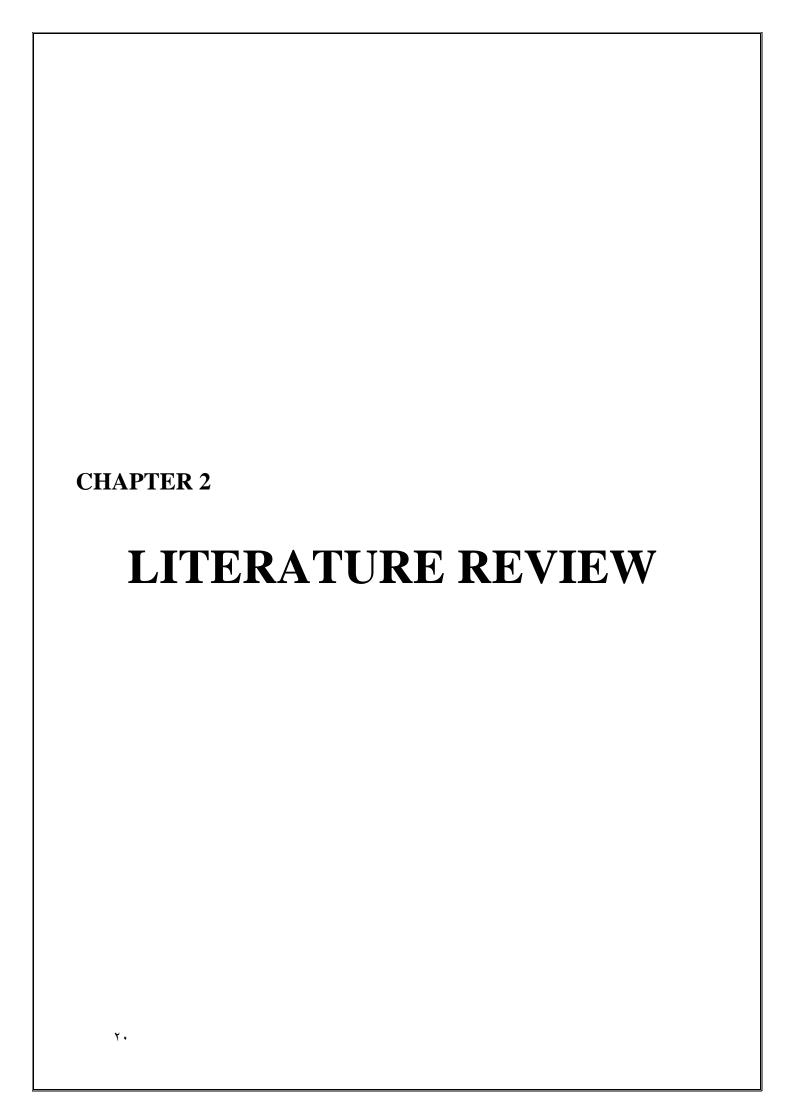
Self-care: "A naturalistic decision making process addressing both the prevention and management of chronic illness, with core elements of self-care maintenance, self-care monitoring, and self-care management" (Ausili et al., 2014; Dickson et al., 2013; Riegel et al., 2017).

Self-efficacy: "Adapted to self-management, self-efficacy reflects the belief of patient capability to organize and integrate physical, social and emotional self-care behaviors to create their own solutions to everyday life problems" (Ausili et al., 2014).

Self-care confidence: It is defined as a person's perception of or confidence in their capabilities to perform specific actions for preventing or treating health conditions, which reflects self-efficacy (Matarese et al., 2018).

Self-care maintenance: "Self-care maintenance refers to behaviors used by individuals with chronic illness to maintain stability of physical and mental health" (Dickson et al., 2017).

Self- care management: "Adapted to chronic illnesses, it refers to the process in which patients take responsibility and decision making for achieving disease control, health and well-being through a wild range of illness-related activities: recognizing symptoms, adhering to treatments, managing physical and psychosocial consequences and lifestyle changes due to their specific condition" (Ausili et al., 2014).



LITERATURE REVIEW

The level of self-care management skills in patients is strongly associated with adhering to a healthy lifestyle for patients with CHD and plays a role in reducing the risk factor associated with the disease. Implementing self-care assessment and interventions leads to enhancing and supporting healthy lifestyle changes in people diagnosed with or at risk of developing CHD (Shajrawi et al., 2020). This chapter presents an overview of CHD and explains the role of self-care assessment in CHD control and outcomes measures used in self-care assessment among patients with CHD. In addition, it describes previous language translations of SC-CHDI.

2.1 Coronary heart disease (CHD)

Cardiovascular disease (CVD) is a group of diseases that affect both the heart and blood vessels, including coronary artery disease (CAD), CHD, and acute coronary syndrome. However, health professionals frequently use the terms CAD and CHD interchangeably. CAD refers to the pathological process affecting the coronary arteries as atherosclerosis, while CHD includes the diagnoses of angina pectoris, myocardial infarction (MI), and silent myocardial ischemia. Thus, CAD is characterized by atherosclerosis in coronary arteries, CHD results from CAD (Sanchis-Gomar et al., 2016).

Furthermore, atherosclerosis is an inflammatory disease of the arteries that is associated with lipid and other metabolic alterations and causes CVD. The pathological process leading to atherosclerosis is complex. It is commonly associated with elevated concentrations of low-density lipoprotein cholesterol, which affect the arterial walls through plaque containing foamy macrophages (which present in the inner layer of vessels) and can lead to plaque fissure or rupture leading to a fatal thrombosis (Barquera et al., 2015).

The risk factors can lead to CVD development are classified into modifiable and non-modifiable risk factors. Modifiable risk factors can be managed or controlled (such as unhealthy diet, physical inactivity, and use of tobacco and alcohol). These factors lead to increased blood pressure, and blood glucose, and blood lipids (Al-Nozha et al., 2004; Alhabib et al., 2020; Hillegass, 2017). All these factors can be controlled through medical treatment and lifestyle changes (Bayrak & Oğuz, 2021).

Of all deaths occurring among Gulf countries, including Saudi Arabia, 45% result from CVD (Alhabib et al., 2020), the prevalence of CAD in Saudi Arabia is 5.5% (Al-Nozha et al., 2004). To reduce the number of cardiac deaths, CHD management is not limited to medical and surgical treatment. Patients with CHD are known to be risk of heart failure, unstable angina pectoris, and MI (Dickson et al., 2017; Sanchis-Gomar et al., 2016). In addition, medical treatment cannot

remove the etiology or reverse the underlying pathophysiology of coronary atherosclerosis (Chen et al., 2021).

In contrast, surgical intervention such as percutaneous coronary intervention, which provides myocardial perfusion is the most effective treatment method because it aims to help reduce the instances of hospitalization. Patients who undergo percutaneous coronary intervention need to be admitted to the hospital for a few days and still continue to be at risk of restenosis of coronary arteries after discharge (Bayrak & Oğuz, 2021).

The coronary artery bypass graft (CABG) was introduced by René Favaloro in 1968 as the first technique for myocardial revascularization. Once the patients undergo this procedure, they require physical recovery to be able to perform daily activities. Additionally, it is important to adopt a healthy lifestyle. The British Association of Cardiovascular Prevention and Rehabilitation recommended cardiac rehabilitation (CR) for post-CABG patients; it is a comprehensive program that provides the physical, psychological and social elements. CR helps patients in the short term to enhance their recovery from CABG, and educate them about healthy routines, and provide them knowledge to manage CHD in the long term (Mendes, 2016).

Moreover, CHD is considered an important causes of global morbidity and mortality (Barham et al., 2019). Additionally, patients with CHD are susceptible to the development of unstable angina, MI, and heart failure, which can negatively impact their life (Dickson et al., 2017). Thus, the American Heart Association recommends the importance of measuring the health-related quality of life (HRQoL), which is a strong predictor of mortality and hospital readmissions in patients with CAD (Lee et al., 2018).

Particularly, CHD management must include self-care to control the risk factors, reduce recurrence, and improve the prognosis and quality of life (Chen et al., 2021)

2.2. Role of self-care in controlling CHD

By 2030, 84 million individuals are expected to be diagnosed with CVD (Pesah et al., 2017). In addition, the Global Burden of Disease study estimated that 29.6% of all deaths worldwide (15616.1 million deaths) in 2010 were caused by CVD (Nichols et al., 2014).

A key to reduce the mortality and morbidity rates is to control the risk factors that contribute to CVD (Dickson et al., 2017). According to the literature, CHD patients who adhere to managing their disease and perform recommended of behavioral in daily activities, achieve an optimal level of disease management (Katch & Mead, 2010).

In addition, the International British and Canadian Associations for Cardiovascular Prevention and Rehabilitation, the American Association of Cardiovascular and Pulmonary Rehabilitation, the Australian Cardiovascular Health and Rehabilitation Association, and the European Association of Preventive Cardiology, have established guidelines to ensure consistency in providing CR delivery to achieve the greatest population health benefits (Pesah et al., 2017).

In particular, CR is an effective secondary prevention strategy for leading burden of the disease and significant cause of deaths globally. In addition, it is associated with improving patients' quality of life, as well as decreasing morbidity and mortality, and is cost-effective (Pesah et al., 2017).

Implementing self-care skill management in CR has many benefits. First, it helps patients with CHD to adopt a healthy lifestyle, which can reduce the risk factors of CHD (Shajrawi et al., 2020). Second, it helps measure patients' knowledge and to evaluate their skills of self-care management to improve their HRQoL (Barham et al., 2019; Lau-Walker, 2007). Third, it can facilitate cardiac rehabilitation programs (Shajrawi et al., 2020), to enhance the patients' adherence to exercises and help them maintain their level of physical activity during the CR program (Lau-Walker 2007). Fourth, it can decrease the burden of CHD in the health care system (Allam et al., 2019; Shajrawi et al., 2020).

Self- care has several definitions. For example, LeBlanc and Jacelon (2018) defined it as "a prerequisite ability that is shaped early in life, develops over time and is highly influenced by cultural factors". Furthermore, Levin (1983) defined it as "activities undertaken to promote health, prevent disease, limit illness, and restore health" (Ausili et al., 2014; Levin, 1983). Meanwhile, cardiac self-efficacy is defined as "cardiac-specific measure of a patient's confidence in his or her capacity to carry out activities which may be affected by symptoms and complications of their CVD" (Barham et al., 2019; Katch & Mead, 2010).

The term self-care was implemented in the Medical Subject of the National Library of Medicine in 1981 and defined as "caring for self when ill or positive actions and adopting behaviors to prevent illness" (Riegel et al., 2019). Additionally, self-care is defined as "a naturalistic decision-making process of maintaining health through health-promoting practices and managing illness" (Dickson et al., 2017).

Self-care is a primary component of patients' daily management and maintenance of chronic conditions at home (Dickson et al., 2017; LeBlanc & Jacelon, 2018). Subsequently, they need to practice behaviors that maintain stability (e.g., adherence to medication, dietary, and exercise regimens), symptom monitoring and management (Dickson et al., 2017). A longitudinal prospective study measured self-efficacy among patients with CHD, which was recommended

to continuously monitor patients' self-care ability to sustain a healthy lifestyle following a CR program (Lau-Walker, 2007).

Alteration of lifestyle is an important aspect of self-care management of CHD. In CR, we guide and educate patients with CHD on how to change their diet, control weight or lose it and quit smoking to lead a healthier lifestyle. Admittedly, self-care is an important factor in making a change in lifestyle because it depends on an individual's daily decisions (Katch& Mead, 2010).

Evidence suggests that the self- care skills assessment for patients with CHD to should be implemented to determine their knowledge, needs, and barriers (Katch & Mead, 2010). In addition, health care utilization, such as emergency visits, hospital admissions, can be reduce by educating and guiding patients to monitor and manage their cardiac symptoms early (Dickson et al., 2017).

Self-efficacy is a prerequisite for the behavioral performance of self-care (Ausili et al., 2014; Eller 2018). Self- care relies on patients' knowledge and ability to perform the required activities. The required activities are divided into adhering to basic activities, such as eating low-salt and less fatty food, exercising daily, attending appointments, taking the prescribed medications, and controlling weight, as well as managing and aware of symptoms, decision- making, self-monitoring, administration of medications and complex treatments (LeBlanc & Jacelon, 2018).

Self- care is a multilevel influence (individual, community, and system levels). The concept of self-care comprises three core functions: self- care maintenance, self- care monitoring and self- care management (Dickson et al., 2017; LeBlanc & Jacelon, 2018). Measuring self-efficacy is key to enhancing self-care management practice, and self-care is associated with HRQoL (Allam et al., 2019; Katch & Mead, 2010; Shajrawi et al., 2020).

The outcomes of CHD treatment can not only be predicted by the frequency and severity of the disease but also by how the treatment affects the patient's wellbeing and quality of life. In particular, quality of life is considered a predictor of outcomes of CHD treatment. However, there are many factors that affect the quality of life of patients with CHD, such as gender, social support, personality, socioeconomic factors, psychological symptoms (e.g., depression and anxiety), angina, and dyspnea (Barham et al., 2019).

There is study reported that enhancing the level of self-care skills can aid in accomplishing the treatment goals. Thus, patients with higher levels of self-care will adhere to diet, exercise, medication, and risk reduction behaviors (e.g., smoking cessation), which in turn leads to improved quality of life (Allam et al., 2020).

