การทดสอบสมบัติการวัดเชิงจิตวิทยาของแบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตาฉบับภาษาไทย

นายวิวัฒน์ ตั้งสถิตเกียรติ์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาเภสัชศาสตรมหาบัณฑิต
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ลิขสิทธิ์ของจุฬาลงกรณ์มหาวิทยาลัย

ศูนย์วิทยทรัพยากร
จุฬาลงกรณ์มหาวิทยาลัย

TESTING THE PSYCHOMETRIC PROPERTIES OF THE THAI VERSION OF THE MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE

Mr. Wiwat Tangsatitkiat

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science in Pharmacy Program in Clinical Pharmacy
Department of Pharmacy Practice
Faculty of Pharmaceutical Sciences
Chulalongkorn University
Academic Year 2009

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Thesis Title	TESTING THE PSYCHOMETRIC PROPERTIES OF THE THAI VERSION OF THE MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE
By	Mr. Wiwat Tangsatitkiat
Field of Study	Clinical Pharmacy
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วิวัฒน์ ตั้งสถิตเกียรติ์ : การทดสอบสมบัติการวัดเชิงจิตวิทยาของแบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตาฉบับภาษาไทย. (TESTING THE PSYCHOMETRIC PROPERTIES OF THE THAI VERSION OF THE MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE) อ.ที่ปรึกษาวิทยานิพนธ์หลัก : ผศ. ดร.พรรณทิพา ศักดิ์ทอง, 120 หน้า.

วัตถุประสงค์ของการศึกษานี้เพื่อทดสอบสมบัติการวัดเชิงจิตวิทยาของแบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตา (Minnesota Living with Heart Failure Questionnaire หรือ MLHFQ) ฉบับภาษาไทย กลุ่มตัวอย่างคือผู้ป่วยนอกโรคหัวใจล้มเหลวแบบเรื้อรังที่มารับการรักษาที่ห้องตรวจโรคหัวใจและอายุรกรรมทั่วไป โรงพยาบาลพระมงกุฎเกล้า ผู้ป่วยแต่ละรายจะได้รับการทดสอบด้วยแบบสอบถาม MLHFQ และแบบสำรวจสุขภาพและความผาสุก (Short Form-36 Health Survey หรือ SF-36) รุ่นที่ 1 ฉบับภาษาไทย จำนวน 2 ครั้ง ณ เวลาเริ่มต้นการศึกษาและเมื่อนัดมาพบแพทย์ครั้งต่อมา ความเป็นไปได้ในทางปฏิบัติประเมินจากเวลาที่ใช้ในการตอบแบบสอบถาม ผลเข้าใกล้ค่าต่ำสุดและสูงสุดของคะแนนแบบสอบถาม ความเที่ยงของแบบสอบถามประเมินจากค่าความเที่ยงเชิงความสอดคล้องภายในที่แสดงด้วยค่าสัมประสิทธิ์แอลฟาและความเที่ยงจากการทดสอบซ้ำด้วยวิธีการสัมภาษณ์ทางโทรศัพท์ ซึ่งแสดงด้วยค่าสัมประสิทธิ์สหสัมพันธ์ภายในชั้น ความตรงทางโครงสร้างของแบบสอบถามประเมินจากความตรงเชิงลู่เข้าและความตรงเชิงการจำแนกโดยอาศัยการพิจารณาสหสัมพันธ์ระหว่างมิติของแบบสอบถาม MLHFQ และ SF-36 การวิเคราะห์องค์ประกอบเชิงสำรวจโดยใช้วิธีการสกัดองค์ประกอบด้วยวิธีแกนหลักและหมุนแกนแบบมุมแหลมชนิดไดเรกต์ออบลิมิน รวมทั้งความตรงเทียบกับกลุ่มที่รู้ซึ่งทำการประเมินจากความสามารถในการจำแนกคะแนนของกลุ่มผู้ป่วยโรคหัวใจล้มเหลวที่มีการจัดประเภทตามเกณฑ์ของ New York Heart Association (NYHA) แตกต่างกัน ความไวต่อการเปลี่ยนแปลงของแบบสอบถามจะประเมินจากขนาดผลที่ได้ จากการศึกษานี้พบว่าแบบสอบถาม MLHFQ ใช้เวลาสัมภาษณ์โดยเฉลี่ยประมาณ 5 นาที ผลเข้าใกล้ค่าต่ำสุดมีค่าสูง (ร้อยละ 11.1 ถึง 27.2) แต่ไม่พบผลเข้าใกล้ค่าสูงสุด ค่าสัมประสิทธิ์แอลฟาและค่าสัมประสิทธิ์สหสัมพันธ์ภายในชั้นของแบบสอบถาม MLHFQ มีค่าอยู่ในช่วง 0.86-0.93 และ 0.61-0.77 ตามลำดับ คะแนนของแบบสอบถาม MLHFQ มีสหสัมพันธ์ปานกลางถึงสูงกับคะแนนของแบบสอบถาม SF-36 ตามสมมติฐานที่ตั้งไว้ (สหสัมพันธ์อันดับของสเปียร์แมน; rho = -0.49 ถึง -0.56, $p < 0.05$) คำถาม 21 ข้อของแบบสอบถาม MLHFQ สามารถจำแนกได้เป็น 4 องค์ประกอบ ได้แก่ ด้านกายภาพ ด้านอารมณ์ ด้านการรักษา และด้านอาการแสดง นอกจากนี้คะแนนของแบบสอบถาม MLHFQ สามารถจำแนกผู้ป่วยที่มีการจัดประเภทตามเกณฑ์ของ NYHA ประเภทที่ 1 2 และ 3 ได้อย่างมีนัยสำคัญทางสถิติ (การทดสอบครูสแคล-วอลลิส; $p < 0.001$) ขนาดผลที่ได้ส่วนใหญ่ของแบบสอบถาม MLHFQ อยู่ในระดับปานกลาง โดยสรุปจากผลการศึกษานี้ แบบสอบถาม MLHFQ ฉบับภาษาไทยมีสมบัติการวัดเชิงจิตวิทยาเบื้องต้นที่ดีและสอดคล้องกับแบบสอบถามต้นฉบับเดิม

ภาควิชา เภสัชกรรมปฏิบัติ ลายมือชื่อนิสิต วิวัฒน์ ตั้งสถิตเกียรติ์

สาขาวิชา เภสัชกรรมคลินิก ลายมือชื่ออ.ที่ปรึกษาวิทยานิพนธ์หลัก

ปีการศึกษา 2552

5076590933 : MAJOR CLINICAL PHARMACY

KEYWORDS : HEART FAILURE / HEALTH-RELATED QUALITY OF LIFE / PATIENT-REPORTED OUTCOMES / PSYCHOMETRIC PROPERTIES

WIWAT TANGSATITKIAT : TESTING THE PSYCHOMETRIC PROPERTIES OF THE THAI VERSION OF THE MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE. THESIS ADVISOR : ASST. PROF. PHANTIPA SAKTHONG, Ph.D., 120 pp.

The purpose of this study was to test the psychometric properties of the Thai version of the Minnesota Living with Heart Failure Questionnaire (MLHFQ). The subjects of the psychometric properties testing were 180 outpatients with chronic heart failure from cardiology and general medicine clinic at Phramongkutklao hospital. The Thai version of the MLHFQ and the Short Form-36 Health Survey (SF-36) version 1 were administered at baseline and next follow-up visit. Practicality was assessed with average time of administration and the floor and the ceiling effects. Reliability was evaluated using Cronbach's alpha coefficients for internal consistency and intraclass correlation coefficients (ICCs) for test retest reliability assessment with telephone interview. Construct validity was supported with convergent and discriminant validity using correlation among the MLHFQ and the SF-36 scores, exploratory factor analysis using principal axis factoring and oblique rotation with direct oblimin, and known-groups validity that referred to ability to discriminate subjects among different New York Heart Association (NYHA) classes. Responsiveness was assessed with effect size. It was found that average time of administration approximately was five minutes and there were high floor (11.1% to 27.2%) and no ceiling effect on the MLHFQ scores. Cronbach's alpha coefficients and ICCs of the MLHFQ were 0.86 to 0.93 and 0.61 to 0.77, respectively. There were significantly moderate or high correlations among the MLHFQ scores and the assumed corresponding SF-36 subscales and component summary scores (Spearman rank order correlation; rho = -0.49 to -0.56, $p < 0.05$). Twenty one items of the Thai version of the MLHFQ loaded on four factors such as physical, emotional, treatment, and symptoms dimensions. In addition, the MLHFQ scores discriminated among NYHA class I, II, and III (Kruskal-Wallis test, $p < 0.001$). Moreover, most observed effect sizes on the MLHFQ were moderate. These results suggest that the MLHFQ (Thai version) indicates acceptable preliminary psychometric properties and agrees with the original version.

Department : Pharmacy Practice Student's Signature Wiwat Tangsatitkiat

Field of Study : Clinical Pharmacy Thesis Advisor's Signature Phantipa Sakthong

Academic Year : 2009

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LIST OF ABBREVIATIONS

ACEIs	=	Angiotensin-converting enzyme inhibitors
ARBs	=	Angiotensin II receptor blockers
BNP	=	Brain natriuretic peptide
BP	=	Bodily pain subscale
CVI	=	Content validity index
ES	=	Effect size
GH	=	General health subscale
HF	=	Heart failure
HRQoL	=	Health-related quality of life
ICCs	=	Intraclass correlation coefficients
KMOMSA	=	Kaiser-Meyer-Olkin Measure of Sampling Adequacy
LVEF	=	Left ventricular ejection fraction
MCS	=	Mental component summary
MH	=	Mental health subscale
MLHFQ	=	Minnesota Living with Heart Failure Questionnaire
MTM	=	Medication Therapy Management
MTMM	=	Multitrait multimethod matrix
NT-proBNP	=	N-terminal prohormone brain natriuretic peptide
NYHA	=	New York Heart Association
PCS	=	Physical component summary
PF	=	Physical functioning subscale
QoL	=	Quality of life
RE	=	Role emotional subscale
RP	=	Role physical subscale
SF	=	Social functioning subscale
SF-12	=	Short Form-12 Health Survey
SF-36	=	Short Form-36 Health Survey
SRM	=	Standardized response mean
VT	=	Vitality subscale

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CHAPTER I

INTRODUCTION

1.1 Rationale and Background

Heart failure (HF) is one of the health care problems worldwide.[1] In the United States, approximately five million patients have HF, and more than 550,000 people are diagnosed with HF each year. The incidence of HF approaches 10 per 1,000 population after age 65.[2] Studies carried out in the United Kingdom have observed that the incidence and prevalence of HF increase progressively with age.[3] The number of hospitalizations with HF is also increasing every year.[4] Moreover, HF has a high mortality rate with a 12-month rate of approximately 15% and a 5-year rate of 50%.[5] HF is one of the highest health service costs for a single condition.[6] In the United States of America, estimated direct and indirect costs of HF were $27.9 billions in 2004.[7] Prevalence of the Thai patients diagnosed with HF is 0.62%[8] and the number of the Thai patients with cardiovascular diseases has been increasing in the past decades.[9] These data indicate that HF is an important health problem in Thailand at this time.

Traditional goals of HF treatments are to relieve symptoms and to improve the prognosis. Another major goal of health care is to maximize function in everyday life and to achieve the highest level of health-related quality of life (HRQoL).[10] Signs and symptoms of HF such as dyspnea, fatigue, edema may be associated with limitation in the patients' daily activities and psychological that worsen their HRQoL.[11,12] The lower HRQoL may affect the HF patients' morbifity and mortality.[13] Several studies have revealed that treatments or interventions with traditional clinical indicators such as New York Heart Association (NYHA) functional classification, left ventricular ejection fraction (LVEF), serum natriuretic peptide, six-minute walk distance may not reflect individual outcomes of treatment or intervention.[14,15] Hence, physicians and other health care practitioners turn to be more interested in HRQoL assessment.

HRQoL is an indicator for assessment of health status obtained from patients directly. It is similar to the concept of holistic care that focuses on not only the disease, but also the whole patient life. HRQoL assessments are used for patient cares such as psychological or functional problems screening, therapeutic monitoring, tools for communication between physicians and patients, assessment of quality in pharmacy services or pharmaceutical cares, and etc. Pharmacists can use HRQoL data for assessment of the drug efficacy in clinical trials or pharmaceutical cares, decision making about drug therapies and suggestion with physicians, consideration of drugs formulary/policies in hospital, and individual therapeutic drug monitoring. For example, adverse drug reactions may have an impact on lower patients' HRQoL resulting in medication nonadherence and drug inefficacy later. Thus, pharmacists can educate and counsel about possible adverse drug reactions to patients for prevention and minimization of these side effects influencing their HRQoL.[16-18] Presently, HRQoL is an outcome measure for patients with HF and is described in several concepts including physical, mental, and social dimensions.[19-21] Furthermore, HRQoL assessments of those with HF are used for prediction of hospital readmission and mortality, intervention developments, and evaluation of the effect of pharmaceutical cares on HRQoL of those with HF.[22-25]

In general, questionnaire is an instrument that is used for assessment of HRQoL in clinical trial regarding HF. It can be divided into two types: generic and disease-specific instruments. The most used generic instrument for evaluation of HRQoL in HF clinical trial is the Short Form-36 Health Survey (SF-36).[26] Two studies conducted in Thailand have found that SF-36 has a good reliability and validity in Thai populations[27,28] and it was used for HRQoL assessment in several diseases. In addition, The SF-36 and the Short Form-12 Health Survey (SF-12) are used for outcome measure in evaluation of pharmaceutical care in patients with HF in several countries including Thailand.[24,29] Although this type of instruement is broadly applicable and may detect unanticipated effects, it may not be responsive to changes in health and not be relevant for specific populations.[30] Regarding the disease-specific instruments, there are many questionnaires used for evaluation of HRQoL in HF clinical trials, such as Minnesota Living with Heart Failure Questionnaire,[31,32] Chronic Heart Failure Questionnaire,[33]

Kansas City Cardiomyopathy Questionnaire,[34] and etc. The MLHFQ is the most used instruments for assessment of HRQoL in HF.[26] Advantages of this instrument type are more relevant for specific populations and more responsive to changes in health, but it can not compare across populations and is less likely to detect unanticipated effects.[26] However, there is no study regarding use of HF-specific instruments in Thailand officially and systematically. The MLHFQ may be a disease-specific instrument used for HRQoL assessment in this population. There are many supportive reasons regarding application of this questionnaire. First, it is the most used disease-specific instruments in clinical trials of HF treatments and studies about the effects of pharmaceutical cares in patients with HF. Second, several studies have found that it has a good psychometric properties in HRQoL measurement.[3,35-41] It has Cronbach's alpha coefficients of the MLHFQ dimensions and global score are higher than 0.7 and correlations with other HRQoL measures were acceptable. In addition, it can classify the groups of patients with HF according to NYHA and is responsive to health status changes. Third, the contents used for this questionnaire are easy to understand and it was translated in several languages such as Dutch, Spanish, Cantonese, and etc. Finally, it was used to assess the impact of symptoms in relation to HF such as edema, fatigue, and shortness of breath, and the side effects of HF treatments.

Although application of developed questionnaire in other languages in Thailand is an approach that is very convenient and is cost saving in development of the new instrument, researchers must consider regarding translation and cross-cultural adaptation between original and target languages for comparison of data from translated instrument in each study.[27] From pilot study of MLHFQ in Thai version, translations are conducted following linguistic validation process of MAPI Research Trust recommendation[42] and are adapted according to appropriateness in this study. It is divided into three processes: forward translation, backward translation, and pretesting with cognitive interviews (probing) in 25 Thai outpatients with HF. The study has found that this questionnaire can be translated to Thai easily. In addition, there are three items such as item 1 (swelling in your ankles and legs), item 9 (recreational pastimes, sports, or hobbies difficult), and item 18 (feeling loss of self control) that have comprehension

problems. Problems found in this study are used for the contents improvement of the Thai version of the MLHFQ later.[43]

As above-mentioned, this study requires testing the psychometric properties of the Thai version of the MLHFQ in next process for using this instrument in HRQoL assessment of Thai patients with HF and comparisons of obtained data with foreign countries in the future studies.

1.2 Objective

1.2.1 General Objective

The general objective of this study was to test the psychometric properties of the Thai version of the MLHFQ.

1.2.2 Specific Objectives

The specific objectives of this study were to evaluate the practicality (administration time and floor and ceiling effects), reliability (internal consistency and test-retest reliability), validity (content and construct validity), and responsiveness (effect size and standardized response mean) of the Thai version of the MLHFQ.

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1.3 Conceptual Framework

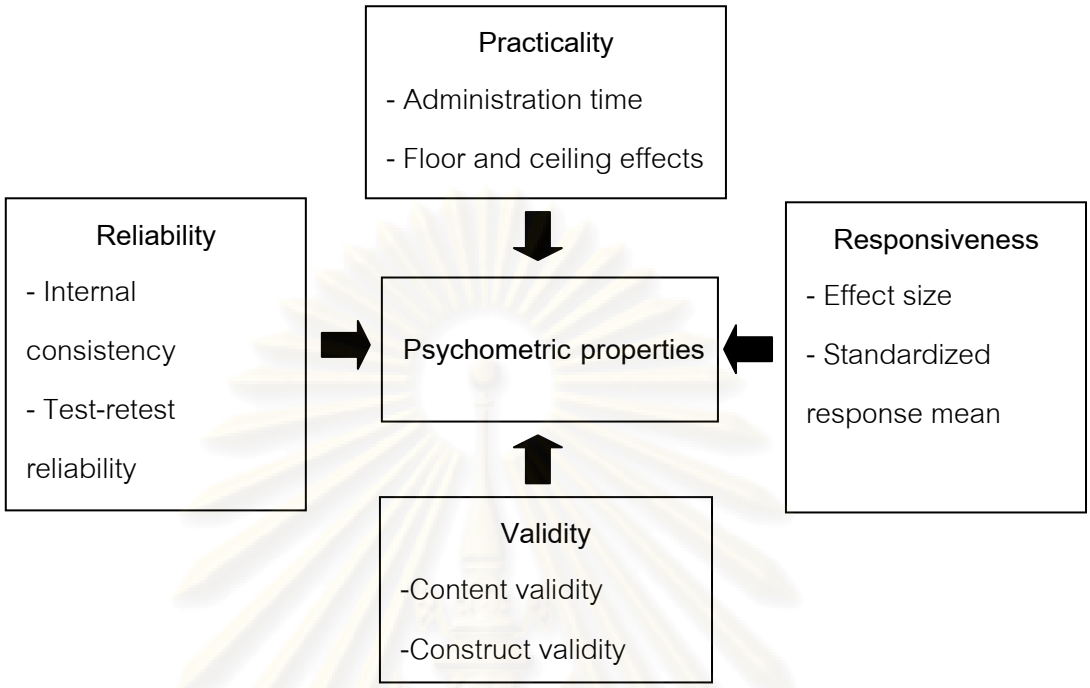

Figure 1 The conceptual framework of this study

1.4 Operational Definitions

Psychometric properties refer to properties of the Thai version of the MLHFQ that shows a good psychometric measure. It consists of:

1) Practicality refers to the feasibility of the Thai version of the MLHFQ that was applicable in practice. This study analyses in aspects of the administration time and the floor and ceiling effects.

2) Reliability refers to the ability of the Thai version of the MLHFQ that is able to give the constant scores when it used to measure in the same stable subjects. This study analyses in issues of test-retest reliability and internal consistency.

3) Validity refers to the ability of the Thai version of the MLHFQ that is able to measure regarding HRQoL in patients with HF. This study analyses in points of content validity, construct validity (convergent and discriminant validity and exploratory factor analysis), and known-groups validity.

4) Responsiveness refers to the ability of the Thai version of the MLHFQ that assesses the health status change in over time. This study shows in responsiveness indices: effect size (ES) and standardized response mean (SRM).

1.5 Hypotheses

1.5.1 Convergent Validity

1.5.1.1 The MLHFQ physical score has moderate to the high correlation with the SF-36 physical functioning, role physical and physical component summary scores.

1.5.1.2 The MLHFQ emotional score has moderate to the high correlation with the SF-36 role emotional, mental health, and mental component summary scores.

1.5.2 Discriminant Validity

1.5.2.1 The MLHFQ physical score has low correlation with the SF-36 role emotional, mental health, and mental component summary scores.

1.5.2.2 The MLHFQ emotional score has low correlation with the SF-36 physical functioning, role physical, and physical component summary scores.

1.5.3 Known-Groups Validity

The MLHFQ scores in the patients with higher level of NYHA functional classes are greater than the patients with lower level of NYHA functional classes.

1.5.4 Exploratory Factor Analysis

The items in the Thai version of the MLHFQ loaded on factor similar to the hypothesized dimensions of the original version.

1.5.5 Test-Retest Reliability

1.5.5.1 There were no differences of the MLHFQ scores in the patients with no changes about their health perceptions within two weeks between the first and the retest assessments.

1.5.5.2 The MLHFQ scores in the patients with no change about their health perceptions have high correlation between the first and the retest assessment.

1.5.6 Responsiveness

1.5.6.1 The MLHFQ scores in the patients with better feeling about their health perception at the second assessment are lower than baseline.

1.5.6.2 The MLHFQ scores in the patients with worse feeling about their health perception at the second assessment are higher than baseline.

1.6 Expected Benefits and Applications

Expected advantages were to use the Thai version of the MLHFQ tested the psychometric properties from this study in HRQoL assessments of pharmaceutical cares and other interventions in Thai patients with chronic HF.

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CHAPTER II

LITERATURE REVIEW

2.1 Heart Failure

2.1.1 Epidemiology[2,44]

HF is a major and growing public health problem in the United States. Approximately 5 million patients are diagnosed with HF for the first time each year. The European Society of Cardiology represents the European countries with a population of over 900 million, suggesting that there are at least 10 million patients with HF in those countries. HF is primarily a condition of the elderly, and thus the widely recognized “aging of the population” also contributes to the increasing incidence of HF. The incidence of HF approaches 10 per 1000 population after age 65 and approximately 80% of patients hospitalized with HF are more than 65 years old. Half of patients carrying a diagnosis of HF will die within 4 years, and in patients with severe HF > 50% will die within 1 year. In 2005, the total direct and indirect cost of HF in the United States will be equal to $27.9 billion. In the United States, approximately $2.9 billion annually is spent on drugs for the treatment of HF.

2.1.2 Definition of Heart Failure[2,44]

As for American College of Cardiology/American Heart Association guideline 2005, HF is a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood. The cardinal manifestations of HF are dyspnea and fatigue, which may limit exercise tolerance, and fluid retention, which may lead to pulmonary congestion and peripheral edema. Both abnormalities can impair the functional capacity and quality of life (QoL) of affected individuals. The majority of patients with HF have symptoms due to an impairment of left ventricular myocardial function. Coronary artery disease, hypertension, and dilated cardiomyopathy are the causes of HF in a substantial

proportion of patients in the Western world. There is no single diagnostic test for HF because it is largely a clinical diagnosis that is based on a careful history and physical examination.

As for European Society of Cardiology guideline 2005, HF is a syndrome in which all patients should have the following features: symptoms of HF, typically breathlessness or fatigue, either at rest or during exertion, or ankle swelling and objective evidence of cardiac dysfunction at rest. Some cases may be considered from response to the treatment directed towards HF.

2.1.3 The Terms of Systolic and Diastolic Heart Failure[44]

Systolic HF is the chronic syndrome manifested by fatigue, dyspnea, and systemic and pulmonary venous congestion resulting from reduced ventricular function and decreased LVEF, most often manifests with progressively worsening symptoms and premature death. Increasingly, prevalence is due to a combination of improved survival of coronary artery disease patients, increased incidence of diabetes and other etiologic conditions, and effective HF treatments that prolong survival. Primary care physicians typically manage most outpatients with mild-moderate chronic HF.[45]

Diastolic HF is a complex syndrome characterized by dyspnea and fatigue secondary to structural and functional changes in the heart resulting from a variety of conditions that occur in conjunction with neurohormonal and cytokine activation. Diastolic dysfunction is caused by an abnormality of the mechanical properties (distensibility, filling, and relaxation) of the left ventricle. Patients with diastolic dysfunction may experience HF symptoms, be asymptomatic, or have a normal or even low LVEF when also associated with systolic impairment. Diastolic dysfunction is caused by factors that are intrinsic to the myocardium, such as those affecting the cardiomyocytes, extracellular matrix, or vascular system.[46]

Characteristics of patients with diastolic HF and those with systolic HF are compared in Table 1.

