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The Impact of Heart Failure on Mental Health and Health-Related Quality of Life in Ethiopia: A Mixed-Methods Study

by Henok Mulugeta Teshome

Thesis submitted in fulfilment of the requirements for the degree of

Doctor of Philosophy (PhD) in Nursing

under the supervision of Professor Amanda Wilson, A/Professor Peter Sinclair, and A/Professor Suzanne Sheppard-Law

University of Technology Sydney

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CERTIFICATE OF ORIGINAL AUTHORSHIP

I, **Henok Mulugeta Teshome**, declare that this thesis is submitted in fulfilment of the requirements for the award of Doctor of Philosophy, in the Faculty of Health at the University of Technology Sydney.

This thesis is wholly my own work unless otherwise referenced or acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

This document has not been submitted for qualifications at any other academic institution.

This research is supported by the Australian Government Research Training Program.

Signature

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Henok Mulugeta Teshome

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STATEMENT OF EDITING

This thesis has been professionally edited by ***Proof, Edit & Style Document Services*** in accordance with the Guidelines for Editing Research Theses published by the Institute of Professional Editors, and the editing did not compromise the content or structure of the thesis. A certificate of Editing is provided in Appendix 13.

DEDICATION

This thesis is dedicated to all my family members who have supported me throughout my study. I am deeply grateful to my parents for their decision to send me to school during my early childhood.

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This thesis is submitted in fulfilment of the requirements for the award of Doctor of Philosophy (PhD) at the School of Nursing and Midwifery, Faculty of Health, University of Technology Sydney (UTS). It comprises a compilation of five peer-reviewed journal articles published in Q1 journals. Each paper included in this thesis represents a significant and original contribution to the field of Nursing.

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1. *Mulugeta, H., Sinclair, P. M., & Wilson, A. (2023). Prevalence of depression and its association with health-related quality of life in people with heart failure in low-and middle-income countries: A systematic review and meta-analysis. PLOS One. 18(3). https://doi.org/10.1371/journal.pone.0283146*
2. *Mulugeta, H., Sinclair, P. M., & Wilson, A. (2024). Health-related quality of life of people with heart failure in low-and middle-income countries: A systematic review and meta-analysis. Quality of Life Research 33, 1175-1189. https://doi.org/10.1007/s11136-023-03563-2*
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GLOSSARY

AOR:	Adjusted Odds Ratio
CI:	Confidence Interval
COPD:	Chronic obstructive pulmonary disease
COR:	Crude Odds Ratio
CVD:	Cardiovascular Disease
DM:	Diabetes Mellitus
DSM-5:	Diagnostic and Statistical Manual of Mental Disorders: 5th Ed.
GBD:	Global Burden of Diseases
GHP:	General Health Perception
HF:	Heart Failure
HRQoL:	Health-Related Quality of Life
HTN:	Hypertension
IRB:	Institutional Review Board
LMICs:	Low- and Middle-Income Countries
MLHFQ:	Minnesota Living with Heart Failure Questionnaire
NYHA:	New York Heart Association
NCDs:	Non-communicable Diseases
OSSS-3:	Oslo Social Support Scale
PHQ-9:	Patient Health Questionnaire
RAs:	Research assistants
S E :	Standard Error
SF-36	36-Item Short Form Survey
SSA:	Sub-Saharan Africa
TSM:	Theory of Symptom Management
UK:	United Kingdom
UTS:	University of Technology Sydney

ABSTRACT

Background: Globally, heart failure is associated with a high morbidity and mortality rate and can affect the physical, emotional, and social functioning of affected populations. Limited studies describe the impact of heart failure on mental health and health-related quality of life in Ethiopia.

Aim: to assess the impact of heart failure on the mental health and health-related quality of life in Ethiopian adults.

Methods: This study consisted of three phases: Phase I involved two systematic reviews. Phase II and III used a sequential explanatory mixed methods design, starting with a quantitative cross-sectional study, followed by a qualitative descriptive study. The revised Wilson and Cleary model of quality of life and the Theory of Symptom Management were used to guide this research. Participants attending a cardiac outpatient clinic at two tertiary-level public hospitals in Addis Ababa, Ethiopia, were invited to participate in the study. Quantitative data were analysed using descriptive analyses, and regression models, while the qualitative data were analysed using thematic analysis. The quantitative and qualitative findings were integrated.

Results: Two systematic reviews examined depression and health-related quality of life in people living with heart failure in low-middle income countries. The first review, comprising 21 studies (N = 5,074), reported a pooled depression prevalence of 51.5%. The second review, which included 33 studies (N= 5,612), reported poor health-related quality of life in people with heart failure. The cross-sectional study (N=383) showed a mean Patient Health Questionnaire-9 score of 11.02±6.14, with 56.6% of participants having depression. The mean Minnesota Living with Heart Failure Questionnaire score was 48.03±19.73, and 54% of participants had poor health-related quality of life. Age ($\beta = 0.12$, 95% CI 0.11, 0.28), diabetes mellitus comorbidity ($\beta = 4.47$, 95% CI 1.41, 7.54), and depression ($\beta = 1.74$, 95% CI 1.52, 1.96) were associated with worse health-related quality of life, while higher social support ($\beta = -1.48$, 95% CI −1.93, −1.03) was linked to better health-related quality of life. Six themes were identified in the qualitative phase: Journey from diagnosis to daily life with heart failure, Symptom experiences, Impact of heart failure on health-related quality of life, Perception of health-related quality of life, Symptom management and coping strategies, and Challenges faced in the journey of living with heart failure.

Conclusions: This study revealed a high prevalence of depression and poor health-related quality of life in Ethiopian people with heart failure. The impact of heart failure on various aspects of their lives, combined with their poor health perceptions, significantly affects their health-related quality of life. The findings have implications for nursing practice and the care of people with heart failure in Ethiopia. Strategies to assist healthcare professionals to identify, manage, and deliver appropriate psychosocial interventions early are recommended.

CHAPTER 1: INTRODUCTION

1.1. Chapter overview

This chapter presents the background information and problem statement, and the context of the issue investigated in this study. It describes the burden of cardiovascular diseases (CVDs), including heart failure (HF), from both a global and local perspective. The chapter explains how people living with HF are affected by their condition, presents the associated factors, and discusses the importance and relevance of the problem in current clinical practice. It introduces the study setting by providing the geographical location of the study area, with a brief introduction of the country, region, city, and the hospitals where the data were collected.

The chapter provides the rational for why this study is needed and articulates the significance of addressing the problem in academic, policy, and practice contexts. It also presents the research aim and objectives that this thesis addresses. Finally, this chapter outlines the structure of the thesis by summarising each chapter, guiding the reader through the organisation of the thesis.

1.2. Background

Cardiovascular diseases cover a variety of heart and blood vessel conditions, including coronary artery disease, heart failure, hypertension, and other heart and blood vessel-related conditions. These conditions contribute to significant health problems around the world, causing widespread morbidity and mortality (Flora & Nayak, 2019; Mensah et al., 2019). According to the Global Burden of Diseases (GBD) study report, CVD was responsible for one-third of all deaths worldwide in 2019 (Roth et al., 2020). It is predicted that over 23 million people worldwide will die from CVDs by 2030 **(**Jayaraj et al., 2018**)**. There are a growing number of deaths due to CVDs in low- and middle-income countries (LMICs) due to various factors including lack of healthcare access (Timmis et al., 2022). In Sub-Saharan Africa (SSA), CVD was responsible for 13% of all deaths in 2020, mainly affecting young populations aged 15-39 years (Yuyun et al., 2020).

In Ethiopia, CVDs are a significant public health challenge, imposing a huge financial burden on the population. In 2017, CVDs affected 2,838,768 of the Ethiopian population, which accounts for approximately 2.7% of the population. The most common types of CVD reported were rheumatic heart disease (33.7%), ischemic heart disease (22.5%), and stroke (11.4%) (Yadeta et al., 2021). Despite the recent development of a new National Strategic Plan in Ethiopia to prevent and control major non-communicable diseases (NCDs), including CVDs (Ministry of Health-Ethiopia, 2020), CVD is still one of the major national public health problems affecting many individuals. For instance, a recently published systematic review and meta-analysis of hospital and community-based studies in Ethiopia reported that CVD prevalence was 5% of all diseases in 2021 (Angaw et al., 2021).

Heart failure (HF), one of the most common CVDs, is defined as a clinical syndrome characterised by signs and symptoms caused by the inability of the heart muscle to pump enough blood to the vital organs. This results in reduced tissue perfusion, which causes a variety of symptoms and complications (Bozkurt et al., 2021; Schwinger, 2021). Coronary heart disease (CHD) is a leading cause of heart failure (HF), characterized by the narrowing or blockage of coronary arteries due to plaque buildup. This restriction in blood flow damages the heart muscle, impairing its ability to pump effectively and leading to HF. Rheumatic heart disease (RHD), another significant cause of HF, results from acute rheumatic fever (ARF), an autoimmune response to streptococcal infections. This autoimmune reaction can cause inflammation and scarring of the heart valves, progressively contributing to HF . (Rwebembera et al., 2021). While CHD is a primary cause of HF, it is essential to differentiate that HF itself encompasses a broader clinical syndrome marked by diverse aetiologies, including CHD and RHD, particularly in LMICs like Ethiopia (Bragazzi et al., 2021).

The diagnosis of HF is usually made either clinically, using signs and symptoms based on the Framingham criteria, or by considering a reduced ejection fraction (<40%) (Hage et al., 2020; Lofstrom et al., 2019). In 2019, HF affected over 64 million people worldwide (A. Groenewegen et al., 2020), and it was the primary cause of more than 300,000 annual deaths (Bowen et al., 2020; Chadda et al., 2018). In Ethiopia, HF is a challenging health concern and its prevalence is increasing, particularly among young individuals aged 15-39 years (Tsega & Demissei, 2018).

Heart failure is a chronic condition that affects numerous aspects of an individual's life. It leads to physical, emotional, and social disruption throughout the progression of the disease. The physical and emotional impact of HF depends on its clinical severity, which is classified according to the New York Heart Association (NYHA) criteria as follows: Class I- no limitation during normal activity, Class II- slight limitation during normal activity, Class III- marked limitation of normal activities without symptoms at rest, and Class IV- inability to engage in physical activity without symptoms, and symptoms may be experienced at rest (Braun et al., 2022).

Depression is a common symptom in people with HF, which significantly affects their health-related quality of life (HRQoL). According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnostic criteria, depression is characterised by persistent feelings of dissatisfaction, poor self-worth, and loss of interest in daily activities, with symptoms lasting at least two weeks (Truschel, 2020). Depression affects more than 30% of all people living with HF (Hooley et al., 2005; Sbolli et al., 2020). The Patient Health Questionnaire-9 (PHQ-9) is a nine-item questionnaire based on DSM-IV criteria, commonly used for screening and diagnosing depression. It is also used to assess the severity of depression (Costantini et al., 2021; Sbolli et al., 2020).

Health-related quality of life is a critical long-term outcome among people with HF. It is a multidimensional concept consisting of physical, social, emotional, psychological, and mental functioning (Anderson & Ozakinci, 2018; Kang et al., 2016). Assessing HRQoL is critical for understanding the subjective impact of HF and its management, and it is considered one way of evaluating the effectiveness of HF treatment (von Haehling et al., 2021). The Minnesota Living with Heart Failure Questionnaire (MLHFQ) is widely used to assess the HRQoL of people with HF (AbuRuz et al., 2016; Jarab et al., 2023).

Depression negatively impacts HRQoL by diminishing an individual's psychological well-being, reducing motivation, and impairing social functioning, all of which are critical domains of HRQoL. Conversely, a decline in HRQoL due to physical health challenges, such as chronic illnesses, can exacerbate depressive symptoms by fostering feelings of helplessness, isolation, and reduced self-worth (Kovacs et al., 2022; Wang et al., 2023). This connection is particularly evident in populations with chronic illnesses like heart failure, where the interplay between mental health and physical health significantly influences overall well-being (Bahall et al., 2020; Freedland et al., 2003).

1.3. Statement of the problem

Heart failure prevalence differs greatly across regions, usually due to differences in infrastructure, health systems, climate, and socioeconomic factors (Scholten et al., 2022; Tromp & Teng, 2024). For instance, the prevalence of HF is 2% in the USA (Roger, 2021), 1% in Latin America (Ciapponi et al., 2016), 1% in the United Kingdom (UK) (Bennett et al., 2012), and ranges from 1% to 2% in Australia (Sahle et al., 2016), and 3% to 3.5% in China (Guo et al., 2016). There are no population-based studies on the prevalence of HF in SSA, but the available hospital-based studies show that 3% to 7% of hospital admissions are due to HF in Africa (Cotter et al., 2013; Damasceno et al., 2007). The global incidence of HF has increased over the past 10 years due to population aging, population growth, and other direct precipitating factors, such as ischemic heart diseases, hypertension, and infection (Lahoz et al., 2021; Lippi & Sanchis-Gomar, 2020).

Heart failure is one of the leading causes of morbidity and mortality. It is the most common reason for hospital admissions, particularly in people over the age of 65 with advanced HF, including pulmonary congestion and cardiogenic shock. Recurrent hospital readmission is correlated with a higher risk of mortality in this cohort (Collins et al., 2013; Savarese et al., 2023). According to a recent meta-analysis, the global one-year mortality rate for HF ranges from 4% to 45%, with an overall rate of 33% (Emmons-Bell et al., 2022). Most HF-related deaths occur in LMICs (Fuster, 2014; Gallagher et al., 2018), with SSA countries having the highest mortality rate (Dokainish et al., 2017). In Africa, the one-year composite outcome of death or hospitalisation ranges from 21.1% to 59.7% (Karaye et al., 2021), with an average HF mortality rate of 34% (Dokainish et al., 2017). In Ethiopia, the burden of HF is increasing with significant adverse outcomes, including prolonged hospital stay, poor HRQoL, and high mortality rates (Ali et al., 2021; Tito et al., 2022).

Heart failure has a significant impact on the health care system due to high readmission rates and costs (A. Groenewegen et al., 2020). It is a devastating disease associated with impairment of cardiac function and has a sizeable psycho-economic burden (Savarese et al., 2023). The global annual cost of HF was US$108 billion in 2012, and this cost will continue to rise as the prevalence of HF rises (Cook et al., 2014). The costs associated with HF are estimated to increase by 127% in 2030 (Mozaffarian et al., 2016). People with HF have total healthcare expenditure four times higher than those without HF (Klein et al., 2021). The highest economic burden of HF is due to costs associated with inpatient treatment. These costs are primarily due to frequent readmission, laboratory tests, imaging, comorbidities, and invasive procedures (Hessel, 2021; Kwok et al., 2021).

Heart failure affects one's physical, mental, and social health (Polikandrioti et al., 2019). People with HF usually experience physical restrictions that have a significant impact on their daily lives. Physical symptoms, such as fatigue and activity intolerance, may lead to psychological and mental health problems, such as depression, as well as reduced HRQoL (Lippi et al., 2020; Thida et al., 2021; Walthall et al., 2019). Due to their physical limitations, people with HF may have limited social activities and relationships, which, in turn, can lead to social isolation and loneliness (Cene et al., 2022; McHorney et al., 2021).

When compared to the general population, people with HF have a higher prevalence of emotional symptoms, such as depression (Audi et al., 2017; Hare et al., 2014; Reavell et al., 2018). This can be caused by the HF disease process, including chronic physical symptoms, polypharmacy, decreased physical activity, fear of death, and financial challenges (Zahid et al., 2018). Poor mental health compounds this situation due to lower treatment adherence, higher healthcare costs, and increased risk of hospitalisation (Gold et al., 2020; Meng et al., 2020). Although several guidelines recommend screening and treating comorbid depression in people with HF, it is often neglected, unrecognised, and under-treated by health professionals (İlhan & Oğuz, 2021; Tran et al., 2022). This has significant impacts on outcomes for this population. For example, people with HF and comorbid depression can have a 2- to 3-fold greater mortality rate than the general population (De Hert et al., 2018). Depression is a significant independent predictor of poor HRQoL (Alemoush et al., 2021; Ishak et al., 2020).

People with HF have poorer HRQoL compared to the normal population, due to both symptoms and a sense of bad health from the heart. The HRQoL status of people with HF is influenced by multiple factors. Hwang et al. (2014) found that age, duration of heart failure, physical symptoms, and depression were independent predictors of HRQoL. While HF is generally considered a disease of aging in high-income countries (Scholten et al., 2022), it is important to highlight that in Ethiopia, HF also affects a significant proportion of younger adults (Tsega & Demissei, 2018). A higher NYHA class has been strongly associated with poorer HRQoL

(Hsiang-Fen & Jung-Hua, 2021). Therefore, improving HF outcomes relies on identifying contributing factors that lead to low HRQoL. Poor HRQoL has been associated with poorer prognosis, which, in turn, is a significant predictor of rehospitalisation. This kind of prognostic estimate is a useful guide for hospital management (Soriano et al., 2010; Westlake et al., 2002). This underlines the need to improve mental health and HRQoL as component parts of HF treatment strategies (Members: et al., 2022).

People with HF have complex experiences. Being diagnosed with HF can lead to emotional and psychosocial reactions, such as stress, frustration, isolation, and depression. Those affected by HF experience devastating physical symptoms that significantly restrict their normal daily activities. Regular hospital visits and taking medications daily can be overwhelming for these individuals (Austin, 2023; Brittain, 2023). Healthcare providers, as well as caregivers and support systems, need knowledge of both mental and physical symptoms to support this population. Exploring the life experiences of people living with HF and their coping strategies are vital to improve HF treatment outcomes (Seah et al., 2016).

Reducing depression and improving HRQoL are important aspects of care in people with HF. Targeted pharmacologic therapies and non-pharmacologic interventions, such as psychosocial interventions, are beneficial in reducing depression and improving HRQoL in this population (IsHak et al., 2021; Mohammed et al., 2016; Samartzis et al., 2013; Woltz et al., 2012; Zambrano et al., 2020). Successful interventions include symptom management and coping strategies, such as supporting medication adherence, regular medical follow-up care, lifestyle changes, and other behavioural managements, such as social support (Bennett et al., 2000; Checa et al., 2020; Li et al., 2019). Adhering to regular medication prescriptions and managing side effects, along with consistent medical follow-up care and making lifestyle changes, are crucial for managing HF. These measures not only reduces rehospitalisation and mortality but also improves HRQoL (Sen et al., 2020).

Cardiovascular diseases account for more than 30% of annual medical admissions in one medical facility in Ethiopia (Mengistu & Benti, 2022) and a significant number of people with HF are receiving follow-up care in the study area. Despite this, the impact of their condition on their physical and emotional functioning has not been extensively studied. This study aimed to address this knowledge gap by examining the impact of HF on mental health and HRQoL in people diagnosed with HF, using sequential explanatory mixed methods and by comparing their current experience with that prior to their diagnosis. Investigating the impact of HF on mental health and HRQoL in a LMIC like Ethiopia is critical to design effective interventions that address the physical and emotional well-being of this population.