2.3 Outcome measures

Evidence strongly recommends implementing self-care assessment as part of patient evaluation (Allam et al., 2019; Barham et al., 2019; Dickson et al., 2017; Katch & Mead, 2010). Self-care management has three components. First, the patient must manage the medical aspects of their conditions, such as following prescribed medication and adhering to a special diet. Second, the patient must adopt a healthy lifestyle to reduce the associated risk factors of CHD. Finally, the patient must have confidence in the ability to effectively perform all elements of self-care including maintenance and management (Dickson et al., 2017; Katch & Mead, 2010).

2.3.1 Arabic version of the Cardiac Self -Efficacy Questionnaire

The Cardiac Self-Efficacy Questionnaire (CSEQ) measures an individual's belief in their ability to perform a given task and is valid and reliable (Shajrawi et al., 2020). CSEQ comprises 16 items, which are divided into two sections: control symptoms (eight items), and maintain function (five items), with an additional three items related to a healthy lifestyle (obesity, smoking, and dietary habits), in which patients are asked to rate their confidence level on a five-point Likert scale: 0 = not at all, 1 = somewhat confident, 2 = moderately confident, 3 = very confident, and 4 = completely confident. A higher score means that the patient

has a higher level of self-efficacy. The completion of the CSEQ, which is a patient self-report scale, takes approximately 10 to 15 minutes (Shajrawi et al., 2020).

According to the results of a psychometric property test of the Arabic version of the CSEQ, face validity reported that the language used, style, and format were clear. The Content Validity Index (CVI) was 1.0, which showed a very good level of content validity. The reliability was good to excellent with the value of Cronbach' alpha ranging from $\alpha = 0.89$ to 0.93 for all questionnaire subscales (Shajrawi et al., 2020).

2.3.2 Arabic version of Self-Efficacy for managing chronic disease 6items

The self-efficacy for managing chronic disease 6-items (SEM6S) comprises six items, each starting with "How confident are you that you can...?" The participants rated each item on a 10-point scale: 1 = "not at all confident", 10 = "totally confident". The total scores range from 6 to 60, with higher scores representing higher perceived self-efficacy for managing chronic diseases (Allam et al., 2019; Barham et al., 2019).

The psychometric properties tested for Arabic version of SEM6S showed that an acceptable reliability of Cronbach's alpha was 0.79. Only physical activity from related factors of self-efficacy was significantly positively correlate with

self-efficacy, while duration of diabetes was significantly negatively correlate with self-efficacy (Allam et al., 2019).

2.3.3 SC-CHDI

SC-CHDI is divided into three parts: maintenance, management and confidence subscales.

2.3.3.1 Self- care maintenance

It refers to behaviors adopted by individuals with chronic illness to maintain the stable of physical and mental health (Dickson et al., 2013). Including the following recommendations from a healthcare provider, as well as autonomous health-promoting practices, ten items on the self-care maintenance scale reflect the ten common behaviors recommended to maintain stability for persons with CHD: keep medical appointments, take aspirin or other blood thinners, check blood pressure, exercise, take medications, eat a low-fat diet, use a medication reminder system, eat fruits and vegetables, avoid cigarettes and smokers, and control body weight (Dickson et al. 2017).

These items are drawn from the American Heart Association's Life's Simple Seven and clinical guidelines for CHD. The respondents rate how frequently they engage in each behavior on an ordinal scale ranging from one (never or rarely) to

four (always or daily). A four-point scale is used to avoid a neutral answer (Dickson et al., 2017).

2.3.3.2 Self-care management

The behaviors include evaluating changes in signs and symptoms, determining if an action is needed, attending to treatment effectiveness, and evaluating whether that action should be used in the future. The self-care management scale is completed and scored if symptoms of chest pain, chest pressure, burning, heaviness, shortness of breath, or fatigue were experienced in the prior month (Dickson et al., 2017).

Six items on the self-care management scale incorporate the concepts of monitoring and management, with questions about symptom recognition and actions in response to symptoms (i.e., slow down, rest, take nitroglycerin if prescribed, call a provider for guidance, and take aspirin) and evaluation of the effectiveness of action for future use.

Recognition is rated on an ordinal scale (0 = not recognized to 4 = very quickly recognized). Management behaviors are rated in terms of how likely the respondent is to take that action in response to a symptom (1 = not likely to 4 = very likely). Treatment effectiveness is judged with a single item asking surety regarding the helpfulness of the action, rated on an ordinal scale (0 = I did not try anything,1not sure to 4 = very sure) (Dickson et al., 2017).

2.3.3.3 The self-care confidence scale

This scale measures self-care self-efficacy (Barham et al., 2019; Dickson et al., 2017; Shajrawi et al., 2020) to assess confidence in the ability to effectively perform all elements of self-care maintenance, monitoring, and management including the ability to stay free of symptoms, follow treatment advice, recognize health changes, evaluate the importance of symptoms, do something to relieve symptoms, and evaluate treatment effectiveness. Six items on the self-care confidence scale are rated on an ordinal scale ranging from one (not confident) to four (very confident) (Dickson et al., 2017; Appendix 1).

2.3.3.4 Scoring system

Each scale of the SC-CHDI scoring system is scored separately and standardized to scores of 0–100. Because SC-CHDI is called an inventory rather than an index, the scores are not aggregated into a single number as in an index. The transformation score of each subscale is calculated separately using the formula (sum the raw, then subtract the lowest possible raw score, then divide it on a possible raw score range) and then multiplied by 100. The scores of the maintenance scale (10-items) are calculated using the following formula: $\frac{(Sum-10)}{(40-10)}$ ×100. Then, to calculate the management scale of six items with a possible score range of 4-24, the following formula is used: $\frac{(Sum-6)}{(24-6)}$ ×100. Next, to calculate the

self- confidence scale of six items with a possible score range of: 6 - 24, the following formula is used: $\frac{(Sum - 6)}{(24-6)} \times 100$. Higher scores indicate better self-care (Dickson et al., 2017).

2.3.3.5 Psychometric properties of SC-CHDI (English version)

Factorial validity was tested through content validation, and all three scales were judged by an expert panel of five cardiovascular nurse clinicians and scientists who were asked to rate the content relevance of each item. In addition, convergent validity was tested with the Medical Outcomes Study Specific Adherence Scale and the Decision-Making Competency Inventory.

In contrast, Cronbach's alpha and factor determinacy scores (FDS) are calculated to assess reliability of SC-CHDI. The self-care maintenance (FDS=.87) items correlation ranges from 0.44 to 0.62. The self-care management (FDS=.76) item test correlation ranged from .55 to .66. The self-care confidence (FDS=.84) items correlation range from .61 to .81. All three scales showed significant associations with both adherence scale and decision-making inventory scale (Dickson et al., 2017).

2.3.3.6 Cross-cultural adaption of SC-CHDI into different languages.

SC-CHDI was translated into many languages (Table 1). The Turkish version of SC-CHDI was performed with 222 patients from three different hospitals at cardiology clinics. Then, after 15 days the test-retest was reapplied to 50 patients. The internal consistency of the SC-CHDI Turkish version was found to be within the reliable range, the maintenance subscale was (α = .63); the management subscale was (α = .76) and the confidence subscale was (α = .95). In contrast, there was no significant difference between the test–retest reliability coefficient scores and a positive significant relationship, which was acceptable as a reliable tool (Bayrak & Oğuz, 2021).

In addition, SC-CHDI was translated into Chinese by following Sousa's guideline, where 301 patients with CHD were recruited from the inpatient department. The construct validity showed a significant correlation among the Chinese version of SC-CHDI, the Perceived Knowledge Scale for Coronary Heart Disease (PKS-CHD) and Chinese version of the Control Attitudes Scale-Revised (CAS-R). In addition, the internal consistency for the maintenance, management and confidence subscales of the Chinese version of SC-CHDI was found to be acceptable (Chen et al., 2021).

Furthermore, Kabargina and Lopatin (2020) performed the cross cultural translation of SC-CHDI into Russian. The measured psychometric properties

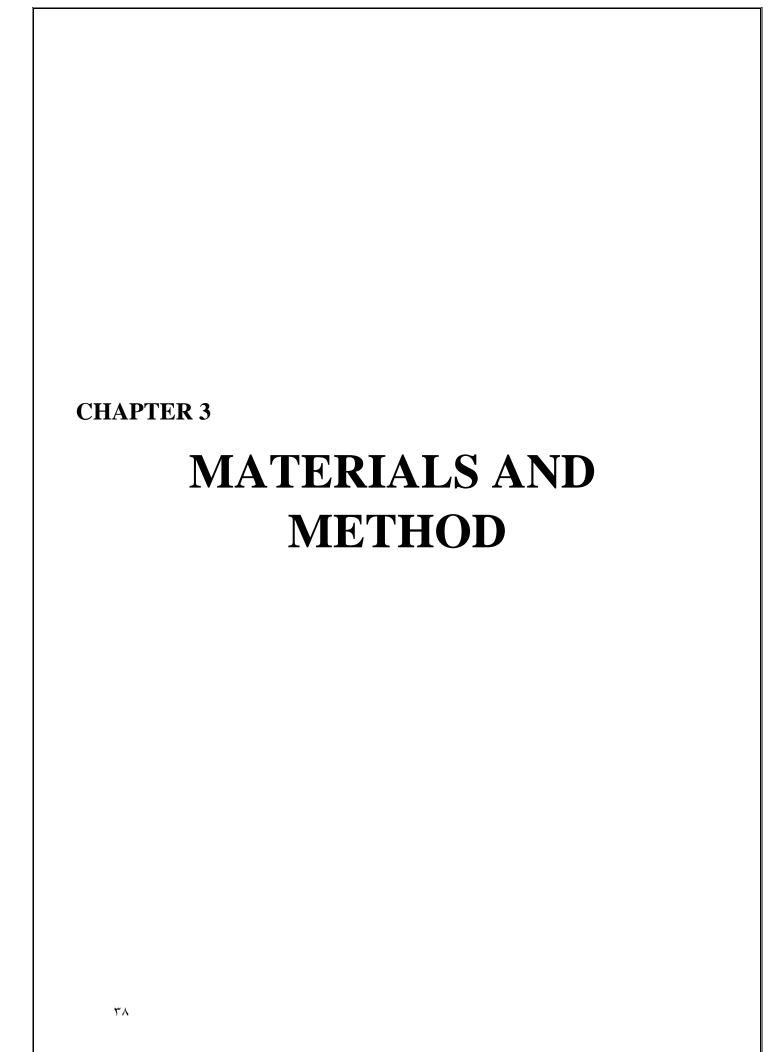
included constructed validity, which correlate the Russian version of the SC-CHDI with health-related quality of life (SF-36), levels of anxiety and depression, type D personality (DS-14 questionnaire), medication adherence (four-item Morisky-Green Medication Adherence Scale), and Charlson comorbidity index. The study was conducted on 100 patients with stable CHD who were admitted to the cardiology department (Kabargina & Lopatin, 2020).

Although self-care related to CHD being highlighted in research and clinical practice nowadays, the Arabic version of SC-CHDI is not available. Therefore, a validity and reliability study of SC-CHDI in Saudi Arabia is required to fill the gap regarding self-care measurement specifically among patients with CHD. This study aimed to translate and cross-culturally adapt SC-CHDI into Arabic to obtain an Arabic instrument for measuring self-care in patients with CHD and evaluating the psychometric properties of the Arabic version of SC-CHDI.

Table 1: Cross-cultural adaption of the SC-CHDI into different languages

Author			Patients'		Cronbach's		
(Year)	Language	No.	conditio ns	Subscales	alpha\ FDS\CR	ICC _{2.1}	SC-CHDI correlation
		392	Adult with CHD from cardiolo gy clinic.	Maintenance	FDS=.87	NA	MOS-SAS (r=.5569*) DMCI (r=.2332*)
(Dickso n et al., 2017)	English			Management	FDS=.76	NA	MOS-SAS (r=.2221*) DMCI (r=0209*)
,				Confidence	α=.84	NA	MOS-SAS (r=.27*)
							DMCI (r=.27*)
(Bayrak			CHD patients	Maintenance	α= .63	NA	NA
&Oğuz, 2021)	&Oğuz, Turkish 2	222		Management	α=.76	NA	NA
				Confidence	α=.95	NA	NA
	et al., Chinese 30		CHD	Maintenance	CR=.88 treatment adherence CR=.71 healthy lifestyle	NA	PKS-CHD (r=.46*) CAS-R (r=.32*)
(Chen et al., 2021)		301	patients from Inpatient departme nt	Management	CR=.69 early response. CR=.71 delayed response.	NA	PKS-CHD (r=.40*) CAS-R (r=.20*)
				Confidence	α=.80	NA	PKS-CHD (r=.40*) CAS-R (r=.20*)
(Kabarg	Russian	ussian 100	CHD patients from Inpatient departme nt	Maintenance	α=.70	0.81	SF-36(r=21) CCI (r=.30)
ina & Lopatin				Management	α=.65	0.79	SAQ (r=2234) Sf-36 (r=3036)
, 2020)				Confidence	α=.72	0.85	MGMAS (r=.26)

FDS=factor determinacy scores; ICC=Interclass correlation coefficient; MOS-SAS=medical outcome study specific Adherence Scale; DMCI= Decision Making Competency Inventory; NA=Not Applicable; CR=composite reliability; α =Cronbach's alpha; PKS-CHD=Perceived Knowledge Scale for Coronary Heart Disease; CAS-R=Control Attitude Scale-Revised; CCI=Charlson's comorbidity index; SAQ= Seattle Angina Questionnaire



3. Materials and Methods

3.1 Study design

This measurement validation study adopted a cohort design to assess the psychometric properties of the Arabic version of SC-CHDI.