Table 1 Characteristics of patients with diastolic heart failure and patients with systolic heart failure[47]

Characteristics	Diastolic HF	Systolic HF
Age	Frequently elderly	All ages, typically 50-70 years
Sex	Frequently female	More often male
LVEF	Preserved or normal, approximately 40% or higher	Depressed, approximately 40% or lower
Left ventricular cavity size	Usually normal, often with concentric left ventricular hypertrophy	Usually dilated
Left ventricular hypertrophy on electrocardiography	Usually present	Sometimes present
Chest radiography	Congestion with or without cardiomagaly	Congestion and cardiomagaly
Gallop rhythm present	Fourth heart sound	Third heart sound
Coexisting conditions		
• Hypertension	+++	++
• Diabetes mellitus	+++	++
• Previous myocardial infarction	+	+++
• Obesity	+++	+
• Chronic lung disease	++	0
• Sleep apnea	++	++
• Long term dialysis	++	0
• Atrial fibrillation	+	+

+ = “occasionally associated with”, ++ = often associated with, +++ = usually associated with, and 0 = not associated with.

2.1.4 Pathophysiology of Heart Failure[2]

Left ventricular dysfunction begins with some injury to, or stress on, the myocardium and is generally a progressive process, even in the absence of a new identifiable insult to the heart. The principal manifestation of such progression is a

change in the geometry and structure of the left ventricle, such that the chamber dilates and/or hypertrophies and becomes more spherical, a process referred to as cardiac remodeling. This change in chamber size and structure not only increases the hemodynamic stresses on the walls of the failing heart and depresses its mechanical performance but may also increase regurgitant flow through the mitral valve. These effects, in turn, serve to sustain and exacerbate the remodeling process. Cardiac remodeling generally precedes the development of symptoms (occasionally by months or even years), continues after the appearance of symptoms, and contributes substantially to worsening of symptoms despite treatment. Progression of coronary artery disease, diabetes mellitus, hypertension, or the onset of atrial fibrillation may also contribute to the progression of HF.

The activation of endogenous neurohormonal systems plays an important role in cardiac remodeling and thereby in the progression of HF. Patients with HF have elevated circulating or tissue levels of norepinephrine, angiotensin II, aldosterone, endothelin, vasopressin, and cytokines, which can act (alone or in concert) to adversely affect the structure and function of the heart. Neurohormonal factors not only increase the hemodynamic stresses on the ventricle by causing sodium retention and peripheral vasoconstriction but may also exert direct toxic effects on cardiac cells and stimulate myocardial fibrosis, which can further alter the architecture and impair the performance of the failing heart. Neurohormonal activation also has direct deleterious effects on the myocytes and interstitium, altering the performance and phenotype of these cells.

2.1.5 Methods for the Diagnosis of Heart Failure[44]

2.1.5.1 Symptoms and Signs of Heart Failure

Symptoms and signs are important as they alert the observer to the possibility that HF exists. Breathlessness, ankle swelling, and fatigue are the characteristic symptoms and signs of HF but may be difficult to interpret, particularly in elderly patients, in obese, and in women.

2.1.5.2 Severity of Heart Failure

Symptoms may be used to classify the severity of HF and should be used to monitor the effects of therapy. NYHA classification is in widespread to use that is shown in Table 2.

Table 2 New York Heart Association functional classification[44]

Class I	No limitation: ordinary physical exercise does not cause undue fatigue, dyspnea, or palpitations
Class II	Slight limitation of physical activity: comfortable at rest but ordinary activity results in fatigue, dyspnea, or palpitations
Class III	Marked limitation of physical activity: comfortable at rest but less than ordinary activity results in symptoms
Class IV	Unable to carry out any physical activity without discomfort: symptoms of HF are present even at rest with increased discomfort with any physical activity

2.1.5.3 Electrocardiogram

Electrocardiographic changes are common in patients suspected of having HF whether or not the diagnosis proves to be correct. An abnormal electrocardiogram, therefore, has little predictive value for the presence of HF.

2.1.5.4 The Chest X-ray

Chest X-ray should be part of the initial diagnostic work-up in HF. It is useful to detect cardiomegaly and pulmonary congestion. However, it has only predictive value in the context of typical signs and symptoms and in abnormal electrocardiogram.

2.1.5.5 Hematology and Biochemistry

Routine diagnostic evaluation of patients with HF includes: complete blood count (hemoglobin, leukocytes, and platelets), serum electrolytes, serum creatinine, serum glucose, serum hepatic enzymes, and urinalysis. Additional tests to evaluate thyroid function should be considered according to clinical findings.

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2.1.5.6 Natriuretic Peptides

Plasma concentrations of certain natriuretic peptides or their precursors, especially brain natriuretic peptide (BNP) and N-terminal prohormone brain natriuretic peptide (NT-proBNP), are helpful in the diagnosis of HF. A low-normal concentration in an untreated patient makes HF unlikely as the cause of symptoms. BNP and NT-proBNP have considerable prognostic potential, although evaluation of their role in treatment monitoring remains to be determined. In clinical practice, the place of BNP and NT-proBNP is as rule out tests to exclude significant cardiac disease. Particularly in primary care but also in certain aspects of secondary care (e.g. the emergency room and clinics.) The cost-effectiveness of the test suggests that a normal result should obviate the need for further cardiological tests such as in the first instance echocardiography as well as more expensive investigations.

2.1.5.7 Echocardiography

Echocardiography is the preferred method for the documentation of cardiac dysfunction at rest. The most important measurement of ventricular function is the LVEF for distinguishing patients with cardiac systolic dysfunction from patients with preserved systolic function.

2.1.5.8 Additional Non-Invasive Tests

In patients in whom echocardiography at rest has not provided enough information and in patients with coronary artery disease (e.g. severe or refractory HF and coronary artery disease), further non-invasive imaging may include stress echocardiography, radionuclide imaging, and cardiac magnetic resonance imaging.

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2.1.6 Treatment of Heart Failure[2,44]

2.1.6.1 Goals of Treatment in Heart Failure

HF treatments are used for prevention and/or controlling of diseases and progression leading to cardiac dysfunction and HF. In addition, they have to maintain or improve in HRQoL and survival of patients with HF.

2.1.6.2 Management of Heart Failure

In 2001, American College of Cardiology/American Heart Association writing committee decided to take a new approach to the classification of 4 stages of HF syndrome, one that emphasized both the development and progression of the disease as follows:

Stage A: Patients with high risk for developing HF such as patients with coronary artery disease, hypertension, or diabetes mellitus who do not yet demonstrate impaired left ventricular hypertrophy function, hypertrophy, or geometric chamber distortion.

Stage B: Patients with cardiac structural abnormailites or remodeling such as left ventricular hypertrophy and/or impaired left ventricular function that have not developed HF.

Stage C: Patients with current or past symptoms of HF associated with underlying structural heart disease.

Stage D: Patients with refractory end-stage HF who might be eligible for specialized, advanced treatment strategies such as mechanical circulatory support, procedures to facilitate fluid removal, continuous inotropic infusions, or cardiac transplantation or other innovative or experimental surgical procedures, or for end-of-life care, such as hospice.

Recommended therapies used for treatment of various stages of HF are shown in Figure 2.

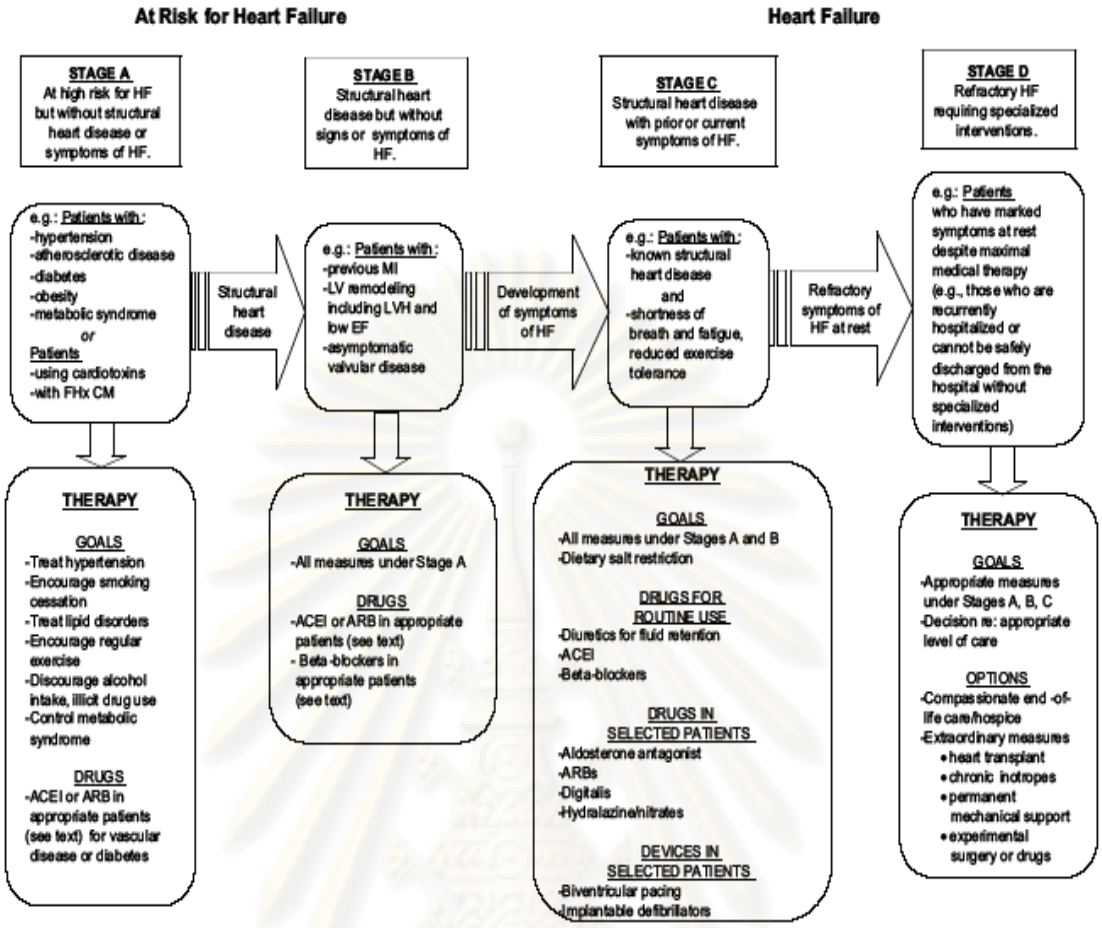

Figure 2 Stages in development of heart failure and recommended therapy by stage[2]

The therapeutic approach in patients with chronic HF that is caused by left ventricular systolic dysfunction includes non-pharmacological management, pharmacological therapy, and mechanical devices and surgery.

2.1.6.2.1 Non-Pharmacological Management

2.1.6.2.1.1 Education Patients and Family

Patients with HF and their close relatives should receive general advice such as explanation what HF is and why symptoms occur, causes of HF, how to recognize symptoms, what to do if symptoms occur, self-weighing, rationale for treatments, and importance of adherence to pharmacological and non-pharmacological prescriptions, smoking cessation, and prognosis.

2.1.6.2.1.2 Weight Monitoring

Patients are advised to weigh on a regular basis to monitor weight gain (preferably as part of a regular daily routine, for instance after morning toilet) and, in case of a sudden unexpected weight gain of > 2 kg in 3 days, to alert a health care provider or adjust their diuretic dose accordingly (e.g. to in crease the dose if a sustained increase in weight is noted). In addition, treatment of HF should include weight reduction in obese patients.

2.1.6.2.1.3 Dietary

It should appropriately counsel regarding dietary in patients with HF. First, controlling the amount of salt in the diet is a problem, that is more important in advanced than in mild HF. Second, instructions on fluid control should be given to the patients with advanced HF, with or without hyponatremia. However, a fluid restriction of 1.5-2 L/day is advised in advanced HF in practice, the exact amount of fluid restriction remains unclear. Finally, moderate alcohol intake (one beer, 1-2 glasses of wine/day) is permitted other than in case of alcoholic cardiomyopathy when is prohibited.

2.1.6.2.1.4 Smoking

Smoking should always be discouraged. The use of smoking cessation aids should be actively encouraged and may include nicotine replacement therapies.

2.1.6.2.1.5 Exercise

Exercise improves skeletal muscle function and therefore overall functional capacity. Patients should be encouraged and advised on how to carry out daily physical and leisure time activities that do not induce symptoms. Exercise training programs are encouraged in stable patients in NYHA classes II-III.

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2.1.6.2.1.6 Drug counseling

The following drugs should be used with caution when coprescribed with any form of HF treatment or avoided such as non-steroidal anti-inflammatory drugs, cyclooxygenase II inhibitors, class I anti-arrhythmic agents, calcium antagonists (Verapamil, Diltiazem, and short-acting dihydropyridine derivatives), tricyclic antidepressants, corticosteroids, and lithium.

2.1.6.2.2 Pharmacological Therapy[2,44,47]

2.1.6.2.2.1 Angiotensin-Converting Enzyme Inhibitors (ACEIs)

ACEIs decrease afterload by interfering with the renin-angiotensin-aldosterone system, resulting in peripheral vasodilatation. They also affect left ventricular hypertrophy, remodeling, and renal blood flow. They are recommended as first-line therapy in all patients with a reduced left ventricular systolic function expressed as a subnormal ejection fraction, i.e. < 40-45% with or without symptoms unless they have a contraindication to their use or have been shown to be unable to tolerate treatment with these drugs. ACEIs improve survival, symptoms, functional capacity, and reduce hospitalization in patients with HF and left ventricular dysfunction. ACEIs are often preferred over the use of angiotensin II receptor blockers (ARBs) or direct-acting vasodilators because of the greater experience and weight of evidence supporting their effectiveness. The dose of ACEIs should always be initiated at low dose level and titrated to the target dose. Regular monitoring of renal function is recommended: (1) before, 1-2 weeks after each dose increment and at 3-6 months interval; (2) when the dose of an ACEI is increased or other treatments, which may affect renal function, are added (e.g. aldosterone antagonists or angiotesin II receptor blockers), (3) in patients with past or present renal dysfunction or electrolyte disturbances more frequent measurements should be made, or (4) during any hospitalization. Important adverse effects associated with ACEIs are cough, hypotension, renal insufficiency, hyperkalemia, and angioedema. Angiotensin receptor

blockers may be used as an effective alternative in patients who develop cough or angioedema on an ACEI.

2.1.6.2.2.2 Angiotensin II Receptor Blockers (ARBs)

The mechanisms of action of ARBs are similar to ACEIs. These drugs such as valsartan and candesartan can be used as alternative drugs in symptomatic patients intolerant to ACEIs because of cough or angioedema to improve morbidity and mortality. ARBs and ACEIs seem to have similar efficacy in HF on mortality and morbidity. ARBs can be considered in combination with ACEIs in patients who remain symptomatic, to reduce mortality, hospital admissions for HF, and more reduction of left ventricle size than either agent alone. Initiation and monitoring of ARBs are similar to the procedures for ACEIs.

2.1.6.2.2.3 Diuretics

Diuretics decrease preload by stimulating natriuresis in the kidneys. Loop diuretics are essential for symptomatic treatment when fluid overload is present and manifest as pulmonary congestion or peripheral edema. The use of diuretics results in rapid improvement of dyspnea and increased exercise tolerance. Diuretics should always be administered with ACEIs and beta-blockers if tolerated. The major side effects of loop diuretics are hypokalemia, hypomagnesemia, hyponatremia, hyperuricemia, glucose intolerance, and acid-base disturbance.

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2.1.6.2.2.4 Beta-Adrenoceptor Antagonists

Beta blockers inhibit the sympathetic nervous system and adrenergic receptors. They slow heart rate, decrease blood pressure, and have a direct beneficial effect on the myocardium, enhancing reverse remodeling. Selected agents that also block the alpha-adrenergic receptors can

cause vasodilatation. They should be considered for treatment of all patients (in NYHA class II-IV) with stable, mild, moderate, and severe HF from ischemic or non-ischemic cardiomyopathies and reduced LVEF on standard treatment, including diuretics, and ACEIs, unless there is a contraindication. Beta-blocking therapy reduces hospitalizations and the risk of mortality, improves the functional class and leads to less worsening of HF. Only bisoprolol, carvedilol, sustained-release metoprolol (succinate) and nebivolol (Europe) can be recommended for treatment of patients with HF. It should not be considered indicative of a beta-blocker class effect. The initial dose should be small and increased slowly and progressively to the target dose used in the large clinical trials. Up-titration should be adapted to individual responses. During titration, beta-blockers may reduce heart rate excessively, temporarily induce myocardial depression, and exacerbate symptoms of HF.

2.1.6.2.2.5 Aldosterone Antagonists

Aldosterone antagonists can counteract the many effects of aldosterone produced by the adrenal glands such as renal sodium retention and potassium excretion and ventricular and vascular hypertrophy. In a large-scale, long term trial, low doses of spironolactone (starting at 12.5 milligrams daily) are recommended in addition to ACEIs therapy for patients with HF symptoms in class III or IV and recent hospitalization to improve survival and morbidity. They are recommended in addition to ACEIs and beta-blockers in HF after myocardial infarction with left ventricular systolic dysfunction and signs of HF or diabetes to reduce mortality and morbidity. The major side effects are hyperkalemia and gynecomastia. To minimize the risk of life-threatening hyperkalemia in patients with low LVEF and symptoms of HF, patients should have initial serum creatinine less than 2.0 milligrams per deciliter to 2.5 milligrams per deciliter without recent worsening and serum potassium less than 5.0 milliequivalences per deciliter without a history of severe hyperkalemia.

2.1.6.2.2.6 Cardiac Glycoside (Digoxin)

Digoxin affects the Na^+/K^+-adenosine triphosphatase pump in the myocardial cell and increasing contractility. It is indicated in atrial fibrillation and any degree of symptomatic HF, whether or not left ventricular dysfunction is the cause. Cardiac glycosides slow the ventricular rate which improves ventricular function and symptoms. Contraindication to the use of cardiac glycosides include bradycardia, second-degree and third-degree atrioventricular block, sick sinus syndrome, carotid sinus syndrome, Wolff-Parkinson-White syndrome, hypertrophic obstructive cardiomyopathy, hypokalemia, and hyperkalemia. The drug of this type is digoxin. The usual dose of oral digoxin is 0.125-0.25 milligrams if serum creatinine is in the normal range (in the elderly 0.0625-0.125 milligrams, occasionally 0.25 milligrams)

2.1.6.2.2.7 Combination of Hydralazine and Nitrates

In case of intolerance for ACEIs and ARBs, the combination of hydralazine and nitrates can be tried to reduce mortality and morbidity and improved quality of life. However, compliance with this combination has generally been poor because of the large number of tablets required and the high incidence of adverse reactions.

2.1.6.2.2.8 Nesiritide

Nesiritide, a recombinant human brain or B-type natriuretic peptide, decreases preload by stimulating diuresis and decreases afterload by vasodilatation. It has been shown to be efficacious in improving subjective dyspnea score as well as including significant vasodilatation when administered intravenous to the patients with acute HF. Clinical experience with nesiritide is still limited. Nesiritide may cause hypotension and some patients are non-responders.

2.1.6.2.2.9 Positive Inotropic Therapy

Repeated or prolonged treatment with oral inotropic agents increase mortality and is not recommended in HF. Intravenous administration of inotropic agents such as dobutamine and milrinone is commonly used in patients with severe HF with signs of both pulmonary congestion and peripheral hypoperfusion. They increase myocardial contractility. However, treatment-related complications may occur and their effect on prognosis is uncertain. Depending on agent level of evidence and strength of recommendation varies.

Primary target of treatment in HF and recommended doses are presented in Figure 3 and Table 3, respectively.

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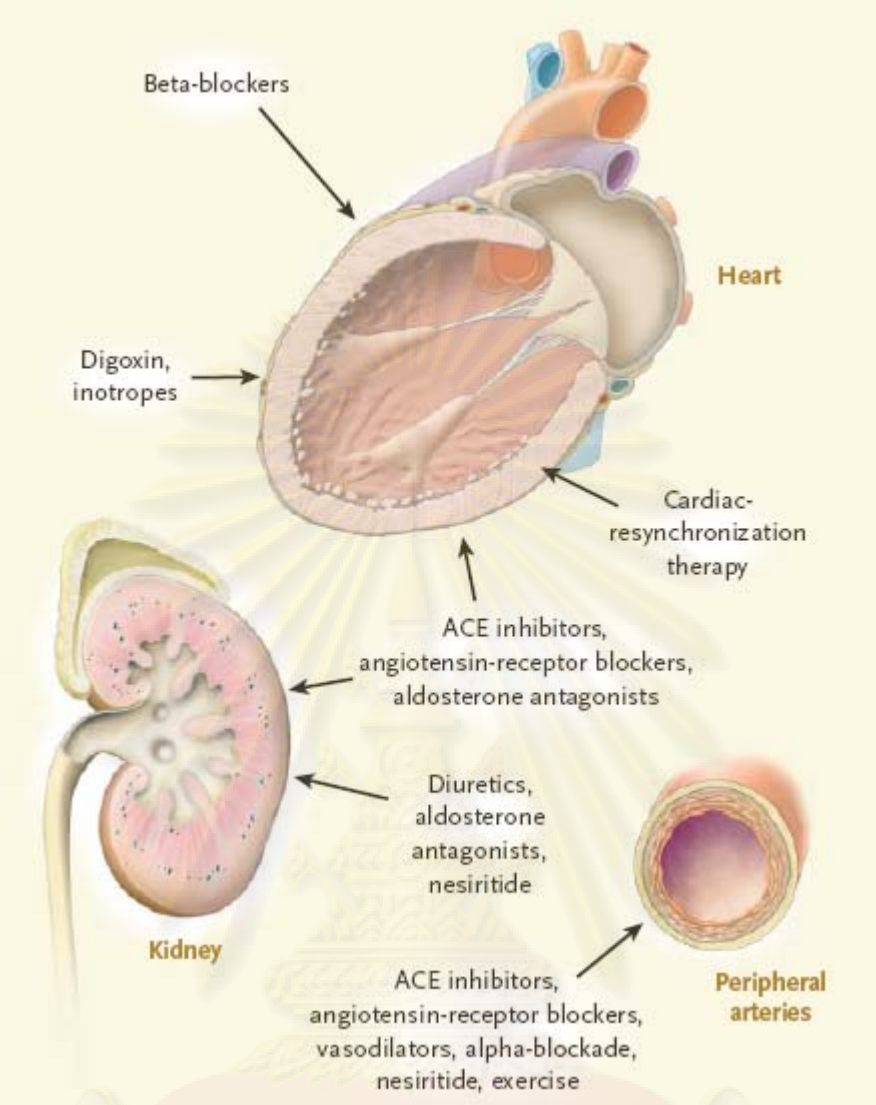

Figure 3 Primary target of treatment in heart failure[47]

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Table 3 Oral medications for the treatment of heart failure[2]

Drugs	Initial daily dose(s)	Maximum dose(s)
ACEIs		
1. Captopril	6.25 mg 3 times	50 mg 3 times
2. Enalapril	2.5 mg twice	10 to 20 mg twice
3. Fosinopril	5 to 10 mg once	40 mg once
4. Lisinopril	2.5-5 mg once	20 to 40 mg once
5. Perindopril	2 mg once	8 to 16 mg once
6. Quinapril	5 mg twice	20 mg twice
7. Ramipril	1.25 to 2.5 mg once	10 mg once
ARBs		
1. Candesartan	4 to 8 mg once	32 mg once
2. Losartan	25 to 50 mg once	50 to 100 mg once
3. Valsartan	20 to 40 mg once	160 mg twice
Loop diuretics		
1. Bumetanide	0.5 to 1.0 mg once or twice	10 mg/day
2. Furosemide	20 to 40 mg once or twice	600 mg/day
3. Torsemide	10 to 20 mg once	200 mg/day
Beta-blockers		
1. Bisoprolol	1.25 mg once	10 mg once
2. Carvedilol	3.125 mg twice	25 mg twice
3. Metoprolol succinate extended release	12.5 to 25 mg once	200 mg once
Aldosterone antagonists		
1. Spironolactone	12.5 to 25 mg once	25 mg once or twice
2. Eplerenone	25 mg once	50 mg once

mg =milligrams

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2.1.6.2.3 Devices and Surgery[48]

If clinical symptoms of HF are present after using optimal non-pharmacological or pharmacological treatments, devices and surgery must always be considered.