1.4. Description of the study setting

The study was conducted in Ethiopia, a country in the Horn of Africa. Ethiopia is the second most populated country in Africa, after Nigeria, with 128 million people. It is a multiethnic and religious society (CSA, 2013; Zewde, 2002) that is divided into 12 administrative regions and two city administrations. The capital city, Addis Ababa, is located in the centre of the country and is the seat of many international organisations, including the United Nations Economic Commission for Africa and African Union (Wubneh, 2013). Ethiopia is known as the land of origin due to its significant contributions to human history, as the oldest hominid, Lucy, was found in Ethiopia (Hopkin, 2005; Mekonnen, 2013; Qiu, 2016).

The Ethiopian healthcare system includes three levels of care: primary, secondary, and tertiary (Figure 1). Primary healthcare is widely recognised as the core of the health system and consists of primary health care units, including health posts, health centres, and district hospitals. It focuses primarily on the delivery of preventive and basic curative health services. Secondary care consists of general hospitals that provide a broad range of medical and surgical services, as well as diagnostic and treatment services, referred from the primary health care units. Tertiary care comprises specialised and teaching hospitals that provide advanced medical and surgical care, and other services. Each specialised hospital typically serves 3.5-5 million people and acts as a referral point for general hospitals. In 2021/22, the Ethiopian health system included a total of 18,200 active health posts, 3,579 health centres, and 353 hospitals (Assefa et al., 2020; Ministry of Health Ethiopia, 2023).

Health investment, health service utilisation, and health status have increased considerably over the last few decades in Ethiopia, but the country's health care sector continues to be characterised by inadequate access and poor resource allocation. Low levels of healthcare financing are the major problem of the Ethiopian health care system. Most health finance comes from Non-Governmental Organisations (NGOs) and donors. The government provides only a very small portion of health finance due to political instability and corruption problems in the country (Debie et al., 2022; Wamai, 2004).

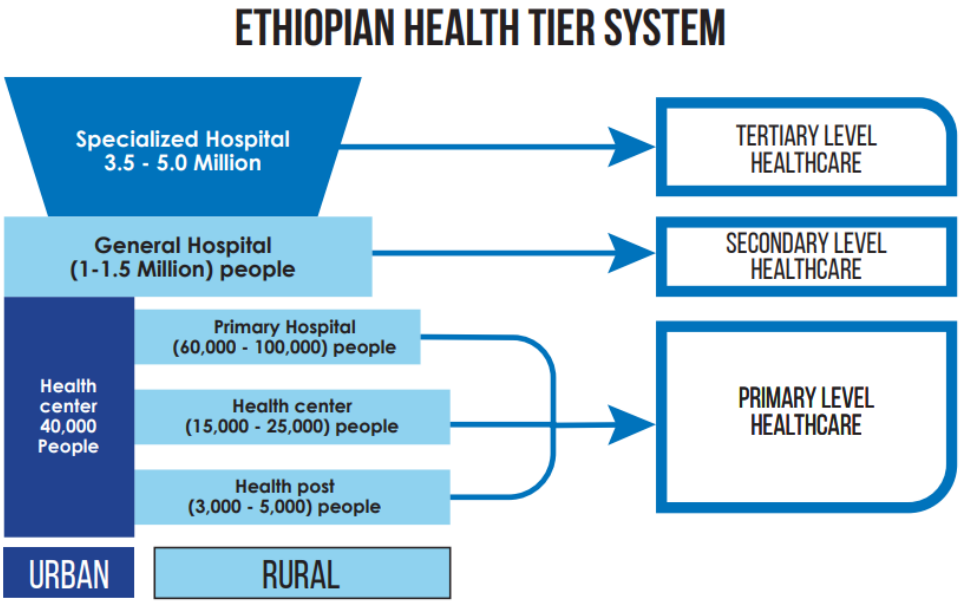

Figure 1: The Ethiopian health care system (Ministry of Health Ethiopia, 2021).

The research in this thesis was conducted in Addis Ababa, the capital city of Ethiopia, where the major tertiary-level hospitals specialising in cardiovascular health-care services are located. According to the Addis Ababa Health Bureau, there are 13 government hospitals in the city, each managed by different bodies. Five of these are managed by the Federal Ministry of Health, six by Addis Ababa Health Bureau, one by the police force, and one by the armed forces. This research was conducted at two tertiary levels public hospitals that are managed by the Ministry of Health: St. Paul's Hospital Millennium Medical College and St. Peter Specialized Hospital. They are both tertiary-level hospitals providing advanced cardiovascular services, in addition to their wide range of specialties and sub-specialties in paediatrics and internal medicines, obstetrics/gynaecology, surgery, and others. They have two cardiac outpatient departments (OPDs), intensive care units, and a catheterisation lab, staffed by cardiologists, cardiac anaesthesiologists, and cardiovascular nurses.

1.5. Justification and significance of the study

The global burden of HF is increasing causing a significant impact on the physical and emotional well-being of affected individuals. Although the Ethiopian government has developed and implemented various strategies and policies to reduce the burden of CVD, HF continues to be the leading cause of mortality and morbidity in Ethiopia (Argaw et al., 2023; Dagnaw et al., 2016). The most common symptoms of HF are fatigue, shortness of breath, oedema, and chest pain (Alpert et al., 2017; Arrigo et al., 2020). People with these symptoms tend to have significantly worse mental health and a lower HRQoL than those who do not (Thida et al., 2021).

The available data indicate that mental health conditions, such as depression, experienced by people with HF are increasing globally (Lam et al., 2023). This phenomenon is highly associated with adverse clinical outcomes, such as reduced HRQoL (Celano et al., 2018). However, little evidence is available regarding the extent of these problems in Ethiopia (Yazew et al., 2019). The experiences of people living with HF and how it affects their HRQoL have also not been well explored in Ethiopia, with no data that captures regional variation as opposed to national data. Remote and regional areas are not well captured, as many of these do not have access to diagnostic technology. This thesis aimed to assess the impact of heart failure on mental health and HRQoL. This was done by determining the prevalence of depression in people with HF and evaluating their HRQoL, and exploring their life experiences to understand how HF affects their HRQoL. These data are essential to accurately describe these populations and their needs. The findings will provide the best evidence to support the development of effective interventions and assist health professionals in making clinical decisions.

1.6. Research aims and objectives.

General aim

To assess the impact of heart failure on mental health and health-related quality of life in Ethiopian adults.

Specific objectives

1. *To determine the prevalence of comorbid depression and identify the associated factors among adults living with heart failure*
2. *To evaluate health-related quality of life and its influencing factors among adults living with heart failure*
3. *To explore and describe the experiences of people living with heart failure and how it affects their health-related quality of life.*

1.7. Research phases

This study consisted of three phases: Phase I: Systematic reviews of research literature, Phase II: Quantitative cross-sectional study, and Phase III: Qualitative descriptive study.

Phase I: Systematic reviews

Phase I of the study identified, appraised, and synthesised the available evidence on the impact of HF on mental health and HRQoL, by determining not only the prevalence of depression and the level of HRQoL, but also their relationships among people with HF in LMICs. This research phase provided a clear understanding of the problem across these diverse countries . In this phase of the study, two systematic reviews were performed, and both are published in peer reviewed Q1 journals. The first systematic review determined the prevalence of depression and its association with HRQoL among people with HF in LMICs (Henok Mulugeta, Peter Sinclair, & Amanda Wilson, 2023). The second systematic review estimated the level of HRQoL in people with HF in the same region (Henok Mulugeta, Peter M Sinclair, & Amanda Wilson, 2023b). These systematic reviews provide an overview of the existing data, identified gaps, and inconsistencies, and have highlighted areas that require further investigation in the subsequent phases of the study.

Phase II: Quantitative cross-sectional study

In the second phase of the study, eligible participants were recruited for a quantitative survey using interviewer-administered questionnaires for assessing sociodemographic and clinical characteristics, prevalence of depression, and level of HRQoL. The objective of this study phase was to assess prevalence of depression and level of health-related quality of life, and associated factors, among adults living with HF in Ethiopia, using the revised Wilson and Cleary’s model.

Phase III: Qualitative descriptive study

In the third and final phase of the study, a purposive sample of Phase II participants were invited to participate in semi-structured interviews (Phase III). The objective of this phase was to explore the experience of people living with HF in Ethiopia, guided by the findings of Phase II and the Theory of Symptom Management (TSM). Table 1 provides details of the study phases, aims, research designs, chapters, and associated publications.

Table 1: Summary of the research project phases

Phase	**Research objectives**	**Design**	**Chapter**	**Publication title**
I	To identify, appraise, and synthesise the available evidence on the prevalence of depression and level of HRQoL, and their relationships, among people with HF in LMICs	Systematic review	2	Mulugeta, H., Sinclair, P. M., & Wilson, A. (2023c). Prevalence of depression and its association with health-related quality of life in people with heart failure in low- and middle-income countries: A systematic review and meta-analysis. *PLOS ONE, 18*(3), e0283146. Mulugeta, H., Sinclair, P. M., & Wilson, A. (2024b). Health-related quality of life of people with heart failure in low-and middle-income countries: A systematic review and meta-analysis. *Quality of Life Research*, *33*, 1175-1189.
II	To assess comorbid depression and associated factors among adults living with HF in Ethiopia To assess the HRQoL and its influencing factors among people living with HF in Ethiopia	Quantitative cross-sectional study	4 and 5	Mulugeta, H., Sinclair, P. M., & Wilson, A. (2024a). Comorbid depression among adults with heart failure in Ethiopia: A hospital-based cross-sectional study. *BMC Psychiatry, 24*, 321. Mulugeta, H., Sinclair, P. M., & Wilson, A. (2023a). Health-related quality of life and its influencing factors among people with heart failure in Ethiopia: Using the revised Wilson and Cleary model. *Scientific Reports*,*13*, Article 20241.
III	To explore the experiences of people with HF in Ethiopia	Qualitative descriptive study	6	Mulugeta H, Sinclair PM, Wilson A (2024) The experience of people living with heart failure in Ethiopia: A qualitative descriptive study. PLoS ONE 19(10): e0310600.

1.8. Structure of the thesis

This thesis is presented as a thesis by compilation with four published papers and one under review. It is arranged in eight chapters.

Chapter One: Introduction

This introductory chapter provides a clear overview of the background information and problem statement and highlights existing gaps regarding the problem. It introduces the study setting, explaining why the research is important and how it contributes to policy and practice. The chapter states the research aim and objectives.

Chapter Two: Literature review

This chapter systematically summarises, synthesises, and discusses relevant evidence from appropriate studies, highlighting the knowledge gaps in the literature that this thesis aimed to fill. It is comprised of two papers: Paper one describes the prevalence of depression and its association with HRQoL in people with HF in LMICs, and paper two examines the HRQoL of people with HF in LMICs.

Chapter Three: Methodology

This chapter outlines the methodological approaches employed to address the research aim and objectives. It provides a detailed description of the research design, study setting, participants, data collection methods and instruments, variables, ethical approval, and data analysis.

Chapters Four and Five: Quantitative findings

These chapters report the quantitative findings from the second phase of the study. Chapter Four presents paper three, which focuses on the prevalence of depression and associated factors in people with HF in Ethiopia, while Chapter Five assesses HRQoL and its influencing factors within the same population, in paper four. Together, these chapters provide a comprehensive quantitative analysis, providing insights into the complex dynamics of depression, heart failure, and HRQoL in the Ethiopian context.

Chapter Six: Qualitative findings

This chapter reports the qualitative findings from the third phase of the study in paper five. This paper explores the experiences of Ethiopian people living with HF and describes how this condition affects their mental health and HRQoL.

Chapter Seven: Discussion and Implications

This chapter presents the interpretation of the findings by comparing them with previous evidence and discussing the significance of the results. The two phases of the thesis are integrated in this section, to provide a more comprehensive understanding of the problem. The chapter also discusses the clinical implications of the findings, limitations, as well as directions for future research.

Chapter Eight: Conclusion

This chapter provides the key findings of the study and concludes with recommendations for health care providers, policymakers, and future research.

CHAPTER 2: LITERATURE REVIEW

2.1. Chapter overview

This chapter provides an overview of the current knowledge about HF and its impact on mental health and HRQoL. First, the chapter provides the global picture of depression and HRQoL among people with HF. Then, it presents the results of two systematic reviews and meta-analyses that summarise and synthesise the prevalence of depression, levels of HRQoL, and their relationships among people with HF living in LMICs. The chapter includes a narrative description of the experiences of people with HF as reported in the literature. Finally, the chapter outlines the gaps identified through the literature review.

2.2. Global prevalence of depression among people with HF

Although the World Health Organization (WHO) in 2019 committed to providing counselling and pharmacological treatments to reduce the burden of CVDs, it remains the leading cause of global mortality and a major contributor to poor mental health and HRQoL (Group, 2019; Mensah et al., 2019). Recently published studies have revealed that the global prevalence of depression, anxiety, and stress among people with CVDs was 31.3%, 32.9%, and 57.7%, respectively, with the highest prevalence of depression observed in Africa (Karami et al., 2023). This demonstrates the significant burden of mental health conditions in this population and the need to address mental health issues in addition to cardiovascular care.

More people living with HF have depressive symptoms and a reduced HRQoL compared to those without HF (Polikandrioti et al., 2019). Several studies and systematic reviews have investigated the impact of HF on mental health and HRQoL. The findings vary across different regions, but they highlight the significant burden of depression common among people with HF. In the USA, depression is a common problem for people with HF, with a stable prevalence of 17% from 2007 through to 2016 (Chobufo et al., 2020). A similar study, that analysed one-year prevalence rates from the 1999 National Health Interview Survey data of 30,801 adults in the USA, reported that the prevalence of major depression was 7.9% in people with HF (Egede, 2007). In the UK, a retrospective cohort study conducted from June 2013 to November 2020, among 302 adults with HF, showed that that the prevalence of depression was 26.2%, with higher depression associated with difficulty performing daily activities (Helal et al., 2023). In a study conducted in 2017 in Turkey, 84% of the participants reported experiencing depression (İlhan & Oğuz, 2021). According to the baseline results from the observational RECODE-HF study in France, the prevalence of depression was 14.1% among people with HF (Eisele et al., 2017). Polikandrioti et al. (2019) studied 190 hospitalised HF patients in Greece and found that 24.2% had major depression. These figures demonstrate that depression is an ongoing challenge for people with HF living in high-income countries.

A critical review of the literature from 1994 to 2019 showed that the prevalence of depression ranged from 10-60% among people with HF (Yohannes et al., 2010). Similarly, Moradi and colleagues (2021) recently combined the results of 149 studies, that were published between January 2000 to December 2020 and estimated the global pooled prevalence of depression among people with HF – although they included only a small number of studies from LMICs. According to the findings of their meta-analysis, the pooled prevalence of any severity and moderate to severe depression among people with HF was 41.9% and 28.1%, respectively (Moradi et al., 2021). Another meta-analysis conducted in 2019 found the pooled prevalence of depression among people with HF in China was 43% (Lin et al., 2020).These results show that depression is a significant problem for people with HF and indicate the need for additional research, especially in underrepresented regions such as LMICs, to fully understand the global burden of depression in this population.

Numerous factors are associated with depression in people with HF, including age, gender, marital status, severity of symptoms, socioeconomic status, social support, and hospitalisation (Chobufo et al., 2020; Graven et al., 2017; Nguyen et al., 2022). In addition, higher NYHA class, sedentary lifestyle, being over 70 years, and a history of readmission to hospital are also significant predictors of depression in this population (Chobufo et al., 2020; Zahid et al., 2018), indicating the multifaceted nature of depression and underscoring the importance of considering these factors during routine care interaction with this population.

2.3. The prevalence of depression among people with HF in LMICs

The prevalence of depression among people with HF in LMICs is high compared to the rates of people living in higher income countries. This could be due to low educational levels and poor socioeconomic status (Allabadi et al., 2019; Tsabedze et al., 2021). Although the global prevalence of depression in people with HF has been well summarised and reported (Moradi et al., 2021), these publications have included very few studies from LMICs, despite the fact that multiple studies have been conducted in many countries in this region, leaving the burden of the problem unknown in this part of the world. To address this gap, a systematic review and meta-analysis was performed to determine the prevalence of depression among people with HF in LMICs, as well as its association with HRQoL. The findings showed that depression affects nearly 50% of people living with HF and is positively associated with HRQoL. The comprehensive search strategy for this systematic review, tailored for each database, is attached in Appendix 1.

Publication: Paper One

Mulugeta, H., Sinclair, P. M., & Wilson, A. (2023). Prevalence of depression and its association with health-related quality of life in people with heart failure in low-and middle-income countries: A systematic review and meta-analysis. *PLOS One, 18*(3), e0283146. https://doi.org/10.1371/journal.pone.0283146

Statement of Authorship

Title of paper	Prevalence of depression and its association with health-related quality of life in people with heart failure in low- and middle-income countries: A systematic review and meta-analysis
Publication status	☒Published in PLOS One ☐ Submitted for Publication ☐ Accepted for Publication ☐ Written in manuscript style
Publication details	https://doi.org/10.1371/journal.pone.0283146

Principal author

Name of principal author	Henok Mulugeta TESHOME	
Contribution to the paper	• *Conceived the study aims and design* • *Performed analysis and interpreted the data* • *Wrote the first draft of the manuscript* • *Revised drafts of the manuscript based on comments from co-authors* • *Acted as corresponding author*	
Overall percentage (%)	80% contribution	
Certification	I hereby certify that this paper has been written by me during the period of my higher degree research candidature, and its content is primarily based on my own original work, unless stated otherwise. All references and all sources of information have been appropriately acknowledged	
Signature	Production Note: Signature removed prior to publication.	Date: 01/05/24

Co-Author contributions.

By signing the Statement of Authorship, each author certifies that:

- *The candidate's stated contribution to the publication is accurate*
- *Permission is granted for the candidate to include the publication in the thesis*
- *The sum of all co-author contributions is equal to 100% less the candidate's stated contribution.*

Name of Co-Author	A/ Professor Peter M. Sinclair	
Contribution to the paper	Contributed to the design of the study, validated the data analysis, interpretation of the findings, and reviewed and approved the final manuscript	
Signature	Production Note: Signature removed prior to publication.	Date: 07.07.24
Name of Co-Author	Professor Amanda Wilson	
Contribution to the paper	Contributed to the design of the study, validated the data analysis, interpretation of the findings, and reviewed and approved the final manuscript	
Signature	Production Note: Signature removed prior to publication.	Date:10/07/24

PLOS ONE

RESEARCH ARTICLE

Prevalence of depression and its association with health-related quality of life in people with heart failure in low- and middle-income countries: A systematic review and meta-analysis

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Abstract

Introduction

Heart failure is a growing public health concern around the world. People with heart failure have a high symptom burden, such as depression, which affects health-related quality of life (HRQoL). The objective of this systematic review and meta-analysis was to estimate the pooled prevalence of depression and evaluate its association with HRQoL among people with heart failure in low- and middle-income countries (LMICs).

Methods

This systematic review was conducted in accordance with the JBI methodology. Electronic databases such as MEDLINE, PsycINFO, EMBASE, CINAHL, Web of Science, Scopus and JBI EBP were searched to identify relevant studies published from January 2012 to August 2022. The methodological quality of each article was assessed using relevant JBI critical appraisal instruments. A random-effects model was employed to estimate the pooled prevalence of depression. Heterogeneity across the studies was investigated using Cochrane's Q test and I^2 statistic. The Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines 2020 were followed for reporting the results. All statistical analyses were performed using STATA version 17 software.