3.2 Sample size estimation

The sample size was determined using the subject-to-item ratio, which is frequently used to estimate a sample size of two to twenty patients per item. Furthermore, the literature review revealed that approximately 90% of the validation studies included a sample size greater than or equal to 100 (Anthoine et al., 2014). To conform to these criteria, the ratio was set as seven patients per item. Therefore, the required sample size was 154 patients, considering a possible dropout, and was increased to 181 participants and 61 patients in the test - retest sample (Mokkink et al., 2010).

3.3 Participants

A convenience sampling method was used to recruit the participants from the outpatient cardiology clinic at King Fahad Medical City (KFMC), the Sultan City Medical Center and AL Habib Hospital in Riyadh. Participants of both genders and who were could read and write Arabic were eligible to participate in this study if they met the following eligibility criteria: age 35 – 75 years old (Shajrawi et al.,

2020) and had undergone a confirmed diagnosis at least 12 months prior to the study of CHD based on a positive electrocardiograph or angiographic evidence of disease (including angina, MI, history of stent placement, or coronary artery bypass graft surgery) (Barham et al., 2019).

The participants were excluded if they had a cognitive impairment, or had severe comorbidities such as a stroke, heart failure, psychological disorders, amputated limbs, were receiving chemotherapy (Barham et al., 2019); or were pregnant (Ashrafi & Curtis, 2017).

3.4 Procedure

This study was conducted in two phases. The first phase entailed the translation and cross-cultural adaptation of SC-CHDI into the Arabic language. The second phase involved the psychometric property measurement of the Arabic version of the SC-CHDI (SC-CHDI-Ar).

3.4.1 Phase 1: Steps of Translation and Cross-Cultural Adaptation

The first phase included the processes of translation and cross-cultural adaptation based on the guidelines suggested by Sousa and Rojjanasrirat (2011) (Figure 1).

• Forward translation step:

This step involved two bilingual native Arabic speakers who had the Arabic as their mother language. The first translator had a medical background and was knowledgeable about health care terminology and the content area of the instrument's construct. The second translator had no knowledge of the contents and terminology of the tool but was familiar with colloquial and commonly used sentences in the Arabic language. They translated the English SC-CHDI into Arabic language independently and produced two forms of forward translation: FT1 and FT2.

• Synthesis I step:

These two versions were then synthesized by a third independent translator, who was bilingual, and a principal researcher through a committee approach, which compared FT1 and FT2 and these versions with the original version of the instrument. Then, the preliminarily translated Arabic version of SC-CHDI-Ar (PI-TL) was generated.

• Backward translation step:

PI-TL was back-translated into English by two independent translators. The translators were completely blind to the original version of SC-CHDI and worked independently. The first translator was familiar with medical terminology, while the second translator was familiar with both colloquial English and Arabic.

This resulted in two back-translated versions of the instrument, which were labeled B-T1 and B-T2.

• Synthesis II step:

Following the completion of the forward and backward translations, a multidisciplinary committee that included all five translators who participated in the forward and backward steps and synthesis I, the principal researcher and a cardiologist consultant produced the pre-final version of SC-CHDI-Ar (P-FTL). The committee evaluated each item in terms of semantic equivalence, idiomatic equivalence, experiential equivalence, and conceptual equivalence between forward translation form, backward translation form and compared these versions with the original version of SC-CHDI to produce P-FTL.

• Content validity:

P-FTL was evaluated by an expert panel to examine content validity and calculate the content validity index (CVI) of the SC-CHDI-Ar in terms of instructions, response format, and items. Nine experts were asked to evaluate each item in the instrument with regard to content-related validity using the following scale: 1 = not relevant, 2 = unable to assess relevance, 3 = relevant but needs minor alterations, and 4 = highly relevant and succinct.

Experts who selected 1 or 2 for any of the items were asked to provide suggestions concerning how to rewrite the statements and make the language clearer (Yusoff, 2019). To calculate the CVI, which has two forms: the item – level content validity index (I-CVI) and the scale-level content validity index (S-CVI). I-CVI was calculated based on the sum of experts in agreement who score 3 or 4, which was divided by the number of experts. The second form, S-CVI, was calculated based on the average method (S-CVI/Ave) and sum of I-CVI scores divided by the number of items. In addition, S-CVI/Ave (based on the sum of proportion relevance rating /number of experts) was measured. The acceptable CVI value was a minimum of 0.78 with at least nine experts (Yusoff, 2019).

• Pilot test step:

In addition, P-FTL was pilot tested using 30 patients with CHD. After answering the questionnaire, each participant was asked to rate the instructions, response format and items in the scale for clarity using a dichotomous scale (clear or unclear). The items that were found to be unclear by at least 20% of the patients had to revised and re-evaluated (Yusoff, 2019). The final SC-CHDI-Ar after this step was sent to the original SC-CHDI developer.

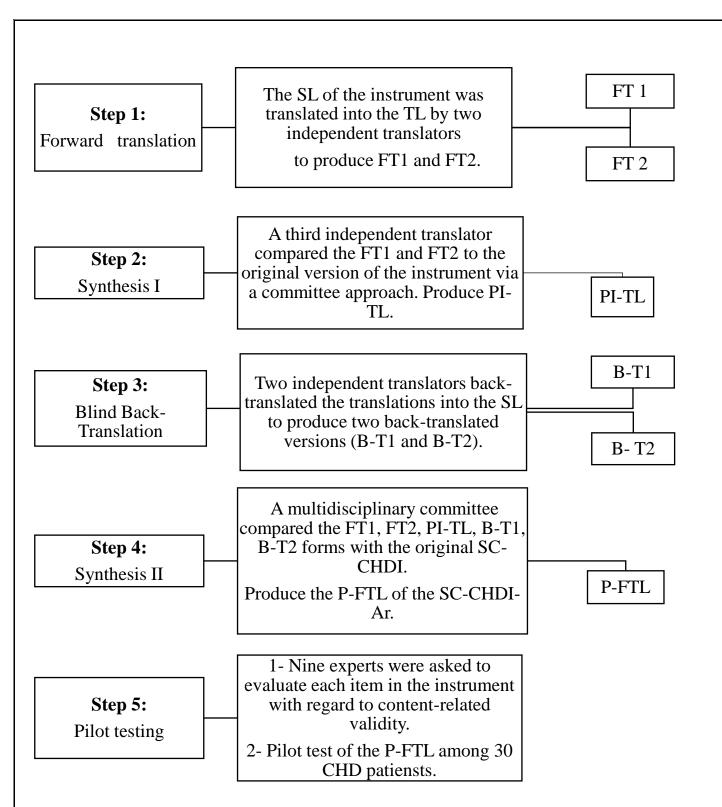


Figure 1: Cross-Cultural adaptation guideline.

Abbreviations: FT1, FT2: forward translations forms, PI-Tl: preliminary translated of the SC-CHDI-Ar B-T1, B-T2: Backward translations forms P-FTL: pre-final SC-CHDI A; CHD: coronary heart disease.

3.4.2 Phase 2: Psychometric property measurement

The second phase involved testing the measurement properties as defined by the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) (Mokkink et al., 2010). The psychometric properties included test-retest reliability, measurement error, internal consistency, floor and ceiling effects, and the construct validity of SC-CHDI-Ar. A patient with CHD was recruited for this validation study based on the eligibility criteria described previously.

The primary researcher collected data from three hospitals. The participants were interviewed in the waiting area, the purpose of the study was explained, and the patients were reassured about the privacy and confidentiality of the collected information. If a participant agreed to participate, they were asked to sign an electronic consent form prior to completing the questionnaire. Demographic information about the patient, such as age, gender, education level, occupational status, smoking status, height and weight, and CHD duration was collected first (Appendix 3).

The participants were then asked to answer the three Arabic-language questionnaires, SC-CHDI-Ar, CSEQ, and SEM6S in a self-reporting manner. The primary researcher answered the participants' questions if they asked any and used an electronic survey to ensure that the patients answered all the questions. The investigator administered a retest of SC-CHDI-Ar from one to two weeks (Polit,

2015). During the second test, the participants were asked to complete the SC-CHDI-Ar and the global rating of change scale.

3.5 Outcome measures

3.5.1 Arabic version of Self-Care of Coronary Heart Disease Inventory (SC-CHDI-Ar)

The patients were asked to rate themselves using a four-point scale that included three subscales. The first part was maintenance subscale, which included ten items that rated the adherence to the treatment regime and a healthy lifestyle. The second part was the management subscale, which included six items to determine whether the patient had experienced symptoms in the past month and to assess early and delayed responses. The third part was the confidence subscale, which measured the patients' self-efficacy levels.

The scoring system for each subscale was scored separately and standardized to scores of 0 –100, because SC-CHDI is an inventory rather than an index; the scores were not aggregated into a single number as in an index. The scores of the maintenance subscale were calculated using the following formula: (Sum - 10) / (40 - 10) ×100. Then, the management subscale depended on the patient status if there were symptoms in the last month = ((Sum - 4) / (24 - 4) ×100) or if there were no symptoms during the last month = ((Sum - 4) / (20 - 4) × 100). Next, the confidence subscale was calculated as (Sum - 6) / (24 - 6) ×100. Higher scores indicate better self-care (Dickson et al., 2017).

3.5.2 Arabic version of the Cardiac Self Efficacy Questionnaire

The Arabic version of CSEQ (CSEQ-A) measures an individual's belief in their ability to perform a given task. The patients were asked to use a five-point Likert scale to rate how confident they felt about the 16 items, which were divided into three sections: the first section included eight questions (1 - 8) related to controlling their symptoms, the second section included five questions (9 - 13) related to maintaining their function, and the third section included three questions (14 - 16) related to healthy lifestyle behavioral. The final score was obtained by summing the three subscales separately and then summing all items ranging from 0 to 64. A higher score indicated a higher level of cardiac self-efficacy. CSEQ-A, which was used in this current study, was found to be valid and reliable, the value of Cronbach's alpha were .89; .92; .93 for the three sections respectively (Shajrawi et al., 2020; Appendix 4).

3.5.3 Arabic version of the Self- Efficacy Management 6 Items Scale

The patients were asked to use a 10-point Likert scale to select a number representing their level of self-efficacy for the six items pertaining to the management of chronic diseases. The overall score was the sum of all items, and the total scores range from 6 to 60, with higher scores representing higher perceived self-efficacy for managing chronic diseases. The Arabic version of the SEM6S (SEM6S-A), which was used in this study, was found to be valid and reliable, the

Cronbach's alpha had a value of 0.79 and the item-total correlations ranged from 0.61 to 0.71 which indicates good reliability (Allam et al., 2019; Appendix 5).

3.5.4 Global rating of change

The global rating of change (GROC) is a simple instrument that measures the extent to which a patient perceives improvement or deterioration over time (Rating & Scales, 2009). In the current study, we used a seven-point GROC scale ranging from -7 = extreme deterioration to 7 = extreme improvement. The participants who scored -3 to 3 were considered unchanged (Appendix 6).

3.6 Ethical considerations

Approval for this study was obtained from the Institutional Review Board of the College of Medicine at King Saud University (No. E-20-4872; Appendix 7), the Institutional Review Board at KFMC (No: 20-291E; Appendix 8), the Institutional Review Board at Habib Medical Group (HMG) (No. RC.20.07.05; Appendix 9), and the Institutional Review Board at Sultan Bin Abdulaziz Humanitarian City (No.:24-2020-IRB; Appendix 10).

3.7 Statistical analyses

All analyses were conducted using the Statistical Package of Social Science (SPSS) version 22.0. The level of significance was set at p < 0.05. Descriptive analyses were performed to describe the participants' characteristics.

3.7.1 Internal consistency

Internal consistency in each SC-CHDI-Ar subscale was determined using Cronbach's alpha. A Cronbach's alpha value ranging from .5 to .6 was considered poor, the ranging from .6 to .7 was considered questionable, that ranging from .7 to .8 was considered acceptable, that ranging from .8 to .9 was considered good, and .9 and above was considered excellent (Gliem et al., 2003).

3.7.2 Test-retest reliability

The test-retest reliability of SC-CHDI-Ar version was determined by using the intraclass correlation coefficient (ICC _{2,1}). An ICC with a value of less than 0.5 was considered poor, values ranging from 0.5 to 0.75 were considered moderate, and those ranging from 0.75 to 0.9 were considered good. Values above 0.90 were regarded as excellent (Koo & Li, 2016).

3.7.3 Measurement of error

The standard error of measurement (SEM) checks for the measurement error in relation to the repeated measurements utilizing (de Vet et al., 2011). SEM was computed as SEM= SD $\times \sqrt{1-ICC}$, where SD was the pooled standard deviation to calculate the following $\sqrt{\frac{(SD_1^2+SD_2^2)}{2}}$ (Burnett et al., 2007; de Vet et al.,

2011). The minimal detectable change (MDC₉₅) was calculated as MDC₉₅ = SEM \times 1.96 \times $\sqrt{2}$ (Nair et al., 2012).

3.7.4 Floor and ceiling effects

Floor and ceiling effects were considered to exist if more than 15% of the participants reported minimum or maximum possible scores for SC-CHDI-Ar (Terwee et al., 2007). SC-CHDI-Ar had limited content validity if the floor and ceiling effects were presented and exceeded 15%.