2.1.6.2.3.1 Cardiac Resynchronisation Therapy

The rationale for cardiac resynchronisation therapy is based on the presence of ventricular dyssynchrony, which is currently defined as QRS duration of at least 120 milliseconds on the surface electrocardiogram. Dyssynchrony can arise between the left and right ventricles and within the left ventricle, impairing the ability of the heart to function as a pump. This disorder can be improved by biventricular pacing, which is accomplished through simultaneous pacing of both the left and right ventricles. Data for this technique show consistently enhanced quality of life, functional status, exercise capacity, and ventricular structure and function, and reductions in morbidity and mortality. Cardiac resynchronisation therapy without an implantable cardioverter defibrillator and with best medical treatment lowered all-cause mortality by 36% compared with best medical treatment alone. At present, patients with LVEF less than or equal to 35%, normal sinus rhythm, and NYHA functional class III or ambulatory class IV symptoms despite best medical treatment who have ventricular dyssynchrony should receive cardiac resynchronisation therapy, unless contraindicated. Few contraindications to this method exist but could include comorbidity expected to limit the success of the procedure and excessive risk in patients who are too ill to undergo device implantation.

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2.1.6.2.3.2 Implantable Cardioverter Defibrillators

Implantable cardioverter defibrillators were initially given to survivors of sudden cardiac death to treat recurrent

episodes of ventricular tachycardia or ventricular fibrillation. People with left ventricular dysfunction, either from ischaemic or non-ischaemic causes, are at increased risk for sudden cardiac death. Thus, the notion that implantable cardioverter defibrillators might be useful for primary prevention of sudden cardiac death in HF patients was tested in a series of randomised controlled trials. This idea was proven in patients with a previous (older than 1 month) myocardial infarction with left ventricular systolic dysfunction with or without symptomatic HF. Implantable cardioverter defibrillator is a prophylactic intervention for management of non-ischaemic HF and a 23–31% reduction in all-cause mortality. The indication for an implantable cardioverter defibrillator has been extended to NYHA class II and III HF patients with reduced ejection fractions less than or equal to 35% who have a reasonable expectation of survival with good functional status for more than 1 year.

2.1.6.2.3.3 Ventricular Assist Devices

Ventricular assist devices are blood pumps used to support the failing heart in patients with end-stage HF. Left-ventricular assist devices are used in three clinical situations: (1) in individuals listed for transplantation but who need support before a suitable donor heart becomes available; (2) as a bridge to recovery in people with potentially reversible forms of HF, such as myocarditis or post-partum cardiomyopathy; and (3) as so-called destination therapy for patients not judged candidates for transplantation. People awaiting transplantation who receive a left-ventricular assist device have good survival to transplantation, and post-transplant survival is equal to that seen with unsupported patients.

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2.1.6.2.3.4 Surgical Approaches

Heart transplantation is an accepted mode of treatment for end stage HF. It is considered to significantly increase survival, exercise capacity, return to work and quality of life. Patients who should be considered for heart transplantation are those with severe symptoms of HF with no

alternative form of treatment and with a poor prognosis. Although cardiac transplantation remains the ultimate surgical strategy for HF, the poor availability of suitable donor organs renders this option epidemiologically insignificant. For the few patients receiving a transplanted heart, 1-year survival approaches 85%, 5-year survival is about 75%, and 50% of adult recipients will be alive at 10 years. Functional status of transplant recipients is very good: 80–85% have no activity limitations for up to 7 years after transplantation and fewer than 5% need total assistance at any time.

Other surgical approaches to HF include revascularisation for ischaemic HF, mitral valve repair to address functional mitral regurgitation associated with pathological ventricular remodelling, and surgical reconstruction of the size and shape of the failing left ventricle to render it a more effective pump. None of these surgical techniques has been tested satisfactorily in adequately powered, randomised controlled trials.

Revascularisation strategies, either percutaneous or surgical, may reduce the frequency of HF in patients with atherosclerotic vascular disease. Coronary revascularisation can relieve symptoms of myocardial ischaemia, and coronary-artery bypass surgery lessens angina and diminishes risk of death in people who have multi-vessel disease, decreased left-ventricular ejection fractions, and stable angina. At the present time, key factors affecting the decision to revascularise the myocardium in HF include medically refractory angina pectoris associated with demonstration of viable myocardium and surgically acceptable target vessels.

Functional mitral regurgitation is typical in patients with left ventricular dysfunction irrespective of cause, and it has been associated with poor long-term outcome. Correction of mitral regurgitation results in partial reversal of left ventricular remodelling, symptomatic improvement, and enhanced outcomes. However, the benefit of this procedure remains to be shown in randomised trials. In addition to functional mitral regurgitation, primary valvular heart disease could be a cause or contributor to HF. In some cases—eg, aortic stenosis and mitral

stenosis—HF can be reversible after surgical or percutaneous treatment of valvular disease.

Surgical ventricular reconstruction or restoration has emerged as a promising approach to dilated cardiomyopathy in patients with previous myocardial infarction. The aim of this procedure is to reduce left ventricular volume and create geometrically the best possible chamber by exclusion of scar in either akinetic or dyskinetic anteroapical and septal segments.

2.2 Health-Related Quality of Life in Heart Failure[30]

2.2.1 Concept of Quality of Life and Health-Related Quality of Life

The use of QoL and related concepts in health care have begun since 1947, when the World Health Organization defined health as a state of physical, mental, and social well-being rather than simply as an absence of disease or infirmity.[49] After the use of this concept, World Health Organization defined QoL as “individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”. This concept is used to develop the World Health Organization Quality of Life Questionnaire. It is a broad ranging concept, incorporating in a complex way individuals' physical health, psychological state, level of independence, social relationships, personal beliefs and their relationships to salient features of the environment.[50]

MacKeigan and Pathakhave suggested that QoL is a term that has been misused and abused in the field of health care.[16] Health cares are not concerned with a person’s global QoL. It is affected by many factors beyond the realm of health care, such as housing, income, and occupation. It is interested in those aspects of QoL that can be attributed to the illness and its consequent therapy. Therefore, the proper term for our purposes is HRQoL. HRQoL assessment is a health status measure that obtains from patient’s perceptions. It may summarize the conceptual model of QoL and HRQoL as shown in Figure 4.

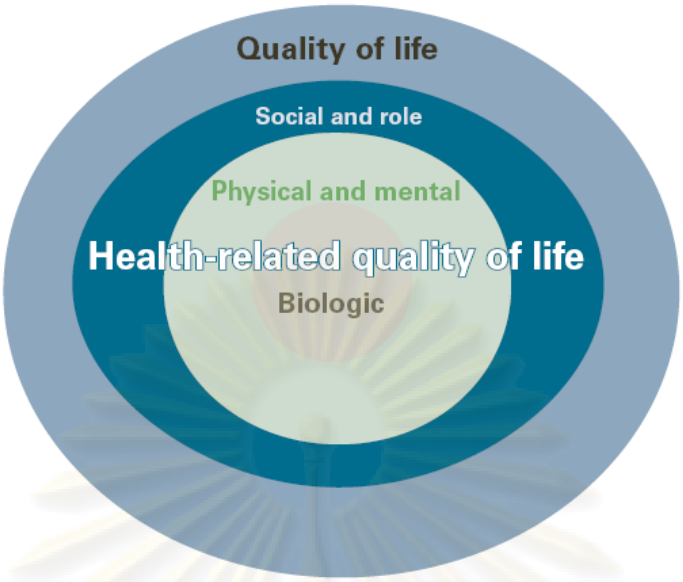

Figure 4 The conceptual model of quality of life and health-related quality of life[51]

2.2.2 Conceptual Model of the Health-Related Quality of Life in Heart failure

HF is a major contributor to the morbidity and mortality in worldwide. Both the longevity of the population and advances in treatment have led to an increase in the prevalence of HF in several countries.[52] HF is held to be a chronic disease. Therefore, a goal of HF treatment is improvement or maintenance of HRQoL of the patients with HF. Figure 5 depicts a conceptual model of HRQoL in relation to HF that patients experience varying frequency and intensity of symptoms from the pathophysiology of HF. Their symptoms such as unusual dyspnea, fatigue, swollen ankles, and orthopnea affect their ability or willingness to do various physical, mental, social, or role functions. Symptoms and functional limitations may lead to negative psychological distress such as feelings of worry and depression. All of these phenomena can directly and indirectly affect a patients' ability to live as they would like to live and their sense of well-being (HRQoL).[12]

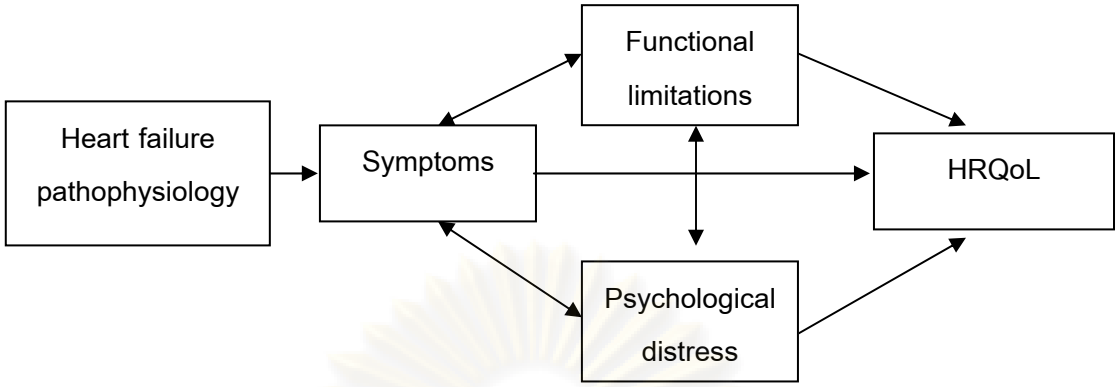

Figure 5 Conceptual model of the health-related quality of life in heart failure[12]

However, HF had higher incidence and poor prognosis that limited in physical activities and affected HRQoL of patients, there were few studies regarding the impact of HF on HRQoL in the past. Recently, there are several studies about HRQoL in patients with HF increasingly and HRQoL becomes to a goal of HF treatments. Several HRQoL instruments can reflect the importance of HRQoL and treatment outcomes in patient with HF including collection of HRQoL data in those with HF and testing the validity of the measuring instruments. Several studies have shown the relationship between HRQoL and clinical outcomes.[53] From literature reviews, there are three main objectives of HRQoL measurement in general studies: 1) to assess and describe HRQoL in patients with HF 2) to describe the impact of interventions on HRQoL, and 3) to examine predictors or the relationship of HRQoL.[54]

2.3 Health-Related Quality of Life Assessment of Heart Failure in Pharmaceutical Cares

HRQoL outcomes may be measured as either a primary outcome or as secondary outcome in addition to other traditional outcome, such as survival, progression of disease, duration of remission of disease, days lost from work, and economic impact of illness. HRQoL assessments are reported with patients, thus it has been grouped with them in the term of patient-reported outcomes. A combination of HRQoL instrument with a measurement of other outcomes can provide a comprehensive assessment of the effects of a disease and/or its treatment. The most common use of

HRQoL assessment is in phase III trials. HRQoL evaluations can be classified under five groups based on the purpose and applications: 1) screening, 2) health profile description, 3) health care (clinical) decision making, 4) predicting outcomes, and 5) preference (utility) assessment. In addition, HRQoL assessment in clinical settings may occur at three level of health care: First, the macro level of government and health care policy-setting relating to population health. Second, the meso level of institutions and clinical trials pertaining to the groups of patients, and Third, the micro level of individual patient care.[18]

Pharmacists have a role in Medication Therapy Management (MTM). MTM is a distinct service or a group service that optimizes therapeutic outcomes for individual patients. One of MTM services is performing or obtaining necessary assessments of the patient's health status for drug therapy plan, other interventions, and therapeutic drug monitoring. HRQoL data is a health status assessment that obtains from patients directly.[30] In recent, there are several studies that assess the effects of clinical pharmacy services on therapeutic outcomes following economic, clinical, and humanistic outcomes model. Many studies have revealed that clinical pharmacy services have an impact on patient's HRQoL in several diseases such as asthma, hypertension, and chronic HF. HRQoL measurement is the operationalization of an outcome central to the practice of pharmacy, as the definition of pharmaceutical care explicitly identifies improved HRQoL as a goal.[55]

2.3.1 Importances of Health-Related Quality of Life Informations for Pharmacists

HRQoL information is important to the pharmacists in three ways[16]:

1) HRQoL outcomes are increasingly being used to evaluate drugs in clinical trials. If pharmacists want to be able to interpret this literature for use their own practices (e.g., therapeutic decisions for individual patients or formulary or other policy decisions), pharmacists must understand both the concept and the measurement of HRQoL.

2) HRQoL data can also be used to evaluate provider performance by assessing the impact of the structure and process of care on clinical and HRQoL outcomes.

3) HRQoL assessment can be a useful tool for monitoring the progress of patients receiving drug therapy. Improvement in HRQoL may be the main goal of treatment in patients with some diseases. In all diseases, a therapeutic goal is to avoid impairment in HRQoL caused by adverse effects of drugs leading to nonadherence later. Patients undergoing treatment for asymptomatic conditions may be particularly susceptible to nonadherence because, for them, drug-induced worsening of HRQoL is not offset by alleviation of the disease symptoms. Pharmacists with a HRQoL orientation will actively seek information about drug-related HRQoL from patients and strive to improve HRQoL by suggesting alternative therapies to the physicians and by advising patients on how to minimize the distress of adverse effects.

HRQoL information should be most useful in evaluation drug therapy under the following circumstances[16]: 1) When the primary purpose of a drug is palliative rather than curative, as is often the case in chronic disease. 2) When a drug is somewhat effective but is also fairly toxic. 3) When lifelong therapy is administered to prevent complications of a relatively asymptomatic disease. 4) When there are several equally effective therapies for a specific condition but the adverse-effect profiles differ.

As above mentioned, HRQoL measures have numerous potential applications in pharmacy practice. HRQoL results from published trials can assist in formulary decisions and in individual patient decisions regarding the selection of drug therapy. Measuring HRQoL in clinical practice may help the clinician in monitoring patient response to the therapy and in assessing the quality of care.

2.3.2 Previous Studies of Health-Related Quality of Life Assessments in Pharmaceutical Cares

Previous studies have indicated that HRQoL assessment is used to evaluate outcomes in pharmaceutical cares as follows:

Verma et al.[24] have studied regarding pharmaceutical cares in 83 elderly patients with HF. All subjects are divided into two groups: intervention and

control group. The intervention group receives pharmaceutical cares from a pharmacist and the control group receives usual care. Follow-up periods are 0, 3, 6, 9, and 12 months. HRQoL instruments were used to measure HRQoL that is an outcome in this study such as the SF-36 (generic instrument) and the MLHFQ (disease-specific instrument). This study has reported that HRQoL score in the intervention group is significantly better than the control group except in the ninth month ($p < 0.05$).

Somskul[29] has studied regarding the effect of education and counseling on outpatients with HF at Lerdsin Hospital. All patients are separated to two groups: intervention and control group. The intervention group receives education and counseling from a pharmacist and the control group receives usual care. The Short Form-12 Health Survey (SF-12) is used to assess HRQoL in this study. However, this study has found that HRQoL score in mental dimension of the intervention group is significantly higher than the control group ($p < 0.01$), but there is no significant difference in HRQoL score in physical dimension between both groups.

Sadik et al.[23] have studied regarding evaluation of pharmaceutical cares in 208 patients with HF. All participants are assigned to two groups: intervention and control group. The intervention group receives pharmaceutical cares from a pharmacist and the control group receives usual care. Follow-up periods are 0, 3, 6, 9, and 12 months. HRQoL instruments were used to measure HRQoL that is an outcome in this study such as the SF-36 (generic instrument) and the MLHFQ (disease-specific instrument). This study has reported that HRQoL score in the intervention group is significantly better than the control group through all follow-up periods ($p < 0.05$).

2.4 Health-Related Quality of Life Instruments in Heart Failure[30]

Technique used to incorporate the effects of treatments and diseases from a patient's viewpoint is HRQoL measurement. HRQoL measures are generally used to represent a patient's estimation of his or her own health at a point in time. To provide an assessment of a patient's HRQoL, researcher can either select tools that focus on health status using generic measures, or they can choose tools that focus on specific aspects

of the disease under study using disease-specific measures. It is often desirable to include the generic and the disease-specific instruments. Table 4 lists advantages and disadvantages of generic versus disease-specific HRQoL measures. Two main approaches to the measurement of HRQoL in patients with HF are available: generic and disease-specific instruments.[52]

2.4.1 Generic Instrument in Heart Failure

A generic instrument is designed to measure the complete spectrum of function, disability, and disease that is relevant to HRQoL. In addition, it gives a comprehension and general overview of HRQoL and to be used with a variety of populations. Therefore, generic instruments permit comparison of HRQoL changes across different diseases. This ability can be useful when HRQoL information is used to compare the value of competing clinical programs.[16,49]

The SF-36[56,57] is the most generic instrument used to measure HRQoL in clinical trials for several diseases including HF. It is tested the reliability and validity in large general population and has a good relationship with disease-specific instruments. Original version is developed by Medical Outcome Trust in the United States of America and is translated to several languages including Thai.[27,28] It is short form questionnaire and is easy to understand. It measures in physical health, mental health, and social functioning of general and patient populations. It consists of 35 questions and is divided into eight subscales: physical functioning or PF (10 items: item 3a-3j), role-physical or RP (4 items: item 4a-4d), bodily pain or BP (2 items: item 7-8), general health or GH (5 items: item1 and 11a-11d), social functioning or SF (2 items: item 6 and 10), vitality or VT (4 items: item 9a, 9e, 9g, and 9i), role-emotional or RE (3 items: item 5a-5c), and mental health or MH (5 items: item 9b-9d, 9f, and 9h). In addition, it has one independent question regarding reported health transition (item 2), thus overall questions were 36 items. Each item has different number of response choices between two and six. Each dimension score is calculated following developer recommendation and possible scores ranges from 0 to 100. Higher score indicates better HRQoL. In addition, it is able to be summarized to two component summary scores: physical component summary (PCS)

and mental component summary (MCS). It is used in several modes of administration such as self administration, face-to-face interview, and telephone interview.[18,27,28] Recently, there are two versions of SF-36 (version 1 and version 2). The main difference of each version is response choice on role physical, vitality, role emotional, and mental health subscales.

2.4.2 Disease-Specific Instruments in Heart Failure

The disease-specific instrument should be more capable of detecting subtle improvements in health resulting from treatment, because it includes only those components that are most important to that disease. The goal in using is to assess responsiveness or clinically significant changes in a particular group. Some HRQoL instruments used in randomized controlled studies of HF are shown in Table 5.

Table 4 Advantages and disadvantages of generic and disease-specific instruments[30]

Type	Advantages	Disadvantages
Generic or general	Broadly applicable	May not be responsiveness to changes in health
	Summarizes range of concepts	May not be relevant for specific populations
	May detect unanticipated effects	Results may be difficult to interpret
Disease-specific	More relevant for specific populations	Cannot compare across populations
	More responsive to changes in health	Less likely to detect unanticipated effects

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Table 5 Example of health-related quality of life instruments used in randomized controlled studies of HF[26]

Generic instruments in HF	Disease-specific instruments in HF
1. Short Form-36 Health Survey	1. Minnesota Living With Heart Failure Questionnaire
2. Sickness Impact Profile	2. Chronic Heart Failure Questionnaire
3. Profile of Mood States	3. Kansas City Cardiomyopathy Questionnaire
4. Nottingham Health Profile	4. Heart Failure Functional Status Inventory
5. Dartmouth COOP Functional Health Assessment Charts	

The MLHFQ[31,32,42] is specifically designed to measure HRQoL in patients with HF and it is the most using of measures in randomized clinical trials.[26] It is used to assess patient's perception regarding living in physical and emotional dimensions. It comprises of 21 items and each item has 6 response choices ranging from 0 (no) to 5 (very much) following Likert scale. HRQoL scores are considered in 3 categories:

1) Physical dimension consists of 8 items: item 2-7 and 12-13. Its score ranges from 0 to 40.

2) Emotional dimension consists of 5 items: item 17-21. Its score ranges from 0 to 25.

3) Global score is summarized from 21 items. Its score ranges from 0 to 105.

Fewer score indicates less dysfunction. It can be used in several modes of administration such as self administration and face-to-face and telephone interviews. The last original version of the MLHFQ is version 3.0.

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2.5 Assessment of Health-Related Quality of Life Instruments[18,30,58]

2.5.1 Cross-Cultural Adaptations of Instruments

Many instruments are adapted or translated for applications across culture. Cross-cultural adaptations have referred to the situations in which instruments have been fully adapted from original or source instruments for cultures or languages different from the original. Therefore, this point is necessary for consideration of use any instrument, that is different in culture and language. The cross-cultural adaptation of an instrument involves evaluations of conceptual equivalence. It is useful if developers provide empirical information on how items work in different cultures and languages. The cross-cultural adaptation of a measure involves two steps:

2.5.1.1 Linguistic Equivalence

It refers to the equivalence of question wording and meaning in the formulation of items, response choices, and all aspects of the instrument and its applications. The commonly recommended steps to achieve linguistic equivalence are 1) at least two forward translations from the source language that yields a pooled forward translation; 2) at least one, preferably more, backward translations to the source language that results in another pooled translation; 3) a review of translated versions by lay and expert panels with revisions; and 4) field tests to provide evidence of comparability.

2.5.1.2 Conceptual Equivalence

It refers to the equivalence in relevance and meaning of the same concepts being measured in different cultures and/or languages. The commonly recommended method to achieve conceptual equivalence is assessment of content validity of the instrument each cultural or language group to which the instrument is to be applied.

2.5.2 Psychometric Properties of Instruments

Patient-based assessments are examples of important outcomes that are more subjective in nature. Therefore, it is important to evaluate the psychometric properties of HRQoL instruments, including practicality, reliability, validity, and responsiveness. It is needed to develop or select the best HRQoL measures for any given application.

2.5.2.1 Practicality or Feasibility

HRQoL instruments must contain a sufficient number of questions to adequately measure the domains of interest, but they must also be short enough to be practical (e.g., not be a burden to the respondents). Researchers must find a balance between obtaining the needed information and minimizing respondent burden. Other issues to be considered when choosing, developing, and assessing HRQoL instruments include the applicability of the domains measured to the research question(s), the ease of its use, and the resources needed to obtain responses.

2.5.2.2 Reliability

Reliability refers to the extent to which a measure yields the same number or score each time is administered, all other things being equal. Three classical approaches for examination of reliability testing are:

2.5.2.2.1 Test-Retest Reliability

It is assessed about the similarity of health status scores over time when no changes in health have occurred. In other words, if the same person completes an HRQoL instrument and then retakes the same survey at a later time and person's health status has not changed, his or her scores from both times should be similar. Minimal standards for test-retest reliability coefficients are 0.70 for group comparisons and 0.90-0.95 for individual measurements over time.

2.5.2.2.2 Internal Consistency

Cronbach's alpha coefficient is an estimate of this reliability based on all possible split-half correlations for a multi-item scale. For example, if two items are measuring the same aspect of health, these questions should elicit similar answers from respondent. Commonly acceptable minimal standards for reliability coefficients are 0.70 for clinical trials and other group comparisons and 0.90-0.95 for individual comparisons.

2.5.2.2.3 Interrater Reliability

It calculates the agreement between two respondents when assessing the HRQoL of the same patient. A comparison of the scores from respondents indicates the level of interrater consistency or agreement. For most HRQoL studies, only the patient completes the questionnaire, so interrater reliability is not commonly seen in this type of research.

In modern test theory applications, the degree of precision of measurement may be expressed in terms of error variance, standard error of measurement, or test information.

2.5.2.3 Validity

Validity studies are necessary to evaluate whether the scores elicits from the instruments truly represent the underlying constructs of HRQoL. In other words, the purpose of validity assessment is to determine whether the instrument is actually measuring what it is supposed to be measuring. Validity refers to the extent to which differences in patients. Scores reflect the differences among individuals that the test developer sought to measure. Three common types of validity assessment are:

2.5.2.3.1 Content Validity

It pertains to whether the HRQoL instrument offers an adequate representation of the relevant variables of interest. Content validation requires the existence of a standard against which one can compare the concepts.