Results

After screening, a total of 21 eligible articles with 5074 participants with heart failure were included in this review. The pooled prevalence of depression among people with heart failure in LMICs was 51.5% (95% CI = 39.7, 63.3%, I^2 = 99.00%). Subgroup analysis revealed, the highest prevalence in studies whose participants were in-patients, and from the Middle

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Abstract

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Results: After screening, a total of 21 eligible articles with 5074 participants with heart failure were included in this review. The pooled prevalence of depression among people with heart failure in LMICs was 51.5% (95% CI 39.7, 63.3, I^2=99.00%). Subgroup analysis revealed, the highest prevalence in studies whose participants were inpatients, and from the Middle East and North Africa, and studies utilising the Beck Depression Inventory (BDI). Depression was positively associated with HRQoL.

Conclusion: This review revealed that almost half of all people with heart failure in low- and middle-income countries have comorbid depression. People with heart failure and depressive symptoms have poor HRQoL. Therefore, early screening of depression is critical for improving HRQoL in this population.

Systematic review registration: PROSPERO CRD42022361759.

Keywords: Heart failure, Depression, HRQoL, Systematic review, LMICs

Introduction

Cardiovascular diseases (CVD) are the leading cause of mortality globally with an estimated 17.9 million deaths in 2019, accounting for 32% of all deaths (Flora & Nayak, 2019). It is predicted that over 23 million people will die annually from CVDs worldwide by 2030 (Jayaraj et al., 2018). The burden of CVD is increasing in low- and middle-income countries (LMICs) where 75% of all deaths are related to CVD (Ruan et al., 2018). This burden can be attributed to a lack of primary health care services to support the early detection and management of cardiovascular risk factors (Roth et al., 2020).

Heart failure is a major CVD associated with high morbidity and mortality (Thida et al., 2021). The global prevalence of heart failure (HF) is increasing due to ageing and population growth, with an estimated 64 million people affected (Amy Groenewegen et al., 2020; Lippi & Sanchis-Gomar, 2020). It is responsible for more than 300,000 global deaths annually (Bowen et al., 2020; Chadda et al., 2018). Although there are limited data from population-based studies, the available data from hospital-based studies show that heart failure is increasingly prevalent in low- and middle-income countries (LMICs) (Agbor et al., 2020). People with heart failure have many debilitating symptoms, such as depression and poor health-related quality of life (HRQoL), compared to the general population due to the unpredictable nature of the disease (Audi et al., 2017; Reavell et al., 2018).

The psychological impact of HF, such as depression, is increasing significantly and leads to a poor prognosis (Freedland et al., 2021). People with HF who are depressed have an increased risk of poor HRQoL, compared to those without depression (Freedland et al., 2021; Senthilkumar et al., 2021). The findings from two recent systematic reviews found the prevalence of any severity of depression in people with HF was 42% (Moradi et al., 2021), and the overall HRQoL in these populations was moderate (Moradi et al., 2020). However, these reviews only included a small number of studies from LMICs. This means there is considerable uncertainty about the prevalence of depression in this region. A systematic review and meta-analysis conducted in China found that 43% of people with heart failure have depressive symptoms (Lin et al., 2020). However, this figure does not represent the burden of the problem in LMICs as all data were from China.

While there are many studies on depression and its association with HRQoL among HF patients in LMICs, the results are inconsistent and inconclusive, meaning the current burden of the problem remains unknown in these populations (Allabadi et al., 2019). In this systematic review, we aimed to estimate the regional burden of depression and assess the association between depression and HRQoL in people with HF in LMICs. The findings of this review will provide contemporary evidence with the potential to assist healthcare policymakers and researchers in developing intervention programs and guidelines for improving the management and care of people with heart failure in LMICs.

Review questions

This review sought to answer the following two questions:

1. *What is the prevalence of depression in people with heart failure in LMICs?*
2. *Is there an association between depression and HRQoL in people with heart failure in LMICs?*

Inclusion and exclusion criteria

Participants (population)

This review included studies from LMICs whose participants are 18 years or older and had a confirmed diagnosis of heart failure.

Condition

The prevalence of depression and/or association of depression with HRQoL in the participants. For the purpose of this review, heart failure is defined as the inability of the heart to effectively pump blood, as evidenced by either signs and symptoms based on Framingham criteria or reduced ejection fraction (<40%) (Hage et al., 2020; Lofstrom et al., 2019). Depression is defined as the persistent feeling of unhappiness and lack of interest in daily activities with symptoms for at least two weeks, based on DSM-5 diagnostic criteria (Truschel, 2020). Health-related quality of life is defined as self-reported physical, mental, emotional, and social health functioning (Karimi & Brazier, 2016).

Context

Low- and middle-income countries. For the purposes of this review, low to middle-income countries were defined using the World Bank atlas method (The World Bank, 2022) based on the stratification of economies based on gross national income (GNI) per capita. Low-income countries are those with a GNI per capita of $US1,045 or less; lower- and upper middle-income economies are those with a GNI per capita between $US1,046 and $US4,095 and $US4,096 and $US12,695, respectively.

Outcomes

The primary outcome of this review was the prevalence of depression. The secondary outcome was the association between depression and HRQoL scores measured using a psychometrically validated instrument.

Types of studies

Observational (cross-sectional, cohort, case-control) studies that reported the prevalence of depression and/or association of depression with HRQoL in people with heart failure.

For the secondary objective of this review, the following inclusion criteria were considered using the PEO (P=Population, E=Exposure, O=Outcome) model.

Population: Adults with a confirmed diagnosis of heart failure

Exposure of interest: depression

Outcome: HRQoL.

Methods

Design

This systematic literature review has followed methodology guidelines outlined by the Joanna Briggs Institute (JBI) methodology for Systematic Reviews (Aromataris & Munn, 2020) and is reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) 2020 guidelines (Page et al., 2021). The protocol for this systematic review was registered in the PROSPERO online database (registration number CRD42022361759) and previously published (Henok Mulugeta, Peter Sinclair, & Amanda Wilson, 2023).

Search strategy

The search strategy aimed to locate both published and unpublished studies. Information sources were electronic databases, conference proceedings, websites, dissertations, and direct contact with the author if required. A preliminary original search of MEDLINE (Ovid) and CINAHL (EBSCO) was undertaken in May 2022 and was updated in August 2022. The last search was done on August 20, 2022. The text words in the titles and abstracts of relevant articles and the index terms used to describe the articles were analysed and used to inform a full search strategy, in collaboration with a faculty librarian. The search strategy was developed using the **CoCoPop** (**Co**=Condition, **Co**=Context, **Pop**=Population) model, considering the **PEO** (P=Population, E=Exposure, O=Outcome) model for the second research question of this review. The databases searched included MEDLINE (Ovid), PsycINFO (EBSCOhost), EMBASE (Ovid), CINAHL (EBSCOhost), Web of Science (Direct access), Scopus (Direct access) and JBI EBP database (Ovid). Index terms (subject headings) and keywords used for the search strategy were adapted for each database. The full search strategy for each database is attached in S1 Table (Appendix 1, Supplement 4). The reference lists of all identified relevant studies and systematic reviews were screened to identify additional studies. A search for unpublished studies was conducted using Google scholar, Mednar, ProQuest, and dissertation databases. Articles published in English language from January 2012 to August 2022 were included to establish the most recent estimate.

Study selection and outcome

Following the search, all identified citations were collated and uploaded into EndNote V20 (Clarivate Analytics, PA, USA). After removing duplicates, two researchers (HM and PS) screened all titles and abstracts from the original search against the predefined inclusion criteria. The full text of selected citations was assessed in detail against the inclusion criteria independently by the reviewers (HM and PS). The reasons for excluding papers were recorded and reported. Any disagreements between the reviewers were resolved through discussion. The search results and the study inclusion process are reported in accordance with the Preferred PRISMA guidelines (Page et al., 2021).

Quality appraisal

Two independent reviewers (HM and PS) critically appraised the eligible studies for methodological quality using a standardised JBI critical appraisal instrument for studies reporting prevalence data (Munn et al., 2015). The tool is comprised of nine items that focus on target population, sample size adequacy, study subject and setting (context), reliability of condition measurement, appropriateness of the statistical test used to analyse the data, and adequacy of the response rate with the option to answer ‘No’, ‘Yes’, or ‘unclear’. Authors of papers were contacted to request missing or additional data for clarification, where required. Following the critical appraisal, the reviewers included or excluded studies based on the overall appraisal quality. A study was excluded if it had more than three ‘No’ or ‘unclear’ quality categories. This threshold criterion is consistent with that used in a similar published systematic review (Nour et al., 2018). The quality of eligible articles to assess the association between depression and HRQoL were also appraised using the JBI cross-sectional studies critical appraisal tool for studies reporting association (etiology/risk) (Moola et al., 2021). Any disagreements were resolved through discussion. The results of the critical appraisal are reported in narrative and table form (Tables 2 and 6).

Data extraction

The JBI data extraction tool for prevalence data and association (etiology/risk) studies were used to extract the following information from each included study for each research question: authors, year of publication, country, region, design, population, sample size, sampling methods, outcome measuring tool, prevalence of depression, HRQoL mean score based on exposure (depression), measure of association, and quality appraisal score. When there was missing data, authors were contacted for relevant information. Two reviewers (HM and AW) independently conducted the primary data extraction and cross-checked for inconsistencies. Any disagreements and discrepancies between the reviewers were resolved by discussion.

Data analysis and synthesis

A narrative presentation of the outcomes, including text, table, and figure, were used to discuss the characteristics of the included studies and synthesise the prevalence of depression and its association with HRQoL. A random effects model with DerSimonian and Laird model was used to estimate the pooled effect size of depression, as recommended by Tufanaru et al. (Tufanaru et al., 2015). Subgroup analyses were conducted to investigate the variation between different study characteristics, such as region, type of outcome measuring instrument, and type of study population. Heterogeneity was assessed statistically using the standard chi-squared and I-squared tests. The sources of heterogeneity were analysed using subgroup analysis and meta-regression. The presence of publication bias was assessed visually using a funnel plot, and statistical tests for funnel plot asymmetry were checked by Egger test statistics. A leave-one-out sensitivity analysis was also conducted for assessing the influence of each study on the overall effect size estimate. The pooled effect size was presented using a forest plot. All statistical analyses were performed using STATA Version 17 statistical software.

Results

Search results

The online electronic search process yielded 4222 articles (4156 from databases and 66 from other sources) of which 1303 were duplicates. After reviewing the title and abstract, we excluded 2844 irrelevant articles. From the remaining 75 articles, 49 were removed after full text assessment. A further five articles were excluded due to poor methodological quality, leaving 21 relevant primary research articles eligible for this systematic review (Figure 2).

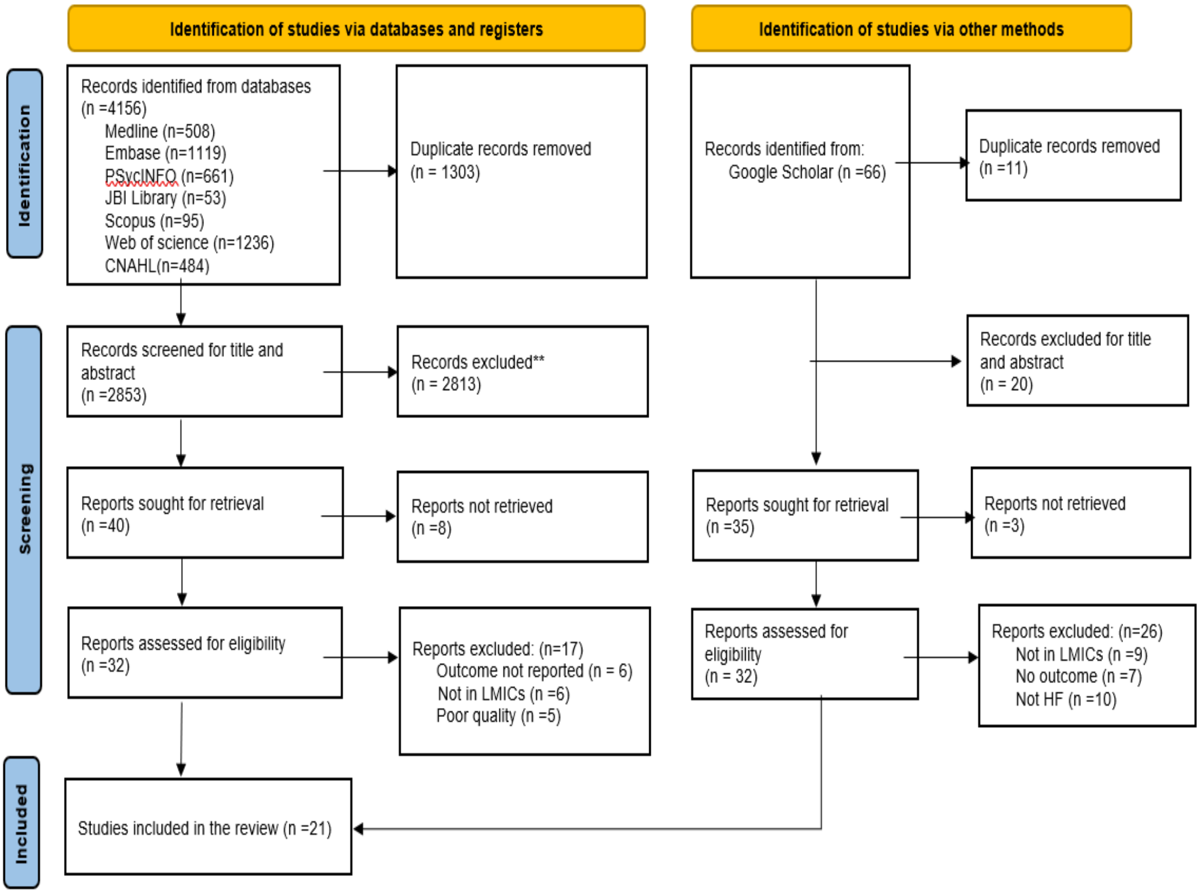


Figure 2: PRISMA flow diagram of literature identification, study selection, and inclusion process for SR-I.

Assessment of methodological quality for prevalence studies

This review included 21 articles with moderate to high methodological quality. One study (Alemoush et al., 2021) scored 9 points, five studies (AbuRuz, 2018; Fan & Meng, 2015; Husain et al., 2019; Tran et al., 2022; Yazew et al., 2019) scored 8 points, and the remaining 15 studies (Dastgeer et al., 2016; DeWolfe et al., 2012; Edmealem & Olis, 2020; Erceg et al., 2013; Ghanbari et al., 2015; Khan et al., 2012; Molayynejad et al., 2019; Okviasanti et al., 2021; Pan et al., 2016; Pushkarev et al., 2018; Son & Seo, 2018; Son et al., 2012; Tsabedze et al., 2021; Zahid et al., 2018; X. Zhang et al., 2020) scored 7 points in the JBI critical appraisal checklist (Munn et al., 2015) for studies reporting prevalence data (Table 2).

Table 2: Methodological quality of included prevalence studies (SR-I).

Included articles	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Quality score/9
(Edmealem & Olis, 2020)	Y	Y	U	Y	Y	U	Y	Y	Y	7
(DeWolfe et al., 2012)	Y	Y	Y	Y	Y	Y	Y	Y	U	7
(Okviasanti et al., 2021)	U	Y	Y	Y	Y	Y	N	Y	Y	7
(Pushkarev et al. (2018)	U	Y	Y	Y	Y	Y	U	Y	Y	7
(Fan & Meng, 2015)	Y	Y	Y	Y	Y	Y	U	Y	Y	8
(Zahid et al., 2018)	U	U	Y	Y	Y	Y	U	Y	Y	7
(Yazew et al., 2019)	Y	Y	Y	Y	Y	Y	U	Y	Y	8
(AbuRuz, 2018)	U	Y	Y	Y	Y	Y	Y	Y	Y	8
(Pan et al., 2016)	U	Y	Y	Y	Y	Y	U	Y	Y	7
(Husain et al., 2019)	Y	Y	Y	Y	Y	Y	U	Y	Y	8
(Tran et al., 2022)	U	Y	Y	Y	Y	Y	Y	Y	Y	8
(Tsabedze et al., 2021)	U	Y	Y	Y	Y	Y	U	Y	Y	7
(Erceg et al., 2013)	U	Y	Y	Y	Y	Y	N	Y	Y	7
(Alemoush et al., 2021)	Y	Y	Y	Y	Y	Y	Y	Y	Y	9

(Dastgeer et al., 2016)	U	Y	Y	Y	Y	Y	U	Y	Y	7
(Ghanbari et al., 2015)	U	Y	Y	Y	Y	Y	U	Y	Y	7
(X. Zhang et al., 2020)	U	Y	Y	Y	Y	Y	U	Y	Y	7
(Khan et al., 2012)	U	Y	Y	Y	Y	Y	N	Y	Y	7
(Molayynejad et al., 2019)	U	Y	Y	Y	Y	Y	N	Y	Y	7
(Son & Seo, 2018)	U	Y	Y	Y	Y	Y	U	Y	Y	7
(Son et al., 2012)	U	Y	Y	Y	Y	Y	U	Y	Y	7

Y=Yes; N=No; U=Unclear

Overall study characteristics

Of the 21 studies, seven were conducted in East Asia and the Pacific region (Fan & Meng, 2015; Okviasanti et al., 2021; Pan et al., 2016; Son & Seo, 2018; Son et al., 2012; Tran et al., 2022; X. Zhang et al., 2020), four in the Middle East and North Africa (AbuRuz, 2018; Alemoush et al., 2021; Ghanbari et al., 2015; Molayynejad et al., 2019), three in Sub-Saharan Africa (Edmealem & Olis, 2020; Tsabedze et al., 2021; Yazew et al., 2019), three in Europe and Central Asia (DeWolfe et al., 2012; Erceg et al., 2013; Pushkarev et al., 2018), and four in South Asia (Dastgeer et al., 2016; Husain et al., 2019; Khan et al., 2012; Zahid et al., 2018). Most studies used a descriptive cross-sectional design (n=17, 81%) and the remaining (n=4, 19%) were prospective cohort studies. Many (57%) of the studies were conducted with outpatient populations, and most (33%) used a consecutive sampling technique. The sample size of the included studies ranged from 43 (Edmealem & Olis, 2020) to 1009 (Husain et al., 2019). Included studies assessed the prevalence of depression using nine different psychometrically validated instruments. Five studies (Dastgeer et al., 2016; Fan & Meng, 2015; Husain et al., 2019; Molayynejad et al., 2019; Pushkarev et al., 2018) used the Beck Depression Inventory (BDI), five (DeWolfe et al., 2012; Okviasanti et al., 2021; Son & Seo, 2018; Yazew et al., 2019; Zahid et al., 2018) used the Patient Health Questionnaire-9 (PHQ-9), four (AbuRuz, 2018; Alemoush et al., 2021; Khan et al., 2012; X. Zhang et al., 2020) used the Hospital Anxiety and Depression Score (HADS), two (Erceg et al., 2013; Son et al., 2012) used the Geriatric Depression Scale (GDS), and the remaining five (Edmealem & Olis, 2020; Ghanbari et al., 2015; Pan et al., 2016; Tran et al., 2022; Tsabedze et al., 2021) each the used

Cardiac Depression Scale (CDS), Patient Health Questionnaire-2 (PHQ-2), Hamilton Rating Scale for Depression (24-items) (HAM-D_{24}), Geriatric Depression Scale (GDS), and International Statistical Classification of Diseases and Related Health Problems V10 (ICD-10) (Table 3).