3.7.5 Construct validity

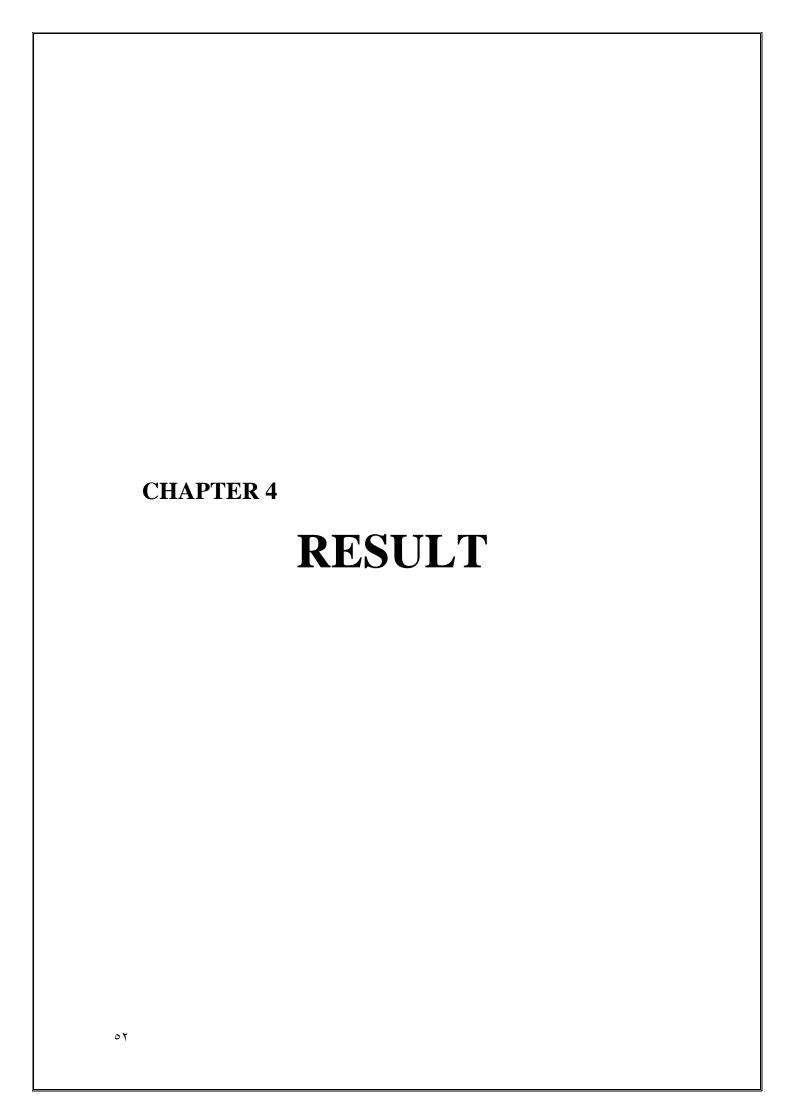
The construct validity of SC-CHDI-Ar was examined using hypothesis testing (Terwee et al., 2007). The following pre-defined hypotheses were examined as part of the convergent validation:

- 1- The maintenance subscale of SC-CHDI-Ar will show positive correlation with the symptoms control domain of CSEQ-A.
- 2- The maintenance subscale of SC-CHDI-Ar will show positive correlation with the functional maintenance domain of CSEQ-A.
- 3- The maintenance subscale of SC-CHDI-Ar will show positive correlation with the modification risk factors domain of CSEQ-A.
- 4- The maintenance subscale of SC-CHDI-Ar will show positive correlation with CSEO-A.
- 5- The management subscale of SC-CHDI-Ar will show positive correlation with the symptoms control domain of CSEQ-A.

- 6- The management subscale of SC-CHDI-Ar will show positive correlation with CSEQ-A.
- 7- The confidence subscale of SC-CHDI-Ar will show positive correlation with the symptoms control domain of CSEQ-A.
- 8- The confidence subscale of SC-CHDI-Ar will show positive correlation with CSEQ-A.
- 9- The confidence subscale of SC-CHDI-Ar will show positive correlation with SEM6S-A.

All pre-defined hypothesis were assessed using the correlation between the SC-CHDI-Ar scores and the validated Arabic versions of CSEQ and SEM6S. Based on the normality test, we will used Pearson correlation (r) if the data were normally distributed or Spearman correlation (rs) if the data were not normally distributed.

The strength of association of the absolute value of r was based on the following guidelines: values < 0.3 = weak association; 0.3 - 0.7 = moderate association; and > 0.7 = strong association (Ratner, 2009). SC-CHDI-Ar can be considered to have high construct validity if up to 75% of the prior hypotheses are met (Terwee et al., 2007).



This chapter presents the main results of the study, which comprise two main phases: (1) the process of translation and cross-cultural adaptation of SC-CHDI into the Arabic language, and (2) the measurement property testing of SC-CHDI-Ar.

4.1 Phase 1: Translation and cross-cultural adaptation

The forward translation step was conducted by two bilingual translators, worked independently produced FT1 and FT2, they did not face problems during translation. Then, a third independent translator, with principal researcher worked together as a committee to synthesize both FT1 and FT2 to produce PI-TL without any difficulty. Subsequently, backward translation was accomplished by another two translators were blinded from the original English version of SC-CHDI and produced two English version B-T1 and B-T2 without any difficulty. The next step was review through an expert committee which made a minor change of a few words of the items while keeping the meaning intact. Then, P-FTL was sent to the developer who approved it.

Content validity

An expert panel member comprising nine experts including three cardiologists, five of cardiac rehabilitation physiotherapists and a nurse. I-CVI had the value of one for all questions except 15, 17 and 22, which had the values of 0.9. While, S-CVI was calculated using the average method (S-CVI/Ave). The S-CVI/Ave based on I-CVI for the maintenance part was 1, the management part was

0.98 and the confidence part was 0.97. In contrast, the value of S-CVI/Ave based on the proportion relevance across the nine experts was 0.98 (Table 2). The CVI values were acceptable and satisfactory based on all three measures.

After receiving expert opinions, some minor changes were made to the scale; thereafter, the pilot study was conducted.

Pilot study

Thirty patients with CHD completed the pre-final version, and asked to rate the clarity of the items. All respondents reported that all items including instructions and rating scale were clear (100%).

There was a minor change in question 14 the phrase "or going to the hospital" was added beside calling the doctor and the term "nurse" was deleted, because the patients consulted the doctor only because this system which followed in the clinical practice according to the Ministry of Health in Saudi Arabia. This was the final SC-CHDI-Ar (Appendix 2).

The sample of 30 participants, diagnosed with CHD included 57% male. The mean age of the patients was 61.87 ± 8.87 years, 90% of the sample was married, and 87% were unemployed. The patients spent 10.47 ± 2.75 minutes to completing the SC-CHDI -Ar scale. The demographic, and clinical characteristics of the pilot sample, and the mean and standard deviation (SD) of the SC-CHDI-Ar subscales are shown in (Table 3

Table 2: Expertise rating (n=9) for content relevance.

Experts Items	1 st	2 nd	3 rd	4 th	5 th	6 th	7 th	8 th	9 th	I-CVI
Q1	1	1	1	1	1	1	1	1	1	1
Q2	1	1	1	1	1	1	1	1	1	1
Q3	1	1	1	1	1	1	1	1	1	1
Q4	1	1	1	1	1	1	1	1	1	1
Q5	1	1	1	1	1	1	1	1	1	1
Q6	1	1	1	1	1	1	1	1	1	1
Q7	1	1	1	1	1	1	1	1	1	1
Q8	1	1	1	1	1	1	1	1	1	1
Q9	1	1	1	1	1	1	1	1	1	1
Q10	1	1	1	1	1	1	1	1	1	1
	S-CVI/Ave (The maintenance subscale) = 1									
Q11	1	1	1	1	1	1	1	1	1	1
Q12	1	1	1	1	1	1	1	1	1	1
Q13	1	1	1	1	1	1	1	1	1	1
Q14	1	1	1	1	1	1	1	1	1	1
Q15	1	1	1	1	1	1	1	1	0	0.9
Q16	1	1	1	1	1	1	1	1	1	1
		S-CV	[/Ave (The n	nanag	ement	subsc	ale) =	0.98	
Q17	1	1	1	1	1	1	1	1	0	0.9
Q18	1	1	1	1	1	1	1	1	1	1
Q19	1	1	1	1	1	1	1	1	1	1
Q20	1	1	1	1	1	1	1	1	1	1
Q21	1	1	1	1	1	1	1	1	1	1
Q22	1	1	1	1	1	1	1	1	0	0.9
S-CVI/Ave (The confidence subscale) = 0.97										
Proportion relevance	1	1	1	1	1	1	1	1	0.86	
	S-CVI/Ave (Average proportion of items judged as relevance across the nine experts) = 0.98									

Table 3: Demographic and clinical characteristics of the participants in the pilot study of the SC-CHDI-Ar (n=30).

Variables	Mean	SD					
Age (Years)	61.87	8.87					
BMI (kg/cm)	28.59	4.13					
CHD duration (Years)	7	7					
Gender:	n	%					
Male	17	57					
Female	13	43					
Educational level:	•						
Elementary school	17	57					
Secondary school	3	10					
High school	7	23					
Bachelor degree and above	3	10					
Marital status:							
Married	27	90					
Single	3	10					
Working status:							
Employment	4	13					
Unemployment	26	87					
Smoking status:							
No	25	83					
Yes	5	17					
History of smoking:	Median	IRQ					
Smoking period (Year)	40	25					
Number of cigarettes\ day	18	8					
Subscales (SC-CHDI-Ar)	Mean	SD					
Maintenance subscale	63.89	15.95					
Management subscale	31.62	16.87					
Confidence subscale	78.33	19.21					
Time spending to complete questionnaire (Minutes)	10.47	2.75					
SD = Standard deviation, BMI = Body Mass Index, IRQ = interquartile Range.							

4.1 Phase 2: Measurement properties of SC-CHDI-Ar

A total of 183 subjects with CHD agreed to participate in the study. However, two participants were excluded due to missing data. The data from the remaining 181 participants were used for the analysis.

The majority of participants were male (57%), and the mean and SD of their age was 59 ± 11 years. The means of the maintenance, management and confidence subscales of SC-CHDI-Ar were 64.68 ± 24.10 ; 43.32 ± 26.24 ; 58.13 ± 27.64 , respectively. The mean of body mass index (BMI) was $28.4 \text{ (kg/m}^2) \pm 5.2$. Most participants were married (84%) and non-smokers (89%). Approximately 82% of the sample was unemployed. Most of the participants had an elementary school degree (59%). The average duration of CHD among the participants in the sample was six years (Table 4).

Table 4: Demographic characteristics of the participants in the measurement properties testing of the SC-CHDI-Ar version (n= 181 patients).

Variables	Mean	SD
Age (Year)	59	11
BMI (kg/cm)	28.4	5.2
CHD duration (Year)	6.2	5.1
Gender	n	%
Male	103	56.9
Female	78	43.1
Educational level:		
Elementary school	107	59
Secondary school	21	12
High school	35	19
Bachelor degree and above	18	10
Marital status:		
Married	152	84
Single	29	16
Working status:		
Employment	33	18
Unemployment	148	82
Exposure to external Smoke:		
Yes	11	6
No	170	94
Smoking status:		
No	161	89
Yes	20	11
	Median	IRQ
Smoking period (Year)	22	24
Number of cigarettes\ day	20	13
SD = Standard deviation, BMI = Body Mass	Index, IRQ = interquartile	e Range.

4.2.1 Internal consistency

The results showed acceptable to excellent internal consistency: the Cronbach's alpha for maintenance, management and confidence subscales of SC-CHDI-Ar were α =.85, .70, and .95, respectively (Table 5).

Table 5: Internal consistency and floor and ceiling effect of the SC-CHDI-Ar version (n = 181)

SC-CHDI subscales (Number of items; lowest score; heights score)	Mean	SD	% Floor effect	% Ceiling effect	Cronbach's alpha (α)	
Maintenance subscale (10; 10; 40)	64.68	24.10	2.8	1.1	.85	
Management subscale (6; 4; 24)	43.32	26.24	8.8	2.2	.70	
Confidence subscale (6; 6; 24)	58.13	27.64	4.4	9.9	.95	
SD: Standard deviation: α: Cronbach's Alpha.						

4.2.2 Test-retest reliability

Seventy participants completed the test-retest, with an average period of 10.03 days between the first and second tests. Of them, 61 participants reported that their health condition had not changed based on the GROC scale. While, nine participants were excluded from the second test, eight participants reported improvement and one reported deterioration based on the GROC scale. Data collection was conducted from October 2020 to June 2021.

The intraclass correlation coefficient (ICC_{2,1}) of agreement between the test and retest scores of the SC-CHDI-Ar subscales showed good reliability of the maintenance subscale; the remaining two subscales were acceptable. The ICC_{2,1} values for the maintenance, management and confidence subscales were ICC_{2,1}= 0.86 (95%CI; 0.70-0.91); 0.76 (95%CI; 0.59-0.85); and 0.76 (95%CI; 0.56-0.85), respectively (Table 6).

Table 6: The Test – Retest reliability and standard error of measurement of the Arabic version of the SC-CHDI- Ar (n=61).

Subscale	Test Mean ± SD	Retest Mean ± SD	ICC _{2,1} (95% CI)	SEM	MCD 95
Maintenance	72.90 ± 15.73	77.54 ± 14.03	.86 (.70 to .91)	5.58	15.47
Management	43.60 ± 19.93	41.10 ± 24.22	.76 (.59 to .85)	10.87	30.12
Confidence	67.94 ± 23.1	75. 14 ± 23.47	.76 (.56 to .85)	11.40	31.60

SD: Standard Deviation; ICC: Interclass Correlation Coefficient;

SEM: Standard Error of Measurement; MCD: Minimal Detectable Change.