Standards can be based on well-accepted theoretical definitions, on existing accepted standards, or from interviews of those who have experiences with the types of problems under study (e.g., patients with the disease or health condition, caregivers, health care providers). Sometimes content validity is referred to as “face validity”.

Currently, A four-stage model of the question response process (comprehension, retrieval, judgment, and response) is applicable in HRQoL research for content validity evaluation of HRQoL instruments because HRQoL assessments require respondents to understand complex questions which are about abstract concepts, effectively retrieve information from long term memory, gather that information, apply frequency judgment, magnitude estimation and decision in response choice selection.

Cognitive interviewing is a qualitative technique, using cognitive model of survey response, in pre-testing before application to formal validation and reliability testing or to questionnaire administration. This approach use a trained interviewer seeks to elicit the cognitive process employed by a respondent in answering survey questions. Respondent are asked to give feedback on their understanding of the question and associated response categories and instructions, and to verbalize how they have gone about producing their answers, with particular emphasis on retrieval from memory and subsequent judgments and decisions. An approach to provide this feedback is respondent debriefing, using concurrent or retrospective probes. Examples of probe are such as: “What kind of information did you think this question was asking for?”; “What sort of things were you thinking about when you answered this question?”; “I noticed that you hesitated before you answered that question. Why was that?; and etc. Probing may be conducted as each question is answered (concurrent probes), or after the question or whole questionnaire has been self-completed (retrospective probes). Probes can be standardized (all respondents are asked about the same cognitive processes, using identical probing questions) or ad hoc (probes vary from the respondent to the respondent and depend on the answer given to the question under review and to initial probes).

2.5.2.3.2 Construct Validity

It is a more abstract and complex concept. A theoretical or conceptual framework should be under in the development of any HRQoL instrument. The constructs under investigation are often a matching set of propositions, assumption, and variables. When construct validation is used, both the HRQoL instrument and the underlying theory must be evaluated. Convergent and discriminant validity, exploratory factor analysis, and known-groups validity are often used to assess and support construct validity. First, convergent validity test determine if the use of different measures of the same construct provides similar results and discriminant validity test examines whether these different measures and their underlying construct can be differentiated from other constructs. Second, exploratory factor analysis is a useful method to identify item clusters that were not hypothesized in advance, because it summarizes the intercorrelations among items in terms of underlying dimensions or factors. Items that correlate more highly with one another than with other items will tend to load together on the same factor. Finally, known-groups validity is used to assess the differences between two patient groups known or theorized to differ in relation to clinical variables of disease status, because a HRQoL measure should reflect the impact of the disease by yielding scores for that group that differ in hypothesized ways from that of other groups.

2.5.2.3.3 Criterion validity

It demonstrates that HRQoL scores are systematically related to one or more external outcome criteria. This is sometimes called “predictive validity” in that instrument scores correlate with, or predict, health outcomes. Examples of the relationships of HRQoL scores with external evidence (criteria) include high HRQoL scores (indicating good health) and low use of medical services and low HRQoL scores (indicating poor health) predicting higher rates of mortality in the following year. However, criterion validity is rarely tested because of the absence of widely accepted criterion measures.

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2.5.2.4 Responsiveness

The responsiveness of a HRQoL instrument refers to its ability to detect changes in health status. It is viewed as an important part of the longitudinal construct validation process. The criterion of responsiveness requires asking whether the measure can detect differences in outcomes, even if those differences are small. Responsiveness can be conceptualized also as the ratio of a signal (the real change over time that has occurred) to the noise (the variability in scores seen over time that is not associated with true change in status).

2.6 Psychometric Properties of the MLHFQ in Previous Studies

2.6.1 Practicality Issue

Several studies have revealed that the MLHFQ has the feasibility to use for HRQoL assessment in patients with HF.[35,38,39] The length of time used for administration is approximately five minutes. In addition, it has the low floor and ceiling effects in all dimensions and global score, indicating ability to detect improvement and deterioration when use to evaluate the effect of HF treatments.

2.6.2 Reliability Issue

Many studies have shown that the MLHFQ has acceptable reliability in internal consistency and test-retest reliability.[3,35-37,39] Cronbach's alpha coefficients used for internal consistency estimation are greater than 0.70 in all dimensions and global score. The test-retest reliabilities of all dimensions and global score are satisfactory, with intraclass correlation coefficients (ICCs) more than 0.70. In addition, a study has reported that the MLHFQ has satisfactory agreement between face-to-face and telephone interviews, with ICCs greater than 0.70, supporting use a difference mode of administration in the data collection.[40]

2.6.3 Validity Issue

Previous studies have found that the MLHFQ shows desirable validity.[3,35] These studies often use the SF-36 for test the convergent and discriminant validity of the MLHFQ. They have reported that the MLHFQ physical dimension has moderate or high correlations with the SF-36 physical subscales, such as physical functioning, role physical, and physical component summary scores. In addition, the MLHFQ emotional dimension has moderate or high correlations with SF-36 mental subscales, such as role emotional and mental health subscales, and mental component summary. These data support convergent validity of two MLHFQ dimensions. However, the discriminant validity of the MLHFQ has been controversy. Garin et al.[35] have found that the discriminant validity of the MLHFQ physical dimension is confirmed with the SF-36 physical functioning and role physical subscales, and SF-36 physical component summary. The MLHFQ emotional dimension is supported with the SF-36 role emotional subscale and mental component summary. Nevertheless, Saccomann et al.[3] have revealed that the discriminant validity of the MLHFQ physical dimension and emotional dimension are supported with the SF-36 physical functioning and mental health subscales, respectively. Therefore, it maybe needs the data in the future studies to confirm specificity of the MLHFQ. The exploratory factor analysis is used to confirm construct validity of the MLHFQ in previous studies.[36,37] Each study has reported that the MLHFQ items loaded on factor are similar to the items defined as the two dimensions of the MLHFQ by developer, especially the emotional dimension. Moreover, several studies have found that the MLHFQ dimensions and global score are sensitive to discriminate among the patients with NYHA functional classes.[35,37,39] These results confirm known-groups validity of the MLHFQ.

2.6.4 Responsiveness Issue

Garin et al.[35] have indicated that the MLHFQ physical dimension and global score are sensitive to detect the improvement of the patients with HF, indicating small or intermediate effect size. Bennett et al.[40] have reported that minimal clinically important difference increase or decrease of 4.84 on the MLHFQ global score will be the

minimal change that is clinically meaningful to the patients, regardless of the statistical significance of the change.

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CHAPTER III
METHODS

In this chapter, materials and methods are described in detail. These include study design, subjects, instruments, procedures, and statistical and data analysis.

3.1 Study Design

This study comprised two parts:

1) The first part is a cross-sectional study about the pretesting of the Thai version of the MLHFQ.

2) The second part is a prospective study with two assessments regarding testing the psychometric properties of the Thai version of the MLHFQ obtained from the first part.

3.2 Subjects

The subjects were Thai outpatients with chronic HF who visited at cardiology and general medicine clinic at Pramongkutklao Hospital, Bangkok, Thailand between December 2008 and August 2009. The subjects were recruited for this study with convenient sampling.

Sample size calculations in this study were divided into two parts:

Part 1: The number of subjects for pretesting process was 10 patients following linguistic validation process of MAPI Research Trust.[42]

Part 2: The number of subjects was calculated from expected minimum correlation coefficient among the MLHFQ and the SF-36 scores for hypothesis testing regarding convergent and discriminant validity.[59] This study stipulated that expected minimum correlation coefficient among the MLHFQ and SF-36 scores was 0.25 or above from Saccomann et al.[3], two-sided α = 0.05, and one-sided β = 0.10.

From $C = 0.5 \times \ln [(1 + r) / (1- r)]$

$n = [(Z_\alpha + Z_\beta) \div C]^2 + 3$

Therefore, the calculated sample size at least was 165 subjects for hypothesis testing of convergent and discriminant validity. This sample size covered the sample sizes using in other hypothesis testing of this reseach.

Inclusion criterias

They met all criterias following:

1. The patients who were diagnosed with HF for three months or above.

2. The patients aged 20 years or above.

3. The patients could communicate with Thai language.

4. The patients who signed informed consent.

Exclusion criterias

They met one criteria following:

1. The patients had psychiatric problems.

2. The patients could not give any information because of having severe signs and symptoms.

3. The patients could not hear in normal range.

4. The patients who canceled before and during study.

3.3 Instruments

The instruments of this study consisted of several parts as follows:

1) Data collection form included sociodemographic and clinical data such as age, gender, education, employment status, income per month, marital status, NYHA functional classes, %LVEF, etiology of HF, comorbidities, and HF medications (APPENDIX A)

2) Original version 3 of the MLHFQ (APPENDIX B)

3) Thai version of the MLHFQ (APPENDIX C)

4) Thai standard version 1 of SF-36 Health Survey (APPENDIX D)

5) Interview manual

6) Cognitive interview form (APPENDIX E)

7) Content validity consideration form (APPENDIX F)

8) Research subject information sheet

9) Informed consent

10) Timer

11) Sound recorder

3.4 Procedures

It comprised several processes as follows:

3.4.1 The Procedure before Study

1) Researcher contacted for license permission of the MLHFQ use and translation from University of Minnesota (the United States of America) and MAPI Research Trust (France), respectively.

2) Translations were conducted following linguistic validation process of MAPI Research Trust recommendation[42] and are adapted according to the appropriateness in this study. It divided into 3 parts as below:

Part 1: Forward translations were conducted with two bilingual experts. One expert was a professor in the field of pharmaceutical sciences and another was a translator that was not associated with any medical or pharmaceutical sciences field. After two translations, they were used to synthesize to one combined the Thai version of the MLHFQ.

Part 2: Backward translations of the translated MLHFQ from Part 1 were conducted with two translator groups. Each group consisted of one Thai translator who was bilingual expert that back translated and another was one monolingual professor using English as mother language approved the grammars of the back translation from the first translator. Two groups were not associated with any medical or pharmaceutical sciences field. Two backward translation versions were used to compare with original version. Then, the alterations of some contents in the Thai version of the MLHFQ were made before pretesting.

Part 3: Pretesting was conducted with cognitive interviews. First, all patients were asked about demographic data. Then, the researcher recorded clinical data from medical record. Next, the subjects completed the MLHFQ with 2 methods

depending on reading capability: self administration and face-to-face interview. While the patients were answering the MLHFQ, the interviewer used probes for cognitive interview in 2 approaches. The patients were interviewed with retrospective probing in self administration group and another group was interviewed with concurrent probing. Interviewer could ask to the patients regarding the other problems except this probe found through these interviews. Question-and-answer problems from the study were used to the consideration for improvement of the contents of the Thai version of the MLHFQ. Then, this Thai version of the MLHFQ was used for this research.

3.4.2 The Procedures of Study

1) Researcher processed for license permission of Thai standard version 1 of the SF-36 from QualityMetric and for certificate of ethic committee from Pramongkutklao Hospital.

2) Four experts consisted of two cardiologists (Major General Chumpol Piamsomboon, M.D. and Colonel Nakarin Sansanayudh, M.D.) and two pharmacist professors (Assistant Professor Phantipa Sakthong, Ph.D. and Assistant Professor Rungpetch Sakulbumrungsil, Ph.D.) considered the contents of the Thai version of the MLHFQ.

3) The content improvements of the Thai version of the MLHFQ following the suggestions from experts were made (if any).

4) Pretesting of the Thai version of the MLHFQ was conducted for two times. Each time consisted of five subjects. These processes were described as follows:

4.1) The subjects were recruited for this study following inclusion and exclusion criteria.

4.2) The enrolled subjects were described about the objective of this study following research subject information sheet from the researcher. All subjects who accepted to participate in this study signed informed consent.

4.3) The beginning time of interviews were recorded and the researcher interviewed demographic data and recorded clinical data from medical record into data collection form.

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4.4) The subjects completed the Thai version of the MLHFQ and the SF-36 with two methods following reading ability of each subject, such as self administration and face-to-face interview. Order of questionnaire administration was conducted with simple random sampling by random number table. It began from the number of the first row in the first line of random number table. Then, it began at the first number of the second line when it was the end of the first line. It kept on this process until the subjects were enrolled completely. The subjects who got the odd number completed the Thai version of the MLHFQ at first and completed the Thai version of the SF-36 later. On the other hand, those who got the even number completed the Thai version of the SF-36 at first and completed the Thai version of the MLHFQ later.

4.5) While the subjects completed the Thai version of the MLHFQ, researcher interviewed with concurrent probing following cognitive interview form together. It divided into two parts:

Part 1: Cognitive interviews were also conducted after the subjects read or listened to the introduction part of the Thai version of the MLHFQ.

Part 2: Cognitive interviews were also conducted after the subjects read or listened to each item of the Thai version of the MLHFQ.

Note: If the researcher found other problems from the Thai version of the MLHFQ administration except probes in cognitive interview form, the researcher could ask to identify those problems immediately.

In the Thai version of the SF-36 administration, the researcher could ask the subjects who wondered in anything about items immediately. Afterwards, the researcher identified the found problems for improvement later.

4.6) After the subjects completed all questionnaires, each subject was assessed NYHA functional classes from a physician whom the subject visited.

4.7) All data from sound recorder were transcribed for problem identifications again. Then, they were used to improve the content in the Thai version of the MLHFQ (if any).

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5) After pretesting processes, all questionnaires were tested the psychometric properties in the subjects at baseline following criteria. These procedures were described as follows:

5.1) The subjects were recruited for this study following inclusion and exclusion criteria.

5.2) The subjects were described about the objective of this study following research subject information sheet from the researcher. All subjects who accepted to participate in this study signed informed consent.

5.3) Next, the researcher interviewed demographic data and recorded clinical data from medical record into data collection form.

5.4) All subjects completed the Thai version of the MLHFQ and the SF-36 with face-to-face interview. Order of questionnaire administration was conducted with simple random sampling by random number table. It began from the number of the first row in the first line of random number table. Then, it began at the first number of the second line when it was the end of the first line. It kept on this process until the subjects were enrolled completely. The subjects who got the odd number completed the Thai version of the MLHFQ at first and completed the Thai version of the SF-36 later. On the other hand, those who got the even number completed the Thai version of the SF-36 at first and completed the Thai version of the MLHFQ later. Each questionnaire, the time at the beginning and the end of the administration were recorded.

5.5) After the subjects completed all questionnaires, each subject was assessed NYHA functional classes from a physician.

6) Some subjects were assessed with the Thai version of the MLHFQ again after 2 weeks (14 days) for test-retest reliability by telephone interview. Sampling for this test was conducted by choosing every three subjects. Before each interview, subjects were asked for assessment with a question about health perception during the past 2 weeks. If any subject has no change in their health perception, he or she will be interviewed. On the other hand, if any subject had change about it, he or she will be excluded in this test and was replaced with next subject.

7) All subjects were made an appointment for the second assessment in the next visit (about 2-3 months). Before each interview, they were asked for comparison about their health transition during the past visit. There were five response choices: 1. much better now than the first visit, 2. somewhat better now than the first visit, 3. about the same as the first visit, 4. somewhat worse now than the first visit, and 5. much worse now than the first visit. Then, all procedures were similar to 5.1 to 5.5.

8) Statistical and data analysis, discussion, and conclusion were made after data collecting finished. Then, report writing and publishing were performed later.

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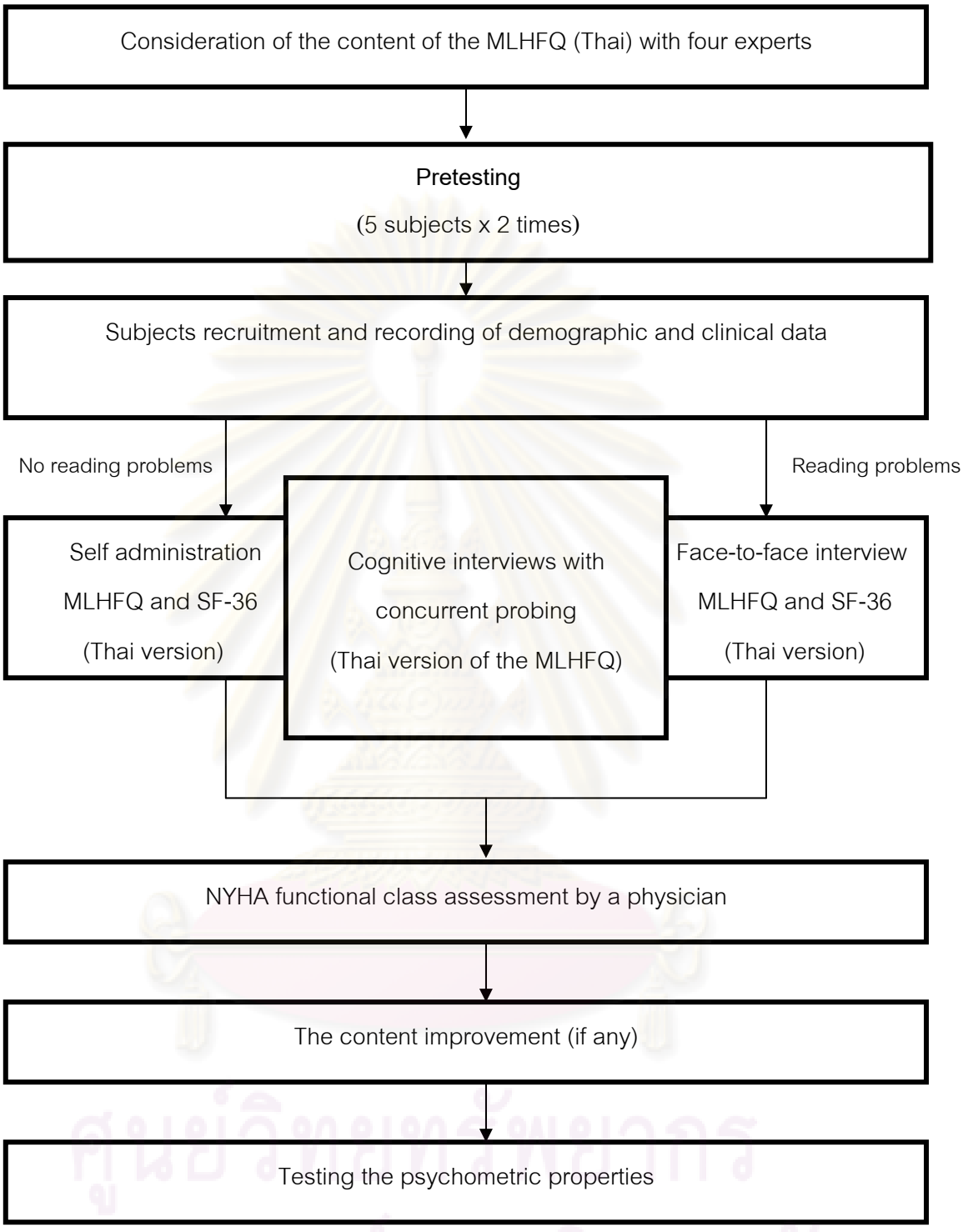

Figure 6 Flow chart of the study procedure

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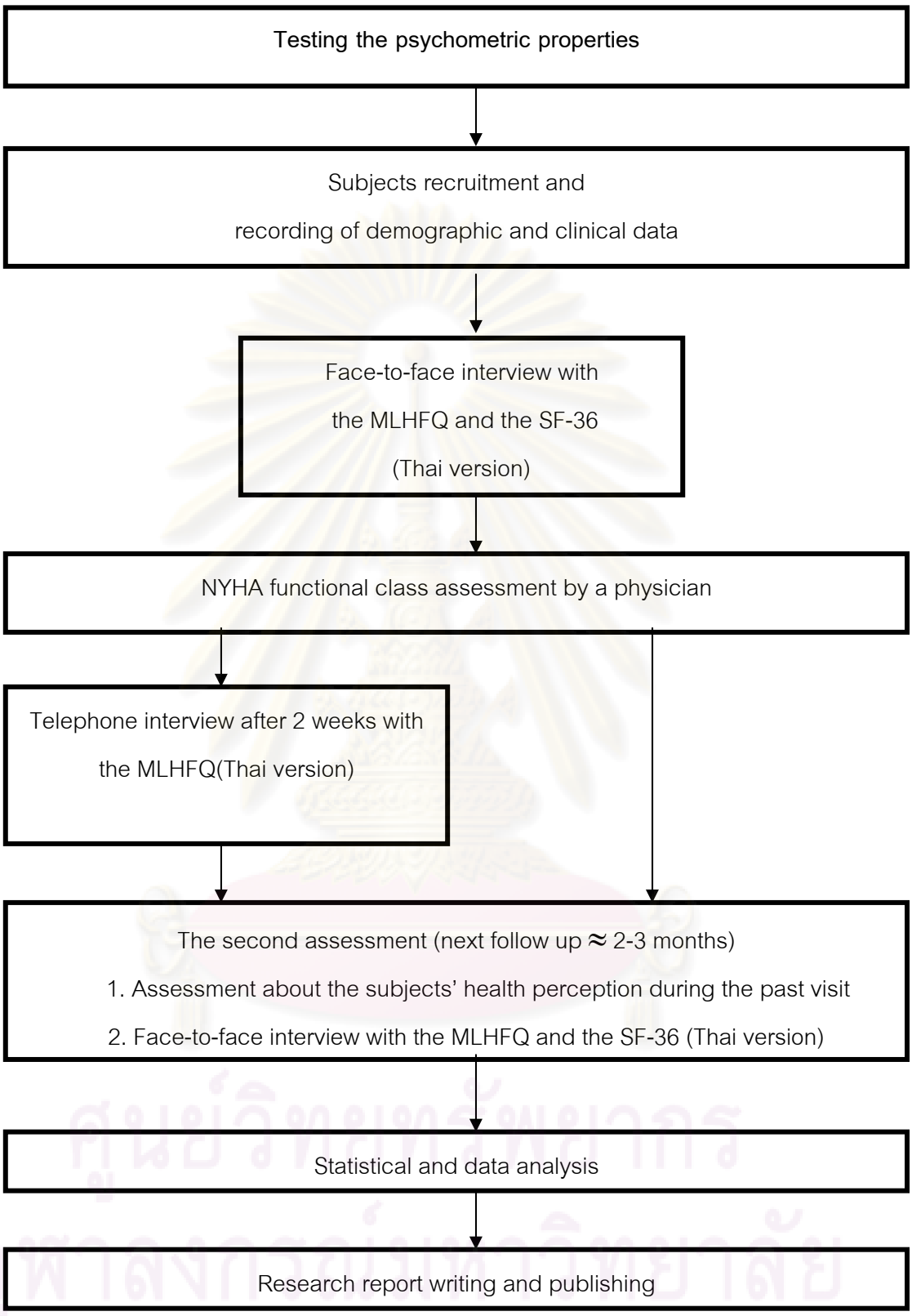

Figure 6 Flow chart of the study procedure (continue)

3.5 Statistical and Data Analysis

In this study, all data were analyzed using SPSS version 17.0 (SPSS Co. Ltd., Bangkok, Thailand). The statistical analysis was described as follows:

1) Patients' sociodemographic, clinical and questionnaire administration data were shown with descriptive statistics such as frequency, percentage, range, median, mean, and standard deviation (SD).

2) Kolmogorov Smirnov test was used for testing of the normal distribution of continuous data. Our study found that most of data had non-normal distributions. Therefore, this study used nonparametric statistics in overall statistical analysis. Differences with $p < 0.05$ were considered to statistically significant.

3.5.1 Practicality

Practicality was evaluated in terms of mean administration time and the percentages of floor and ceiling effects. The ceiling and floor effects should be within the limits of 15%.[60]

3.5.2 Reliability

Reliability was assessed in terms of internal consistency and test-retest reliability.