Table 3: Characteristics of included studies for prevalence of depression among people with heart failure in LMICs

ID	Author (reference)	Publication year	Country	Region	Study design	Population	Sample size	Sampling method	Outcome measuring tool	Prevalence	Quality score
1	(Edmealem & Olis, 2020)	2020	Ethiopia	Sub-Saharan Africa	Cross-Sectional	Outpatient	43	Stratified	PHQ-2	11.1	7
2	(DeWolfe et al., 2012)	2012	Georgia	Europe and Central Asia	Prospective cohort	Outpatient	314	Unreported	PHQ-9	13.0	8
3	(Okviasanti et al., 2021).	2020	Indonesia	East Asia and Pacific	Cross-Sectional	Outpatient	155	Consecutive	PHQ-9	85.2	7
4	(Pushkarev et al., 2018)	2018	Russia	Europe and Central Asia	Prospective cohort	Outpatient	260	Unreported	BDI	60.0	7
5	(Fan & Meng, 2015)	2015	China	East Asia and Pacific	Cross-Sectional	Inpatient	152	Consecutive	BDI	44.0	8
6	(Zahid et al., 2018)	2018	Pakistan	South Asia	Cross-Sectional	Outpatient	170	Consecutive	PHQ-9	60.0	7
7	(Yazew et al., 2019)	2019	Ethiopia	Sub-Saharan Africa	Cross-Sectional	Outpatient	422	Systematic random	PHQ-9	51.1	8
8	(AbuRuz, 2018)	2018	Jordan	Middle East and North Africa	Cross-Sectional	Outpatient	200	Convenient	HADS	65.0	8
9	(Pan et al., 2016)	2016	China	East Asia and Pacific	Cross-Sectional	Inpatient	366	Consecutive	HAM-D24	57.4	7

10	(Husain et al., 2019)	2019	Pakistan	South Asia	Cross-Sectional	Outpatient	1009	Unreported	BDI	66.0	8
11	(Tran et al., 2022)	2022	Vietnam	East Asia and Pacific	Cross-Sectional	Inpatient	128	Convenient	ICD-10	46.9	8
12	(Tsabedze et al., 2021)	2021	South Africa	Sub-Saharan Africa	Cross-Sectional	Outpatient	103	Consecutive	DASS-21	52.4	7
13	(Erceg et al., 2013)	2013	Serbia	Europe and Central Asia	Cross-Sectional	Inpatient	136	Consecutive	GDS	55.9	7
14	(Alemoush et al., 2021)	2021	Jordan	Middle East and North Africa	Prospective follow-up	Outpatient	127	Consecutive	HADS	47.3	9
15	(Dastgeer et al., 2016)	2016	Pakistan	South Asia	Prospective follow-up	Inpatient	400	Unreported	BDI	64.7	7
16	(Ghanbari et al., 2015)	2015	Iran	Middle East and North Africa	Cross-Sectional	Inpatient	239	Gradual sampling	CDS	57.7	7
17	(X. Zhang et al., 2020)	2020	China	East Asia and Pacific	Cross-Sectional	Inpatient	254	Convenient	HADS	18.1	7
18	(Khan et al., 2012)	2012	Pakistan	South Asia	Cross-Sectional	Inpatient	121	Consecutive	HADS	30.0	7
19	(Molayynejad et al., 2019)	2019	Iran	Middle East and North Africa	Cross-Sectional	Inpatient	151	Convenient	BDI	97.0	7
20	(Son & Seo, 2018)	2018	South Korea	East Asia and Pacific	Cross-Sectional	Outpatient	190	Convenient	PHQ-9	30.0	7
21	(Son et al., 2012)	2012	South Korea	East Asia and Pacific	Cross-Sectional	Outpatient	134	Unreported	GDS	67.9	7

Prevalence of depression in people with heart failure in LMICs

In total, 21 studies reported the prevalence of depression in people with heart failure in LMICs. The lowest and highest prevalence of depression were 11.1% (Edmealem & Olis, 2020) and 97.0% (Molayynejad et al., 2019), respectively (Table 3). The pooled regional prevalence of depression among people with heart failure in LMICs was 52% (95% CI 39.73, 63.30, I^2=99.00%). The overall pooled effect size of depression is presented using forest plot (Figure 3).

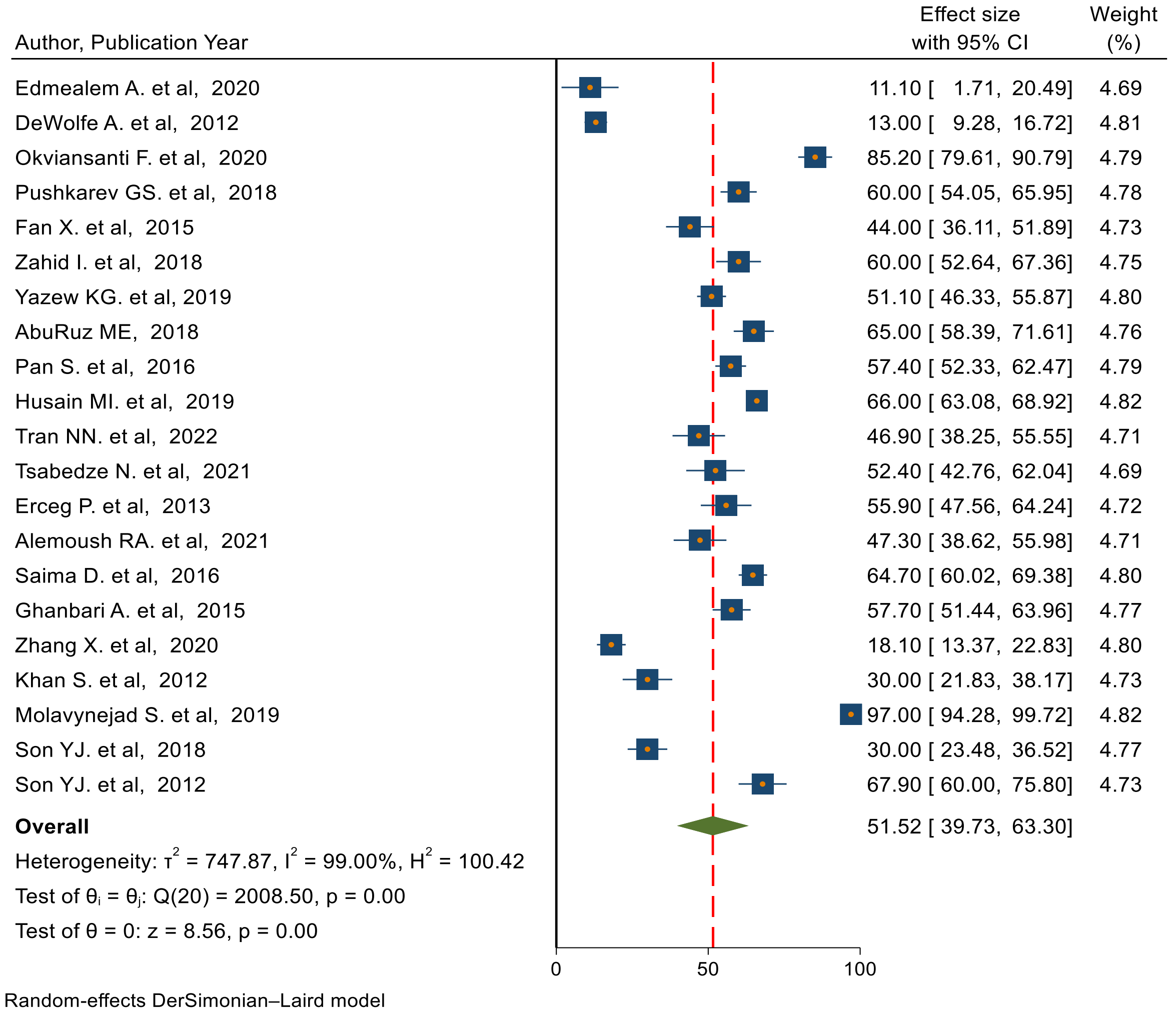


Figure 3: The pooled prevalence of depression in people with heart failure in LMICs

Subgroup analysis

Subgroup analysis was done using the region where the studies were conducted, study population, and the outcome measuring instrument. The result showed that the highest prevalence was observed among studies conducted in the Middle East and North Africa, among inpatients, and studies that screened depression using the BDI (Table 4).

Table 4: Subgroup analysis on the prevalence of depression among people with heart failure in LMICs

Subgroup	**Number of studies**	**Sample size**	**Pooled prevalence**	**Heterogeneity**	
				***I*²**	**P-value**
By region					
East Asia and Pacific	7	1379	49.91	98.5	<0.001
South Asia	4	3708	55.62	95.6	<0.001
Middle East and North Africa	4	717	66.91	98.8	<0.001
Sub-Saharan Africa	3	568	38.35	96.6	<0.001
Europe and Central Asia	3	710	42.86	99.1	<0.001
Latin America and Caribbean	0	…	….	…	…
By Population					
Outpatient	12	3127	50.79	98.6	<0.001
Inpatient	9	1947	52.47	99.2	<0.001
By outcome measurement tool					
BDI	5	1972	66.51	99	<0.001
PHQ-9	5	1251	47.82	99.2	<0.001
HADS	4	702	40.04	97.8	<0.001
GDS	2	270	61.98	76.1	0.04
Others (CDS, HAM-D24, PHQ-2, ICD-10, DASS-21)	5	879	45.35	95	<0.001

Assessment of heterogeneity

The result of this meta-analysis using the random effects model revealed a high heterogeneity across the included studies (I^2=99%, p=0.001). Heterogeneity is inevitable in meta-analysis due to differences in study quality, methodology, sample size and inclusion criteria for participants (Higgins, 2008; Melsen et al., 2014). Consequently, meta-regression was performed using publication year, sample size, and quality score as covariates, to find possible sources of heterogeneity among the included studies. The result of the meta-regression analysis showed that no significant linear relationship existed between the outcome (depression) and the covariates. Therefore, none of the three covariates were significantly associated with the presence of heterogeneity (Table 5). The high heterogeneity can be attributed to chance or other factors not included in this review.

Table 5: Meta-regression analysis of factors associated with heterogeneity (SR-I).

Heterogeneity source	**Coefficients**	**Standard error**	**P-value**
Sample size	0.02	0.03	0.49
Publication year	1.09	1.99	0.58
Quality score	-7.53	10.90	0.49

Assessment of publication bias

Visual inspection of the funnel plot suggested asymmetry, as eight studies lay to the left and 13 to the right of the line (Figure 4). However, this was not statistically significant as evidenced by Egger's test p=0.81), which confirmed the results were not influenced by publication bias. It is worth noting that asymmetry in funnel plots is not always linked to publications bias (Tang & Liu, 2000) and that high heterogeneity may explain the visual asymmetry in the funnel plot.

Sensitivity analysis

The result of the leave-one-out sensitivity analysis using a random effects model demonstrated that no single study unduly influenced the pooled estimate of depression. For each study, the displayed effect size corresponds with the overall effect size computed from the meta-analysis excluding that study (Figure 5).

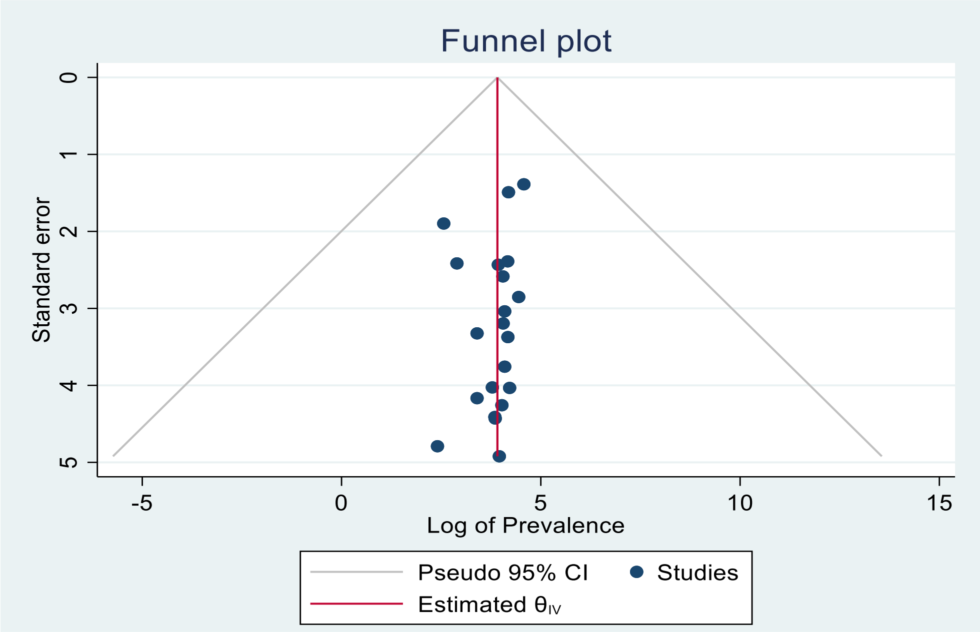
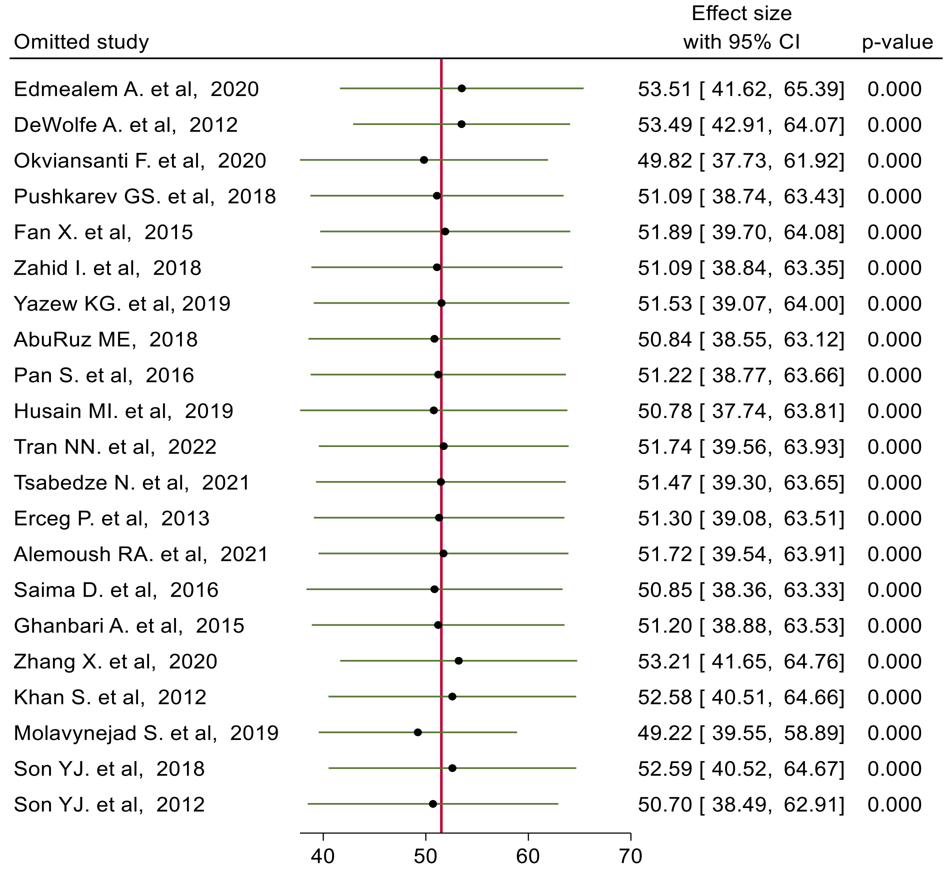


Figure 4: Funnel plot to test the publication bias of the 21 studies (SR-I).



Omitted study	Effect size with 95% CI	p-value
Edmealem A. et al, 2020	53.51 [41.62, 65.39]	0.000
DeWolfe A. et al, 2012	53.49 [42.91, 64.07]	0.000
Okviansanti F. et al, 2020	49.82 [37.73, 61.92]	0.000
Pushkarev GS. et al, 2018	51.09 [38.74, 63.43]	0.000
Fan X. et al, 2015	51.89 [39.70, 64.08]	0.000
Zahid I. et al, 2018	51.09 [38.84, 63.35]	0.000
Yazew KG. et al, 2019	51.53 [39.07, 64.00]	0.000
AbuRuz ME, 2018	50.84 [38.55, 63.12]	0.000
Pan S. et al, 2016	51.22 [38.77, 63.66]	0.000
Husain MI. et al, 2019	50.78 [37.74, 63.81]	0.000
Tran NN. et al, 2022	51.74 [39.56, 63.93]	0.000
Tsabedze N. et al, 2021	51.47 [39.30, 63.65]	0.000
Erceg P. et al, 2013	51.30 [39.08, 63.51]	0.000
Alemoush RA. et al, 2021	51.72 [39.54, 63.91]	0.000
Saima D. et al, 2016	50.85 [38.36, 63.33]	0.000
Ghanbari A. et al, 2015	51.20 [38.88, 63.53]	0.000
Zhang X. et al, 2020	53.21 [41.65, 64.76]	0.000
Khan S. et al, 2012	52.58 [40.51, 64.66]	0.000
Molavynejad S. et al, 2019	49.22 [39.55, 58.89]	0.000
Son YJ. et al, 2018	52.59 [40.52, 64.67]	0.000
Son YJ. et al, 2012	50.70 [38.49, 62.91]	0.000

Random-effects DerSimonian–Laird model

Figure 5: Result of sensitivity analysis of the 21 studies (SR-I)

The association between depression and HRQoL

Of the 21 eligible studies, only six reported an association between depression and HRQoL using depression as an exposure variable and HRQoL as an outcome. There were variations in the ways that depression and HRQoL were measured among these studies. For instance, two studies (Erceg et al., 2013; Son et al., 2012) used the GDS, two studies (AbuRuz, 2018; Alemoush et al., 2021) used the HADS, one study (Tsabedze et al., 2021) used the DASS-21, and one study (DeWolfe et al., 2012) used the PHQ-9 to measure depression. Likewise, four studies (DeWolfe et al., 2012; Erceg et al., 2013; Son et al., 2012; Tsabedze et al., 2021) used the MLHFQ and the other two studies (AbuRuz, 2018; Alemoush et al., 2021) used the SF-36 to measure HRQoL. Regarding the critical appraisal, the JBI cross-sectional studies critical appraisal tool for studies reporting association (etiology/risk) was used to assess the quality of each study, and the result showed that all six studies had good methodological quality (Table 6).