4.2.3 Measurement error and minimal detectable change of SC-CHDI-Ar

The SEM values for the maintenance, management and confidence subscales of the SC-CHDI-Ar were 5.58, 10.87, and 11.40, respectively, and MDC₉₅ values of the SC-CHDI-Ar scores were 15.47, 30.12, and 31.60 (Table 6).

4.2.4 Floor and ceiling effects

According to the data in the current study, SC-CHDI-Ar did not have any floor or ceiling effects. The ceiling effect of the maintenance, management, and confidence subscales of SC-CHDI-Ar were 1.1%, 2.2%, and 9.9% respectively, while the floor effects were 2.8%, 8.8% and 4.4% (Table 5).

4.2.5 Construct validity

The scores of the participants' self-reported questionnaires were not normally distributed. The Spearman correlation showed a moderate positive significant correlation between the maintenance subscales of SC-CHDI-Ar and the symptoms control domains of CSEQ-A; (r = .58; p = .000), functioning maintenance domains (r = .56; p = .000), and modification risk factors domains (r = .58; p = .000) and with the total score of the CSEQ-A (r = .60; p = .000).

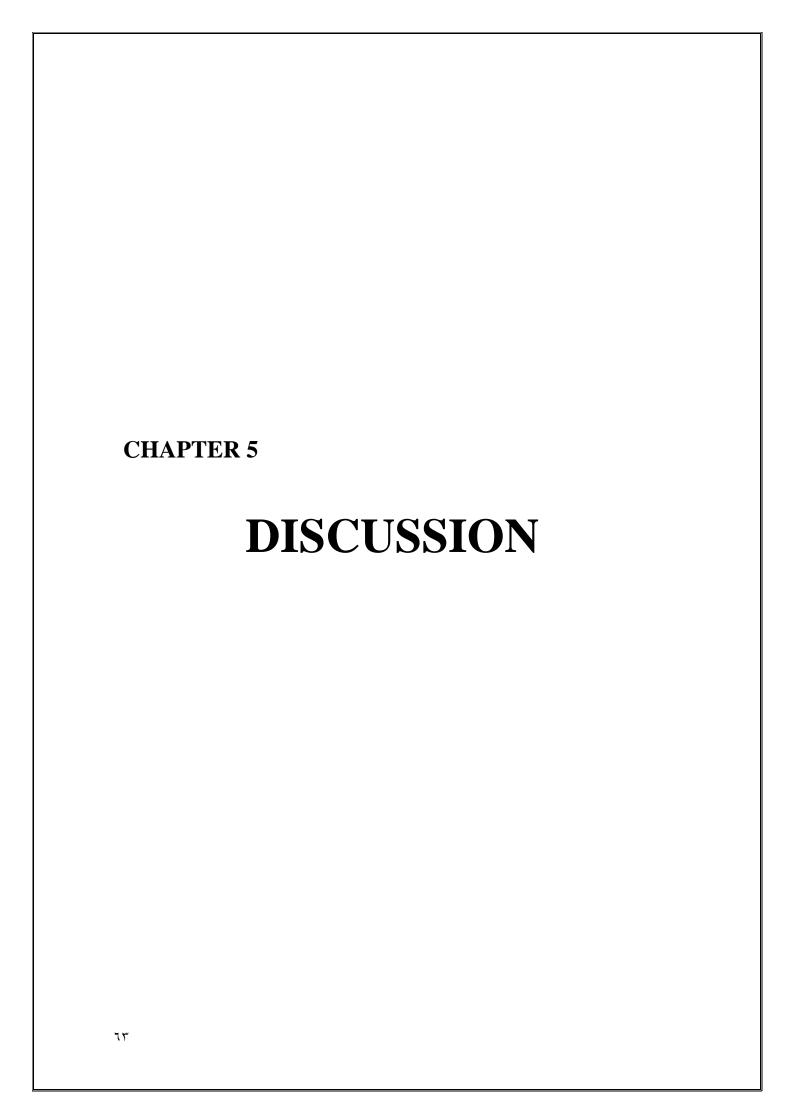
There were weak correlations between the management subscale of SC-CHDI-Ar and the symptoms control domain of the CSEQ-A (r = .26; p = .000) and with the total score of the CSEQ-A (r = .26; p = .001). However, strong correlation was found between the confidence subscale of the SC-CHDI-Ar and the symptoms control domain of CESQ-A and the total score of CSEQ-A (r = .81; 83; p = .000) respectively. In addition, a strong positive correlation was found between the confidence subscale of SC-CHDI-Ar and SEM6S-A (r = .75; p = .000) (Table 7).

Thus, all the hypotheses posed in the research question, all of them were supported by the results, providing evidence to support the construct validity of SC-CHDI-Ar.

Table 7: Spearman's correlation between SC-CHDI -Ar, CSEQ-A and SEM6S-A (n=181)

Outcome measurement		Correlation with SC-CHDI-Ar				
		Maintenance Management subscale subscale		Confidence Subscale		
	Symptom control	rs= .58**	rs= .26**	rs= .81**		
CSEQ-A	Functional maintenance	rs= .56**	rs= .19**	rs= .77**		
CSE	Modification risk factors	rs= .58**	rs= .25**	rs= .80**		
	Total score	rs= .60**	rs= .26**	rs= .83**		
SEM6S - A		rs= .56**	rs= .21**	rs= .75**		

SC-CHDI -Ar= Arabic version of the Self-Care of Coronary Heart Disease, CSEQ-A = Cardiac Self-Efficacy Questionnaire, SEM6S-A= Arabic version of Self - Efficacy Managing Chronic Disease 6 – item scale, rs= Spearman's correlation, ** = Correlation is significant at the 0.01 level, * = Correlation is significant at the 0.05 level.



The purposes of this study to translate and cross-culturally adapted the English version of SC-CHDI into Arabic. Additionally, the reliability and validity SC-CHDI. A were evaluated. To be used in a different culture, a scale needs to have the same psychometric properties as the original form. Thus, the psychometric properties of SC-CHDI-Ar were tested in terms of internal consistency, test-retest reliability, measurement error, floor and ceiling effects and construct validity. In line with our hypotheses, the results of this study provided evidence that SC-CHDI-Ar is valid and reliable among patients with CHD.

5.1 Translation and cross-cultural adaptation

The processes in this phase followed Sousa's guideline (2011), which comprises five steps: starting with forward translation by two bilingual translators, who translated the English version of SC-CHDI from into Arabic. Used standard Arabic language, thus produced this scale to be used in any Arabic speaking country. In the second step, a third translator and a principal researcher are integrated the two forward versions to synthesize SC-CHDI-Ar.

Third, back translation was performed by another two other bilingual translators, who translated the Arabic version of the SC-CHDI into English. The fourth step, performed by a committee, included all five translators who participated in the previous steps, a health care professional and research methodologists. They compared all versions from both forward and backward translation with the original

version of the SC-CHDI and to formulated the pre-final version of the Arabic version of the SC-CHDI. Minor change of few words which suggested during the committee without change in the meaning. Finally, P-FTL was sent to the developer, who approved it.

The fifth step determined the conceptual and content equivalence of the items of the pre-final SC-CHDI-Ar through an expert panel and the pilot tested among 30 participants. The content validity measured by the panel committee included nine experts who reviewed the P-FTL. The CVI was measured and the value of I-CVI was (1) for most items except 15, 17 and 22 were (.90). In addition, the values of S-CVI were (1) for the maintenance subscale, (.98) for the management subscale and (.97) for the confidence subscale.

The results indicate that the value of content validity is acceptable and the instrument is valid. This result is similar to that obtained for CVI measured for the English version by five cardiovascular nurses the resulted showed (1) for all three subscales (Dickson et al., 2017) and in the Turkish version, reported by eight experts, both I-CVI and S-CVI values were (.99) (Bayrak & Oğuz, 2021).

In addition, a pilot test was conducted to measure the conceptual, experiential, idiomatic and semantic equivalence of the pre-final of SC-CHDI-Ar among 30 patients with CHD. We recruited 17 males and 13 females who met the inclusion criteria of the current study. The participants reported that the instructions and items were clear and understandable.

Furthermore, pilot-testing of P-FTL added more clarification to question 14, which could not be explored in the previous stages. Most of the patients mentioned that they go to the hospital instead of calling the doctor. According to the Ministry of Health in Saudi Arabia, a calling system has not yet been activated and the consultation take place with the doctor only not through the nurse. Thus, in question 14 "or going to the hospital for consultation" was added and "nurse" was removed.

The end result was a high-quality translation both linguistically and semantically. The final version of SC-CHDI-Ar was achieved and approved by the developer and submitted to the main developer website.

5.2 Psychometric properties of the SC-CHDI-Ar

According to the literature, self-care level is predictable and influences the management of chronic disease (Allam et al., 2019). Thus, to implement a tool to assess self-care among patients with CHD, a valid and reliable instrument is required. The validity and reliability of SC-CHDI-Ar was measured, and the results showed that it can be used in clinics and research.

In this study, the final version of SC-CHDI-Ar was tested among Arabic speaking population on a sample of 181 patients with CHD. Most participants were male, with a mean age 59 years and an average disease duration of 6 years. The patients spent approximately 8 to 13 minutes completing the SC-CHDI-Ar.

The internal consistency analysis should be undertaken when assessing the reliability of adopting measures (Terwee et al., 2007). The present study showed that SC-CHDI-Ar has acceptable to excellent internal consistency and good test-retest reliability. Cronbach's analysis is the most widely used approach for determining the reliability of Likert-type scales. Cronbach's alpha provides information regarding to the scale items consistency with each other (deVet et al., 2011). As the total score cannot be obtained from SC-CHDI, in the current study, Cronbach's alpha coefficients were separately calculated for the three subscales of SC-CHDI.

The maintenance subscale was good (α = .85), the management subscale was acceptable (α = .70), and the confidence subscale was excellent (α = .95). these results agreed with those obtained for the original version of SC-CHDI, where the Cronbach's alpha values were (α = .87; .76; .84), respectively (Dickson et al., 2017). This result indicates that most items in the subscales are closely interrelated and are homogeneous and not redundant (Terwee et al., 2007).

In addition, the Cronbach's alpha values of the three subscales of the SC-CHDI Turkish version were similar to the result of the current study, except for the maintenance subscale, which had a value of ($\alpha = .63$). The management subscale and confidence subscale had values of ($\alpha = .76$; .95), respectively (Bayrak & Oğuz, 2021).

The internal consistency of the Chinese version of SC-CHDI was good (α =.80) for the confidence subscale (Chen et al., 2021). The Cronbach's alpha values of the Russian version of the SC-CHDI were (α =.69; .64; .71) for the maintenance, management and confidence subscales respectively (Kabargina and Lopatin 2020).

A tool's reliability is defined as its ability to produce constant results across different occasions (Polit, 2014). This study examined the test-retest reliability for SC-CHDI-Ar by using $ICC_{2,1}$ model Two-way random with absolute agreement, the acceptable values of the ICC is 0.7.

ICC is the most suitable method to examine test–retest reliability has compared to other types of correlations coefficients, such as Pearson's correlation. This is because it considers the measurement error (de Vet et al., 2006).

In this study, the average interval between the test and retest was ten days, which was determined based on the following evidence: the interval between the test and retest should be decided to be within 2 to 14 days because if it is shorter, it might cause recall of the items, and if it is longer, it might be permit cause clinical change (Marx et al., 2003; Park et al., 2018; Terwee et al., 2007).

The participant enrolled in examining the test-retest reliability scored themselves from -3 to +3 the GROC scale, they were stable or had no change in their health condition during the period between the test and retest. The GROC scale is an accurate method for assessing health condition changes over time (Rating &

Scales, 2009). Sixty-one participants completed the retest of SC-CHDI-Ar, which ia an adequate number for examining the reliability (Mokkink, 2018).

SC-CHDI-Ar achieved acceptable to good test-retest reliability, and the ICC _{2,1} values were for the maintenance, management and confidence subscales of the SC-CHDI-Ar were = 0.86; 0.76 and 0.76 respectively which supported the study hypotheses.

Furthermore, the Turkish version of SC-CHDI did not have any significant difference in the mean scores between the test–retest, and the interval between the test and retest was 15 days (Bayrak & Oğuz, 2021). Kabargina and Lopatin (2020) reported that the patients performed the retest four days after the first test, and the ICC_{2,1} values for the maintenance, management and confidence subscales calculated as = .81; .79 and ,85, respectively.

In addition to the reliability, this study calculated SEM, which is a measure of how far apart are the outcomes of the repeated measurement (de Vet et al., 2011). The results were 5. 58 points for the maintenance subscale, 10.87 points for the management subscale and 11.40 points for the confidence subscale. The values of MDC₉₅, which refers to the minimal value indicating a real change in a single subject (95%CI) of the three subscales of SC-CHDI-Ar, were (15.47; 30.12; 31.60 points), respectively. Both SEM and MDC₉₅ exhibited clinical importance in evaluating the real effects of interventions and change over time. These values seem acceptable, as there was no SEM and MDC₉₅ reported for the original version of SC-CHDI, as well

as for the Turkish, Chinese and Russian versions (Bayrak & Oğuz, 2021; Chen et al., 2021; Dickson et al., 2017; Kabargina & Lopatin, 2020).

SC-CHDI-Ar had no floor or ceiling effects, which confirmed the content validity. In addition, SC-CHDI-Ar dose not having a total score because it is an inventory has calculated each subscale separately. Therefore, the celling effects for the three subscales of maintenance, management and confidence were: 1.1%; 2.2% and 9.9%, respectively. The floor effects were 2.8%; 8.8% and 4.4% for the three subscales respectively. The original version of the SC-CHDI and previous studies did not measure floor and ceiling effects (Bayrak & Oğuz, 2021; Chen et al., 2021; Dickson et al., 2017; Kabargina & Lopatin, 2020).