3.5.2.1 Internal Consistency:

Cronbach's alpha coefficient was used to evaluate internal consistency. Commonly accepted minimal standards for Cronbach's alpha coefficients are 0.70 for group comparisons and 0.90-0.95 for individual comparisons.[58] Moreover, there were considerations regarding the problems of some items affecting questionnaire reliability using corrected item-total correlation analysis and Cronbach's alpha coefficient if item deleted. Each item, corrected item-total correlation should be more than 0.3 and Cronbach's alpha coefficient if item deleted should be lower than overall Cronbach's alpha coefficient, indicating satisfactory internal consistency of this version.[61]

3.5.2.2 Test-Retest Reliability:

Median differences of the MLHFQ scores were tested with Wilcoxon signed ranks test. ICC was also used to evaluate the test-retest reliability. Criteria for ICC consideration were as follows: ICC < 0.40 (low agreement), 0.40 ≤ ICC ≤ 0.75 (moderate agreement), and ICC > 0.75 (high agreement).[17] As with internal consistency reliablity, minimal standards for ICC are also typically considered to be 0.70 for group comparisons and 0.90-0.95 for individual measurements over time.[58]

3.5.3 Validity

3.5.3.1 Content Validity: It divided into two parts as follows:

Part 1: Content validity index (CVI) was used to quantify the extent of agreement between the experts. The CVI was defined as proportion of items given a rating of quite/very relevant by both raters. The CVI was calculated from the number of contents given a rating of quite/very relevant by raters.[62] The acceptable CVI was 0.8 or above.[63]

$$CVI = \frac{\text{Number of contents given a rating of quite/very relevant by raters}}{\text{The overall number of rated contents}}$$

Part 2: Problems found in pretesting processes were classified following four stages of question-and-answer process, such as comprehension, retrieval, judgment, and response.[18,64,65]

3.5.3.2 Construct Validity

Construct validity analyses were divided into three parts as follows:

Part 1: Convergent and discriminant validity were evaluated using correlation coefficients among the MLHFQ and the SF-36 scores. They were presented in correlation matrix pattern. Correlation coefficients were performed with Spearman rank order correlation coefficients (rho). Considerations of correlation level

were described as follows: < 0.30 (low correlation), 0.30-0.50 (moderate correlation), and > 0.50 (high correlation).[3] In addition, discriminant validity was assessed with differences of the correlation coefficients between the MLHFQ physical dimension and emotional dimension with the SF-36 physical and mental subscales using t-test for the significance testing of the difference between dependent correlations.[66]

Part 2: Exploratory factor analysis was used to determine the construct of the Thai version of the MLHFQ for comparisons with the original version. In this study, factor extraction with principal axis factoring and oblique rotation with direct oblimin were used for factor extraction and axis rotation, respectively. Testing assumptions of factor analysis[67] were as follows: 1) Pearson product moment correlation coefficients between items should be more than 0.30 2) Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMOMSA) must exceed 0.50 for both the overall test and each individual variable. 3) Bartlett's test of sphericity must be statistically significant ($p < 0.05$). In addition, factors with eigenvalues above 1.0 and factors shown by the scree test before inflection point were used for number of factors selection. Moreover, items loaded on the same trait if factor loadings were 0.40 or above.[67] Cronbach's alpha coefficients of each extracted factor were calculated for confirmation of reliability.

Part 3: Known-groups validity was evaluated from median differences of the MLHFQ scores among patients with different NYHA classes using Kruskal-Wallis test. In addition, Mann-Whitney U test was applied for pairwise comparisons. This analysis was also used for confirmation of construct validity of the MLHFQ dimensions defined by this research.

3.5.4 Responsiveness

Median differences of the MLHFQ scores between two assessments were evaluated with Wilcoxon signed ranks test. In addition, ES and SRM were also used to perform responsiveness indices. ES was calculated with mean score divided by standard deviation at baseline and SRM was calculated with mean score divided by standard deviation of change. Scores of 0.2, 0.5, and 0.8 are considered to be small, medium, and large changes for the ES and SRM.[17,18] Mean changes of each dimension

were used to present the minimally important differences of each subgroup. This analysis was also used for confirmation of responsiveness of the MLHFQ dimensions classified by our research.

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CHAPTER IV
RESULTS

This chapter gives the details of the results regarding patients' characteristics, practicality, reliability, validity, and responsiveness of the Thai version of the MLHFQ.

4.1 Patients' Characteristics

Table 6 summarizes the sociodemographic and clinical characteristics of the samples. The numbers of patients with chronic HF enrolled in pretesting, test–retest reliability and psychometric properties testing in the first assessment were 10, 60, and 180, respectively. During the next follow-up, 55 (30.6%) patients dropped out from the study because of failing to keep their appointment (n = 35) and a change of mind to be on the study (n = 20). Therefore, the subjects in the second assessment subgroup were 125. This study grouped the patients to three subgroups for data analysis: the patients who felt better about their health perception or improvement subgroup (n =66), worse about their health perception or deterioration subgroup (n = 19), and no change about their health perception or stable subgroup (n = 40).

In the overall psychometric properties testing group, the subjects were 105 (58.3%) men and 75 (41.7%) women. The mean age of the participants was 64.7 $\pm$ 12.0 years, ranging in age from 30 to 87, and 123 (68.3%) of the participants were age 60 years and older. Approximately 87 (48.3%) of the patients were unemployed and 48 (26.5%) were retired. Only fifteen subjects (8.3%) had no formal education. All patients were categorized in three NYHA classes: 67 (37.3%) were in NYHA class I, 71 (39.4%) in class II, and 42 (23.3%) in class III. Sixty two patients (34.4%) had LVEF < 40%. The most prevalent possible etiology of HF was coronary artery disease, 80 (44.4%); heart valve disease, 32 (17.8%); and dilated cardiomyopathy, 28 (15.6%). All patients had at least one comorbidity in addition to chronic HF. The most predominant number of comorbidities was three, which comprised 57 patients (31.7%). The most common comorbid conditions were hypertension, 129 (71.7%) and dyslipidemia, 126 (70.0%).

The most frequent medications used for HF treatment were beta blockers, 128 (71.1%); loop diuretics, 102 (56.7%); and ACEIs, 93 (51.7 %).

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Table 6 Sociodemographic and clinical characteristics of the subjects

Characteristics		Pretesting subgroup (n =10)	Psychometric properties testing				
			First assessment group (n=180)	Test-retest reliability subgroup (n=60)	Second assessment		
					Improvement subgroup (n = 66)	Stable subgroup (n = 40)	Deterioration subgroup (n = 19)
Age (Years)	Mean ± SD	64.9 ± 10.7	64.7 ± 12.0	64.9 ± 11.6	63.5 ± 12.8	65.3 ± 11.2	67.6 ± 9.3
	[Median]	[64]	[66]	[65]	[66]	[66]	[71]
	(range)	(50-79)	(30-87)	(30-87)	(30-82)	(34-82)	(51-80)
Gender	No. of subject (%)						
Male		8 (80.0)	105 (58.3)	34 (56.7)	39 (59.1)	23 (57.5)	10 (52.6)
Female		2 (20.0)	75 (41.7)	26 (43.3)	27 (40.9)	17 (42.5)	9 (47.4)
Education	No. of subject (%)						
No formal education		0 (0.0)	15 (8.3)	3 (5.0)	7 (10.6)	0 (0.0)	0 (0.0)
Elementary school		3 (30.0)	65 (36.1)	19 (31.6)	26 (39.4)	16 (40.0)	7 (36.8)
Secondary school		3 (30.0)	55 (30.6)	24 (40.0)	21 (31.8)	12 (30.0)	9 (47.4)
Vocational certificate		0 (0.0)	11 (6.1)	3 (5.0)	1 (1.5)	5 (12.5)	0 (0.0)
High vocational certificate		2 (20.0)	2 (1.1)	1 (1.7)	0 (0.0)	0 (0.0)	1 (5.3)
Diploma		1 (10.0)	6 (3.3)	1 (1.7)	1 (1.5)	2 (5.0)	1 (5.3)
University/College		1 (10.0)	26 (14.5)	9 (15.0)	10 (15.2)	5 (12.5)	1 (5.3)

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Table 6 Baseline sociodemographic and clinical characteristics (continue)

Characteristics		Pretesting subgroup	Psychometric properties testing				
			First assessment group	Test-retest reliability subgroup	Second assessment		
					Improvement subgroup	Stable subgroup	Deterioration subgroup
		(n =10)	(n=180)	(n=60)	(n = 66)	(n = 40)	(n = 19)
Employment status	No. of subject (%)						
Employed		4 (40.0)	45 (25.2)	11 (18.4)	20 (30.3)	7 (17.5)	4 (21.1)
Unemployed		1 (10.0)	87 (48.3)	32 (55.3)	27 (40.9)	23 (57.5)	13 (68.4)
Retired		5 (50.0)	48 (26.5)	17 (28.3)	19 (28.8)	10 (25.0)	2 (10.5)
Income (Baht) per month	No. of subject (%)						
< 5000		2 (20.0)	57 (31.7)	20 (33.3)	20 (30.3)	15 (37.5)	8 (42.1)
5,000-9,999		2 (20.0)	51 (28.3)	17 (28.3)	20 (30.3)	11 (27.5)	3 (15.9)
10,000-19,999		2 (20.0)	38 (21.1)	10 (16.7)	16 (24.2)	5 (12.5)	4 (21.0)
≥ 20,000		4 (40.0)	28 (18.9)	13 (21.7)	10 (15.2)	9 (22.5)	4 (21.0)
Marital status	No. of subject (%)						
Married		6 (60.0)	120 (66.6)	42 (70.0)	45 (68.2)	24 (60.0)	14 (73.7)
Single		1 (10.0)	12 (6.7)	2 (3.3)	7 (10.6)	2 (5.0)	1 (5.3)
Widowed		2 (20.0)	43 (23.9)	13 (21.7)	13 (19.7)	12 (30.0)	5 (21.1)
Divorced		1 (10.0)	5 (2.8)	3 (5.0)	1 (1.5)	2 (5.0)	0 (0.0)

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Table 6 Baseline sociodemographic and clinical characteristics (continue)

Characteristics		Pretesting subgroup (n =10)	Psychometric properties testing				
			First assessment group (n=180)	Test-retest reliability subgroup (n=60)	Second assessment		
					Improvement subgroup (n = 66)	Stable subgroup (n = 40)	Deterioration subgroup (n = 19)
Living situation	No. of subject (%)						
Living alone		1 (10.0)	10 (5.6)	1 (1.7)	4 (6.1)	3 (7.5)	1 (5.3)
Living with other persons		9 (90.0)	170 (94.4)	59 (98.3)	62 (93.9)	37 (92.5)	18 (94.7)
NYHA functional classes	No. of subject (%)						
I		1 (10.0)	67 (37.3)	22 (36.7)	27 (40.9)	17 (42.5)	2 (10.5)
II		7 (70.0)	71 (39.4)	27 (45.0)	26 (39.4)	18 (45.0)	9 (47.4)
III		2 (20.0)	42 (23.3)	11 (18.3)	13 (19.7)	5 (12.5)	8 (42.1)
LVEF (%)	No. of subject (%)						
< 40		5 (50.0)	62 (34.4)	20 (33.3)	28 (42.4)	13 (32.5)	6 (31.6)
≥ 40		5 (50.0)	118 (65.6)	40 (66.7)	38 (57.6)	27 (67.5)	13 (68.4)

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Table 6 Baseline sociodemographic and clinical characteristics (continue)

Characteristics		Pretesting subgroup (n =10)	Psychometric properties testing				
			First assessment group (n=180)	Test-retest reliability subgroup (n=60)	Second assessment		
					Improvement subgroup (n = 66)	Stable subgroup (n = 40)	Deterioration subgroup (n = 19)
Hospitalizations for HF in the past year	No. of subject (%)						
None		9 (90.0)	104 (57.7)	39 (65.0)	34 (51.5)	25 (62.5)	11 (57.9)
One time		1 (10.0)	52 (28.9)	13 (21.7)	21 (31.8)	11 (27.5)	3 (15.8)
Two times		0 (0.0)	10 (5.6)	3 (5.0)	5 (7.6)	1 (2.5)	2 (10.5)
More than two times		0 (0.0)	14 (7.8)	5 (8.3)	6 (9.1)	3 (7.5)	3 (15.8)
Etiology of HF	No. of subject (%)						
Hypertensive heart disease		0 (0)	6 (3.3)	3 (5.0)	5 (7.6)	0 (0)	0 (0.0)
Coronary artery disease		6 (60.0)	80 (44.4)	16 (26.7)	28 (42.5)	16 (40.0)	11 (57.9)
Heart valve disease		1 (10.0)	32 (17.8)	13 (21.7)	9 (13.6)	8 (20.0)	3 (15.8)
Dilated cardiomyopathy		3 (30.0)	28 (15.6)	12 (20.0)	11 (16.7)	8 (20.0)	2 (10.5)
Alcoholic cardiomyopathy		0 (0)	5 (2.8)	0 (0.0)	3 (4.5)	1 (2.5)	0 (0.0)
Atrial fibrillation		0 (0)	22 (12.2)	12 (20.0)	9 (13.6)	6 (15.0)	2 (10.5)
Chronic kidney disease		0 (0)	7 (3.9)	4 (6.6)	1 (1.5)	1 (2.5)	1 (5.3)

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Table 6 Baseline sociodemographic and clinical characteristics (continue)

Characteristics		Pretesting subgroup (n =10)	Psychometric properties testing				
			First assessment group (n=180)	Test-retest reliability subgroup (n=60)	Second assessment		
					Improvement subgroup (n = 66)	Stable subgroup (n = 40)	Deterioration subgroup (n = 19)
Number of co-morbidities	No. of subject (%)						
One		0 (0.0)	27 (15.0)	12 (20.0)	13 (19.7)	2 (5.0)	1 (5.3)
Two		0 (0.0)	34 (18.9)	15 (25.0)	12 (18.2)	6 (15.0)	3 (15.8)
Three		4 (40.0)	57 (31.7)	16 (26.7)	22 (33.3)	16 (40.0)	6 (31.6)
Four		4 (40.0)	40 (22.2)	12 (20.0)	13 (19.7)	10 (25.0)	5 (26.3)
More than four		3 (30.0)	22 (12.2)	5 (8.3)	6 (9.1)	6 (15.0)	4 (21.1)
History of co-morbidity	No. of subject (%)						
Hypertension		9 (90.0)	129 (71.7)	41 (68.3)	48 (72.7)	31 (77.5)	15 (78.9)
Coronary artery disease		8 (80.0)	70 (38.9)	14 (23.3)	26 (39.4)	17 (42.5)	9 (47.4)
Dyslipidemia		8 (80.0)	126 (70.0)	41 (68.3)	41 (62.1)	36 (90.0)	13 (68.4)
Diabetes mellitus		4 (40.0)	63 (35.0)	16 (26.7)	23 (34.8)	16 (40.0)	9 (45.0)
Atrial fibrillation		6 (60.0)	45 (25.0)	17 (28.3)	17 (25.8)	7 (17.5)	8 (42.1)
Valvular heart disease		1 (10.0)	35 (19.4)	13 (21.7)	9 (13.6)	7 (17.5)	4 (21.1)
Anemia		0 (0.0)	3 (1.7)	1 (1.7)	1 (1.5)	1 (2.5)	1 (5.3)
Chronic kidney disease		3 (30.0)	34 (18.9)	10 (16.7)	10 (15.2)	10 (25.0)	4 (21.1)

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Table 6 Baseline sociodemographic and clinical characteristics (continue)

Characteristics		Pretesting subgroup (n =10)	Psychometric properties testing				
			First assessment group (n=180)	Test-retest reliability subgroup (n=60)	Second assessment		
					Improvement subgroup (n = 66)	Stable subgroup (n = 40)	Deterioration subgroup (n = 19)
History of co-morbidity (continue)	No. of subject (%)						
Gout		1 (10.0)	12 (6.7)	2 (3.3)	5 (7.6)	1 (2.5)	2 (10.5)
Osteoarthritis		0 (0.0)	4 (2.2)	3 (5.0)	0 (0.0)	1 (2.5)	0 (0.0)
Hyperthyroidism		0 (0.0)	1 (0.6)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)
Hypothyroidism		1 (10.0)	4 (2.2)	1 (1.7)	2 (3.0)	0 (0.0)	1 (5.3)
Cirrhosis		0 (0.0)	4 (2.2)	1 (1.7)	3 (4.5)	0 (0.0)	0 (0.0)
Asthma		0 (0.0)	2 (1.1)	0 (0.0)	1 (1.5)	1 (2.5)	0 (0.0)
Chronic obstructive pulmonary disease		1 (10.0)	3 (1.7)	1 (1.7)	0 (0.0)	2 (5.0)	0 (0.0)
Benign prostatic hyperplasia		0 (0.0)	4 (2.2)	2 (3.3)	0 (0.0)	3 (7.5)	0 (0.0)
Number of HF medications	No. of subject (%)						
None		0 (0.0)	3 (1.7)	3 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)
One		2 (20.0)	23 (12.8)	6 (10.0)	7 (10.6)	7 (17.5)	2 (10.5)
Two		2 (20.0)	55 (30.5)	15 (25.0)	21 (31.8)	8 (20.0)	4 (21.1)
Three		3 (30.0)	54 (30.0)	19 (31.7)	19 (28.8)	17 (42.5)	9 (47.4)
Four or above		2 (30.0)	45 (25.0)	17 (28.3)	19 (28.8)	8 (20.0)	4 (21.1)

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Table 6 Baseline sociodemographic and clinical characteristics (continue)

Characteristics		Pretesting subgroup (n =10)	Psychometric properties testing				
			First assessment group (n=180)	Test-retest reliability subgroup (n=60)	Second assessment		
					Improvement subgroup (n = 66)	Stable subgroup (n = 40)	Deterioration subgroup (n = 19)
HF medications	No. of subject (%)						
ACEIs		2 (20.0)	93 (51.7)	33 (55.0)	29 (43.9)	25 (62.5)	10 (52.6)
ARBs		3 (30.0)	42 (23.3)	15 (25.0)	19 (28.8)	8 (20.0)	3 (15.8)
Aldosterone antagonists		6 (60.0)	49 (27.2)	18 (30.0)	22 (33.3)	9 (22.5)	3 (15.8)
Beta blockers		6 (60.0)	128 (71.1)	43 (71.7)	50 (75.8)	28 (70.0)	19 (100.0)
Digoxin		2 (20.0)	57 (31.7)	19 (31.7)	20 (30.3)	10 (25.0)	7 (36.8)
Loop diuretics		10 (100.0)	102 (56.7)	33 (55.0)	39 (59.1)	22 (55.0)	10 (52.6)
Thiazide diuretics		0 (0.0)	14 (7.8)	3 (5.0)	6 (9.1)	6 (15.0)	1 (5.3)

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4.2 Content Validity of the Thai Version of the MLHFQ

4.2.1 Experts Review

Expert ratings of all contents of the Thai versions of the MLHFQ are shown in APPENDIX G. CVI for the total instrument was the proportion of items rated as quite relevant or very relevant (3 or 4). It was found that the overall CVI was 1.0, indicating the excellent content validity for this Thai version of the MLHFQ. In addition, all experts were asked to comment on individual contents in relation to the appropriateness, clarity, style, and cultural adaptation of this translated version. Then, overall opinions were improved some contents of this version to ensure that it reflected the best practicality (APPENDIX H). A final Thai version of the MLHFQ used for data collection in this study is shown in APPENDIX C.

4.2.2 Pretesting of the Thai Version of the MLHFQ

The mode of administrations used in cognitive interviews were face-to-face interview (n = 6, 60%) and self administration (n = 4, 40%). The length of time for these interviews was approximately 30 minutes per one subject. Overall number of problems in the first and the second cognitive interviews were eight and one, respectively. They were identified in three categories, but there was no problem regarding retrieval process in this study.

As shown in Table 7, there were two problems with comprehension in the first interview. Two subjects in the face-to-face interviews did not understand introduction because the researcher read introduction section quickly. Five problems with judgment were identified. It was found that there were two patients who only considered about drug allergy in judgment of item 16 (side effect from treatments) responses. In addition, there were two subjects thought that regular sleeping in the afternoon was also considered in item 2 (sit or lie down to rest during the day) answers. Moreover, a patient explained that a reason for response in item 6 (difficulty in sleeping well at night) was no hypnotic drug use. Response was involved in one of identified problems. One respondent will select the response choice “0” if there were no changes in the next follow-up (response choice “2” was selected before). In the second

assessment, only one problem was identified with judgment. A subject described that a reason for response in item 12 (short of breath) was dyspnea from respiratory disease.

As mentioned above, there were few problems found in the first and second interview and there was no serious problem about contents of this questionnaire. Therefore, there was no improvement for any content. However, researcher adjusted speed in interviews and emphasized the subjects for response of this questionnaire that they should only recall about influence of heart condition influencing their life in the past month as far as possible and read the main question with each item every time for all interviews.

Table 7 Number of problems identified in cognitive interviews of the Thai version of the MLHFQ

Problems	The first Interview (n = 5)	The second interview (n = 5)	Overall (n =10)
1. Comprehension	2	0	2
2. Retrieval	0	0	0
3. Judgment	5	1	6
4. Response	1	0	1
Total	**8**	**1**	**9**

4.3 Practicality of the Thai Version of the MLHFQ

Practicality was assessed with the length of time used for questionnaire administration and score distributions. The average time used at baseline, retesting, and the second assessment for the MLHFQ were 5.6 $\pm$ 2.1 minutes, 5.4 $\pm$ 1.5 minutes, and 4.5 $\pm$ 1.7 minutes, respectively.

Score distributions for the MLHFQ are presented in Table 8. It was found that the highest floor effect was in item 16 (88.9%) and the highest ceiling effect was in item 10 (10.0%). As shown in Table 9, the range of the floor effect for the MLHFQ scores was 11.1 to 27.2%. There was the highest floor effect in the emotional dimension. However, the ceiling effects of the MLHFQ scores were not found in this study. As shown in Table

10, the floor effects of all MLHFQ scores in the patients with NYHA class I was higher than those with NYHA class II and III.

Table 8 Means and percentages of the responses of each MLHFQ item at baseline (n =180)

Items	Dimensions	Mean ± SD	% Response					
			0	1	2	3	4	5
1	-	0.68 ± 1.22	66.7	16.7	7.2	3.3	3.9	2.2
2	Physical	0.79 ± 1.31	63.9	15.6	6.7	7.2	4.4	2.2
3	Physical	1.37 ± 1.56	43.9	18.3	12.2	13.3	7.2	5.0
4	Physical	1.06 ± 1.59	62.2	7.8	8.9	8.3	8.3	4.4
5	Physical	1.18 ± 1.66	59.4	9.4	4.4	11.7	10.6	4.4
6	Physical	1.36 ± 1.63	49.4	11.1	12.8	12.8	8.3	5.6
7	Physical	0.91 ± 1.50	65.0	10.6	9.4	4.4	5.0	5.6
8	-	0.75 ± 1.50	74.4	7.2	3.9	3.3	5.6	5.6
9	-	1.18 ± 1.61	55.0	13.9	7.8	10.0	7.8	5.6
10	-	0.87 ± 1.70	73.3	7.8	2.2	1.7	5.0	**10.0**[a]
11	-	0.82 ± 1.36	63.3	15.6	7.8	6.1	3.3	3.9
12	Physical	1.12 ± 1.49	54.4	12.8	11.1	13.3	4.4	3.9
13	Physical	1.56 ± 1.61	35.6	23.3	14.4	8.9	11.7	6.1
14	-	0.35 ± 1.02	86.7	3.9	2.8	2.2	3.3	1.1
15	-	0.47 ± 1.23	84.4	3.9	2.2	2.2	4.4	2.8
16	-	0.23 ± 0.81	**88.9**[b]	5.6	2.2	1.1	1.1	1.1
17	Emotional	0.82 ± 1.40	66.1	12.8	5.0	8.3	4.4	3.3
18	Emotional	0.94 ± 1.39	57.2	18.3	8.3	8.3	4.4	3.3
19	Emotional	1.12 ± 1.44	48.3	22.8	10.6	8.9	5.6	3.9
20	Emotional	1.28 ± 1.52	47.8	14.4	13.3	15.0	5.0	4.4
21	Emotional	0.61 ± 1.17	70.0	16.1	3.9	5.6	2.2	2.2

a. Bolded value indicates the highest ceiling effect.

b. Bolded value indicates the highest floor effect.