Table 6: Methodological quality of included studies for association of depression and HRQoL

Included articles	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Quality score/8
(DeWolfe et al., 2012)	Y	Y	Y	Y	Y	Y	Y	Y	8
(AbuRuz, 2018)	Y	Y	Y	Y	Y	Y	Y	Y	8
(Tsabedze et al., 2021)	Y	Y	Y	Y	Y	Y	Y	Y	8
(Erceg et al., 2013)	Y	Y	Y	Y	Y	Y	Y	Y	8
(Alemoush et al., 2021)	Y	Y	Y	Y	Y	Y	Y	Y	8
(Son & Seo, 2018)	Y	Y	Y	Y	Y	Y	Y	Y	8

Y=Yes; N=No; U=Unclear

Concerning the effect size, five studies (AbuRuz, 2018; Alemoush et al., 2021; DeWolfe et al., 2012; Erceg et al., 2013; Son et al., 2012) used beta(β) as the effect size to report the association between depression and HRQoL, while one study (Tsabedze et al., 2021) used Odds Ratio (OR) to indicate the strength of the association, with all six studies reporting a statistically significant association between depression and HRQoL. All included studies evaluating the association between depression as the exposure variable and HRQoL as an outcome are profiled in Table 7.

Table 7: The association between depression and health-related quality of life in people with heart failure

Author (year of publication)	Country	Sample size	Depression measuring tool	HRQoL measuring tool	Outcome (HRQoL score) based on exposure		Type of comparison	Outcome measure with result	Conclusion
					Depressed	Non-Depressed			
(Erceg et al., 2013)	Serbia	136	GDS	MLHFQ	57.9±17.6	40.9±17.1	Linear regression	β=0.41, p=0.001	1 unit increase in the depression score was associated with a 0.41 unit increase in MLHFQ QoL score
(Tsabedze et al., 2021)	South Africa	103	DASS-21	MLHFQ	28 (10–54)	5(0–17)	Logistic regression	OR=1.04, p=0.001	Depressed people are 1.04 times more likely to have poor HRQoL as compared to non-depressed one
(Son et al., 2012)	South Korea	134	GDS	MLHFQ	59.4±9.97	45.1±8.8	Linear regression	β=0.44, p=0.001	1 unit increase in the depression score was associated with a 0.44 unit increase in MLHFQ QoL score
(DeWolfe et al., 2012)	Georgia	314	PHQ-9	MLHFQ,	74.9±11.9	58.4±13.5	Linear regression	β=1.83, p=0.001	1 unit increase in the depression score was associated with a 1.83 unit increase in MLHFQ QoL score
(Alemoush et al., 2021)	Jordan	127	HADS	SF-36	……	………	Linear regression	β=-0.37, p=0.001	1 unit increase in the depression score was associated with a 0.37 unit decrease in SF-36 QoL score
(AbuRuz, 2018)	Jordan	200	HADS	SF-36	……	………	Linear regression	β=-0.32, p=0.001	1 unit increase in the depression score was associated with a 0.32 unit decrease in SF-36 QoL score

Discussion

The burden of heart failure has increased over the past decade in LMICs, with a significant economic impact and alteration in psychological, physical, and emotional well-being (Polikandrioti et al., 2019). Evidence regarding the burden of depression and its impact on HRQoL in people with HF from LMICs is limited. This review was conducted to estimate the pooled regional prevalence of depression, and to investigate the association between depression and HRQoL among people with heart failure in LMICs. To our knowledge, this is the first review to estimate the current prevalence of depression in people with HF in LMICs. The result of this review revealed that the pooled regional prevalence of depression in people with heart failure in LMICs was 51.5% (95% CI 39.73, 63.30, I^2=99.00%). This reinforces the understanding that depression is a common comorbid condition in people with heart failure and is consistent with the findings of the previous systematic review (Ishak et al., 2020). Our estimate is higher than the global prevalence of depression in people with heart failure (Moradi et al., 2021). The higher prevalence in LMICs might be due to variation in the sociodemographic characteristics of the study participants, discrepancy of instruments, sample size, study setting, and level of economic status (Ahmed et al., 2016; Husain et al., 2019).

The subgroup analysis of this review showed significant variation in the prevalence of depression among different groups. For instance, the highest (66.9%) and the lowest (38.4%) pooled prevalence was observed in studies from the Middle East and North Africa regions and Europe and Central Asia, respectively. This variation might be due to socioeconomic, health care coverage, sample size, and methodological differences among the included studies across the regions. In the present review, the prevalence of depression is higher among inpatients than outpatients. A similar finding was observed in a previous systematic review (Rutledge et al., 2006). This might be due to the severity of the disease or the fact that hospitalised patients are more unwell and have more socioeconomic burdens than outpatients. Consistent with the previous systematic review conducted in China (Lin et al., 2020), the pooled prevalence of depression in the current review was highest (66.5%) when measured using the Beck Depression Inventory (BDI). The lowest prevalence of depression (40.1%) was observed when measured using the Hospital Anxiety and Depression Score (HADS). This difference could be due to differences in definitions of depression and cut-off points to diagnose depression across the various scales. However, further research would be helpful to investigate the factors that might lead to such differences across the depression measuring scales.

The association of depression with HRQoL has been reported in several recent studies. The results of this systematic review also demonstrated that six studies among the included studies showed a significant association between depression and HRQoL, although there were insufficient data to estimate the pooled effect size. This finding is similar to previous studies conducted in Europe (Aggelopoulou et al., 2017; Müller-Tasch et al., 2007; Serafini et al., 2010). These studies found that people with heart failure who have depressive symptoms had poor quality of life compared to those who did not have depressive symptoms, and this was also correlated with an increased burden of morbidity and mortality due to HF (Son et al., 2012). The findings of this review highlight the need to understand the factors that contribute to the increased incidence of depression in people with heart failure living in LMICs, as well as the factors that contribute to a poorer quality of life. This will enable targeted interventions and support strategies to be designed and evaluated to improve outcomes for this population.

The findings of this meta-analysis have implications for clinical practice. We included articles published between 2012 and 2022. This cut-off date was decided arbitrarily by the authors to estimate the most recent prevalence rate, which should have more relevance to current clinical practice. Determining the most recent prevalence of depression provides up-to-date evidence to develop comorbid depression prevention strategies in this group and ultimately improving HRQoL. Determining the effect of depression on HRQoL can help health care providers prioritise during their routine clinical practice, which will reduce the overall burden of morbidity and mortality. However, some limitations should be considered for future research. First, the interpretation of the results must be taken cautiously as the meta-analysis had statistically significant heterogeneity across the included studies, which was not fully explained by the variables examined. Second, the conclusion of a positive association between depression and HRQoL, as reported in six studies, should be interpreted cautiously due to our inability to summarise the pooled effect size.

Conclusion

This systematic review and meta-analysis revealed that one in two people with heart failure in LMICs have comorbid depression. Depression is positively associated with HRQoL in people with heart failure. Early detection and treatment of depression in people with heart failure is highly recommended to reduce its burden in LMICs. Future research should investigate the factors associated with depression and HRQoL in this population.

List of abbreviations

CVD: Cardiovascular diseases; HF: Heart failure; HRQoL: Health-related quality of life, JBI: Joanna Briggs Institute; LMICs: Low- and middle-income countries; PRISMA: Preferred Reporting Items for Systematic reviews and Meta-Analyses.

Declarations

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Competing interests

The authors report no competing interests.

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Availability of data and materials

All the data are available from the corresponding author upon a reasonable request.

Author contributions

HM conceived the study and drafted the protocol. PS and AW provided support and guidance on the search strategy and screening process. All three authors (HM, PS, and AW) were involved in data extraction, quality assessment, and analysis. All authors have read and approved the final draft of the manuscript.

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2.4. Health-related quality of life in people with HF

HRQoL reflects the multifaceted impact of disease on one's life. Regular assessment of HRQoL is recommended for people with HF, as improving HRQoL is an important goal of HF management (Lewis et al., 2017; Lin et al., 2020).

The Minnesota Living with Heart Failure Questionnaire (MLWHFQ) is the most widely used disease-specific instrument for assessing HRQoL in people with heart failure. The MLWHFQ measures physical, emotional, and social dimensions of life (Barnett et al., 2019; Zahwe et al., 2020). The maximum score of the MLHFQ is 105, with scores less than 24, 24–45, and above 45, indicating good, moderate, and poor quality of life, respectively (Behlouli et al., 2009; Rector, 2017). The Short Form Survey-36 (SF-36) is a psychometrically validated multidimensional generic tool covering eight health domains: physical functioning, physical role, pain, general health, vitality, social function, emotional role, and mental health. The score on all the subscales is transformed into 0-100, with higher scores representing better quality of life (Mahesh et al., 2018).

It has been reported that people with HF in higher income countries have a better HRQoL compared to those in LMICs (Agbor et al., 2020). The mean MLHFQ score of people with HF is 24.2 in the USA (Carson et al., 2009), 28.7 in Australia (Kularatna et al., 2020), 27.8 in Spain (Mogle et al., 2017), 44±21 in the Netherlands (Hoekstra et al., 2013), 34.9±24.8 in Brazil (Pelegrino et al., 2011), and 16.78±3.44 in China (Yu et al., 2004). A study conducted in Germany involving 205 people with HF, using the German version of the SF-36, showed that the mean subscale score for physical functioning was 48.3±26.9 and for mental health, 61.2±20.8 (Juenger et al., 2002). These figures show a significant variation in quality-of-life scores across different high-income countries, possibly due to the use of different measurement instruments, indicating that consideration must be used when interpreting HRQoL data.

Moradi and colleagues (2020) conducted a systematic review and meta-analysis of 70 studies with 25,180 people living with HF in 23 countries. The MLWHFQ and SF-36 and were the most commonly used tools to measure quality of life. The pooled MLHFQ score from 41 studies, comprising12,575 participants, was 44.1 out of a maximum score of 105, indicative of moderate HRQoL and a significant impact of HF on overall well-being. In addition, 21 studies, with 2,034 participants, used the SF-36 tool to measure HRQoL, and the pooled means of the

Physical Component Summary (PCS) and the Mental Component Summary (MCS) scales were 33.3 and 50.6, respectively, indicating poor to moderate HRQoL, with the mental component showing a higher degree of well-being than the physical component (Moradi et al., 2020).

Being female, young, single, low income, low educational level, experiencing depression, diagnosed with a high NYHA functional class, tobacco exposure, low ventricular ejection, history of hospitalisation, comorbidity, polypharmacy, poor medication adherence, and long duration of HF are significant predictors of poor quality of life (Boombhi et al., 2019; Chu et al., 2014; Demir & Unsar, 2011; Erceg et al., 2013; Shojaei, 2008; Silavanich et al., 2019). Understanding these factors could be important for designing interventions to improve quality of life in this population.

2.5. Health-related quality of life for people with HF in LMICs

Although Moradi et al. (2020) provide a high level of evidence from 70 studies across the world, their review was based on data from higher income countries and only included a small number of studies from LMICs, which limits its generalisability to these areas. To fill this evidence gap, a systematic review and meta-analysis was conducted to estimate the HRQoL of people with HF in LMICs. This review revealed that people with HF in LMICs had poor HRQoL in both MLHFQ and SF-36 scores. The comprehensive search strategy for this systematic review, tailored for each database, is attached in Supplement 5 of Appendix 1.

Publication: Paper Two

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Statement of Authorship

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Principal author

Name of principal author	Henok Mulugeta TESHOME	
Contribution to the paper	• *Conceived the study aims and design* • *Performed analysis and interpreted the data* • *Wrote the first draft of the manuscript* • *Revised drafts of the manuscript based on comments from co-authors* • *Acted as corresponding author*	
Overall percentage (%)	80% contribution	
Certification	I hereby certify that this paper has been written by me during the period of my higher degree research candidature, and its content is primarily based on my own original work, unless stated otherwise. All references and all sources of information have been appropriately acknowledged	
Signature	Production Note: Signature removed prior to publication.	Date: 01/05/24

Co-Author contributions.

By signing the Statement of Authorship, each author certifies that:

- *The candidate's stated contribution to the publication is accurate*
- *Permission is granted for the candidate to include the publication in the thesis*
- *The sum of all co-author contributions is equal to 100% less the candidate's stated contribution.*

Name of Co-Author	A/Professor Peter M. Sinclair	
Contribution to the paper	Contributed to the design of the study, validated the data analysis, interpretation of the findings, and reviewed and approved the final manuscript	
Signature	Production Note: Signature removed prior to publication.	Date: 07.07.24
Name of Co-Author	Professor Amanda Wilson	
Contribution to the paper	Contributed to the design of the study, validated the data analysis, interpretation of the findings, and reviewed and approved the final manuscript	
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REVIEW

Health-related quality of life of people with heart failure in low- and middle-income countries: a systematic review and meta-analysis

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Abstract

Purpose Heart failure is a global health concern and associated with poor health-related quality of life and increased mortality. There is a disproportionate burden on patients and health systems in low- and middle-income countries. This systematic review and meta-analysis estimates the health-related quality of life of people with heart failure in low- and middle-income countries.

Methods A systematic literature search was conducted to identify relevant studies from January 2012 to November 2022 using the following databases: MEDLINE, EMBASE, PsycINFO, CINAHL, Web of Science, Scopus and JBI EBP database. Study screening, quality appraisal and data extraction were conducted using JBI methodology. A random-effects model was used to perform the meta-analysis. Heterogeneity was assessed using the I^2 statistic. All statistical analyses were done in STATA version 17.

Results A total of 33 studies with 5612 participants were included in this review. The Minnesota Living with Heart Failure Questionnaire (MLHFQ) and the Short-Form-36 questionnaire (SF-36) were the most used instruments across 19 and 8 studies, respectively. The pooled mean MLHFQ and SF-36 scores using the random-effects model were 46.08 (95% CI 35.06, 57.10) and 41.23 (95% CI 36.63, 45.83), respectively. In a subgroup analysis using both instruments, the highest health-related quality-of-life scores occurred in studies with inpatient participants.

Conclusion The overall health-related quality of life of people with heart failure in low- and middle-income countries is poor. Strategies should be strategically developed to improve the health-related quality of life of people with heart failure in these countries.

Systematic review registration PROSPERO CRD42022377781.

Keywords Heart failure · HRQoL · Systematic review · Low- and middle-income countries

Abbreviations

HF	Heart failure
HRQoL	Health-related quality of life
JBI	Joanna Briggs Institute
KCCQ	Kansas City Cardiomyopathy Questionnaire
LMICs	Low- and middle-income countries
LVD-36	Left Ventricular Dysfunction Questionnaire-36
MLHFQ	Minnesota Living with Heart Failure Questionnaire
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
SF-36	Short-Form-36 Questionnaire
WHOQOL-BREEF	WHO Quality of Life-BREF

Background

Heart failure (HF) is a global health problem characterised by a variety of devastating symptoms, whose severity is measured by changes in symptoms with exercise [1, 2]. It is one of the major causes of morbidity, mortality and

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Background

Heart failure (HF) is a global health problem characterised by a variety of devastating symptoms, whose severity is measured by changes in symptoms with exercise (Bragazzi et al., 2021; Reddy et al., 2020). It is one of the major causes of morbidity, mortality, and rehospitalisation internationally. In 2019, more than 64 million people were living with HF globally (A. Groenewegen et al., 2020), a number predicted to increase despite advances in medical therapy (Lippi et al., 2020). Heart failure is a significant health concern and economic burden with a growing prevalence in low- and middle-income countries (LMICs) (Ruan et al., 2018). Although there are little data on the prevalence of HF in these settings, one population-based study from Northern China reported a prevalence of 3.5% (N=2230) (Guo et al., 2016).

Health-related quality of life (HRQoL) is defined as an individual's perception of their physical, mental, emotional, and social health functioning (Karimi & Brazier, 2016). People with HF are more likely to experience a variety of symptoms, such as shortness of breath, fatigue, pain, and oedema, and to develop emotional conditions, like depression, compared to the general population (Alpert et al., 2017; K. S. Lee et al., 2020). These symptoms affect activities of daily living and can adversely affect HRQoL (Audi et al., 2017). In LMICs, HF is associate with poorer outcomes, including longer hospital stays, lower HRQoL, and significant in-hospital mortality (Agbor et al., 2020). People with HF and associated poor HRQoL are at further risk of the deleterious effects of rehospitalisation and increased healthcare costs. Consequently, there is an imperative to evaluate the level of HRQoL in these populations (Erceg et al., 2013; Long et al., 2019).

To date, there is a paucity of systematic reviews or meta-analyses estimating the HRQoL of people with HF in LMICs. A recently published systematic review determined the global level of HRQoL in people with HF (Moradi et al., 2021). However, this estimate was mainly based on data from developed countries, with little data from developing countries, which limits generalisability to populations in LMICs. Additionally, this review only used three international databases (PubMed, Scopus, and Web of Science) which is inconsistent with data collection and reporting standards for systematic reviews (Aromataris & Munn, 2020). Consequently, this paper reports a systematic review and meta-analysis which estimated the

HRQoL among people with HF in LMICs. The findings will indicate a need to develop strategies to improve management, care, and HRQoL in these populations.

Review question

What is the HRQoL of people with heart failure in low- and middle-income countries?

Inclusion criteria

Participants

Studies including adult participants with a confirmed diagnosis of HF were included in this review.

Condition

This review included studies that reported the HRQoL of people with HF measured using a psychometrically validated instrument. HRQoL was defined as an individual's perceived physical and mental health functioning over time (Malik et al., 2021).

Context

This review included studies from LMICs. For the purposes of this review, low- to middle-income countries were defined using the World Bank atlas method based on the stratification of economies based on gross national income (GNI) per capita. Low-income countries were those with a GNI per capita of $1,045 or less; lower- and upper middle-income economies, those with a GNI per capita between $1,046 and $4,095, and $4,096 and $12,695 and respectively (The World Bank, 2022).

Types of studies

Observational (cross-sectional, cohort, case-control) studies that reported the HRQoL of people with HF published in English from January 2012 to November 2022 were included in this review.

Methods

The Joanna Briggs Institute (JBI) methodology for Systematic Reviews (Aromataris & Munn, 2020) was used to inform the process for this review and the protocol was registered with the PROSPERO database (registration number CRD42022377781).

Search strategy

A three-step search strategy was undertaken on November 9, 2022, using several databases including MEDLINE (Ovid), EMBASE (Ovid), PsycINFO (EBSCOhost), CINAHL (EBSCOhost), Web of Science (direct access), Scopus (direct access), and JBI EBP database (Ovid), to identify relevant research from January 2012 to November 2022. The **CoCoPop** (**Co**=Condition, **Co**=Context, **Pop**=Population) framework was used to develop the search strategy using a combination of subject headings (index terms) and text words, including "quality of life", "health-related quality of life", QoL, HRQoL, "heart diseases", "heart failure", "cardiac failure", and all LMICs (The World Bank, 2022). Boolean operators were used to combine search terms. The search strategy and results are reported in Supplement 5 of Appendix 1.