Construct validity was determined by examining the pre-defined hypotheses.

The result of this study provides strong evidence to support the construct and discriminant validity of SC-CHDI-Ar by supporting all nine pre-defined hypotheses.

The results showed a moderate positive significant correlation between the maintenance subscale of SC-CHDI-Ar within the three domains and the total score of CSEQ-A (r = .56, .60). The correlation was weak positive significant between the management subscale of SC-CHDI-Ar within the symptoms control domains and the total score of CSEQ-A (r = .26, .26) respectively.

In addition, the correlations among the confidence subscale of SC-CHDI-Ar, the symptoms control domain, and the total scores of CSEQ-A and SEM6S-A were

strong positive significant (r = .81; .83; .75) respectively. These results support all nine hypotheses.

In contrast, Dickson et al. (2017) found a significant correlation between the maintenance and confidence subscales of the SC-CHDI English version, MOS-SAS and DMCI. While, management subscale significantly associated with MOS-SAS only. However, in the Chinese version of SC-CHDI, PKS-CHD, CAS-R, and the three subscales of SC-CHDI were found to be significantly correlated (Chen et al., 2021).

Additionally, in the Russian version, the criterion-related validity revealed correlation among the maintenance, management, and confidence subscales with the SF-36 physical functioning scale (r=-0,212, p<0,05), Charlson comorbidity index (r=0,282, p<0,01), physical activity restriction (r=-0,218, p<0,05) and the frequency of angina episodes (r=-0,340, p<0,05) of the SAQ questionnaire, duration of CCS (r=0,354, p<0,01) and Morisky-Green scale value (r=0,25, p<0,05) (Kabargina & Lopatin, 2020).

In this study, we used CSEQ-A as a self-reported outcome measure for evaluating the self-efficacy of patients with CHD and has been widely use (Shajrawi et al., 2020). Meanwhile, SEM6S-A is a validated Arabic questionnaire that measures a person's confidence in their ability to manage fatigue, discomfort, pain, emotional distress, or any other symptoms associated with managing a chronic condition (Allam et al., 2019).

5.3 Strength of the study

This study followed a commonly used guideline during each step of translation and cross- cultural adaptation (Sousa & Rojjanasrirat, 2011) to ensure quality and equivalence with the original version of SC-CHDI. Moreover, we used a published recommendation to measure psychometric proprieties (Polit, 2015) of SC-CHDI-Ar with a sufficient sample size.

5.4 Limitation

Applying the inventory with a larger sample can provide stronger evidence. Finally, we did not perform exploratory and confirmatory factor analyses.

5.5 Recommendation and future research

Future studies should to be conducted to address the limitations of the current study. Additionally, they should examine the psychometric properties of the SC-CHDI-Ar among different Arabic speaking countries to generalize the outcome measurements of SC-CHDI-Ar. Furthermore, they can consider an exploratory and a confirmatory factor analysis to confirm the factorial structure of SC-CHDI-Ar.

5.6 Clinical implications

SC-CHDI-Ar is a specific outcome measure that is applicable patients with CHD, which can measure maintenance, management and confidence in self-care. It

is a valid and reliable scale that can be used by researchers. Additionally, in clinical practice, cloud uses this instrument during patient assessment.

5.7 Conclusion

The Arabic version of the SC-CHDI proved to be an understandable and a reliable and valid tool to assess self-care among patients with CHD. The CVI of SC-CHD-Ar was good and acceptable. In addition, the reliability of SC-CHDI-Ar was good to excellent in terms of internal consistency and acceptable to good in the teat retest. A positive significant correlation was found among the three subscales of SC-CHDI-Ar, the three domains of CSEQ-A and SEM6S-A. Therefore, SC-CHDI-Ar is a useful tool that can be used in clinical settings and research.

CHAPTER 6

SUMMARY, RECOMMENDATIONS, AND CONCLUSION

SUMMARY, RECOMMENDATIONS, AND CONCLUSION

6.1 Summary

Background: CHD is a chronic disease and considered as the leading of deaths worldwide. Patients with CHD are at high risk of developing MI or angina or heart failure. Thus, self-care should be implemented among these patients to control the symptoms and reduce the burden of CHD. The Self-Care of Coronary Heart Disease Inventory (SC-CHDI) is a recently developed instrument. It is a patient reported outcome measure specifically designed for patients with CHD. It measures the patient's adherence to medications and help them in maintaining a healthy lifestyle, recognizing and responding to their symptoms and self-confidence level.

However, no validated Arabic version of the SC-CHDI is available.

Objective: This study aimed to cross culturally adapted SC-CHDI into the Arabic language and to measure the psychometric properties of SC-CHDI-Ar among patients with CHD.

Subjective and method: A cross sectional study was conducted in Riyadh on 181 patients with CHD (≥35 years old) of both genders. This study included the samples from three hospitals, KFMC, HMG, and SBAHC, from cardiology outpatient clinics.

This study followed Sousa's guideline on translation. In the reliability analysis, internal consistency and test-retest reliability were verified. To determine the

construct validity the Spearman correlation among SC-CHDI-Ar, CSEQ-A and SEM6S-A was used.

Findings: The following results were obtained:

- CVI: I-CVI was 1 for all questions except questions 15, 17 and 22, which had the value of 0.9. In addition, the S-CVI, calculate (S-CVI/Ave) use this method (sum of I-CVI scores divided by the number of items).
 - The maintenance part was 1.
 - The management part was 0.98.
 - The confidence part was 0.96.
- The times required for completing SC-CHDI-Ar was approximately 11 minutes.
- -Internal consistency was good to excellent: the value of Cronbach's alpha for maintenance, management and confidence subscales of SC-CHDI-Ar were α =.85, .70, and .95, respectively.
- The test and retest scores of the SC-CHDI-Ar subscales showed good reliability of the maintenance subscale; the remaining two subscales were acceptable. The ICC_{2,1} of the three subscales had values of 0.86 (95%CI; 0.70-0.91); 0.76 (95%CI; 0.59-0.85); and 0.76 (95%CI; 0.56-0.85), respectively.
- The SEM values were 5.58 points for the maintenance subscale, 10.87 points for the management subscale and 11.40 points for the confidence subscale.
- The MDC₉₅ of the three subscales of SC-CHDI-Ar were (15.47; 30.12; 31.60 points), respectively.

- Both SEM and MDC₉₅ were acceptable, as there were no reported values for the original version of SC-CHDI, Turkish version, Chinese version and Russian version.
- In all three subscales, less than 15% of the participants reported minimum or maximum possible scores of SC-CHDI-Ar for the floor and ceiling.
- Spearman correlation showed a moderate positive significant correlation among the maintenance subscales of the SC-CHDI-Ar and the symptoms control domains of CSEQ-A; (r = .58; p = .000), functioning maintenance domains (r = .56; p = .000), and modification risk factors domains (r = .58; p = .000) and with the total score of CSEQ-A (r = .60; p = .000).
- Weak correlations were found between the management subscale of SC-CHDI-Ar and the symptoms control domain of CSEQ-A (r = .26; p = .000) and with the total score of the CSEQ-A (r = .26; p = .001).
- A strong correlation was found between the confidence subscale of SC-CHDI-Ar and the symptoms control domain of CESQ-A and the total CSEQ-A score (r = .81; 83; p = .000) respectively. In addition, strong positive correlation was observed between the confidence subscale of SC-CHDI-Ar and SEM6S-A (r = .75; p = .000).

6.2 Recommendation

Future studies should evaluate the psychometric properties of SC-CHDI-Ar among different Arabic speaking countries to generalize the outcome measurements of SC-CHDI-Ar. Additionally, an exploratory analysis and a confirmatory factor analysis can be conducted in the future study to confirm the factorial structure of SC-CHDI-Ar.

6.3 Conclusion

The Arabic version of the SC-CHDI proved to have a good CVI, acceptable reliability, and significant correlation in constructed validity. A positive significant correlation was found among the three subscales of SC-CHDI-Ar, and among the three domains of CSEQ-A and SEM6S-A. Thus, this study showed that SC-CHDI-Ar can be used in clinical settings and research.

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Appendices

Appendix 1: English version of the SC-CHDI Questionnaire (Original)

SELF-CARE OF CORONARY HEART DISEASE INVENTORY (SC-CHDI V2.1)

All answers are confidential.

Think about how you have been feeling in the last month or since we last spoke as you complete these items.

SECTION A:

Listed below are common instructions given to persons with heart disease. How routinely do you do the following?

		Never or rarely	Sometimes	Frequently	Always or daily
1.	Keep doctor or nurse appointments?	1	2	3	4
2.	Take aspirin or other blood thinner?	1	2	3	4
3.	Check your blood pressure?	1	2	3	4
4.	Exercise for 30 minutes?	1	2	3	4
5.	Take your medicines as prescribed?	1	2	3	4
6.	Ask for low fat items when eating out or visiting others?	1	2	3	4
7.	Use a system to help you remember your medicines? For example, use a pill box or reminders.	1	2	3	4
8.	Eat fruits and vegetables?	1	2	3	4
9.	Avoid cigarettes and/or smokers?	1	2	3	4
10	Try to lose weight or control your body weight?	1	2	3	4

SC-CADI V2.1 March 15, 2016

SECTION B:

Heart disease may appear as chest pain, chest pressure, burning, heaviness, shortness of breath, or fatigue.

In the past month, have you had any of these symptoms? Circle one.

- 0) No
- 1) Yes
- 11. If you had any of these symptoms of heart disease in the past month...

(circle one number)

	Have not had these	I did not recognize it	Not Quickly	Somewhat Quickly	Quickly	Very Quickly
How quickly did you recognize it as a symptom of heart disease?	N/A	0	1	2	3	4

Listed below are actions that people with heart disease use. If you have symptoms, how likely are you to try one of these actions?

(circle one number for each remedy)

	(encie one number for each remed)				
	Not Likely	Somewhat Likely	Likely	Very Likely	
12. Change your activity level (slow down, rest)	1	2	3	4	
 Take nitroglycerin (If you do not have nitroglycerin prescribed, skip this item) 	1	2	3	4	
14. Call your doctor or nurse for guidance	1	2	3	4	
15. Take an aspirin	1	2	3	4	

16. Think of an action you tried the last time you had symptoms of heart disease,

(circle one number)

	I did not try anything	Not Sure	Somewhat Sure	Sure	Very Sure
How sure were you that the	0	1	2	3	4

SC-CADI V2.1 March 15, 2016

action helped or did not	
help?	

SECTION C:

In general, how confident are you that you can:

	Not Confident	Somewhat Confident	Very Confident	Extremely Confident
17. Keep yourself <u>free of</u> <u>symptoms?</u>	1	2	3	4
18. <u>Follow the treatment advice</u> you have been given?	1	2	3	4
19. <u>Recognize changes</u> in your health?	1	2	3	4
20. <u>Evaluate the importance</u> of your symptoms?	1	2	3	4
21. Do something that will relieve your symptoms?	1	2	3	4
22. Evaluate how well a remedy works?	1	2	3	4

SC-CADI V2.1 March 15, 2016

Appendix 2: Final Arabic version of the SC-CHDI

قائمة الرعاية الذاتية لمرض شرايين القلب التاجية

كل الإجابات في سرية

أثناء تعبئة الاستبيان، تذكر كيف كنت تشعر في الشهر الماضي أو منذ حديثنا الأخير. أ. القسم الأول:

القائمة التالية هي عبارة عن إرشادات شائعة تعطى للأشخاص المصابين بأمراض القلب، بشكل روتيني ما مدى التزامك بها؟

دائماً			أبدأ	
أو	غالبأ	أحيانأ	أو	
يوميا			نادرا	
4	3	2	1	 المحافظة على مواعيد طبيبك أو ممرضك؟
4	3	2	1	 تناول الاسبرين أو أي دواء آخر من مسيلات الدم؟
4	3	2	1	3. فحص ضغط الدم؟
4	3	2	1	 ممارسة التمارين الرياضية لمدة 30 دقيقة?
4	3	2	1	 تناول الأدوية بناء على الوصفة الطبية؟
4	3	2	1	 6. تطلب أطعمة قليلة الدسم عند تناول طعامك خارج المنزل أو عند
				زيارة الأخرين؟
4	3	2	1	7. استخدام وسيلة تساعدك على تذكر تناول أدويتك، مثل: استخدام
				علبة للأدوية أو وسائل التنكير؟
4	3	2	1	 الفواكه والخضروات؟
4	3	2	1	9. تجنب التدخين و/ أو المدخنين؟
4	3	2	1	10.محاولة إنقاص الوزن أو المحافظة عليه؟

ب. القسم الثاني:

تظهر أعراض أمراض القلب: مثل ألم الصدر أو ضغط في الصدر أو حرقة أو الإحساس بالثقل أو ضيق في التنفس أو الشعور بالإرهاق.