Table 9 Score distributions of the MLHFQ at baseline (n =180)

MLHFQ	Observed range	Mean ± SD	Median	% Floor	% Ceiling	Skewness	Kurtosis
Physical (8 items)	0-35	9.4 ± 9.5	6.0	18.3	0	0.98	-0.15
Emotional (5 items)	0-23	4.8 ± 5.6	3.0	27.2	0	1.49	1.72
Global (21 items)	0-84	19.5 ± 19.6	12.0	11.1	0	1.14	0.38

Table 10 Floor and ceiling effects of the MLHFQ by NYHA classes at baseline (n =180)

MLHFQ	% Floor			% Ceiling		
	NYHA Class I (n = 67)	NYHA Class II (n = 71)	NYHA Class III (n = 42)	NYHA Class I (n = 67)	NYHA Class II (n = 71)	NYHA Class III (n = 42)
Physcial (8 items)	37.3	9.9	2.4	0.0	0.0	0.0
Emotional (5 items)	46.3	21.1	7.1	0.0	0.0	0.0
Global (21 items)	25.4	2.8	2.4	0.0	0.0	0.0

4.4 Reliability of the Thai Version of the MLHFQ

4.4.1 Internal Consistency

Table 11 presents the internal consistency demonstrated by Cronbach's alpha coefficients for all MLHFQ dimensions at baseline. It was found that Cronbach's alpha coefficients of global score and physical and emotional dimensions were higher than 0.70 (0.93, 0.90, and 0.86, respectively).

Table 11 Cronbach's alpha coefficients of the MLHFQ at baseline (n = 180)

MLHFQ	Number of items	Cronbach's alpha coefficients
Physical	8	0.90
Emotional	5	0.86
Global	21	0.93

Bolded values indicate Cronbach's alpha coefficients less than 0.70.

Item-total statistics of the Thai version of the MLHFQ are shown in Table 12. It was found that 19 of 21 items had corrected item-total correlations more than 0.30, ranging in value from 0.38 to 0.81. However, only two items had corrected item-total correlation coefficients less than 0.30 and Cronbach's alpha coefficient after item deleted increased (overall Cronbach's alpha coefficients = 0.932) such as item 14 and 16.

4.4.2 Test-Retest Reliability

Table 13 illustrates average score changes and ICCs for all MLHFQ scores in test-retest reliability subgroup. It was found that there were no significant differences of the MLHFQ scores between baseline (face-to-face interview) and retesting (telephone interview). In addition, the observed ICCs higher than 0.75, indicating high agreement were found in physical dimension (ICC = 0.77) and global scores (ICC = 0.76).

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Table 12 Item-total statistics of the MLHFQ at baseline (n = 180)

Items	Corrected item-total correlations[a]	Cronbach's alpha coefficients if item deleted
1	0.38	0.932
2	0.59	0.929
3	0.70	0.927
4	0.67	0.927
5	0.70	0.927
6	0.56	0.930
7	0.67	0.927
8	0.52	0.930
9	0.68	0.926
10	0.41	0.932
11	0.51	0.930
12	0.66	0.928
13	0.81	0.925
14	0.20[b]	0.934[c]
15	0.38	0.932
16	0.20[b]	0.934[c]
17	0.62	0.928
18	0.58	0.929
19	0.68	0.928
20	0.54	0.930
21	0.57	0.930

a. Overall values presented in this column are Spearman rank order correlation coefficients.

b. Corrected item-total correlation coefficients are less than 0.30.

c. Cronbach's alpha coefficients if item deleted are more than 0.932 (Overall Cronbach's alpha coefficients = 0.932).

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Table 13 Score changes and intraclass correlation coefficients for the MLHFQ in test-retest reliability subgroup (n =60)

MLHFQ	Baseline assessment	Retest assessment	Baseline assessment	Retest assessment	p-value[a]	ICCs
	Mean ± SD	Mean ± SD	Median	Median		
Physical	8.2 ± 8.5	7.5 ± 8.7	5.0	3.5	0.43	0.77
Emotional	4.2 ± 5.6	4.6 ± 4.7	2.0	3.0	0.39	0.61
Global	16.3 ± 17.6	15.2 ± 16.1	10.0	7.5	0.41	0.76

a. Differences of median scores between baseline and retesting are tested using Wilcoxon signed ranks test.

4.5 Construct Validity of the Thai Version of the MLHFQ

4.5.1 Convergent and Discriminant Validity

Table 14 presents multitrait multimethod matrix (MTMM) among the MLHFQ and the SF-36 scores. As regards the correlations among the MLHFQ scores, this study found that the MLHFQ physical dimension had high correlation with the MLHFQ emotional dimension (Spearman rank order correlation; rho = 0.74, $p < 0.05$). In addition, the MLHFQ global score had strong correlation with physical and emotional dimensions (Spearman rank order correlation; rho = 0.96 and 0.85, respectively; all $p < 0.05$).

Regarding the correlation among the MLHFQ and the SF-36 scores, it was found that the MLHFQ physical dimension had significantly moderate or strong reverse correlations with all SF-36 subscales and component summary scores (Spearman rank order correlation; rho = -0.41 to -0.53, all $p < 0.05$). Correlations among the MLHFQ physical dimension and two subscales (physical functioning and role physical) and physical component summary score were stronger than the MLHFQ emotional dimension. Moreover, the MLHFQ emotional dimension had significantly moderate or strong reverse correlations with all SF-36 subscales and component summary scores (Spearman rank order correlation; rho = -0.39 to -0.56, all $p < 0.05$). Correlations among the MLHFQ emotional dimension and two subscales (role emotional

and mental health) and mental component summary score were higher than MLHFQ physical dimension.

Table 14 Multitrait multimethod matrix among the MLHFQ and the SF-36 scores at baseline (n = 180)

Instruments	MLHFQ		
MLHFQ	Physical	Emotional	Global
Emotional	0.74		
Global	0.96	0.85	
SF-36			
PF	-0.49	-0.39	-0.48
RP	-0.51	-0.48	-0.55
BP	-0.45	-0.49	-0.49
GH	-0.47	-0.51	-0.51
VT	-0.50	-0.47	-0.54
SF	-0.41	-0.47	-0.46
RE	-0.53	-0.56	-0.56
MH	-0.47	-0.51	-0.51
PCS	-0.53	-0.47	-0.55
MCS	-0.46	-0.53	-0.50

Overall values are presented with Spearman rank order correlation coefficients ($p < 0.05$).

Comparisons of the Spearman rank order correlation coefficients with the SF-36 subscales and component summary scores between the MLHFQ physical and emotional dimensions are illustrated in Table 15. This study indicated that there was a significant difference on correlation with the SF-36 physical functioning subscale between the MLHFQ physical and emotional dimensions (t-test, $p = 0.04$).

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Table 15 Comparisons of the Spearman rank order correlation coefficients of the MLHFQ physical and emotional dimensions with the SF-36 subscales and component summary scores at baseline (n = 180)

Instruments	MLHFQ		p-value[a]
SF-36	Physical	Emotional	
Physical			
PF	-0.49	-0.39	**0.04**
RP	-0.51	-0.48	0.52
PCS	-0.53	-0.47	0.20
Mental			
RE	-0.53	-0.56	0.50
MH	-0.47	-0.51	0.38
MCS	-0.46	-0.53	0.12

Overall values are presented with Spearman rank order correlation coefficients ($p < 0.05$).

Bolded value indicates that there is statistically significant difference of the correlation.

a. Pairwise comparisons of correlation coefficients are tested using t-test for the significance testing of the difference between dependent correlations.

4.5.2 Exploratory Factor Analysis of the Thai version of the MLHFQ

The exploratory factor analysis of all MLHFQ items with principal axis factoring and oblique rotation with direct oblimin is shown in Table 16. As for inter-item correlations, this study found that 194 of the 210 correlations (92.4%) were significant at $p < 0.05$ (data not shown). There were no significances in correlations with several items found in item 14, 15, and 16. The KMOMSA was in the acceptable range (above 0.50) with a value of 0.91, indicating that the present data were appropriate for exploratory factor analysis. In addition, the Bartlett's test of sphericity was significant at $p < 0.001$, indicating sufficient correlations among the variables to proceed with the analysis. Using the criterion of eigenvalues over 1.0 and consideration of scree test, a four-factor solution provided the suitable extraction. Our study found that item 10 and 16 had factor loading on any factor less than 0.40. In addition, item 2 and 3 had cross-loading on several factors and difficulty for interpretation. However, this study considered that all items of the Thai version of the MLHFQ were important for HRQoL assessments in Thai patients with chronic HF. Therefore, our study tried to respecify all problematic items on

all extracted factors with ignoring criteria of factor loading. First, item 10 and 16 were respecified to load on factor that they had the highest factor loading. Therefore, item 10 and 16 of this study load on Factor 4 and 3, respectively. Second, item 2 and 3 were considered to load on Factor 1 because they seem to be easier to interpret on this factor than other factors.

This study identified all 21 items of the Thai version of the MLHFQ on four factors. These four factors cumulatively accounted for 52.27% of the common variance:

Factor 1 accounted for 41.29% of the variance and had seven items such as item 2-5 and 7-9 (factor loadings = 0.30 to 0.72). It was defined as physical dimension.

Factor 2 accounted for 4.61% of the variance and consisted of five items such as item 17-21 (factor loadings = -0.53 to -0.84). It was labeled as emotional dimension.

Factor 3 accounted for 3.41% of the variance and comprised three items such as item 14-16 (factor loadings = 0.39-0.48). It was named as treatment dimension.

Factor 4 accounted for 2.96% consisted of six items such as item 1, 6, and 10-13 (factor loadings = 0.36-0.59). It was classified as symptom dimension.

Factor 1 had high inverse correlation with Factor 2 (r = -0.61), low correlation with Factor 3 (r = 0.27), and moderate correlation with Factor 4 (r = 0.50). Factor 2 had low inverse correlation with Factor 3 (r = -0.24) and moderate inverse correlation with Factor 4 (r = -0.50). Factor 3 had low correlation with Factor 4 (r = 0.21). Cronbach's alpha coefficients for three factors were more than 0.70, except Factor 3.

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Table 16 Exploratory factor analysis of the MLHFQ items using factor extraction with principal axis factoring and oblique rotation with direct oblimin at baseline (n =180)

Items		Factor				Communality
		1	2	3	4	
1	Swelling in your ankles or legs	0.13	-0.10	-0.17	**0.41**	0.29
2	Resting during the day	**0.30**	-0.28	-0.06	0.24	0.45
3	Walking about or climbing stairs difficult	**0.34**	-0.15	0.40	0.20	0.65
4	Working around the house or yard difficult	**0.58**	-0.04	0.20	0.20	0.65
5	Going places away from home difficult	**0.61**	-0.14	0.24	0.05	0.69
6	Sleeping well at night difficult	0.29	0.03	0.01	**0.48**	0.44
7	Relating to or doing things with friends or family difficult	**0.72**	-0.06	-0.17	0.19	0.70
8	Working to earn a living difficult	**0.62**	-0.02	0.14	0.01	0.48
9	Recreational pastimes, sports or hobbies difficult	**0.64**	-0.13	-0.02	0.19	0.70
10	Sexual activities difficult	0.18	-0.09	0.03	**0.36**	0.29
11	Eating less of the foods you like	0.05	-0.08	0.10	**0.59**	0.48
12	Short of breath	0.06	-0.20	0.13	**0.56**	0.59
13	Fatigue	0.16	-0.30	0.10	**0.52**	0.74
14	Hospitalization	-0.14	0.04	**0.48**	0.33	0.33
15	Medical costs	0.21	-0.24	**0.40**	-0.10	0.37
16	Side effects from treatments	0.14	-0.03	**0.39**	-0.06	0.20
17	Feeling burden to your family or friends	0.16	**-0.61**	-0.08	0.11	0.59
18	Feeling loss of self-control	-0.12	**-0.84**	-0.09	0.13	0.68
19	Anxiety	0.03	**-0.73**	0.12	0.00	0.62
20	Difficulty for concentrating or remembering	0.22	**-0.53**	0.01	-0.05	0.44
21	Depression	-0.09	**-0.83**	0.05	-0.03	0.60
Cronbach's alpha coefficients		0.90	0.86	0.48	0.82	-

Bolded values indicate factor loadings $\geq$ 0.4.

Bolded values with underlying line indicate factor loadings considered with ignoring criteria.

Cronbach's alpha coefficients are estimated from only items loading on each factor.

4.5.3 Known-Groups Validity

Table 17 depicts the MLHFQ scores among three NYHA classes. This study found that there were significant differences of all median scores of the MLHFQ among three NYHA classes (Kruskal-Wallis test with Mann-Whitney U test, all $p < 0.001$). The lowest median scores found in the patient with NYHA class I and the highest in those with NYHA class III.

Table 18 shows scores of the MLHFQ dimensions identified with exploratory factor analysis in this study among three NYHA classes. Our study found that there were significant differences of median scores of the MLHFQ physical, emotional, and symptoms dimensions among three NYHA classes (Kruskal-Wallis test with Mann-Whitney U test, all $p < 0.01$). The lowest median scores found in the patient with NYHA class I and the highest in those with NYHA class III. Although there was no statistically significant difference of median scores of the MLHFQ treatment dimension between NYHA class I and class II and between class II and class III, there was significant difference of median scores between NYHA class I and III (Kruskal-Wallis test with Mann-Whitney U test, $p = 0.002$).

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Table 17 Scores of the original MLHFQ dimensions among NYHA classes at baseline

MLHFQ	NYHA Class I (n = 67)		NYHA Class II (n = 71)		NYHA Class III (n = 42)		Pairwise comparisons[a]					
	Mean ± SD	Median	Mean ± SD	Median	Mean ± SD	Median	I & II	p-value	I & III	p-value	II & III	p-value
Physical	4.3 ± 6.2	3.0	8.7 ± 7.5	6.0	18.5 ± 10.5	20.5	I < II	< 0.001	I < III	< 0.001	II < III	< 0.001
Emotional	2.6 ± 4.4	1.0	4.4 ± 4.3	4.0	8.9 ± 6.8	7.5	I < II	< 0.001	I < III	< 0.001	II < III	< 0.001
Global	9.4 ± 13.1	7.0	17.9 ± 15.1	14.0	38.3 ± 21.9	39.5	I < II	< 0.001	I < III	< 0.001	II < III	< 0.001

Median differences of all scores among NYHA classes are tested using Kruskal-Wallis test.

a. Pairwise comparisons are tested using Mann-Whitney U test.

Table 18 Scores of the MLHFQ dimensions identified with exploratory factor analysis among NYHA classes at baseline

MLHFQ	NYHA Class I (n = 67)		NYHA Class II (n = 71)		NYHA Class III (n = 42)		Pairwise comparisons[a]					
	Mean ± SD	Median	Mean ± SD	Median	Mean ± SD	Median	I & II	p-value	I & III	p-value	II & III	p-value
Physical	2.8 ± 5.3	1.0	6.6 ± 6.6	5.0	15.2 ± 10.0	17.0	I < II	< 0.001	I < III	< 0.001	II < III	< 0.001
Emotional	2.6 ± 4.4	1.0	4.4 ± 4.3	4.0	8.8 ± 7.2	7.5	I < II	< 0.001	I < III	< 0.001	II < III	0.001
Treatment	0.5 ± 1.2	0	1.0 ± 2.0	0	2.3 ± 3.3	0	I ≈ II	0.126	I < III	0.002	II ≈ III	0.053
Symptoms	3.5 ± 4.5	2.0	5.8 ± 5.2	5.0	11.6 ± 7.4	9.5	I < II	< 0.001	I < III	< 0.001	II < III	< 0.001

Median differences of all scores among NYHA classes are tested using Kruskal-Wallis test.

a. Pairwise comparisons are tested using Mann-Whitney U test.

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4.6 Responsiveness of the Thai Version of the MLHFQ

Differences of mean scores in patients with change of health transition perception were used to assess responsiveness

Table 19 illustrates the MLHFQ responsiveness in 66 patients with better feeling about their health. This study found that all medians of two MLHFQ dimensions and global score in this group at the second assessment were significantly lower than baseline (Wilcoxon signed ranks test, all $p < 0.01$). ES of physical and emotional dimension and global score were 0.49, 0.23, and 0.44, respectively. SRM of physical and emotional dimensions and global score were 0.64, 0.38, and 0.68, respectively. In addition, minimally important differences for improvement in physical and emotional dimensions and global score were 4.9, 1.4, and 9.4 points, respectively. In 19 patients with worse feeling about their health perception, only the MLHFQ physical dimension and global score at the second assessment were significantly higher than baseline (Wilcoxon signed ranks test, $p < 0.01$). ES of physical and emotional dimensions and global score were -0.68, -0.25, and -0.52, respectively. SRM of physical and emotional dimensions and global score in this group were -1.07, -0.25, and -0.71, respectively. Moreover, minimally important differences for deterioration in physical and emotional dimensions and global score were -6.1, -1.4, and -9.3 points, respectively. Regarding 40 patients with no change about their health perception, there were no significant differences for all median of the MLHFQ scores between baseline and the second assessments.

Estimates of the responsiveness of the MLHFQ dimensions identified with exploratory factor analysis in each subgroup are shown in Table 20. Our study found that all medians of the MLHFQ dimensions defined by this study in the patients with better feeling about their health perception were significantly lower than baseline (Wilcoxon signed ranks test, all $p < 0.01$). ES of physical, emotional, treatment, and symptoms dimensions were 0.47, 0.23, 0.33, and 0.42, respectively. SRM of physical, emotional, treatment, and symptoms dimensions were 0.67, 0.38, 0.42, and 0.53, respectively. In addition, minimally important differences for improvement in physical, emotional, treatment, and symptoms dimensions were 4.4, 1.4, 0.8, and 3.0 points,

respectively. In those with worse feeling about their health perception, only the MLHFQ physical and symptoms dimensions were significantly higher than baseline (Wilcoxon signed ranks test, $p < 0.01$). ES of physical, emotional, treatment, and symptoms dimensions were -0.56, -0.25, -0.27, and -0.70, respectively. SRM of physical, emotional, treatment, and symptoms dimensions in this group were -0.92, -0.25, -0.17, and -0.79, respectively. Furthermore, minimally important differences for deterioration in physical, emotional, treatment, and symptoms dimensions were -4.8, -1.4, -0.4, and -3.4 points, respectively. Regarding those with no change about their health perception, there were no significant differences for medians of the MLHFQ scores between baseline and the second assessments in emotional and symptoms dimensions except physical and treatment dimensions.

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Table 19 Estimates of the responsiveness of the original MLHFQ dimensions in the patient subgroups

Instruments	Patients with better feeling about their health perception (n = 66)							
MLHFQ	Mean change	SD_b	SD_c	$Median_1$	$Median_2$	p-value	ES	SRM
Physical	4.9	10.1	7.7	7.0	2.0	**<0.001**	0.49	0.64
Emotional	1.4	6.0	3.7	3.0	2.0	**0.001**	0.23	0.38
Global	9.4	21.3	13.9	14.5	6.0	**<0.001**	0.44	0.68
Instruments	Patients with worse feeling about their health perception (n = 19)							
MLHFQ	Mean change	SD_b	SD_c	$Median_1$	$Median_2$	p-value	ES	SRM
Physical	-6.1	9.0	5.7	7.0	13.0	**0.001**	-0.68	-1.07
Emotional	-1.4	5.5	5.5	3.0	7.0	0.38	-0.25	-0.25
Global	-9.3	17.8	13.1	14.0	30.0	**0.009**	-0.52	-0.71
Instruments	Patients with no change about their health perception (n = 40)							
MLHFQ	Mean change	SD_b	SD_c	$Median_1$	$Median_2$	p-value	ES	SRM
Physical	1.2	8.2	5.6	5.0	2.5	0.15	0.15	0.21
Emotional	0.5	5.0	3.5	3.0	2.0	0.54	0.10	0.14
Global	2.2	16.5	10.1	10.0	6.5	0.23	0.13	0.22

Mean change = mean score at baseline – mean score at second assessment.

SD_b = standard deviation at baseline, SD_c = standard deviation of change, $Median_1$ = median of score at baseline, $Median_2$ = median of score at second assessment.

Bolded values indicate that median differences of scores between assessments are statistically significant using Wilcoxon signed ranks test.

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Table 20 Estimates of the responsiveness of the MLHFQ dimensions identified with exploratory factor analysis in the patient subgroups

Instruments	Patients with better feeling about their health perception (n = 66)							
MLHFQ	Mean change	SD_b	SD_c	$Median_1$	$Median_2$	p-value	ES	SRM
Physical	4.4	9.3	6.6	4.0	0.5	**< 0.001**	0.47	0.67
Emotional	1.4	6.0	3.7	3.0	2.0	**0.001**	0.23	0.38
Treatment	0.8	2.4	1.9	0	0	**0.002**	0.33	0.42
Symptoms	3.0	7.1	5.7	5.0	3.0	**< 0.001**	0.42	0.53
Instruments	Patients with worse feeling about their health perception (n = 19)							
MLHFQ	Mean change	SD_b	SD_c	$Median_1$	$Median_2$	p-value	ES	SRM
Physical	-4.8	8.5	5.2	5.0	11.0	**0.002**	-0.56	-0.92
Emotional	-1.4	5.5	5.5	3.0	7.0	0.38	-0.25	-0.25
Treatment	0.4	1.5	2.4	0	0	0.47	-0.27	-0.17
Symptoms	-3.4	4.8	4.3	5.0	9.0	**0.003**	-0.70	-0.79
Instruments	Patients with no change about their health perception (n = 40)							
MLHFQ	Mean change	SD_b	SD_c	$Median_1$	$Median_2$	p-value	ES	SRM
Physical	1.6	7.8	4.5	2.0	0.5	**0.03**	0.20	0.36
Emotional	0.5	5.0	3.5	3.0	2.0	0.54	0.10	0.14
Treatment	0.4	1.3	1.2	0	0	**0.03**	0.31	0.33
Symptoms	0.2	5.2	3.5	4.5	3.0	0.71	0.04	0.06

Mean change = mean score at baseline – mean score at second assessment.

SD_b = standard deviation at baseline, SD_c = standard deviation of change, $Median_1$ = median of score at baseline, $Median_2$ = median of score at second assessment.

Bolded values indicate that median differences of scores between assessments are statistically significant using Wilcoxon signed ranks test.

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CHAPTER V
DISCUSSION AND CONCLUSION

The purpose of study was to test the psychometric properties of the Thai version of the MLHFQ. The subjects of this study in the psychometric properties testing were 180 outpatients with chronic HF visited to the department of cardiology and general medicine at Phramongkutklao Hospital.

Practicality was evaluated with the length of time used for administration and the floor and ceiling effects of each MLHFQ dimension and global score. It was found that average of time needed to complete the Thai version of the MLHFQ on face-to-face or telephone interviews was approximately five minutes. It indicates that it does not be a burden for these modes of administration. In addition, the floor effect from each dimension and global score were high (greater than 15%). However, the ceiling effect was not found in this study. These results disagree with previous studies[35,39] that the MLHFQ dimensions and global score indicate low floor effects. One possible explanation for the high floor effects found in this study may be high proportion of the patients with NYHA class I, while these ratios in other studies were low. Therefore, the MLHFQ could not detect improvement when effective treatments are applied in this group. Table 21 shows the floor and ceiling effects for all MLHFQ dimensions and global scores among three studies.

Table 21 Comparisons of floor and ceiling effects for the MLHFQ dimensions and global score among studies

Studies	Number of subjects	MLHFQ physical dimension		MLHFQ emotional dimension		MLHFQ global score	
		% Floor	% Ceiling	% Floor	% Ceiling	% Floor	% Ceiling
This study	180	18.3	1.1	27.8	0.6	11.1	0.6
Garin et al.[35]	653	0.6	4.6	0.6	8.5	0.2	0.6
Bennett et al.[39]	211	2.0	11.0	15.0	12.0	9.0	24.0

Reliability was assessed in terms of internal consistency estimated with Cronbach's alpha coefficient and test-retest reliability indicated with ICC. This study found that the Thai version of the MLHFQ presented acceptable reliability, in term of internal consistency with reliability coefficients over minimum recommended standard[18] on all dimensions and global score. In addition, Cronbach's alpha coefficients were 0.90 or above on physical dimension and global score, which were reliability standard for group or individual comparisons in practice. These results are consistent with previous studies.[3,35-37,39,40] Cronbach's alpha coefficients for all MLHFQ dimensions and global score among studies present in Table 22.