Study Selection

All identified records were imported into EndNote V20 (Clarivate Analytics, PA, USA). After the removal of duplicates, all identified articles were exported into Microsoft Excel (Redmond, Washington, USA) for screening. Blinded screening was done by two independent reviewers, starting with a title and abstract screening, followed by a full text screening. First, all titles and abstracts were screened by two authors (HM and PS) in accordance with the predetermined inclusion criteria and a preliminary list of articles for full text screening was generated. Then, the two reviewers (HM and PS) screened the full text articles against the inclusion criteria. The percent agreement between the two reviewers was calculated by dividing the number of agreements by total number of studies reviewed. The authors reported a percent agreement of 88%, indicating a high level of agreement between the two reviewers in their screening decision. Any disagreements between the reviewers were resolved through discussion. References of included studies and related articles were hand searched to identify any additional relevant studies. The search for unpublished studies and grey literature was conducted using Google scholar, Mednar, ProQuest, and dissertation databases.

Quality assessment

The methodological quality of eligible articles was appraised independently by two reviewers (HM and PS) using the standardised JBI critical appraisal instrument for studies reporting prevalence data (Munn et al., 2015), which provides a numerical quality score out of 9 points. A threshold cut-off criterion was set so that studies with a quality score of six or less would be excluded. This cut-off was consistent with other published systematic reviews in this area. Disagreements between the reviewers were resolved through discussion. The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (Page et al., 2021) were followed in the reporting of the review.

Data extraction

Two authors (HM and AW) independently conducted the primary data extraction from the included studies using the JBI data extraction tool for prevalence data studies (Munn et al., 2017) and PS cross-checked for accuracy. Any disagreements and discrepancies between the reviewers were resolved by discussion. The following data from each included study were extracted: authors, year of publication, country, region, study design, population, sample size, sampling methods, outcome measuring tool, mean HRQoL score, and quality appraisal score.

Data analysis

The meta-analysis to estimate the pooled mean HRQoL score was performed using the DerSimonian and Laird random effects model (Tufanaru et al., 2015). Heterogeneity was assessed using standard chi-squared and I-squared tests. Sources of heterogeneity were analysed using subgroup analysis and meta-regression. Publication bias was assessed visually by funnel plot and statistically using Egger test. A leave-one-out sensitivity analysis was also conducted for assessing the influence of each study on the overall effect size estimate. The pooled effect size was presented using a forest plot. All statistical analysis was performed using STATA Version 17.0 (StataCorp, College Station, TX, USA).

Results

Search results

A total of 4249 initial records (4126 from databases and 123 from the grey literature) were retrieved. Of these, 1562 duplicate articles were removed. Then, 2622 articles were excluded after screening titles and abstracts. From the remaining 65 articles, 32 were removed after full text review and quality appraisal, leaving a total of 33 articles that met the inclusion criteria and were subsequently included in this review and meta-analysis (Figure 6).

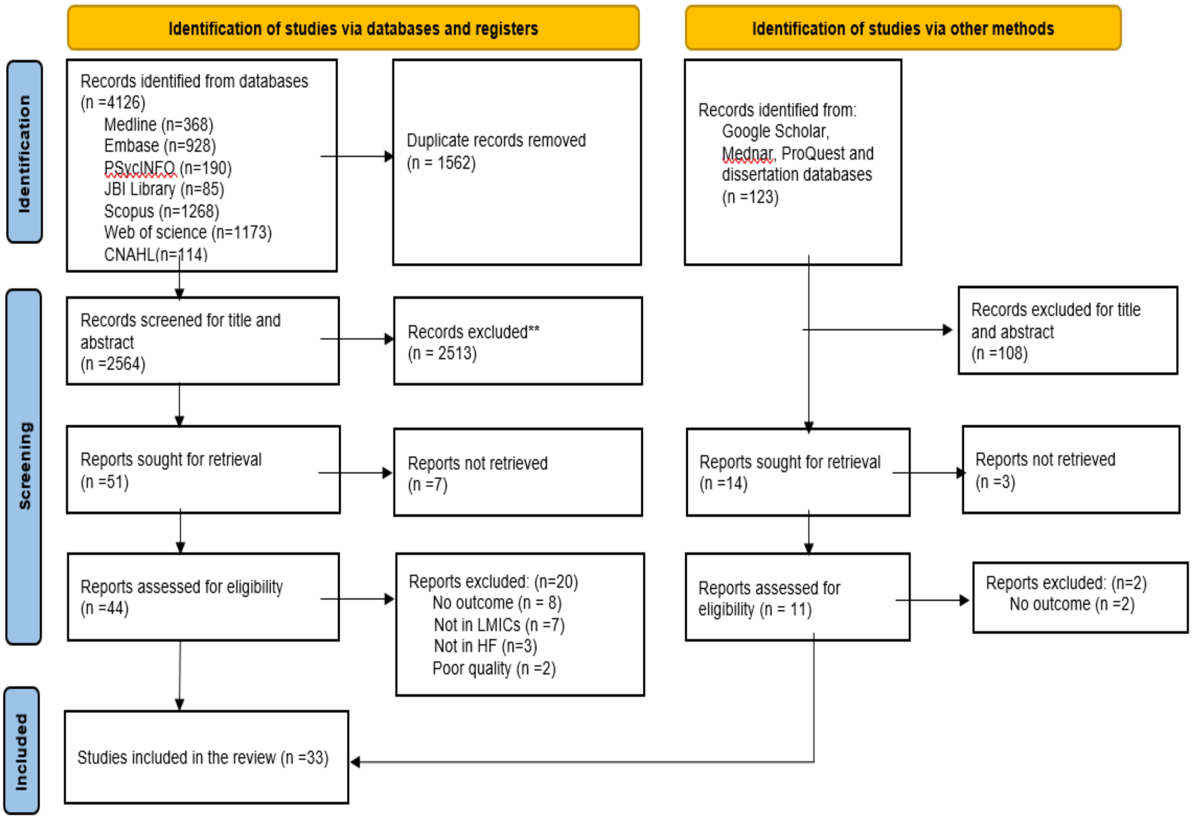

Figure 6: PRISMA flow diagram of literature identification, study selection and inclusion process (SR-II).

Assessment of methodological quality

The methodological quality of included studies was appraised using the JBI critical appraisal checklist. Of the 33 studies, two scored the maximum 9 points and 14 scored 8 points. The remaining 17 articles scored 7 points in the checklist (Table 8).

Table 8: Methodological quality of included studies for HRQoL of people with heart failure in LMICs

ID	Author, Date	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Quality score/9
1	(Costa et al., 2020)	Y	U	Y	Y	Y	Y	Y	Y	Y	8
2	(Paz et al., 2019)	U	Y	Y	Y	Y	Y	U	Y	Y	7
3	(de Sousa et al., 2017)	U	Y	Y	Y	Y	Y	N	Y	Y	7
4	(Sousa et al., 2017)	Y	Y	Y	Y	Y	Y	U	Y	Y	8
5	(Jorge et al., 2017)	N	Y	Y	Y	Y	Y	U	Y	Y	7
6	(An et al., 2022)	Y	Y	Y	Y	Y	Y	U	Y	Y	8
7	(Wang & Yang, 2020)	U	Y	Y	Y	Y	Y	U	Y	Y	7
8	(J. Zhang et al., 2020)	Y	Y	Y	Y	Y	Y	U	Y	Y	8
9	(Olivera et al., 2021)	U	Y	Y	Y	Y	Y	N	Y	Y	7
10	(Molla et al., 2021)	Y	Y	Y	Y	Y	Y	U	Y	Y	8
11	(Seid, 2020)	Y	U	Y	Y	Y	Y	U	Y	Y	7
12	(Tarekegn et al., 2020)	Y	Y	Y	Y	Y	Y	U	Y	Y	8
13	(DeWolfe et al., 2012)	Y	Y	Y	Y	Y	Y	Y	Y	U	7
14	(Asadi et al., 2019)	U	Y	Y	Y	Y	Y	Y	Y	Y	8
15	(Poorshadan et al., 2019)	U	Y	Y	Y	Y	Y	N	Y	Y	8
16	(Borumandpour et al., 2016)	U	Y	Y	Y	Y	Y	U	Y	Y	7
17	(Molayynejad et al., 2019)	U	Y	Y	Y	Y	Y	N	Y	Y	7
18	(AbuRuz, 2018)	U	Y	Y	Y	Y	Y	Y	Y	Y	8
19	(Alaloul et al., 2017)	U	Y	Y	Y	Y	Y	Y	Y	Y	8
20	(Alemoush et al., 2021)	Y	Y	Y	Y	Y	Y	Y	Y	Y	9

21	(Iyad Mahmoud Hassan Odeh et al., 2019)	Y	Y	Y	Y	Y	Y	U	Y	Y	8
22	(Ahmeti et al., 2016)	U	Y	Y	Y	Y	Y	U	Y	Y	7
23	(Thida et al., 2021)	Y	Y	Y	Y	Y	Y	Y	Y	Y	9
24	(Mbakwem et al., 2013)	U	Y	Y	Y	Y	Y	U	Y	Y	7
25	(Erceg et al., 2013)	U	Y	Y	Y	Y	Y	N	Y	Y	7
26	(Jovanic et al., 2018)	Y	U	Y	Y	Y	Y	N	Y	Y	7
27	(Chu et al., 2014)	Y	Y	Y	Y	Y	Y	U	Y	Y	8
28	(Jeong et al., 2022)	Y	U	Y	Y	Y	Y	Y	Y	Y	8
29	(H. Lee et al., 2020)	Y	U	Y	Y	Y	Y	Y	Y	Y	8
30	(Son et al., 2012)	U	Y	Y	Y	Y	Y	U	Y	Y	7
31	(Silavanich et al., 2019)	U	Y	Y	Y	Y	Y	U	Y	Y	7
32	(Barutcu & Mert, 2013)	Y	Y	Y	Y	Y	Y	N	U	Y	7
33	(Gok Metin & Gulbahar, 2021)	U	Y	Y	Y	Y	Y	N	Y	Y	7

Y=Yes; N=No; U=Unclear

Characteristics of included studies

A total of 33 studies consisting of 5612 participants with HF in LMICs were included in this review. Eight studies (AbuRuz, 2018; Alaloul et al., 2017; Alemoush et al., 2021; Asadi et al., 2019; Borumandpour et al., 2016; Iyad Mahmoud Hassan Odeh et al., 2019; Molayynejad et al., 2019; Poorshadan et al., 2019) were conducted in Middle East and North Africa, five studies (de Sousa et al., 2017; Jorge et al., 2017; Olivera et al., 2021; Paz et al., 2019; Sousa et al., 2017) were conducted in Latin America and the Caribbean, nine studies (An et al., 2022; Chu et al., 2014; Jeong et al., 2022; H. Lee et al., 2020; Silavanich et al., 2019; Son et al., 2012; Thida et al., 2021; Wang & Yang, 2020; J. Zhang et al., 2020) were conducted in East Asia and the Pacific, four studies (Mbakwem et al., 2013; Molla et al., 2021; Seid, 2020; Tarekegn et al., 2020) were conducted in Sub-Saharan Africa, six studies (Ahmeti et al., 2016; Barutcu

& Mert, 2013; DeWolfe et al., 2012; Erceg et al., 2013; Gok Metin & Gulbahar, 2021; Jovanic et al., 2018) were conducted in Europe and Central Asia, and one study (Costa et al., 2020) was conducted in South Asia. A cross-sectional study design was used in most of the studies (n=31). The remaining two studies used a prospective cohort study design. Twenty-two studies recruited participants from outpatient departments and eleven recruited participants while they were inpatients. Sample sizes ranged from 59 to 500 participants and the majority of studies (n=21) used a consecutive sampling technique. Five different psychometrically validated instruments were used to measure HRQoL: 19 used the Minnesota Living with Heart Failure Questionnaire (MLHFQ), eight used the Short Form Survey-36 questionnaire (SF-36), three studies used the WHO Quality of life-BREF (WHOQOL-BREF), two used the Kansas City Cardiomyopathy Questionnaire (KCCQ), and one used the Left Ventricular Dysfunction Questionnare-36 (LVD-36). Mean scores of HRQoL ranged from 13 to 94 (Table 9).

Table 9: Characteristics of included studies for HRQoL of people with heart failure in LMICs

ID	Authors	Publication year	Country	Region	Study design	Population	Sample size	Sampling method	Instrument	QoL score ±SD	Quality score
1	(Costa et al., 2020)	2020	Bangladesh	South Asia	Cross-Sectional	Inpatient	142	Convenient	MLHFQ	94.16±3.20	8
2	(Paz et al., 2019)	2019	Brazil	Latin America and Caribbean	Cross-Sectional	Outpatient	101	Convenient	MLHFQ	34.30±21.60	7
3	(de Sousa et al., 2017)	2017	Brazil	Latin America and Caribbean	Cross-Sectional	Outpatient	84	Consecutive	MLHFQ	33.13±19.66	7
4	(Sousa et al., 2017)	2017	Brazil	Latin America and Caribbean	Cross-Sectional	Outpatient	84	Consecutive	MLHFQ	33.10±19.7	8
5	(Jorge et al., 2017)	2017	Brazil	Latin America and Caribbean	Cross-Sectional	Outpatient	59	Consecutive	SF-36	53.10± 29.6	7
6	(An et al., 2022)	2022	China	East Asia and Pacific	Cross-Sectional	Inpatient	302	Consecutive	SF-36	50.00±9.20	8
7	(Wang & Yang, 2020)	2020	China	East Asia and Pacific	Cross-Sectional	Outpatient	301	Convenient	SF-36	38.45±17.28	8
8	(J. Zhang et al., 2020)	2020	China	East Asia and Pacific	Cross-Sectional	Inpatient	310	Convenient	MLHFQ	42.20	8
9	(Olivera et al., 2021)	2021	Colombia	Latin America and Caribbean	Cross-Sectional	Outpatient	80	Convenient	MLHFQ	53.70±19.6	7
10	(Molla et al., 2021)	2021	Ethiopia	Sub-Saharan Africa	Cross-Sectional	Outpatient	372	Simple random	MLHFQ	46.40±20.63	8
11	(Seid, 2020)	2020	Ethiopia	Sub-Saharan Africa	Cross-Sectional	Outpatient	284	Consecutive	MLHFQ	46.40± 22.4	8
12	(Tarekegn et al., 2020)	2021	Ethiopia	Sub-Saharan Africa	Cross-Sectional	Outpatient	468	Consecutive	WHOQOL-BREF	41.60±11.6	8
13	(DeWolfe et al., 2012)	2012	Georgia	Europe and Central Asia	Prospective cohort	Outpatient	314	Consecutive	MLHFQ	60.90±14.6	8
14	(Asadi et al., 2019)	2019	Iran	Middle East and North Africa	Cross-Sectional	Inpatient	77	Convenient	SF-36	38.45±17.28	8

15	(Poorshadan et al., 2019)	2019	Iran	Middle East and North Africa	Cross-Sectional	Inpatient	80	Convenient	WHOQOL-BREF	48.60±8.5	8
16	(Borumandpour et al., 2016)	2016	Iran	Middle East and North Africa	Cross-Sectional	Inpatient	147	Consecutive	WHOQOL-BREF	49.50±18.51	7
17	(Molayynejad et al., 2019)	2019	Iran	Middle East and North Africa	Cross-Sectional	Inpatient	151	Convenient	MLHFQ	62.30± 19.4	7
18	(AbuRuz, 2018)	2018	Jordan	Middle East and North Africa	Cross-Sectional	Outpatient	200	Convenient	SF-36	38.60±10.4	8
19	(Alaloul et al., 2017)	2017	Jordan	Middle East and North Africa	Cross-Sectional	Outpatient	99	Consecutive	SF-36	40.14±21.7	8
20	(Alemoush et al., 2021)	2021	Jordan	Middle East and North Africa	Prospective cohort	Outpatient	127	Consecutive	SF-36	40.20±23.2	9
21	(Iyad Mahmoud Hassan Odeh et al., 2019)	2019	Jordan	Middle East and North Africa	Cross-Sectional	Outpatient	85	Convenient	SF-36	31.70±18.6	8
22	(Ahmeti et al., 2016)	2016	Kosovo	Europe and Central Asia	Cross-Sectional	Inpatient	103	Consecutive	MLHFQ	49.60± 17.7	7
23	(Thida et al., 2021)	2021	Myanmar	East Asia and pacific	Cross-Sectional	Outpatient	140	Purposive	MLHFQ	39.90±12.8	9
24	(Mbakwem et al., 2013)	2013	Nigeria	Sub-Saharan Africa	Cross-Sectional	Outpatient	190	Consecutive	KCCQ	59.60± 23.8	7
25	(Erceg et al., 2013)	2013	Serbia	Europe and Central Asia	Cross-Sectional	Inpatient	136	Consecutive	MLHFQ	50.40±19.3	7
26	(Jovanic et al., 2018)	2018	Serbia	Europe and Central Asia	Cross-Sectional	Inpatient	200	Consecutive	MLHFQ	51.67±24.1	7
27	(Chu et al., 2014)	2014	South Korea	East Asia and Pacific	Cross-Sectional	Outpatient	118	Consecutive	MLHFQ	34.50±22.8	8
28	(Jeong et al., 2022)	2022	South Korea	East Asia and Pacific	Cross-Sectional	Inpatient	122	Consecutive	MLHFQ	56.09±22.46	8

29	(H. Lee et al., 2020)	2020	South Korea	East Asia and Pacific	Cross-Sectional	Outpatient	142	Consecutive	MLHFQ	18.50± 21.0	8
30	(Son et al., 2012)	2012	South Korea	East Asia and Pacific	Cross-Sectional	Outpatient	134	Consecutive	MLHFQ	54.60±11.7	7
31	(Silavanich et al., 2019)	2019	Thailand	East Asia and Pacific	Cross-Sectional	Outpatient	180	Consecutive	MLHFQ	13.00±8.6	7
32	(Barutcu & Mert, 2013)	2013	Turkey	Europe and Central Asia	Cross-Sectional	Outpatient	150	Convenient	LVD-36	69.25±23.12	7
33	(Gok Metin & Gulbahar, 2021)	2021	Turkey	Europe and Central Asia	Cross-Sectional	Outpatient	130	Consecutive	KCCQ	47.70 ± 9.50	7

HRQoL of people with HF in LMICs

The overall meta-analysis for the HRQoL score was performed as a subgroup analysis using the QoL measuring instruments across the included studies. The disease-specific tools included MLHFQ, KCCQ, and LVD-36, whereas the general tools included SF-36 and WHOQOL-BREF. The overall pooled HRQoL score is presented in Figure 7.