هل شعرت بأي من هذه الأعراض في الشهر الماضي؟ (اختر إجابة واحدة).

y (0

1) نعم

11- في حال تعرضت لأي من أعراض أمراض القلب في الشهر الماضي. (اختر إجابة واحدة)

سريعاً جدا	سريعأ	سريعاً نوعاً ما	لم أتعرف عليها سريعا	لم أتعرف عليها	ليس لدي أعراض	
4	3	2	1	0	غير مطابق	ما مدى سرعة تعرفك بأن تلك الأعراض هي من أعراض أمراض القلب؟

في القائمة أدناه مجموعة من التصرفات التي يقوم بها المصابون بأمراض القلب، في حال شعورك بأحد تلك الأعراض ما مدى احتمالية قيامك بهذه التصرفات؟ (اختر إجابة واحدة لكل تصرف)

محتمل	1 -	محتمل	غير	
جدا	محتمل	نوعأما	محتمل	
4	3	2	1	12- تغيير مستوى النشاط البدني (تخفيف السرعة، أخذ استراحة).
4	3	2	1	13- تناول النتروجليسرين (إذا لم يكن النتروجلسيرين من ضمن ادويتك
				تخطى هذا البند).
4	3	2	1	14- الاتصال بالطبيب (أو الذهاب إلى المستشفى) للاستشارة.
4	3	2	1	15- تناول الاسبرين.

16- تذكر التصرف الذي حاولت القيام به في آخر مرة تعرضت فيها لأعراض أمراض القلب.(اختر إجابة واحدة).

متاكداً جداً	متاكدا	متاكدأ نوعاً ما	لست متاكدأ	لم أحاول القيام بأي شيء	
4	3	2	1	0	ما مدى <u>تأكدك</u> من أن ذلك التصرف ساعدك أو لم يساعدك؟

ج. القسم الثالث:

بشكل عام، ما مدى ثقتك بقدرتك على:

واثقاً للغاية	واثقاً جداً	واثقاً نوعاً ما	غير واثقاً	
4	3	2	1	17- المحافظة على نفسك دون ظهور الأعراض؟
4	3	2	1	18- اتباع النصائح العلاجية الموصى بها؟
4	3	2	1	19- ملاحظة التغيرات التي تطرأ على صحتك؟
4	3	2	1	20- تقييم أهمية أعراضك؟
4	3	2	1	21- القيام بشيء ما لتخفيف الأعراض؟
4	3	2	1	22- تقييم مدى فاعلية العلاج؟

Appendix 3: Demographic data sheet

		الطول	الوزن	كثلة الجسم				
الجنس	□ ذكر □ أنتَى							
المستوى التعليمي		تانوي متوسط ابتدائي اخرى جامعي						
الحالة الاجتماعية	لْكَىٰ الْمَ	زوج\ـه □مط اله	یاء □ متز □أرمل\	□أعزب \عن				
هل أنت موظف∖ـه		حم □ لا	ے ت					
هل انت مدخن∖ـه؟	□ نعم □ لا							
	ن ما يلي:	نرجو الإجابة علم	ت الإجابة نعم	إذا كات				
		متى وانت تدخن؟	1- منذ					
	رم؟	جارة تَدخن في اليو	2- كم سپ					
هل انت مدخن								
سلبي؟ او تتعرض		حم □ لا	□ د					
لدخان خارجي؟								
كم مدة إصابتك								
بمرض الشرايين								
التاجية (عدد								
السنوات)؟								
كم عدد أدويتك؟								

Appendix 4: CSEQ-A Questionnaire

Final Arabic Version of Cardiac Self-Efficacy Questionnaire (CSEQ)

مقياس مستوى الكفاءة الذاتية لمرضى القلب

الرجاء الأجابة على الأسئلة التالية بوضع عائمة × على الأجابة المناسبة أو أختيار أقرب أجابة ممكنة:

وائق تماما 4	وائتی ائی حد کبیر 3	ئقة متوسطة 2	واتق إلى حدما 1	لائقة على الإطلاق 0	السوال	
					كم أنت والق أنك تعرف أن تستطيع:	i
					السيطرة على الألم في الصدر عن طريق تغيير مستوى تشاطك البدني	1
					السيطرة على صحوية التنفس عن طريق تخيير مستوى نشاطك البدني	2
					السيطرة على الألم في الصدر عن طريق أخذ الأدوية الخاصة بك	3
					الموطرة على صعوبة التنفس عن طريق أخذ الأدوية الخاصة بك	4
					الاتصال أو زيارة طبيب القلب للأستفسار حول مرضك	5
					كوفوة جعل طبيب القاب يفهم مشاوفك حول مرضك	6

7 كينية اتخاذ الأدوية الخاصة بك لعلاج مرض الطاب 8 فائدة النتاط البدني لصحتك 9 المحافظة على أنشطتك الاجتماعية المحذادة 10 المحافظة على أنشطتك الاجتماعية المحذادة في المدن المحافظة على أنشطتك المحذادة في المدن المحافظة على أنشطتك المحذادة في المدل المحافظة على علاقتك الجنسية مع زوجك 11 المحافظة على علاقتك الجنسية مع زوجك 12 المحافظة على علاقتك الجنسية المنتظمة (المدل حتى التحرق وزيادة محل صريات الظب) 13 عم انت قاهر على: 14 انتخاص وزنك (إذا كنت بدينا) 15 تخيير النظام المخذائي المخاص بك (إذا أوصمي المليب					
	7	كيفية اتخاذ الأدوية الخاصة بك لعلاج مرض القلب			
9 المحافظة على أنتطنك الاجتماعية المعتادة 10 المحافظة على أنتطنك المعتادة في المنزل مع أسرتك 11 المحافظة على أنتطنك المعتادة في الممل 12 المحافظة على علاقتك الجنسية مع زوجك 13 الحصول على التمارين الرياضية المنتظمة (العمل حتى 14 انتاص وزنك (إذا كنت بدينا) 15 التوقف عن التنخين (إذا كنت مدخن) 16 تتوير النظام الخذائي الخاص بك (إذا أرصي الطبيب	8	فائدة النشاط البدني لصحتك			
10 المحافظة على أنتطتك المحدّادة في المنزل مع أسرتك 11 المحافظة على أنتطتك المحدّادة في العمل 12 المحافظة على علاقتك الجنسية مع زوجك 13 الحصول على التمارين الرياضية المنتظمة (العمل حتى 13 التحرق وزيادة معدل ضريات القلب) 2 كم الله قادر على: 14 انقاص وزنك (إذا كنت بدينا) 15 التوقف عن التدخين (إذا كنت مدخن)	بر	كم اتت واثق في :			
11 المحافظة على انتطائك المحادة في العمل 12 المحافظة على علاقتك الجنسية مع زوجك 13 الحصول على التمارين الرياضية المنتظمة (العمل حتى 13 التحرق وزيادة معدل ضريات القلب) 2 كم اتت قادر على: 14 انقاص وزنك (إذا كنت بدينا) 15 التوقف عن التدخين (إذا كنت مدخن)	9	المحافظة على أنشطتك الاجتماعية المعتادة			
12 المحافظة على علاقاك الجنسية مع زوجك 13 الحصول على التمارين الرياضية المنتظمة (العمل حتى 14 التعرق وزيادة معدل ضريات القاب) 14 انقاص وزنك (إذا كنت بدينا) 15 التوقف عن التدخين (إذا كنت مدخن)	10	المحافظة على أنسّطتك المحلدة في المنزل مع أسرتك			
13 الحصول على النمارين الرياضية المنتظمة (العمل حتى التعرق وزيادة معدل ضريات القلب) 2 كم اتت قادر على: 14 انقاص وزنك (إذا كنت بدينا) 15 التوقف عن التدخين (إذا كنت مدخن) تخيير النظام الغذائي الخاص بك (إذا أوصى الطبيب	11	المحافظة على أنسّطنك المعادة في العمل			
التعرق وزيادة معدل ضريات القاب) ع كم اتت قادر على: 14 انقاص وزنك (إذا كنت بدينا) 15 التوقف عن التدخين (إذا كنت مدخن) تغيير النظام الغذائي الخاص بك (إذا أوصعي الطبيب	12	المحافظة على علاقتك الجنسية مع زوجك			
14 انقاص وزنك (إذا كنت بدينا) 15 التوقف عن التدخين (إذا كنت مدخن) تخيير النظام الغذائي الخاص بك (إذا أوصعي الطبيب	13	الحصول على التَمارين الرياضية المنتَظمة (العمل حتَى التَعرق وزيدة معدل ضريات القلب)			
15 التوقف عن التدخين (إذا كنت مدخن) تخيير النظام الخذائي الخاص بك (إذا أوصبي الطبيب	ε	كم اتت قادر على:			
تغيير النظام الغذائي الخاص بك (إذا أوصى الطبيب	14	انقاص وزنك (إذا كنت بدينا)			
كتربير النظام الغذائي الخاص بك (إذا أوصى الطبيب	15	التَوقَف عن النَّدخين (إذا كنت مدخن)			
10 الخاص بك بذلك)	16	تغيير النظام الغذائي الخاص بك (إذا أوصى الطبيب الخاص بك بذلك)			

Appendix 5: SEM6S-A Questionnaire



كفاءة النفس في إدارة المرض المزمن (مقياس ٦ بند)

نود أن نعرف مدى ثقتك في أداء أنشطه معينه. لكل من الأسئلة التالية ، يرجى اختيار الرقم الذي يتوافق مع ثقتك بأنه يمكنك القيام بالمهام بإنتظام في الوقت الحاضر

الغيام بالمهام بالنصام في الوقت الخاصر					
ا ا ا ا ا واثق ه ۲ ۷ ۸ ۹ ۸ ۲ تماما		 ما مدى شعورك بالثقة في أنه بإمكانك منع الإرهاق الناجم عن مرضك من التدخل في الأشياء التي تريد القيام بها؟ 			
ا ا ا ا ا واثق ه ۲ ۷ ۸ ۹ ۰۱ تماما	غير واثق على الإطلاق ۲ ۳ ٤	 ما مدى شعورك بالثقة في أنه بإمكانك منع عدم الراحة الجمدية أو الألم الناجم عن مرضك من التدخل في الأشياء التي تريد القيام بها؟ 			
ا ا ا ا ا واثق ه ۲ ۷ ۸ ۹ ۰۱ تماما		 ما مدى شعورك بالثقة في أنه بإمكانك منع الاضطراب العاطفي الناجم عن مرضك من التدخل في الأشياء التي تريد القيام بها؟ 			
ا ا ا ا ا ا واثق ه ۲ ۷ ۸ ۹ ۰۱ تماما		ما مدى شعورك بالثقة في أنه بإمكانك منع أي أعراض 4. أخرى أو مشاكل صحية لديك من التدخل في الأشياء التي تريد القيام بها؟			
ا ا ا ا ا ا واثق ه ۲ ۷ ۸ ۹ ۰۱ نماما	4517.511.1	 ما مدى شعورك بالثقة في أنك تستطيع القيام بالمهام و الأنشطة المختلفة اللازمة لإدارة حالتك الصحية لتقليل حاجتك إلى زيارة الطبيب؟ 			
ا ا ا ا ا واثق تماما	ا ا ا	 ما مدى شعورك بالثقة في أنك تستطيع القيام بأشياء أخرى غير مجرد تناول الأدوية لتقليل مقدار تأثير مرضك على حياتك اليومية؟ 			

Appendix 6: The Arabic version of the Global rating of change (GROC)

الرجاء تقييم الوضع الحالي للإصابة أو المشكلة التي لديك بالمقارنة بوضعها في الزيارة السابقة التي قمت فيها بتعينة الاستباتة

الرجاء اختيار إجابة واحدة فقط

الإسم: التاريخ:

أفضل بقدر كبير جدأ	7
أفضل بقدر كبير	6
أفضل بشكل ملحوظ	5
أفضل بشكل متوسط	4
أفضل نوعا ما	3
أفضل بشكل بسيط	2
أفضل بشكل طفيف, تقريبا نفس الشيء	1
لا يوجد تغير	0
أسوأ بشكل طقيف, تقريبا نفس الشيء	1-
أسوأ بشكل بسيط	2-
أسوأ نوعا ما	3-
أسوأ بشكل متوسط	4-
أسوا بشكل ملحوظ	5-
أسوأ بقدر كبير	6-
أسوا بقدر كبير جدأ	7-

Appendix 7: Institutional Review Board of collage medicine at King Saud

University

Kingdom of Sandi Arebia King Sandi University (034) p.o. Box 7805 Riyadh (1472) (st) +966 11 467 00 11 fax: +96611 467 19 92 المملكة العربية السعودية جامعة الملك سعود (PE) ص. ب م ۷۸ الرياض BEV۲ ماتقد ال BE۲۷ | PTT || ETV فاكس: PTT || ETV || 1997



المدينة الطبية الحاممية Institutional Review Board

25.10.2020 (08.03.1442) Ref. No. 20/0757/IRB

To: Mr. Ahad Mohammed Aliaber

Master Student in Physical Therapy Department of Rehabilitation Sciences

King Saud University College of Applied Medical Sciences Email: ahad.357@hotmail.com, 439204115@student.ksu.edu.sa

Physiotherapist in Rehabilitation Department

Sultan Bin Abdelaziz Humanitarian City - Sultan City Medical Center

Principal Investigator

Cc: Rehab Farrag Gwada – rgwada@ksu.edu.sa

Co-Investigator

Subject: IRB Approval of Research Project No. E-20-4872

Study Title: "Cross-cultural Adaptation and Validation of the Arabic Version of Self-Care of

Coronary Heart Disease Inventory"

Type of Review: Expedite

Date of Approval: 20 October 2020 Date of Expiry: 20 October 2021

Dear Mr. Ahad Mohammed Aljaber,

I am pleased to inform you that your above-mentioned research project submitted to the IRB was reviewed and approved on 20 October 2020 (03 Rabi-I 1442). You are now granted permission to conduct this study given that your study does not disclose participant's identity and poses no risk to the patients.