Table 22 Comparisons of Cronbach's alpha coefficients for the MLHFQ dimensions and global score among studies

Studies	Number of subjects	Cronbach's alpha coefficients		
		MLHFQ physical dimension	MLHFQ emotional dimension	MLHFQ global score
This study	180	0.90	0.86	0.93
Garin et al.[35]	653	0.90	0.82	0.91
Saccomann et al.[3]	170	0.85	0.64	0.85
Ho et al. [36]	247	0.95	0.94	0.95
Heo et al.[37]	638	0.91	0.85	0.91
Bennett et al.[39]	211	0.94	0.89	0.95

As for test-retest reliability, self-report about perceived change in health over two weeks from subjects was used for confirmation of stable health status in our study. Telephone interview was considered to apply for retesting in this study, because it was difficult to make appointment to the subjects for retesting with face-to-face interview in this period. Our study found that ICCs were over 0.70 on physical dimension and global score. These values indicate acceptable reproducibility and are minimal standards for group comparisons.[58] This result is consistent with a previous study[40] in that there were no statistically significant differences for all MLHFQ scores between two modes of administration. Although the consistency is imperfect, the ICCs show that all dimensions

and global score have moderate or high agreement between face-to-face and telephone interviews. Table 23 presents comparisons of intraclass correlation coefficients between studies.

Table 23 Comparisons of intraclass correlation coefficients between studies

MLHFQ	Number of subjects		Mean change ± SD		ICCs	
	This study[a]	Bennett et al.[40] b	This study[a]	Bennett et al.[40] b	This study[a]	Bennett et al.[40] b
Physical dimension	60	173	0.6 ± 5.8	0.5 ± 7.2	0.77	0.82
Emotional dimension	60	173	-0.3 ± 4.5	0.3 ± 4.9	0.61	0.81
Global score	60	173	1.1 ± 11.7	1.4 ± 13.4	0.76	0.87

a. Face-to-face interview at baseline and 14-day telephone interview at retesting.

b. Face-to-face interview at baseline and 2-day telephone interview at retesting.

Validity of this study was considered in terms of content validity and construct validity. Previous pilot study found that the original version of the MLHFQ was translated to Thai language easily.[43] The Thai version of the MLHFQ indicated good content validity from rating with expert and there were few problems found in cognitive interviews. The problems found in cognitive interviews indicate that some patients cannot judge the handicaps of their life caused with their heart conditions particularly. In our study, most of subjects are elderly patients and have several comorbidities. It appears to be not easy to distinguish between those symptoms or handicaps caused with their HF and those with other causes. Therefore, researcher emphasizes all respondents that they recall those symptoms and handicaps that are caused with their HF as far as possible in questionnaire administrations every time. We assume that the instructions and the core question of the MLHFQ are possible to help correctly in answering the question.

Construct validity was confirmed with convergent and discriminant validity. It was found that the MLHFQ physical dimension was significantly correlated in a moderate or high magnitude, with the hypothesized physical subscales (physical

functioning and role physical subscales) and physical component summary of the SF-36. In addition, the MLHFQ emotional dimension was significantly correlated in a moderate or high magnitude, with the respective mental subscales of the SF-36 mental subscales (role emotional and mental health subscales). Therefore, convergent validity of the Thai version of the MLHFQ was confirmed with these results. However, correlations with some hypothesized SF-36 subscales and component summary scores described as above were not significantly differences between the MLHFQ physical and emotional dimensions, except physical functioning subscale that confirmed the discriminant validity in physical dimension of the MLHFQ. These results agree with a previous study,[3] that indicates lack of specificity in the correlations with some subscales of the SF-36 between the MLHFQ physical and emotional dimensions. However, this study does not support findings of a previous research,[35] that indicates confirmation of both validities of all MLHFQ dimensions with expected SF-36 subscales and component summary scores. Possible explanations of the confirmation or lack of specificity of the correlations may be related to the contents of the SF-36 subscales that may be less representative in the MLHFQ physical and emotional dimensions or may be inappropriate meanings for the elderly patients. In addition, it is possible that correlation between the MLHFQ physical and emotional dimensions found in this study is very strong, thus the correlation differences between both dimensions with subscales and component summary scores of the SF-36 are difficult to find out. Comparisons of the Spearman rank order correlation coefficients among the MLHFQ dimensions and the SF-36 subscales or component summary scores in several studies are shown in Table 24.

This study also used the exploratory factor analysis to confirm construct validity. As the results of the factor analysis before items deletion, our study found that 21 items of the Thai version of the MLHFQ load on four factors defined as physical, emotional, treatment, and symptoms dimensions. All dimensions except treatment dimension indicated acceptable internal consistency, known-groups validity, and responsiveness. Treatment dimension is likely to have few numbers of items and the items (item 14, 15, and 16) loading on this factor may not have impacts on our subjects. Thus, it may shows poor psychometric properties for this study. Nevertheless, this dimension should be evaluated together with other dimensions. This dimension may be an importance for

HRQoL assessments in other populations. Three items (item 4-5 and 7) loading on Factor 1 and five items (item 17-21) loading on Factor 2 are similar to the items loading on the MLHFQ physical and emotional dimensions of the original version, respectively. Our results disagree with a previous research.[36] They have reported that 20 of 21 items load on three factors defined as physical, emotional, and social dimensions. Item 14 and 16 load on physical dimension and item 8 and 10 load on social dimension. Nevertheless, item 15 does not load on any factor. One possible explanation of the inconsistency may be the cultural differences of study population between studies. It indicates that cross-cultural adaptation of the questionnaire before applications is an important issue for appropriate interpretations of each culture.

Table 24 Comparisons of the Spearman rank order correlation coefficients among the MLHFQ dimensions and the SF-36 subscales or component summary scores in several studies

SF-36	This study (n = 180)		Garin et al.[35] (n = 677)		Saccomann et al.[3] (n = 170)	
	MLHFQ physical	MLHFQ emotional	MLHFQ physical	MLHFQ emotional	MLHFQ physical	MLHFQ emotional
Physical						
PF	-0.49	-0.39	-0.74	-0.48	-0.70	-0.53
RP	-0.51	-0.48	-0.52	-0.34	-0.50	-0.32
PCS	-0.53	-0.47	-0.63	-0.35	-	-
Mental						
RE	-0.53	-0.56	-0.46	-0.63	-0.40	-0.31
MH	-0.47	-0.51	-0.39	-0.39	-0.49	-0.65
MCS	-0.46	-0.53	-0.41	-0.58	-	-

Overall values are presented with Spearman rank order correlation coefficients.

Spearman rank order correlation coefficients between the MLHFQ physical and emotional dimensions of this study, Garin et al.,[35] and Saccomann et al.[3] are 0.74, 0.66, and 0.56, respectively.

Validity of the Thai version of the MLHFQ was also supported with known-groups validity, which refers to the ability of the MLHFQ scores to discriminate among NYHA

classes. Our findings are consistent with previous studies[35,39] in that all original MLHFQ dimensions and global score are sufficiently sensitive to identify among patients with NYHA class I, II, and III.

Responsiveness of the Thai version of the MLHFQ was evaluated with ability of two original MLHFQ dimensions or global score in change detection over time. It was found that the effect sizes obtained on the MLHFQ scores were close to 0.5, defined as moderate according to Cohen's criteria.[68] It may refer to require few subjects when the researchers use this questionnaire, especially on physical dimension and global score, for changes detection in clinical trials or intervention studies. It is an important factor to consider in term of research costs.

There are several limitations in this study. First, this study only bases on interviews. Therefore, it may be lack of information about missing data and burdens when this questionnaire was used in self administration. Second, the evaluation of test-retest reliability is based on comparison of data between face-to-face and telephone interviews. Hence, it may also have an impact on observed ICCs that are not perfect in our study because of different types of administration. It may use other designs of the study in data collection for support regarding reproducibility of the Thai version of the MLHFQ in the future studies. Third, confirmations of convergent and discriminant validity only depend on the SF-36. It may insufficiently support these validities in our research. It may use the other generic or disease-specific instruments for HF to confirm these validities. Fourth, this research only uses exploratory factor analysis in evaluation of the underlying constructs of the Thai version of the MLHFQ. Future research should confirm with methods based on modern test theory such as confirmatory factor analysis. It may be necessary for support of measure construct. In addition, our research has the problems of psychometric properties testing in some items (item 14, 15, and 16). There are many reasons for explanations of these findings. Most of patients are civil servant medical benefit scheme, thus they do not concern about medical costs. In addition, most of subjects are not hospitalized for HF in the past year and they do not involve in side effects of treatments. Therefore, most of patients do not involve in these items. Future studies may require various populations to capture the problems for comfirmation of psychometric properties of these items. Fifth, this study uses the report of change

from patients, which is only an indirect health status change measurement, for comparison of HRQoL scores in responsiveness analysis. Our study suggests that it may be necessary for uses of other clinical measures (NYHA functional classes or 6-minute walk distance, and etc.) or interventions which clarify improvement in health status to support for ability of the MLHFQ scores to detect health status change in future studies for further confirmation of responsiveness of this questionnaire. Furthermore, the numbers of patients who reported changes in condition over time are small. Thus, this may be limitation of our ability to detect changes in HRQoL scores for some MLHFQ dimensions. Future studies in a large population may be required. Finally, it may be a limitation when applies in other populations because our study is conducted in one setting and all subjects are outpatients with chronic HF. Therefore, further research should investigate in other settings or populations for confirmation of the psychometric properties of the Thai version of the MLHFQ.

Our findings indicate that this Thai version of the MLHFQ tends to apply for HRQoL assessments of Thai patients with chronic HF. Administration time is approximately five minutes and the contents of this questionnaire do not complicated to understand. Therefore, it reduces burdens for interviewers and respondents, especially elderly patients. This study suggests that telephone interviews tend to be used in data collection with face-to-face interviews for this questionnaire because our results indicate moderate to high agreements between these modes of administration. It may reduce the respondent burdens, expenses, and time in the research. Our study recommends that it should use the MLHFQ dimensions defined by developers for comparisons of data with studies in other countries. However, the MLHFQ dimensions defined by this research such as physical, emotional, treatment, and symptoms dimensions may be used for preliminary data for additional interpretations of HRQoL in Thai culture. In addition, minimally important differences obtained in this study may apply for consideration of improvement and deterioration according to health perception in the treatments or interventions of Thai patients with HF. Moreover, it appears to detect changes before the changes of NYHA functional classes in chronic stage of HF. This questionnaire in the future is likely to be applied at several levels in clinical settings. In clinical trials level, it may be used for a patient-reported outcomes in evaluation of drugs treatment for HF or

used for the research about relationships between HRQoL of patients with chronic HF and other outcomes such as medical costs, medication adherence, hospitalization, readmission, survival time, and etc. It may provide more comprehensive information regarding the effects of HF and its treatment for new drug or interventions developments on HF. In practice level, health care practitioners can apply the obtained data from HRQoL assessments for policy consideration regarding hospital drug formulary, for provider performance evaluations by assessing the impact of the process of care on HRQoL outcomes, or for drug therapeutic monitoring in individual patient with chronic HF. Furthermore, some contents of this questionnaire may be used for other questionnaire developments for assessments about HRQoL in patients with chronic HF.

In conclusion, this study indicates that this Thai version of the MLHFQ has acceptable psychometric properties in terms of practicality, reliability, validity, and responsiveness and its psychometric properties tend to be consistent with the original version. Our results are preliminary data for consideration of uses of the Thai version of the MLHFQ in clinical trials or interventions for comparisons between other countries for future research in Thailand.

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APPENDICES

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APPENDIX A

แบบบันทึกข้อมูลผู้เข้าร่วมวิจัย

การทดสอบสมบัติการวัดเชิงจิตวิทยาของแบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตาฉบับภาษาไทย

	No……..
วันที่ทำการสัมภาษณ์	...../...../.....
ข้อมูลทั่วไป (<u>การประเมินครั้งที่ 1</u>)	**สำหรับผู้วิจัย**
1. **เพศ** ☐ 1.ชาย ☐ 2. หญิง	Sex .....
2. **อายุ**.....**ปี หรือ เดือนและปีเกิด** (...../.....)	Age .....
3. **ระดับการศึกษาสูงสุด** ☐ 1.ไม่ได้เรียนหนังสือ ☐ 2.ต่ำกว่าประถมศึกษา ☐ 3.ประถมศึกษาปีที่……. ☐ 4. มัธยมศึกษาปีที่..... ☐ 5. ปวช. ☐ 6. ปวส. ☐ 7. อนุปริญญา ☐ 8. ปริญญาตรี ☐ 9. ปริญญาโท ☐ 10. ปริญญาเอก ☐ 11. อื่นๆ ระบุ.....	Education status .....
4. **อาชีพ** ☐ 1. ทำงาน ☐ 2. ไม่ได้ทำงาน/กำลังว่างงาน ☐ 3. เกษียณอายุราชการ	Job.....
5. **รายได้เฉลี่ยต่อเดือน**.....**บาท**	Salary .....
6. **สถานภาพสมรส** ☐ 1. แต่งงาน ☐ 2.โสด ☐ 3. หม้าย ☐ 4. หย่าร้าง	Marital Status …….....
7. **ผู้ร่วมพักอาศัย** ☐1. อยู่คนเดียว ☐2. ครอบครัว/ญาติพี่น้อง ☐3. ผู้ดูแล/คนรับใช้	Living situation …….……
ข้อมูลการรักษา	สำหรับผู้วิจัย
1. **ค่า** Left ventricular ejection fraction (LVEF) **เท่ากับ**.....% (ตรวจครั้งล่าสุดเมื่อ...../...../.....)	LVEF…..……
2. **การเข้ารักษาตัวในโรงพยาบาลด้วยโรคหัวใจล้มเหลวเมื่อปีที่แล้วจำนวน**.....**ครั้ง**	Hospitalization…..

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ข้อมูลการรักษา (ต่อ)	สำหรับผู้วิจัย
3. โรคร่วมอื่นๆ (ทำเครื่องหมายได้มากกว่า 1 ข้อ) ☐ 1. โรคความดันโลหิตสูง (Hypertension) ☐ 2. โรคเกี่ยวกับหลอดเลือดเลี้ยงหัวใจโคโรนารี (Coronary artery disease) ☐ 3. ภาวะไขมันในเลือดสูง (Dyslipidemia) ☐ 4. เบาหวาน (Diabetes mellitus) ☐ 5. ภาวะ Atrial fibrillation ☐ 6. โรคเกี่ยวกับลิ้นหัวใจ (Valvular heart disease) ☐ 7. อื่นๆ ระบุ.....	Number of comorbidities..... Type of comorbidites.....
4. สาเหตุของโรคหัวใจล้มเหลว ☐ 1. Hypertensive heart disease ☐ 2. Coronary artery disease ☐ 3. Heart valve disease ☐ 4. Dilated cardiomyopathy ☐ 5. Alcoholic cardiomyopathy ☐ 6. อื่นๆ.....	Cause.....
5. กลุ่มยารักษาที่ใช้ในปัจจุบัน (ทำเครื่องหมายได้มากกว่า 1 ข้อ) ☐ 1. ACEIs ☐ 2. ARBs ☐ 3. Aldosterone antagonists ☐ 4. Beta blockers ☐ 5. Digoxin ☐ 6. Loop diuretics ☐ 8. Thiazide diuretics	Number of medications..... Type of medications.....
6. New York Heart Association Functional Classification (First assessment) ☐ 1. I ☐ 2. II ☐ 3. III ☐ 4. IV	1st NYHA …….
7. New York Heart Association Functional Classification (Second assessment) ☐ 1. I ☐ 2. II ☐ 3. III ☐ 4. IV	2nd NYHA …….
☐ **การประเมินความเที่ยงจากการทดสอบซ้ำ วันที่สัมภาษณ์** (...../...../.....)	
☐ **การประเมินครั้งที่** 2 **วันที่สัมภาษณ์** (...../...../.....) **โทร.** .....**เวลาติดต่อที่สะดวก**.....	
คุณจะประเมินสุขภาพโดยทั่วไปของคุณในตอนนี้เปรียบเทียบกับเมื่อพบกันครั้งที่ผ่านมาว่าอย่างไร (สำหรับการประเมินครั้งที่ 2) ☐ 1. ตอนนี้ดีกว่าเมื่อพบกันครั้งที่ผ่านมามาก ☐ 2. ตอนนี้ค่อนข้างดีกว่าเมื่อพบกันครั้งที่ผ่านมา ☐ 3. คล้ายๆ กับเมื่อพบกันครั้งที่ผ่านมา ☐ 4. ตอนนี้ค่อนข้างแย่กว่าเมื่อพบกันครั้งที่ผ่านมา ☐ 5. ตอนนี้แย่กว่าเมื่อพบกันครั้งที่ผ่านมามาก	Transition of health.....

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APPENDIX B

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -		No				Very Little	Very Much
1.	causing swelling in your ankles or legs?	0	1	2	3	4	5
2.	making you sit or lie down to rest during the day?	0	1	2	3	4	5
3.	making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4.	making your working around the house or yard difficult?	0	1	2	3	4	5
5.	making your going places away from home difficult?	0	1	2	3	4	5
6.	making your sleeping well at night difficult?	0	1	2	3	4	5
7.	making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8.	making your working to earn a living difficult?	0	1	2	3	4	5
9.	making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10.	making your sexual activities difficult?	0	1	2	3	4	5
11.	making you eat less of the foods you like?	0	1	2	3	4	5
12.	making you short of breath?	0	1	2	3	4	5
13.	making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14.	making you stay in a hospital?	0	1	2	3	4	5
15.	costing you money for medical care?	0	1	2	3	4	5
16.	giving you side effects from treatments?	0	1	2	3	4	5
17.	making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18.	making you feel a loss of self-control in your life?	0	1	2	3	4	5
19.	making you worry?	0	1	2	3	4	5
20.	making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21.	making you feel depressed?	0	1	2	3	4	5

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APPENDIX C

การประเมินครั้งที่.... **เริ่มต้น....:.....น.**

แบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตา

คำถามต่อไปนี้ต้องการถามว่าโรคหัวใจล้มเหลว (สภาวะการทำงานของหัวใจ) มีผลกระทบต่อการดำเนินชีวิตของท่านในช่วงหนึ่งเดือน (4 สัปดาห์) ที่ผ่านมามากน้อยเพียงใด หลังคำถามแต่ละข้อ ให้วงกลมรอบตัวเลข 0 1 2 3 4 หรือ 5 เพียงตัวเลขเดียว เพื่อแสดงว่าการดำเนินชีวิตของท่านได้รับผลกระทบมากน้อยเพียงใด หากคำถามใดไม่เกี่ยวข้องกับท่าน ให้วงกลมรอบตัวเลข 0 หลังคำถามนั้น

	โรคหัวใจล้มเหลวทำให้ท่านไม่สามารถดำเนินชีวิตได้ตามที่ท่านต้องการในช่วงหนึ่งเดือน (4 สัปดาห์) ที่ผ่านมาโดยทำให้	**ไม่เลย**	**น้อยมาก**				**มาก**
1.	ข้อเท้าหรือขาทั้ง 2 ข้างของท่านบวมน้ำ	0	1	2	3	4	5
2.	ท่านต้องนั่งหรือนอนพักในระหว่างวัน	0	1	2	3	4	5
3.	การเดินไปมาหรือเดินขึ้นบันไดของท่านเป็นไปได้ยาก	0	1	2	3	4	5
4.	การทำงานบ้านหรืองานในสวนของท่านเป็นไปได้ยาก	0	1	2	3	4	5
5.	การออกจากบ้านไปไหนมาไหนของท่านเป็นไปได้ยาก	0	1	2	3	4	5
6.	การนอนหลับสนิทของท่านในตอนกลางคืนเป็นไปได้ยาก	0	1	2	3	4	5
7.	การสร้างความสัมพันธ์หรือการทำกิจกรรมร่วมกับเพื่อนฝูงหรือครอบครัวของท่านเป็นไปได้ยาก	0	1	2	3	4	5
8.	การทำงานหาเลี้ยงชีพของท่านเป็นไปได้ยาก	0	1	2	3	4	5
9.	การพักผ่อนยามว่าง การออกกำลังกาย หรือการทำงานอดิเรกของท่านเป็นไปได้ยาก	0	1	2	3	4	5
10.	การมีกิจกรรมทางเพศของท่านเป็นไปได้ยาก	0	1	2	3	4	5
11.	ท่านรับประทานอาหารที่ท่านชอบได้น้อยลง	0	1	2	3	4	5
12.	ท่านมีอาการหายใจลำบาก	0	1	2	3	4	5
13.	ท่านเหนื่อย ล้าหรือไม่ค่อยมีแรง	0	1	2	3	4	5
14.	ท่านต้องนอนรักษาตัวในโรงพยาบาล	0	1	2	3	4	5
15.	ท่านต้องเสียเงินในการรักษาพยาบาล	0	1	2	3	4	5
16.	ท่านได้รับผลข้างเคียงจากการรักษาหรือการใช้ยา	0	1	2	3	4	5
17.	ท่านรู้สึกว่าท่านเป็นภาระต่อครอบครัวหรือเพื่อนฝูง	0	1	2	3	4	5
18.	ท่านรู้สึกว่าสูญเสียความสามารถในการควบคุมอารมณ์ของตนเอง	0	1	2	3	4	5
19.	ท่านรู้สึกกังวล	0	1	2	3	4	5
20.	ท่านมีสมาธิหรือจดจำสิ่งต่าง ๆ ได้ยาก	0	1	2	3	4	5
21.	ท่านรู้สึกซึมเศร้า	0	1	2	3	4	5

สิ้นสุด....:.....**น.**

APPENDIX D

Thai Standard Version 1 Short Form Health Survey-36 (SF-36)

การประเมินครั้งที่.... **เริ่มต้น....:.....น.**

สุขภาพและความผาสุกของคุณ

แบบสอบถามนี้ถามความคิดเห็นของคุณเกี่ยวกับสุขภาพของคุณ ข้อมูลนี้จะช่วยในการบันทึกว่าคุณรู้สึกอย่างไร และคุณสามารถทำกิจกรรมต่าง ๆ ตามปกติของคุณได้ดีแค่ไหน
ขอบคุณที่ให้ความร่วมมือในการตอบ แบบสอบถามนี้

ในแต่ละคำถามต่อไปนี้ โปรดทำเครื่องหมาย ☒ ลงในช่องเพียงช่องเดียวที่ตรงกับคำตอบของคุณมากที่สุด

1. **โดยทั่วไป คุณจะบอกว่าสุขภาพของคุณ:**

ดีที่สุด	ดีมาก	ดี	พอใช้	แย่
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. **คุณจะประเมินสุขภาพโดยทั่วไปของคุณ <u>ในตอนนี้ เปรียบเทียบกับเมื่อ 1 ปีที่ผ่านมา</u> ว่าอย่างไร**

ตอนนี้ดีกว่าเมื่อ 1 ปีที่ผ่านมามาก	ตอนนี้ค่อนข้างดีกว่าเมื่อ 1 ปีที่ผ่านมา	คล้ายๆ กับเมื่อ 1 ปีที่ผ่านมา	ตอนนี้ค่อนข้างแย่กว่าเมื่อ 1 ปีที่ผ่านมา	ตอนนี้แย่กว่าเมื่อ 1 ปีที่ผ่านมามาก
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. **คำถามต่อไปนี้เป็นคำถามเกี่ยวกับ กิจกรรมที่คุณอาจจะทำในช่วงวันปกติทั่ว ๆ ไป <u>สุขภาพของคุณในตอนนี้ ทำให้คุณถูกจำกัด</u>ในการทำกิจกรรมเหล่านี้หรือไม่ ถ้าใช่ ถูกจำกัดมากน้อยแค่ไหน**

	ใช่ ถูกจำกัดมาก	ใช่ ถูกจำกัด เล็กน้อย	ไม่ใช่ ไม่ถูก จำกัดเลย
a <u>กิจกรรมที่ใช้แรงมาก</u> เช่น การวิ่ง การยกของหนัก การเล่นกีฬาที่ต้องออกแรงมาก	☐ 1	☐ 2	☐ 3
b <u>กิจกรรมที่ใช้แรงปานกลาง</u> เช่น การย้ายโต๊ะ การกวาดพื้น การทำสวน การปั่นจักรยาน หรือการว่ายน้ำ	☐ 1	☐ 2	☐ 3
c การยกหรือถือถุงใส่ของชำ	☐ 1	☐ 2	☐ 3
d การเดินขึ้นบันไดขึ้นตึก <u>2-3</u> ชั้น	☐ 1	☐ 2	☐ 3
e การเดินขึ้นบันไดขึ้นตึก <u>1</u> ชั้น	☐ 1	☐ 2	☐ 3
f การก้ม การคุกเข่า หรือการงอตัว	☐ 1	☐ 2	☐ 3
g การเดินเป็นระยะทาง<u>มากกว่า 1 กิโลเมตร</u>	☐ 1	☐ 2	☐ 3
h การเดินเป็นระยะทาง<u>หลายช่วงตึก</u>	☐ 1	☐ 2	☐ 3
i การเดินเป็นระยะทาง<u>หนึ่งช่วงตึก</u>	☐ 1	☐ 2	☐ 3
j การอาบน้ำหรือแต่งตัวเอง	☐ 1	☐ 2	☐ 3