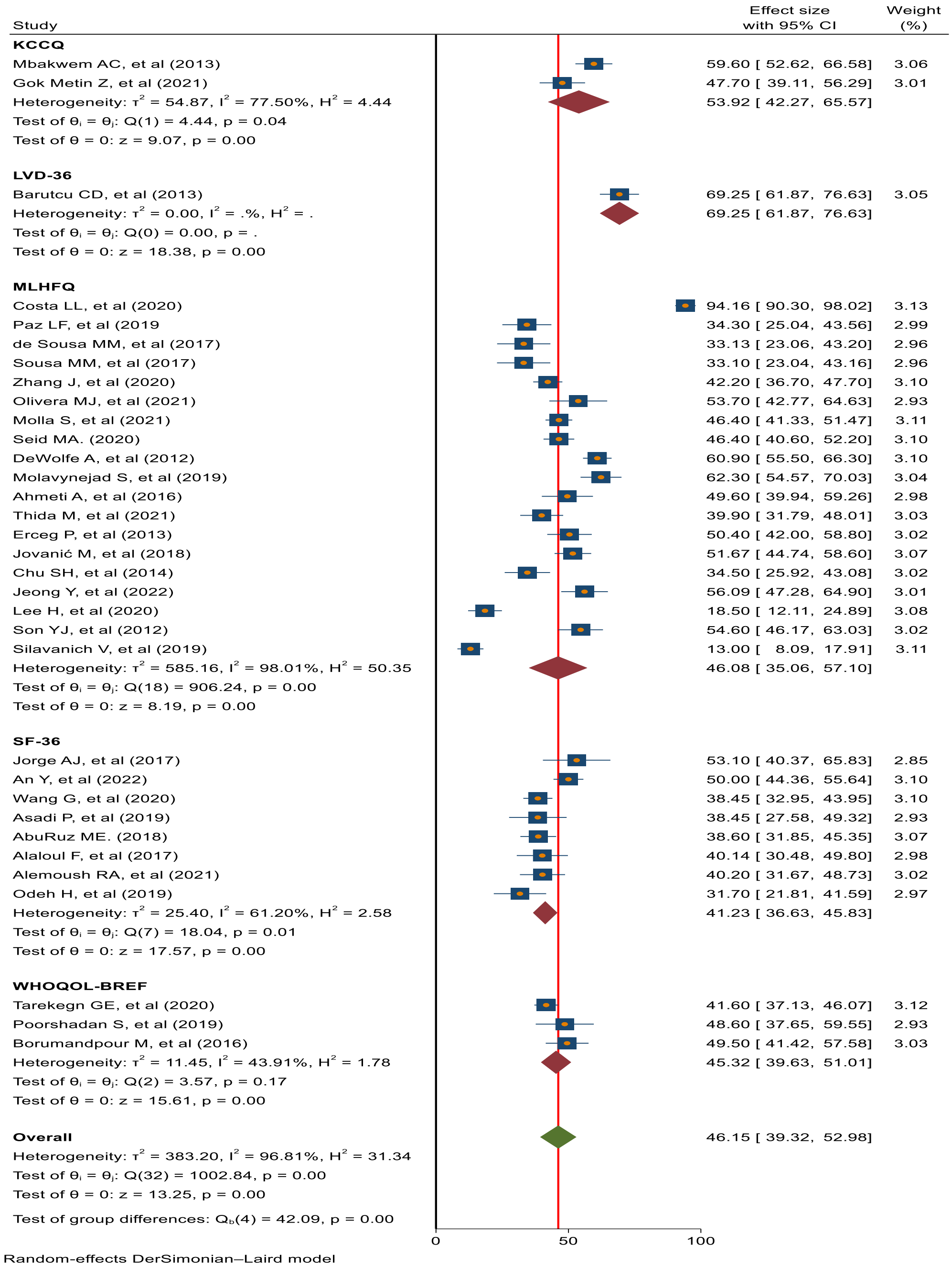

Figure 7: Forest plot showing the mean HRQoL score by tools

Health-related quality of life based on MLHFQ.

Nineteen (n=3197) of the thirty-three studies used the Minnesota Living with Heart Failure Questionnaire (MLHFQ), which is a psychometrically validated disease-specific instrument used to assess HRQoL. The pooled mean MLHFQ score using the random effects model was 46.08 (95% CI 35.06, 57.10). The meta-analysis found significant heterogeneity across studies (I^2=98.01%, p<0.001) (Figure 8).

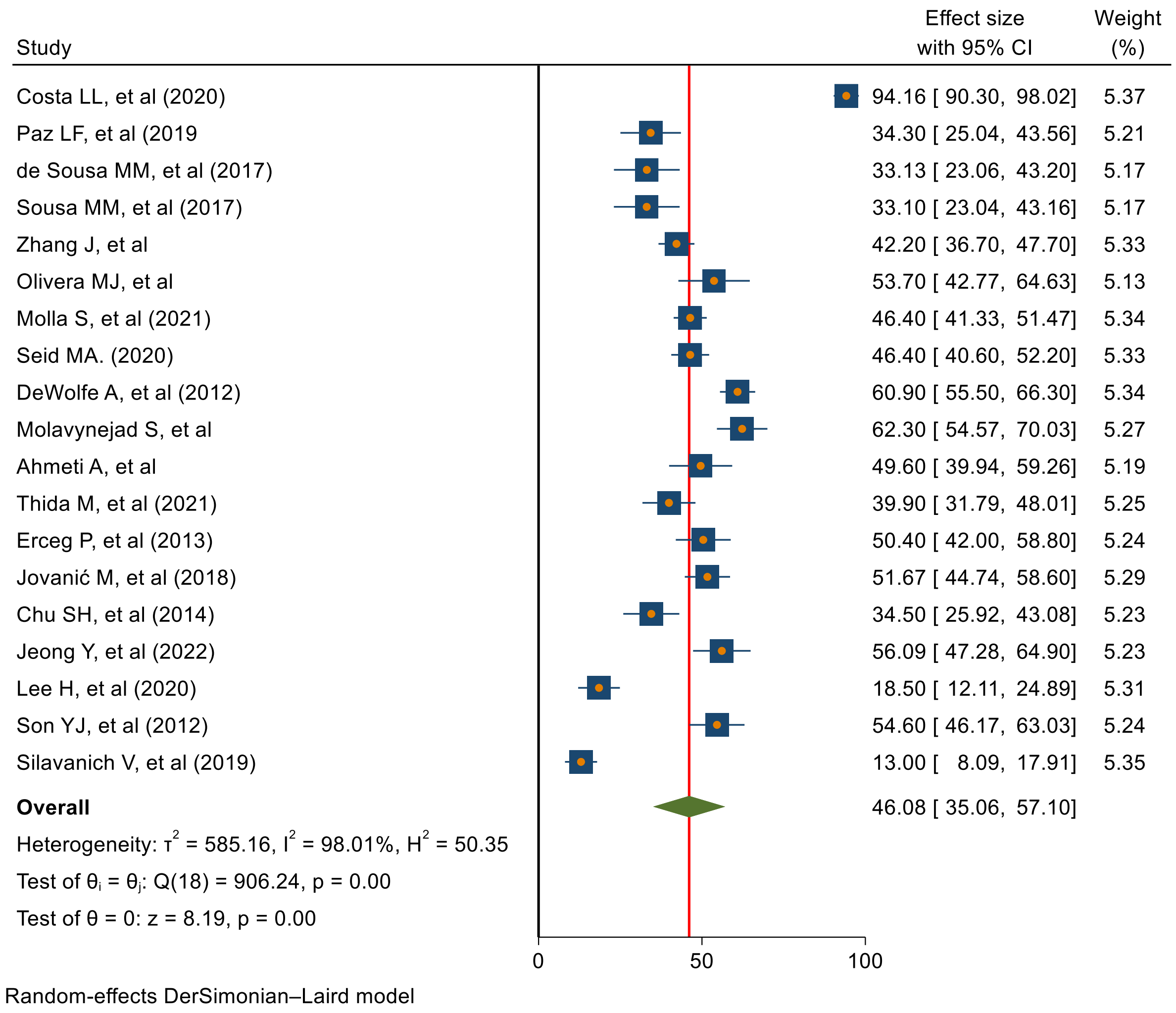

Figure 8: Forest plot showing the pooled mean MLHFQ score

Subgroup analysis

The subgroup analysis demonstrated that higher MLHFQ scores were observed among studies with inpatient participants (58.15, 95% CI 39.77, 76.53) and one study from South Asia (94.16, 95% CI 90.30, 98.02) (Figure 9).

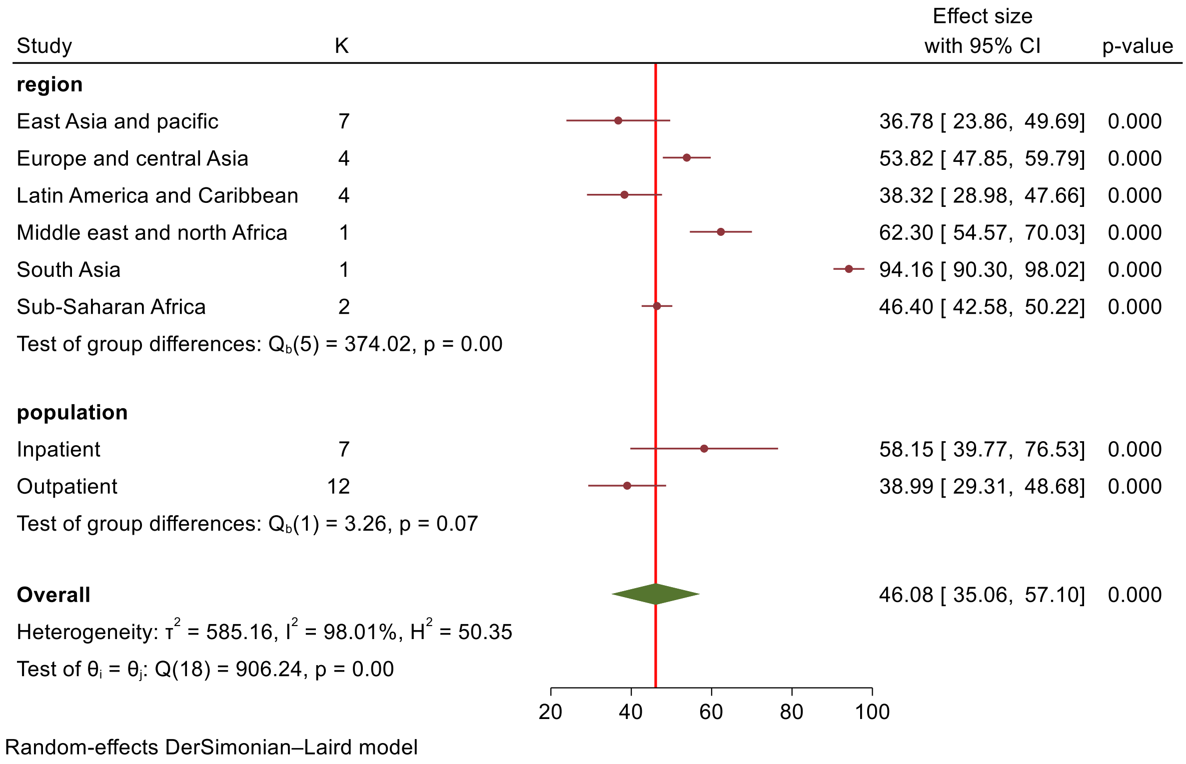

Figure 9: Subgroup analysis on MLHFQ score

Assessment of heterogeneity and publication bias

The heterogeneity test showed significant $p \leq 0.001$) variation across the MLHFQ based studies. The meta-regression analysis using publication year, sample size, and quality score found none of the three covariates were significantly associated with the presence of heterogeneity (Table 10). The Egger's test demonstrated no statistically significant publication bias p=0.41).

Table 10: Meta-regression analysis of factors with heterogeneity across MLHFQ based studies (SR-II).

Heterogeneity source	Coefficients	Std. Err.	P-value
Publication year	-0.336	2.044	0.87
Sample size	0.018	0.075	0.80
Quality score	0.590	11.291	0.86

Sensitivity analysis

The leave-one-out sensitivity analysis using a random effects model revealed that the omission of Study 1 (Costa et al., 2020) had a relatively larger influence on the pooled estimate of MLHFQ score compared to other studies. The omission of Study 1 caused the overall MLHFQ score to decrease by 2.76, which would make the overall level of HRQoL moderate. This suggests that the results of the meta-analysis may be sensitive to the inclusion or exclusion of this particular study. The effect size displayed for each study corresponds to an overall effect size computed from a meta-analysis excluding that study (Figure 10).

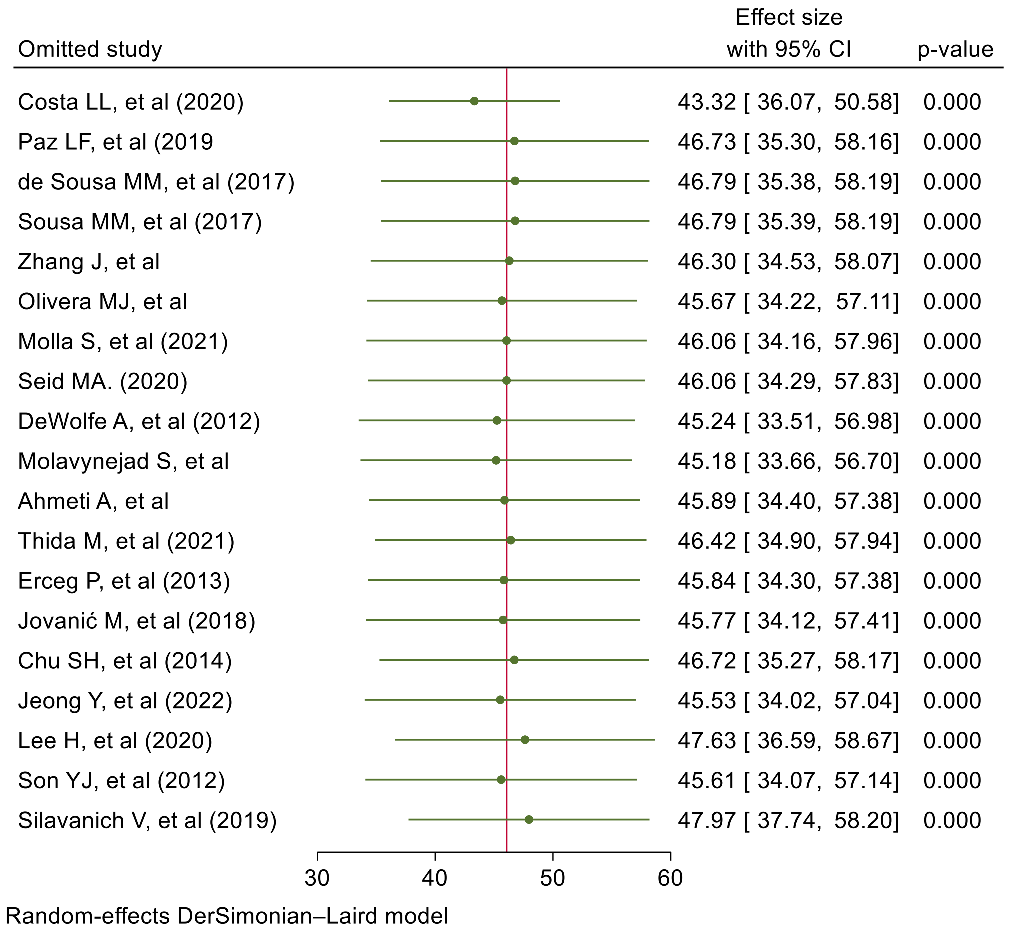

Figure 10: Result of sensitivity analysis of the 19 studies using the MLHFQ (SR-II)

Health-related quality of life based on SF-36

Of the 33 included studies, eight studies (n=1,250) evaluated HRQoL using the SF-36. The Short Form Survey-36 (SF-36) questionnaire is a general, psychometrically validated instrument used to assess HRQoL. In this study, we have used the overall mean SF-36 score as reported in the included paper, whenever available. In cases where the overall score was not provided, we computed the mean SF-36 score by using the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. To calculate the overall mean QoL score of SF-36 from PCS and MCS, the following formula was used: Overall SF-36 score = PCS score + MCS score. Subsequently, the mean SF-36 QoL score was computed as the overall score divided by 2. The pooled mean SF-36 score using the random effects model was 41.23 (95% CI 36.63, 45.83). The meta-analysis found significant heterogeneity across the SF-36 based studies (I^2=61.20%, p=0.01) (Figure 11).

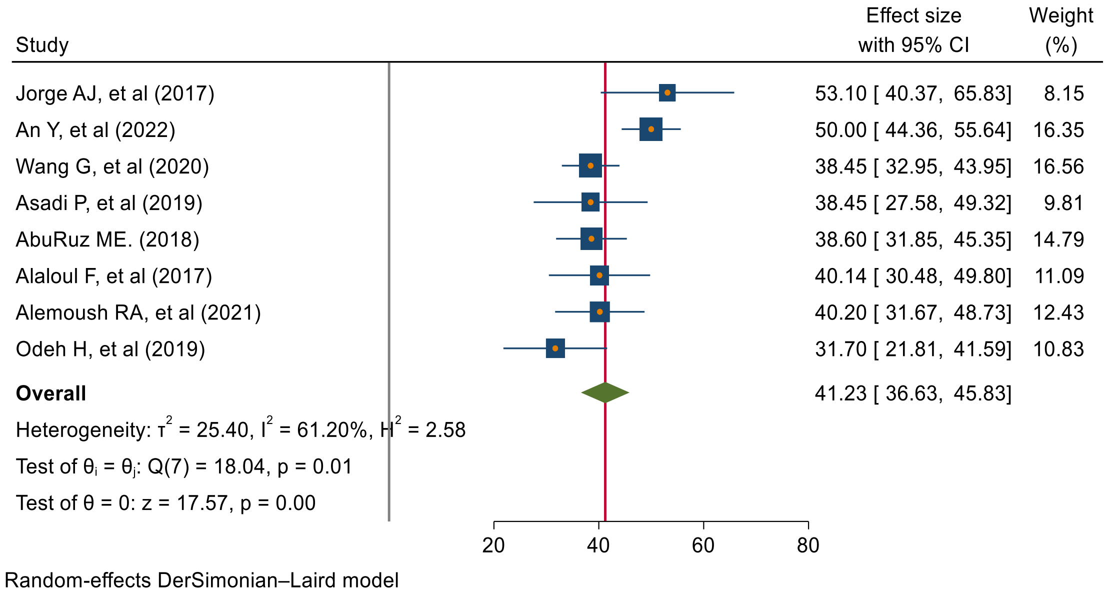

Figure 11: Forest plot showing the pooled mean SF-36 score (SR-II).

Subgroup analysis

The subgroup analysis found the highest SF-36 score was in one study from the Latin America and Caribbean region (53.10, 95% CI 40.37, 65.83) and studies with inpatient participants (45.20, 95% CI 34.04, 56.35) (Figure 12).