As principal investigator, you are required to abide by the rules and regulations of the Kingdom of Saudi Arabia and the research policies and procedures of the KSU IRB. If you make any changes to the protocol during the period of this approval, you must submit a revised protocol for IRB approval prior to implementing the changes. This approval shall remain valid until the expiry date noted above assuming timely and acceptable responses from the IRB's periodic requests for surveillance and monitoring information. If you wish to have your protocol approved for continuation, please submit a completed request for reapproval of an approved protocol form (KSU-IRB o17E) at least 30 days before the expiry date. Failure to receive approval for continuation before the expiration date will result in automatic suspension of the approval of this protocol on the expiration date. Information collected following suspension is unapproved research and can never be reported or published as research data. Please quote the project number shown above in any future correspondence or follow-ups related to this study.

We wish you success in your research and request you to keep the IRB informed about the progress of the study on a regular basis by submitting a Study Progress Report every 6 months and a Final Report when the study has been completed.

Thank you!

Sincerely yours,

Prof. Abdulrahman AlSultan

Chairman of IRB

Health Sciences Colleges Research on Human Subjects

King Saud University College of Medicine

P. O. B ox 7805 Riyadh 11472 K.S.A. Email: aalsultan1@ksu.edu.sa



Appendix 8: Institutional Review Board of collage medicine at King Fahad

Medical City

Kingdom of Saudi Arabia Ministry of Health King Fahad Medical City (162)



المملكة العربية السعودية وزارة الصحة مدينة الملك فهد الطبية (١٦٢)

IRB Registration Number with KACST, KSA: IRB Registration Number with OHRP/NIH, USA: Approval Number Federal Wide Assurance NIH, USA: H-01-R-012 IRB00010471 FWA00018774

May 10, 2020

IRB Log Number: 20-291E

Department: External - King Saud University

Category of Approval: EXEMPT

Dear Ahad Aljaber,

I am pleased to inform you that your submission dated May 10, 2020 for the study titled 'Cross-Cultural Adaptation and Validation of the Arabic Version of Self-Care of Coronary Heart Disease Inventory' was reviewed and was approved according to Good Clinical Practice guidelines. Please note that this approval is from the research ethics perspective only. You will still need to get permission from the head of department or unit in KFMC or an external institution to commence data collection.

We wish you well as you proceed with the study and request you to keep the IRB informed of the progress on a regular basis, using the IRB log number shown above.

Please be advised that regulations require that you submit a progress report on your research every 6 months. You are also required to submit any manuscript resulting from this research for approval by IRB before submission to journals for publication.

As a researcher you are required to have current and valid certification on protection human research subjects that can be obtained by taking a short online course at the US NIH site or the Saudi NCBE site followed by a multiple choice test. Please submit your current and valid certificate for our records. Failure to submit this certificate shall a reason for suspension of your research project.

Approved

If you have any further questions feel free to contact me.

Sincerely yours,

The transfer of the control of the c

Omar Kasule

Prof. Omar H. Kasule Chairman, Institutional Review Board (IRB) King Fahad Medical City, Riyadh, KSA

Tel: + 966 1 288 9999 Ext. 26913 E-mail: okasule@kfmc.med.sa

Appendix 9: Institutional Review Board of collage medicine at HMG



HAP-01-R-082

Al Habib Research Center

Study Number	RC200705				
Study Title	Cross-cultural Adaptation and Validation of the Arabic Version of Self- Care of Coronary Heart Disease Inventory				
IRB Approval Date	17/07/20				
IRB Review Type	□ Exempt Review	■ Expedited Review □Full-Board			
Type of the Study	□ Retrospective	■Prospective □Observational □Case Study			
Consent Form	 Require 	Do Not Require			
Interventions	□ Yes	■ No			

Dear Mrs. Ahad Aljaber,

This is to clarify that IRB committee has reviewed and APPROVED the study titled above.

The approval of the research study is valid for one year from the above approval date.

On behalf of the committee, best of luck as you move forward with your research.

Terms of approval:

- Approval is only valid while you hold a position at HMG.
- No changes may be made in the procedures nor any study materials until such modifications have been submitted to the IRB for review and have been given approval.
- The principal investigator is responsible for the storage and retention of original data relating to a project for a period of three years.
- · After completion of the study, a final report must be send to the IRB.
- Any amendments to the approved protocol or any element of the submitted documents should NOT be undertaken without prior re-submission to, and approval of the IRB for prior approval.
- The PI and Investigators are expected to submit a final report at the end of the study.
- The PI and Investigators must provide to IRB a conclusion abstract and the manuscript before publication.

Dr. Abbas Al Mutair Head of the IRB

Dr. Awad Al Omari Associate VP – Academic Affairs

Appendix 10: Institutional Review Board of collage medicine at Sultan Bin

Abdulaziz Humanitarian City



Date: 05/07/2020 IRB No.: 24-2020-IRB

To: Ms. Ahad Al Jaber

PI: "Cross-cultural Adaptation and Validation of the Arabic Version of Self-Care of Coronary

Heart Disease Inventor, King Saud University

E-mail: aaljaber@sbahc.org.sa / Ahad.357@hotmail.com

Subject: Approval for Research No. 20/SBAHC/MSc/2020

Study Title: "Cross-cultural Adaptation and Validation of the Arabic Version of Self-Care

of Coronary Heart Disease Inventory"

Study Code: 20/SBAHC/MSc/2020

Date of Approval: 02/07/2020 Date of Expiry: 02/05/2021

Board approval: All members except the absentee Ph. Manar Sweiss.

Dear Ms. Al Jaber,

Your Project has been approved and you have the permission to conduct this study following your submitted documents as follow:

- 1. Curriculum Vitae for the PI researcher
- 2. Letter from researcher's affiliating Organization/College
- 3. Letter from the researcher requesting SBAHC participation in the clinical study
- 4. Letter from the researcher's supervisor requesting supervision in the clinical study
- 5. Research proposal according to SBAHC IRB Guidelines
- 6. SBAHC Informed Consent Template
- 7. Research Obligatory Agreement, Available upon the completion of the other requirements

You are required to obey by the rules and regulations of the Government of Saudi Arabia, the SBAHC IRB Policies and procedures and the ICH-GCP guidelines. You have to note that this approval mandate responding to IRB's periodic request and surveillance result. Drawing your attention to the following:

- Amendment of the project with the required modification to providing Periodical report for this
 project specially when study extension is required or expiry before study completion
- All unforeseen events that might affect continued ethical acceptability of the project should be reported to the IRB as soon as possible
- Any serious unexpected adverse events should be reported within 48 hours (2 days)
- Personal identifying data should only be collected when necessary for research.
- Secondary disclosure of personal identifiable data is not allowed.
- Monitoring: projects may be subject to an audit by the IRB at any time.

Page 1 of 2

- The PI is responsible for the storage and retention of original data pertaining to the project for a minimum period of five (5) years.
- Data should be stored securely so that a few authorized users are permitted access to the database.

The IRB registered with the IRB KACST Registration No. H-01-R-090. It is authorized to conduct the ethical review of clinic studies and operates in accordance with ICH-GCP Guidelines and all applicable national/local and institutional regulations and guidelines which govern Good Clinical Practices.

For Future Correspondence, please quote the project number and project title above and you are requested to keep IRB informed about your study progress and submit project progress report every six (6) months. A final report should be provided upon completion of the study.

Wish you a success in your research project.

Yours sincerely,

Prof. Khalid Al-Rubeaan

Chairman-IRB

Sultan Bin Abdulaziz Humanitarian City

Appendix 11: Patient Consent Form

نموذج موافقة على الاشتراك في البحث العلمي

أسم الباحثة عهد الجابر

عنوان البحث \ التكبيف الثقافي والتحقق من موثوقية النسخة العربية لمخزون الرعاية الذاتية لأمراض القلب التاجية.

عزيزي المراجع، أنت مدعو للمشاركة في بحث علمي يهدف إلى ترجمة حصيلة الرعاية الذاتية المتعلقة بأمراض القلب التاجية إلى اللغة العربية.

طريقة البحث: في حال مو افقتك على المشاركة بالبحث ستقوم بتعبئة الاستبيان الذي يحتوي على أسئلة متعلقة بأمراض القلب التاجية.

أهمية البحث:

من خلال إجابتك على هذا الاستبيان ستمكننا من معرفة مدى مصداقية هذا المقياس في تحديد مستوى قدرة والتزام المرضى المصابين بأمراض القلب التاجية على قيامهم بالرعاية الذاتية. وبالتالي سيساعد ذلك المختصين والباحثين في المجال الطبي على فهم وتقييم أفضل وأكثر دقة للمرضى.

المشاركة في هذه الدراسة البحثية ستكون تطوعية، ويحق للمتطوع رفض المشاركة بدون فرض عقوبات ولا يؤثر ذلك على الخطة العلاجية.

جميع المعلومات في هذا البحث سيتم التعامل معها بسرية تامة.

لقد قرأت وفهمت مضمون النموذج، وتمت الإجابة على جميع أسئلتي، وبناء على ذلك فإني أوافق على المشاركة تطوعاً في هذا البحث ولي الحق بالانسحاب من المشاركة في أي وقت.

التوقيع:	لاسم:

ملخص الرسالة

المقدمة: يعتبر قياس الرعاية الذاتية من المقاييس المهمة في العيادة والأبحاث. وذلك لان، الرعاية الذاتية هي الجزء الأساسي في إدارة المرضى يومياً والمساعدة في إعاقة تطور مرض شرايين القلب التاجية. إن قائمة الرعاية الذاتية لأمراض القلب التاجية (SC-CHDI) هو مقياس نتائج أبلغ عنها المريض مخصصة للمرضى المصابين بمرض شرايين القلب التاجية. حيث أنه لا توجد نسخة عربية مصدقة متاحة من هذا الاستبيان.

الأهداف: إن الغرض من هذا الدراسة هو ترجمة استبيان مخزون الرعاية الذاتية لأمراض القلب التاجية وتكييفه الى اللغة العربية. والتحقق من موثوقية وصلاحية هذه النسخة على المرضى الذين يعانون من أمراض القلب التاجية والناطقين بالعربية.

الطريقة: في هذه الدراسة تم إتباع إرشادات (Sousa) في الترجمة، ومن ثم تم اختبار الخصائص السيكومترية للنسخة العربية من استبيان مخزون الرعاية الذاتية لأمراض القلب التاجية على عينة ١٨١ مريضاً بأمراض القلب التاجية. ٢٦ منهم أظهروا وجود أعراض مستقرة في تقييم موثوقية اختبار إعادة الاختبار. جمعت العيينة من العيادات الخارجية/ قسم القلب من ثلاث مستشفيات في الرياض. في تحليل الموثوقية، تم التحقق من الاتساق الداخلي بالإضافة إلى موثوقية الاختبار وإعادة الاختبار. ولتحديد الصلاحية المتقاربة تم استخدام ارتباط سبيرمان بين النسخ العربية لكل من استبيان مخزون الرعاية الذاتية لأمراض القلب التاجية ومقياس مستوى الكفاءة الذاتية لمرضى القلب و استبيان كفاءة النفس في إدارة المرض المزمن (مقياس ٢ بند).

النتائج: كان مؤشر صحة المحتوى للأقسام الفرعية الثلاثة مقبولًا. أشار المشاركون في هذه الدراسة أن استبيان مخزون الرعاية الذاتية لأمراض القلب التاجية كان واضحاً ومفهوماً. الاتساق الداخلي تراوحت قيمة المعامل كرونباخ ألفا من 0.00, إلى 0.00, وكانت نتيجة موثوقية اختبار إعادة الاختبار (معامل الارتباط بين الطبقات) مقبول الى جيد للأقسام الفرعية الثلاثة كالتالي القسم الأول الاستقرار عند 0.00, عند (فاصل الثقة 0.00, من 0.00, إلى 0.00, والقسم الثالث الثقة عند 0.00, عند (فاصل الثقة من 0.00, إلى 0.00, إلى المتبيان مخزون الرعاية الذاتية لأمراض القلب التاجية باللغة العربية مع الثلاث اقسام الفرعية من مقياس مستوى الكفاءة الذاتية لمرضى القلب وكانت قيم الارتباط (0.00

p=0.00 (26; p=0.00) في حين ان قسم الاستقرار كانت قيم الارتباط مع القسمين p=0.00 (26; p=0.00) فرعية من مقياس مستوى الكفاءة الذاتية لمرضى القلب وكانت قيم الارتباط كالتالي (26; p=0.00). بالإضافة الى ذلك ان قسم الثقة من استبيان مخزون الرعاية الذاتية لأمراض القلب التاجية مع قسم واحد بالإضافة الى المجموع الكلي من مقياس مستوى الكفاءة الذاتية لمرضى القلب وكانت قيمة الارتباط (p=0.000) بينما كانت قيمة الارتباط (p=0.000) بينما كانت قيمة الارتباط (p=0.000) مع استبيان كفاءة النفس في إدارة المرض المزمن (مقياس p=0.000).

الخلاصة: إن النسخة العربية من مخزون الرعاية الذاتية لأمراض القلب التاجية هو أداة مفهومة وصالحة وموثوقة لتحديد احتياجات الرعاية الذاتية لمرضى أمراض القلب التاجية في المملكة العربية السعودية.

الكلمة الدلالية: مرض القلب التاجي، الرعاية الذاتية، أداة، الخصائص السيكومترية.



كلية العلوم الطبية التطبيقية

قسم علوم التأهيل الصحي

التكييف الثقافي والتحقق من موثوقية النسخة العربية لمخزون التكييف الرعاية الذاتية لأمراض القلب التاجية

إعداد: عهد محمد الجابر

بكالوريوس في العلاج الطبيعي

١٠٢2ه / ٩١٤٤٣