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4. **ในช่วง 4 สัปดาห์ที่ผ่านมา คุณมีปัญหาต่าง ๆ ต่อไปนี้ ในการทำงานหรือทำกิจวัตรประจำวันอื่น ๆ อันเนื่องมาจากสุขภาพทางกายของคุณ หรือไม่**

	มี	ไม่มี
a จำเป็นต้องลดระยะเวลาที่คุณใช้ในการทำงานหรือกิจกรรมอื่นๆ	☐ 1	☐ 2
b ทำงานหรือกิจวัตรประจำวันอื่นๆ สำเร็จได้น้อยกว่าที่คุณต้องการ	☐ 1	☐ 2
c ถูกจำกัดชนิดของงานหรือกิจกรรมที่คุณสามารถทำได้	☐ 1	☐ 2
d มีความลำบากในการทำงาน หรือ กิจกรรมอื่นๆ (เช่น ต้องใช้ความพยายามมากขึ้น)	☐ 1	☐ 2

5. **ในช่วง 4 สัปดาห์ที่ผ่านมา คุณมีปัญหาต่าง ๆ ต่อไปนี้ ในการทำงานหรือทำกิจวัตรประจำวันอื่น ๆ ของคุณ อันเนื่องมาจากปัญหาด้านอารมณ์ (เช่น รู้สึกซึมเศร้า หรือวิตกกังวล) หรือไม่**

	มี	ไม่มี
a จำเป็นต้องลดระยะเวลาที่คุณใช้ในการทำงานหรือกิจกรรมอื่นๆ	☐ 1	☐ 2
b ทำงานหรือกิจวัตรประจำวันอื่นๆ สำเร็จได้น้อยกว่าที่คุณต้องการ	☐ 1	☐ 2
c ทำงานหรือกิจกรรมอื่นๆ ด้วยความระมัดระวังน้อยกว่าปกติ	☐ 1	☐ 2

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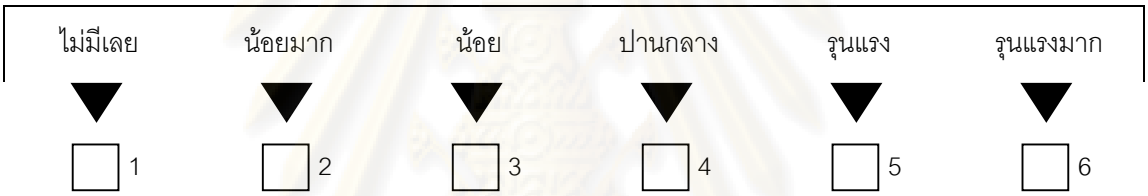
6. **ในช่วง 4 สัปดาห์ที่ผ่านมา สุขภาพทางกายหรือปัญหาด้านอารมณ์ของคุณ มีผลรบกวนกิจกรรมทางสังคม ตามปกติของคุณ ที่มีกับครอบครัว เพื่อนฝูง เพื่อนบ้าน หรือกลุ่มคนอื่น ๆ มากน้อยแค่ไหน**

7. **คุณมีความเจ็บปวดทางร่างกายมากน้อยแค่ไหน ในช่วง 4 สัปดาห์ที่ผ่านมา**



8. **ในช่วง 4 สัปดาห์ที่ผ่านมา ความเจ็บปวดมีผลรบกวนการทำงานตามปกติของคุณ (ทั้งงานนอกบ้านและงานบ้าน) มากน้อยแค่ไหน**

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9. **คำถามต่อไปนี้จะถามเกี่ยวกับว่าคุณรู้สึกอย่างไร และคุณเป็นอย่างไร ในช่วง <u>4 สัปดาห์ที่ผ่านมา</u> แต่ละคำถามต่อไปนี้ โปรดเลือกเพียงคำตอบเดียว ที่ใกล้เคียงกับความรู้สึกของคุณมากที่สุด ในช่วง <u>4 สัปดาห์ที่ผ่านมา</u> บ่อยแค่ไหน ที่...**

	ตลอดเวลา	เป็นส่วนใหญ่	บ่อย ๆ	เป็นบางครั้ง	นาน ๆ ครั้ง	ไม่เคยเลย
	▼	▼	▼	▼	▼	▼
a คุณรู้สึกมีชีวิตชีวา	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
b คุณวิตกกังวลเกินกว่าเหตุ.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
c คุณรู้สึกหดหู่จนไม่มีอะไรที่จะทำให้คุณรู้สึกดีขึ้นได้.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
d คุณรู้สึกใจเย็นและสงบ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
e คุณรู้สึกเต็มไปด้วยพลัง.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
f คุณรู้สึกท้อแท้และซึมเศร้า.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
g คุณรู้สึกหมดเรี่ยวแรง.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
h คุณมีความสุข.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
i คุณรู้สึกเหนื่อย.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

10. **ในช่วง <u>4 สัปดาห์ที่ผ่านมา</u> บ่อยแค่ไหน ที่<u>สุขภาพทางกายหรือปัญหาด้านอารมณ์</u> ของคุณ มีผลรบกวนกิจกรรมทางสังคมของคุณ (เช่น การไปเยี่ยมเพื่อน หรือ ญาติมิตร เป็นต้น)**

ตลอดเวลา	เป็นส่วนใหญ่	เป็นบางครั้ง	นาน ๆ ครั้ง	ไม่เคยเลย
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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11. **<u>แต่ละ</u>ข้อความต่อไปนี้เป็น<u>จริง</u> หรือ <u>ไม่จริง</u> สำหรับคุณแค่ไหน**

	จริงแน่นอน	จริงเป็นส่วนใหญ่	ไม่ทราบ	ไม่จริงเป็นส่วนใหญ่	ไม่จริงเลย
a ฉันดูเหมือนจะเจ็บป่วยได้ค่อนข้างง่ายกว่าคนอื่น	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b ฉันมีสุขภาพดีพอๆ กับคนอื่นที่ฉันรู้จัก	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c ฉันคาดว่าสุขภาพของฉันจะแย่ลง	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d สุขภาพของฉันดีเยี่ยม	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

ขอบคุณที่ให้ความร่วมมือในการตอบคำถาม

สิ้นสุด....:.....**น.**

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APPENDIX E

Cognitive Interview Form

แบบสัมภาษณ์กระบวนการคิดในการตอบแบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตาฉบับภาษาไทย

<u>ส่วนที่ 1</u> คำแนะนำก่อนการตอบแบบสอบถาม (สัมภาษณ์หลังจบการอ่านหรือฟังคำแนะนำในการตอบแบบสอบถาม)
คำถาม
1. หลังจากท่านได้อ่าน (ฟัง) คำแนะนำแล้ว ท่านไม่เข้าใจคำแนะนำในส่วนนี้หรือไม่ หากท่านไม่เข้าใจ ท่านไม่เข้าใจตรงส่วนใด 2. คำแนะนำนี้ทำให้ท่านทราบหรือไม่ว่าเป็นแบบสอบถามเกี่ยวกับโรคอะไร 3. คำแนะนำนี้ทำให้ท่านทราบหรือไม่ว่าแบบสอบถามนี้ให้ท่านนึกถึงเหตุการณ์ย้อนกลับไปในช่วงกี่เดือนหรือกี่สัปดาห์ที่ผ่านมา 4. ท่านมีข้อเสนอแนะเพิ่มเติมเพื่อให้ท่านสามารถเข้าใจข้อความเหล่านี้ได้ดียิ่งขึ้น
<u>ส่วนที่ 2</u> วิธีการคิดในการตอบแบบสอบถามในส่วนของคำถาม (สัมภาษณ์หลังจากเลือกตัวเลือกจบในแต่ละข้อ)
คำถาม
1. ท่านเข้าใจคำถามข้อนี้หรือไม่ หากไม่เข้าใจ ท่านไม่เข้าใจคำว่าอะไร 2. คำถามข้อนี้ยากต่อการนึกคำตอบสำหรับท่านหรือไม่ 3. ตามความคิดของท่านแล้ว คำถามข้อนี้น่าจะมีส่วนเกี่ยวข้องกับโรคหัวใจล้มเหลวที่ท่านเป็นอยู่ด้วยหรือไม่ ถ้าไม่เกี่ยวข้องท่านคิดว่าที่ท่านเลือกตัวเลขนี้น่าจะมีสาเหตุมาจากอะไร 4. สมมติว่าในครั้งหน้าท่านรู้สึกว่าตนเอง**ดีขึ้น**เมื่อเปรียบเทียบกับในครั้งนี้ ท่านคิดว่าจะเลือกตัวเลขใดบ้างสำหรับคำถามข้อนี้ 5. สมมติว่าในครั้งหน้าท่านรู้สึกว่าตนเอง**แย่ลง**เมื่อเปรียบเทียบกับในครั้งนี้ ท่านคิดว่าจะเลือกตัวเลขใดบ้างสำหรับคำถามข้อนี้ 6. สมมติว่าในครั้งหน้าท่านรู้สึกว่าตนเอง**ไม่เปลี่ยนแปลง**เมื่อเปรียบเทียบกับในครั้งนี้ ท่านคิดว่าจะเลือกตัวเลขใดบ้างสำหรับคำถามข้อนี้

หมายเหตุ : หากพบปัญหาใด ๆ ที่เกิดขึ้นนอกเหนือจากคำถามที่มีอยู่ในแบบสัมภาษณ์วิธีการคิดในการตอบแบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตาฉบับภาษาไทย ให้สอบถามผู้ป่วยเพิ่มเติมเกี่ยวกับปัญหาและสาเหตุที่พบ

APPENDIX F

Content Validity Form

แบบพิจารณาความตรงทางเนื้อหาของแบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตาฉบับภาษาไทย

กรุณาพิจารณาความสอดคล้องของเนื้อหาของแบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตาฉบับภาษาไทยในแต่ละข้อกับแบบสอบถามต้นฉบับ (Original version) หลังจากนั้นให้ทำเครื่องหมาย √ ตามระดับสอดคล้องของเนื้อหาที่ตรงกับความรู้สึกของท่านมากที่สุดเพียงตัวเลขเดียว รวมทั้งให้ข้อเสนอแนะในส่วนของเนื้อหาที่ต้องการแก้ไข ความหมายของตัวเลือกแต่ละระดับมีดังต่อไปนี้

ระดับ 1 หมายถึง เนื้อหาไม่มีความสอดคล้องกันเลย (Not relevant)

ระดับ 2 หมายถึง เนื้อหาไม่สามารถประเมินความสอดคล้องได้ ควรต้องมีการแก้ไขภาษาที่ใช้ใหม่ (Somewhat relevant)

ระดับ 3 หมายถึง เนื้อหามีความสอดคล้องกัน แต่ควรมีการแก้ไขภาษาที่ใช้ (Relevant)

ระดับ 4 หมายถึง เนื้อหามีความสอดคล้องกันดีมาก (Very relevant)

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เนื้อหาฉบับภาษาไทย	เนื้อหาต้นฉบับ	ระดับ				เนื้อหาที่ควรแก้ไข	การแก้ไขและเหตุผล
		1	2	3	4		
ชื่อแบบสอบถาม							
1. แบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตา	1. MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE						
คำแนะนำ							
1. คำถามต่อไปนี้ต้องการถามว่าโรคหัวใจล้มเหลว (สภาวะการทำงานของหัวใจ) มีผลกระทบต่อชีวิตของท่านในช่วงหนึ่งเดือน (4 สัปดาห์) ที่ผ่านมามากน้อยเพียงใด	1. The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks).						
2. หลังจากอ่านคำถามในแต่ละข้อแล้ว ให้วงกลมเลือกรอบเลข 0, 1, 2, 3, 4 หรือ 5 เพียงตัวเลือกเดียว เพื่อแสดงว่าชีวิตของท่านได้รับผลกระทบมากน้อยเพียงใด	2. After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected.						

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เนื้อหาฉบับภาษาไทย	เนื้อหาต้นฉบับ	ระดับ				เนื้อหาที่ควรแก้ไข	การแก้ไขและเหตุผล
		1	2	3	4		
3. หากคำถามใดที่ไม่เกี่ยวข้องกับท่าน ให้วงกลมเลือกรอบเลข 0 หลังคำถามนั้น	3. If a question does not apply to you, circle the 0 after that question.						
คำถามรวม							
1. โรคหัวใจล้มเหลวของท่านเป็นอุปสรรคในการใช้ชีวิตตามที่ท่านต้องการในช่วงหนึ่งเดือน (4 สัปดาห์) ที่ผ่านมาโดย	1. Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -						
ตัวเลือก							
1. ไม่เลย	1. No						
2. น้อยมาก	2. Very Little						
3. มาก	3. Very Much						

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เนื้อหาฉบับภาษาไทย	เนื้อหาต้นฉบับ	ระดับ				เนื้อหาที่ควรแก้ไข	การแก้ไขและเหตุผล
		1	2	3	4		
ข้อคำถาม							
1. ทำให้ข้อเท้าหรือขาของท่านบวมน้ำ	1. causing swelling in your ankles or legs?						
2. ทำให้ท่านต้องนั่งหรือนอนพักในระหว่างวัน	2. making you sit or lie down to rest during the day?						
3. ทำให้การเดินไปมาหรือเดินขึ้นบันไดของท่านเป็นไปได้ยาก	3. making your walking about or climbing stairs difficult?						
4. ทำให้การทำงานบ้านหรืองานในสวนของท่านเป็นไปได้ยาก	4. making your working around the house or yard difficult?						
5. ทำให้การออกจากบ้านไปไหนมาไหนของท่านเป็นไปได้ยาก	5. making your going places away from home difficult?						
6. ทำให้การนอนหลับสนิทของท่านในตอนกลางคืนเป็นไปได้ยาก	6. making your sleeping well at night difficult?						

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เนื้อหาฉบับภาษาไทย	เนื้อหาต้นฉบับ	ระดับ				เนื้อหาที่ควรแก้ไข	การแก้ไขและเหตุผล
		1	2	3	4		
7. ทำให้การสร้างความสัมพันธ์หรือการทำกิจกรรมร่วมกับเพื่อนฝูงหรือครอบครัวของท่านเป็นไปได้ยาก	7. making your relating to or doing things with your friends or family difficult?						
8. ทำให้การทำงานหาเลี้ยงชีพของท่านเป็นไปได้ยาก	8. making your working to earn a living difficult?						
9. ทำให้การพักผ่อนยามว่าง การออกกำลังกาย หรือการทำงานอดิเรกของท่านเป็นไปได้ยาก	9. making your recreational pastimes, sports or hobbies difficult?						
10. ทำให้การมีกิจกรรมทางเพศของท่านเป็นไปได้ยาก	10. making your sexual activities difficult?						
11. ทำให้ท่านรับประทานอาหารที่ท่านชอบได้น้อยลง	11. making you eat less of the foods you like?						
12. ทำให้ท่านต้องหายใจลำบาก	12. making you short of breath?						
13. ทำให้ท่านเหนื่อย ล้าหรือไม่ค่อยมีแรง	13. making you tired, fatigued, or low on energy?						

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เนื้อหาฉบับภาษาไทย	เนื้อหาต้นฉบับ	ระดับ				เนื้อหาที่ควรแก้ไข	การแก้ไขและเหตุผล
		1	2	3	4		
14. ทำให้ท่านต้องนอนรักษาตัวในโรงพยาบาล	14. making you stay in a hospital?						
15. ทำให้ท่านต้องเสียเงินในการรักษาพยาบาล	15. costing you money for medical care?						
16. ทำให้ท่านได้รับผลข้างเคียงจากการรักษาหรือการใช้ยา	16. giving you side effects from treatments?						
17. ทำให้ท่านรู้สึกว่าท่านเป็นภาระต่อครอบครัวหรือเพื่อนฝูง	17. making you feel you are a burden to your family or friends?						
18. ทำให้ท่านรู้สึกว่าสูญเสียความสามารถในการควบคุมอารมณ์ของตนเอง	18. making you feel a loss of self-control in your life?						
19. ทำให้ท่านรู้สึกกังวล	19. making you worry?						
20. ทำให้ท่านมีสมาธิหรือจดจำสิ่งต่าง ๆ ได้ยาก	20. making it difficult for you to concentrate or remember things?						

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เนื้อหาฉบับภาษาไทย	เนื้อหาต้นฉบับ	ระดับ				เนื้อหาที่ควรแก้ไข	การแก้ไขและเหตุผล
		1	2	3	4		
21. ทำให้ท่านรู้สึกซึมเศร้า	21. making you feel depressed?						

ขอบพระคุณทุกท่านที่กรุณาให้ความร่วมมือในการพิจารณาความตรงทางเนื้อหาของแบบสอบถามในครั้งนี้

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APPENDIX G

Table 25 Scores of the MLHFQ (Thai version) contents rated with four experts

Contents	Scores				Mean
	1	2	3	4	
1. Name of questionnaire แบบสอบถามการใช้ชีวิตอยู่กับโรคหัวใจล้มเหลวของมินเนโซตา	3	4	4	4	3.75
2. Introduction 2.1 First sentence คำถามต่อไปนี้ต้องการถามว่าโรคหัวใจล้มเหลว (สภาวะการทำงานของหัวใจ) มีผลกระทบต่อชีวิตของท่านในช่วงหนึ่งเดือน (4 สัปดาห์) ที่ผ่านมามากน้อยเพียงใด	4	3	4	3	3.50
2.2 Second sentence หลังจากอ่านคำถามในแต่ละข้อแล้ว ให้วงกลมเลือกรอบเลข 0, 1, 2, 3, 4 หรือ 5 เพียงตัวเลือกเดียว เพื่อแสดงว่าชีวิตของท่านได้รับผลกระทบมากน้อยเพียงใด	3	3	4	3	3.25
2.3 Third sentence หากคำถามใดไม่เกี่ยวข้องกับท่าน ให้วงกลมเลือกรอบเลข 0 หลังคำถามนั้น	3	4	4	3	3.50
3. Main question โรคหัวใจล้มเหลวเป็นอุปสรรคในการใช้ชีวิตตามที่ท่านต้องการในช่วงหนึ่งเดือน (4 สัปดาห์) ที่ผ่านมาโดย	3	4	4	3	3.50
4. Response choice					
4.1 ไม่เลย	3	4	4	4	3.75
4.2 น้อยมาก	3	4	4	4	3.75
4.3 มาก	3	4	4	4	3.75
5. Items 5.1 ทำให้ข้อเท้าหรือขาของท่านบวมน้ำ	4	3	4	3	3.50
5.2 ทำให้ท่านต้องนั่งหรือนอนพักในระหว่างวัน	4	4	4	4	4.00
5.3 ทำให้การเดินไปมาหรือเดินขึ้นบันไดของท่านเป็นไปได้ยาก	4	4	4	4	4.00

Table 25 Scores of the MLHFQ (Thai version) contents rated with four experts (continue)

Contents	Scores				Mean
5. items (continue)					
5.4 ทำให้การทำงานบ้านหรืองานในสวนของท่านเป็นไปได้ยาก	4	4	4	4	4.00
5.5 ทำให้การออกจากบ้านไปไหนมาไหนของท่านเป็นไปได้ยาก	4	4	4	4	4.00
5.6 ทำให้การนอนหลับสนิทของท่านในตอนกลางคืนเป็นไปได้ยาก	4	4	4	4	4.00
5.7 ทำให้การสร้างความสัมพันธ์หรือการทำกิจกรรมร่วมกับเพื่อนฝูงหรือครอบครัวของท่านเป็นไปได้ยาก	4	4	3	4	3.75
5.8 ทำให้การทำงานหาเลี้ยงชีพของท่านเป็นไปได้ยาก	4	4	4	4	4.00
5.9 ทำให้การพักผ่อนยามว่าง การออกกำลังกาย หรือการทำงานอดิเรกของท่านเป็นไปได้ยาก	4	4	4	3	3.75
5.10 ทำให้การมีกิจกรรมทางเพศของท่านเป็นไปได้ยาก	4	3	4	4	3.75
5.11 ทำให้ท่านรับประทานอาหารที่ท่านชอบได้น้อยลง	4	4	4	4	4.00
5.12 ทำให้ท่านต้องหายใจลำบาก	4	4	3	4	3.75
5.13 ทำให้ท่านเหนื่อย ล้าหรือไม่ค่อยมีแรง	4	4	4	4	4.00
5.14 ทำให้ท่านต้องนอนรักษาตัวในโรงพยาบาล	4	3	4	4	3.75
5.15 ทำให้ท่านต้องเสียเงินในการรักษาพยาบาล	4	4	4	4	4.00
5.16 ทำให้ท่านได้รับผลข้างเคียงจากการรักษาหรือการใช้ยา	4	4	4	3	3.75
5.17 ทำให้ท่านรู้สึกว่าท่านเป็นภาระต่อครอบครัวหรือเพื่อนฝูง	4	4	4	3	3.75
5.18 ทำให้ท่านรู้สึกว่าสูญเสียความสามารถในการควบคุมอารมณ์ของตนเอง	4	4	3	4	3.75
5.19 ทำให้ท่านรู้สึกกังวล	4	4	4	4	4.00
5.20 ทำให้ท่านมีสมาธิหรือจดจำสิ่งต่าง ๆ ได้ยาก	4	4	3	4	3.75
5.21 ทำให้ท่านรู้สึกซึมเศร้า	4	4	4	4	4.00

APPENDIX H

Table 26 Content improvements of the Thai version of the MLHFQ

Contents for experts consideration	Content improvements
1. The first sentence of introduction คำถามต่อไปนี้ต้องการถามว่าโรคหัวใจล้มเหลว (สภาวะการทำงานของหัวใจ) มีผลกระทบต่อชีวิตของท่านในช่วงหนึ่งเดือน (4 สัปดาห์) ที่ผ่านมามากน้อยเพียงใด	1. The first sentence of introduction คำถามต่อไปนี้ต้องการถามว่าโรคหัวใจล้มเหลว (สภาวะการทำงานหัวใจ) มีผลกระทบต่อการดำเนินชีวิตของท่านในช่วงหนึ่งเดือน (4 สัปดาห์) ที่ผ่านมามากน้อยเพียงใด
2. The second sentence of introduction หลังจากอ่านคำถามในแต่ละข้อแล้ว ให้วงกลมเลือกรอบเลข 0, 1, 2, 3, 4 หรือ 5 เพียงตัวเลือกเดียว เพื่อแสดงว่าชีวิตของท่านได้รับผลกระทบมากน้อยเพียงใด	2. The second sentence of introduction หลังคำถามแต่ละข้อ ให้วงกลมรอบตัวเลข 0 1 2 3 4 หรือ 5 เพียงตัวเลขเดียว เพื่อแสดงว่าการดำเนินชีวิตของท่านได้รับผลกระทบมากน้อยเพียงใด
3. The third sentence of introduction หากคำถามใดไม่เกี่ยวข้องกับท่าน ให้วงกลมเลือกรอบเลข 0 หลังคำถามนั้น	3. The third sentence of introduction หากคำถามใดไม่เกี่ยวข้องกับท่าน ให้วงกลมรอบตัวเลข 0 หลังคำถามนั้น
4. Main question โรคหัวใจล้มเหลวเป็นอุปสรรคในการใช้ชีวิตตามที่ท่านต้องการในช่วงหนึ่งเดือน (4 สัปดาห์) ที่ผ่านมาโดย	4. Main question โรคหัวใจล้มเหลวทำให้ท่านไม่สามารถดำเนินชีวิตได้ตามที่ต้องการในช่วงหนึ่งเดือน (4 สัปดาห์) ที่ผ่านมาโดยทำให้
5. Item 1 ข้อเท้าหรือขาของท่านบวมน้ำ	5. Item 1 ข้อเท้าหรือขาทั้ง 2 ข้างของท่านบวมน้ำ

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