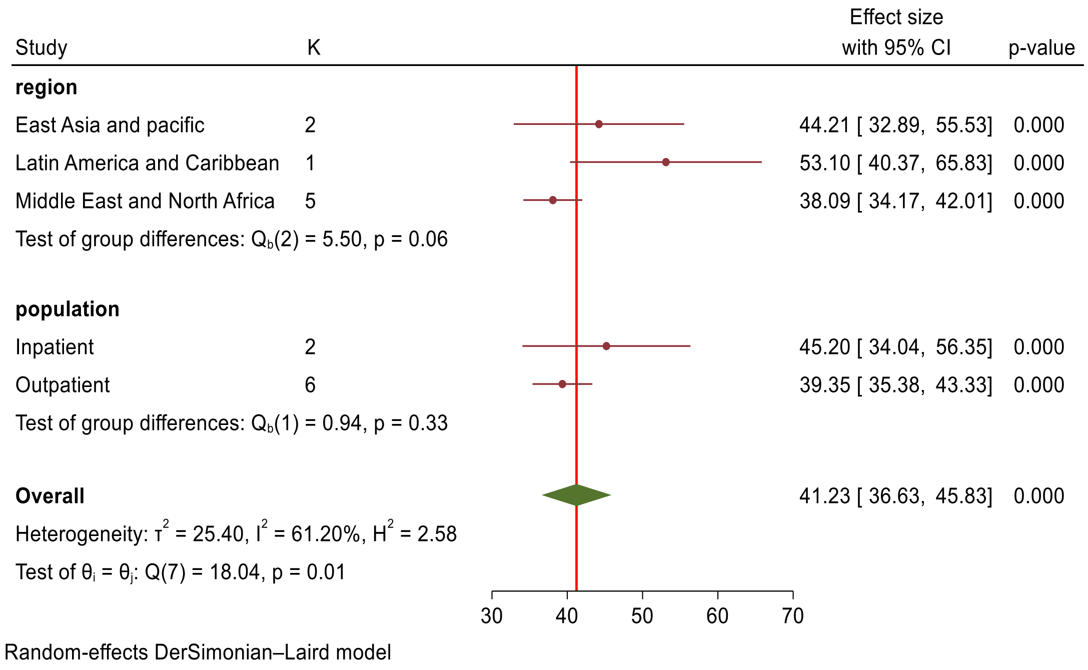

Figure 12: Subgroup analysis on SF-36 score (SR-II).

Assessment of heterogeneity and publication bias

The heterogeneity test showed significant variation p=0.01) across SF-36 based studies. Meta-regression analysis using publication year, sample size, and quality score found none of the three covariates were significantly associated with the presence of heterogeneity. No statistically significant publication bias was detected on Egger's test p=0.99).

Sensitivity analysis

The result of the leave-one-out sensitivity analysis using a random effects model showed that no single study unduly influenced the pooled SF-36 score. For each study, the displayed effect size corresponds to an overall effect size computed from a meta-analysis excluding that study (Figure 13).

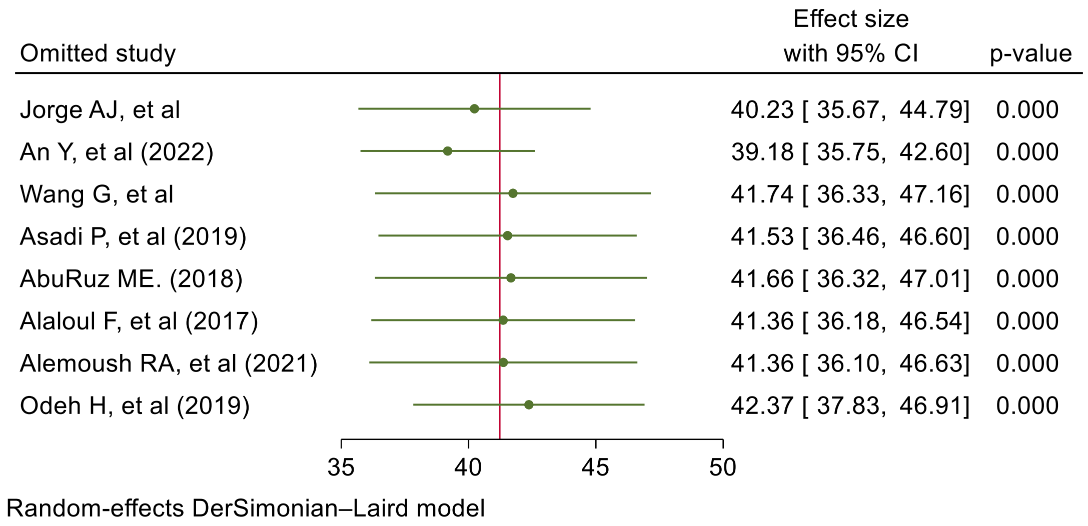

Figure 13: Result of sensitivity analysis of the 8 studies using the SF-36 (SR-II)

Discussion

Heart failure is a chronic condition with poor prognosis (Wu et al., 2016). Health-related quality of life (HRQoL) is an important predictor of poor HF outcomes, such as hospitalisation and death (Johansson et al., 2021; Ramos et al., 2017). To the best of our knowledge, this is the first systematic review on HRQoL of people with HF in LMICs. This review identified 33 relevant studies that reported the HRQoL of people with HF. Study characteristics, such as study area, study participants, and outcome measuring instruments, varied considerably across the included studies.

Instruments used to quantify HRQoL varied significantly among the included studies. The MLHFQ, KCCQ, and LVD-36 (disease-specific instruments) and SF-36 and WHOQOL-BREF (generic instruments) were used across the included studies. The most frequently used disease-specific and generic measures were the MLHFQ and the SF-36, respectively. The MLHFQ has 21 questions about how participant feels HF has affected their life over the previous month using a six-point Likert-type scale that ranges from 0 (no effect) to 5 (very much effect). The score ranges from 0 to 105 with higher scores representing a poorer quality of life (Audi et al., 2017; Rector, 2017). The SF-36 questionnaire consists of 36 items and eight dimensions that are summarised into the PCS and MCS scores. The scores on all subscales are transformed linearly to a possible range of 0-100 with higher scores representing better HRQoL. The cut-off points for poor HRQoL are: MLHFQ score ≥45 and SF-36 score <60 (Hsu et al., 2018). It is important to note that these new cut-off points are specific to heart failure patients and may not be applicable to other health conditions.

In this review, the pooled mean HRQoL score based on the MLHFQ was 46.08 (95% CI 35.06, 57.10) showing poor HRQoL in people with HF in LMICs. This conclusion differs from a recently published meta-analysis by Moradi et al. on a global MLHFQ based pooled HRQoL score (Afsharipour et al., 2016) which found a moderate HRQoL (Moradi et al., 2020). The higher MLHFQ score in the current review could be due to differences in the sociodemographic characteristics of the study participants or because the majority of the studies in Moradi et al. were conducted in upper-income countries. People with HF in LMICs are generally diagnosed at a later stage, have poor health literacy, less access to HF healthcare services, and poorer prognosis, than those in upper-income countries (Curry et al., 2018; Negesa et al., 2019; Nugent, 2008). The pooled mean SF-36 score in this review was 41.23 (95% CI 36.63, 45.83), which suggests that participants in the cohorts had a poor HRQoL. This finding is consistent with previous systematic reviews of the SF-36 tool on other chronic diseases (hypertension and tuberculosis), which revealed poor HRQoL (Guo et al., 2009; Trevisol et al., 2011). Based on the result of this review, inpatient participants had higher HRQoL scores than outpatient participants. This is likely due to inpatient participants generally being more acutely unwell than outpatient participants.

This review has several implications for clinical practice. Heart failure has a negative impact on outcomes such as morbidity, mortality, and QoL. The key finding in this review was people with HF in LMICs had poor HRQoL, which highlights the greater impact of HF on overall HRQoL scores. This evidence helps health professionals in these countries to consider changing HF care practice and develop strategies to improve the HRQoL of these populations. The findings of a recent systematic review provide evidence that better HRQoL is associated with lower mortality risk (Phyo et al., 2020). Therefore, health care professionals should give clinical priority for assessment of the HRQoL of people with HF during their routine follow-up care to reduce the risk of poor outcomes such as death.

This systematic review involved a systematic search of seven large databases and identified a larger number of studies conducted in LMICs than previous reviews. However, there are some limitations that should be considered. The cut-off date of 2012 was selected arbitrarily to estimate the most recent evidence relevant to current clinical practice today, there may be previous important studies that were not included. The included articles were restricted to the English language, which may have excluded important studies published in other languages. The results of this meta-analysis should be interpreted with caution as it had statistically significant heterogeneity across the included studies, which can affect the quality of the evidence and the conclusion of the review. Additionally, several factors that were not examined in this review may confound the HRQoL of these populations.

Conclusion

This systematic review and meta-analysis revealed that people with HF in LMICs had poor HRQoL. These findings provide evidence-based data about the need for improving HRQoL to reduce the risk of morbidity and mortality in these populations. Therefore, early interventions should focus on improving HRQoL to achieve a better prognosis and to enhance the overall experience of living with HF. Large-scale prospective studies are needed to verify these findings and to investigate factors influencing the HRQoL of people with HF.

List of abbreviations

HF: Heart failure; HRQoL: Health-related quality of life, JBI: Joanna Briggs Institute; KCCQ: Kansas City Cardiomyopathy Questionnaire; LMICs: Low- and middle-income countries; LVD-36: Left Ventricular Dysfunction Questionnare-36; MLHFQ: Minnesota Living with Heart Failure Questionnaire; PRISMA: Preferred Reporting Items for Systematic reviews and Meta-Analyses; SF-36: Short Form Survey-36 questionnaire; WHOQOL-BREF: WHO Quality of life-BREF

Declarations

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Competing interests

The authors report no competing interests.

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Availability of data and materials

All the data are available from the corresponding author upon request.

Author contributions

HM conceived the study and drafted the protocol. PS and AW provided support and guidance on the search strategy and screening process. All three authors (HM, PS, and AW) were involved in data extraction, quality assessment, and analysis. All authors have read, edited, and approved the final draft of the manuscript.

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Summary of the systematic reviews

Two systematic reviews examined depression and health related quality of life in people living with heart failure in low-middle income countries. The findings demonstrate that depression is highly prevalent in this region and positively associated with HRQoL. In addition, people with HF in LMICs have poor HRQoL. The supplementary information utilised in these systematic reviews can be found in Appendix 1.

2.6. The experience of people with heart failure

The experience of people living with HF can be overwhelming due to the disturbing and unpredictable character of the illness (Seah et al., 2016). The HF journey usually starts with a formal diagnosis. Shock is a very common experience at this point. In a study conducted in the UK, many participants reported being shocked at their diagnosis of HF, particularly those who perceived themselves to be in good health (Thornhill et al., 2008). This underscores the psychological impact of receiving such devastating news. HF can significantly change a person's lifestyle due to its multifaceted physical impact, especially on activities such as activities of daily living (Fry et al., 2016; Nordfonn et al., 2019; Walsh et al., 2018). This results in the need to make many lifestyle adjustments and seek ongoing medical attention.

People with HF experience a variety of physical and emotional symptoms, including fatigue, shortness of breath, and chest pain. Fatigue is the most prevalent physical symptom reported in many studies (Niklasson et al., 2022; Nordgren & Sorensen, 2003; Seah et al., 2016). People with HF experience physical limitations in their daily activities, such as lifting and carrying objects, difficulty walking long distances, walking at fast speeds, and climbing stairs. These physical limits affect their ability to participate in social activities and relationships (Aldred et al., 2005; McHorney et al., 2021; Niklasson et al., 2022). In addition, several studies (Checa et al., 2020; Li et al., 2019; Ryan & Farrelly, 2009; Thornhill et al., 2008) found that people with HF experience negative emotions, such as depression and anxiety, associated with their physical limitations.

Studies of people with HF describe their overall well-being in the context of their physical health, mental health, and social functioning. Heo et al. (2009) found that most participants define health-related quality of life as the ability to independently perform daily activities to meet their needs. They identify mental health, social support, symptoms, economic status, and self-care behaviour as important factors affecting their QoL. In a similar study, participants described HRQoL as being happy and satisfied with living (Hayeah et al., 2017). Understanding how they perceive their HRQoL, and the influencing factors is critical for assessing and improving the well-being of this population.

People living with HF use self-management strategies, including medication adherence and dietary modifications (Bennett et al., 2000; Checa et al., 2020; Li et al., 2019). Acceptance, distraction, and adjustment are the common behavioural strategies people with HF use to cope with their condition (Bennett et al., 2000; Checa et al., 2020; Mahoney, 2001; Seah et al., 2016). Similarly, people benefit from socialising and sharing experiences with other people living with HF. Interacting with people going through the same experience helps provide coping strategies to adapt to their condition (Checa et al., 2020; Lockhart et al., 2014; Thornhill et al., 2008). However, research also highlights that knowledge regarding the disease process and available social support is essential for HF people to cope with the disease. Lack of knowledge and poor social support significantly affect an individual's ability to cope effectively, leading to poor functioning. Spiritual activities such as prayer are important coping mechanisms in many populations (Hopp et al., 2012; Seah et al., 2016; Sepehrian et al., 2020). These findings indicate the importance of symptom management and disease coping mechanisms used by people living with HF. Understanding these strategies could help health professionals optimise the medical management of people with HF and improve their HRQoL.

2.7. Gaps identified from the literature reviews

The literature reviews highlighted several significant gaps in the current understanding of HF, depression, and HRQoL, particularly in the context of LMICs:

- *Limited understanding of the relationship between depression and HRQoL*
- *Lack of comprehensive understanding of contextual factors that affect both depression and HRQoL*
- *Mono-method studies and inconsistent methodological approaches*
- *Scarcity of data on qualitative exploration of experiences of people living with HF, coping strategies, and its impact on HRQoL, particularly from LMICs*
- *Lack of substantial evidence originating from Ethiopia.*

These gaps initiate the need for more holistic and context-specific research that can provide a deeper understanding of the impact of HF on mental health and HRQoL. Addressing these gaps is necessary to develop evidence-based interventions with the aim of improving the HRQoL of people living with HF, particularly in under-researched areas like LMICs, including Ethiopia.

CHAPTER 3: METHODOLOGY

3.1. Chapter overview

This chapter describes the methodology applied throughout this thesis. It begins with detailing the timeframe during which the research was undertaken and introduces the study settings, by providing a brief description of the hospitals where the data were collected to establish the context within which the research was conducted. The philosophical foundations and theoretical framework guiding this body of work are then discussed, highlighting the intellectual underpinnings that informed the research approach. The chapter then proceeds to describe the mixed methods design used and explains the rationale for choosing a sequential explanatory mixed methods study design. It outlines the phases of the research process, presenting a roadmap of how the research was conducted. The description of the study population includes the eligibility criteria and the approach to calculating the sample size in the quantitative phase of this work. The following section presents the data collection and analysis methods, detailing the qualitative and quantitative techniques used. Finally, the chapter considers the ethical aspects of this research, including the information provided to participants, the informed consent process, and measures taken to maintain participant privacy and confidentiality.

3.2. Research setting and timeline

The research was conducted in the cardiac outpatient clinics of two tertiary-level public hospitals in Addis Ababa, the capital of Ethiopia: St. Paul's Hospital Millennium Medical College and St. Peter Specialized Hospital.

St. Paul's Hospital Millennium Medical College, established under a decree from the Council of Ministers in 2010, initially opened as a medical school in 2007. The associated hospital was originally founded by Emperor Haile Selassie in 1968. The college has over 2800 clinical, academic, administrative, and support staff. It offers a range of medical specialty services, serves as a teaching institution for medicine and nursing, and conducts basic and applied research. With an inpatient capacity of over 700 beds, the hospital sees an average 1200 emergency and outpatient clients daily.

St. Peter Specialized hospital is one of the largest public hospitals in Ethiopia, providing tertiary-level medical services, teaching, and serving as a specialised cardiac centre in collaboration with St Paul's hospital. The hospital has 1392 health professionals, 774 technical, and 618 administrative staff members. It has around 350 inpatient beds and a catheterisation laboratory for cardiovascular care and interventions, with 4 ICU beds.

Together these two hospitals provide care to patients with various medical needs and serve as a collaborative national referral centre for cardiac care. They have cardiac OPDs, intensive care unit beds, and a catheterisation lab supported by a management team, including cardiologists, interventional cardiologists, cardiac anaesthesiologists, and cardiovascular nurses. Each hospital has an average of thirty people with HF who come to the outpatient clinics for their regular follow-up care.

The participants in this study were people with HF receiving care at the two tertiary level hospitals in Addis Ababa. The participants represented a diverse socio-demographic, with some coming from Addis Ababa itself, while others travelled from regional areas across the country for specialised healthcare services. Socioeconomic status among the participants varied, with many facing economic challenges that significantly impacted their access to healthcare, medications, and follow-up care.

Phase II of the study was conducted from 21 November 2022 to 22 January 2023. After the completion of Phase II data collection and analysis, in-depth interviews were conducted to gather qualitative data from 22 February to 31 March 2023 (Phase III).

3.3. Philosophical position, research paradigm, and theoretical framework

Philosophical position and research paradigm: Pragmatism

A research paradigm is a fundamental worldview or set of assumptions that guide researchers in their work, influencing not only the choice of methodology but also the interpretation and validation of data. It acts as a philosophical framework that delineates the nature of knowledge (epistemology), the nature of reality (ontology), the ways of knowing (methodology), and the nature of ethics (axiology) (Khatri, 2020; Levers, 2013; Mertens, 2010).

Among the most prominent research paradigms are positivism, constructivism, post-positivism, and pragmatism. Positivism asserts that reality is objective and can be discovered through measurable instruments and observed empirically. Research guided by a positivist world view utilises quantitative methods for hypothesis testing and prediction, emphasising the observability and measurability of phenomena. Constructivism, on the other hand, views knowledge as constructed rather than discovered, emphasising subjective interpretations of phenomena. Consequently, research in this paradigm utilises qualitative approaches to understand the variability and complexity of human experience. Post-positivism acknowledges that while reality can be approximated, it can never be fully understood due to human limitations and biases. Post-positivist researchers typically employ mixed methods, combining qualitative and quantitative approaches, to offset the limitations inherent in each method. Finally, building on post-positivism's recognition of methodological plurality, pragmatism takes a step further by operating on the premise of employing the most effective methods to explore real-world issues (Kaushik & Walsh, 2019; Kumatongo & Muzata, 2021; Turyahikayo, 2021; Ugwu et al., 2021).

The word pragmatism originates from the Greek word *pragma*, meaning action (Bansal et al., 2010). It values practical actionable outcomes in determining meaning and truth over strict philosophical allegiances. Pragmatism supports the use of diverse data sources and knowledge types to comprehensively answer research questions. This flexibility makes pragmatism well-suited for mixed methods research, which integrates quantitative and qualitative data in a single study, as well as multimethod research that utilises various quantitative or qualitative data forms (Allemang et al., 2022; Kaushik & Walsh, 2019).

A pragmatic paradigm was adopted for this body of work because it aligns with the practical goals and accommodated the integration of multiple methodologies, models, and frameworks, to inform the design and assist in answering the research questions. Pragmatism allows this study to integrate statistical analysis with an exploration of participants' experiences. This approach aligns with the objectives of identifying prevalence and predictors while also understanding the contextual and subjective factors influencing depression and HRQoL in people with HF in Ethiopia. By addressing the multifaceted nature of HF and its impact on mental health and HRQoL, pragmatism provides a comprehensive and practical framework for this research.

3.4. Research design

This study employed a mixed methods research approach, which involves gathering and analysing data using both qualitative and quantitative methods within a single study. This approach allows for the integration of findings and the drawing of conclusions that maximise the strengths and minimise the weaknesses of each type of research design (Connelly, 2009; Creswell, 2014; Creswell & Clark, 2017). Together, these complementary approaches facilitate a more thorough exploration and understanding of complex phenomena (Mitchell & Education, 2018).

Mixed methods research typically employs one of four fundamental designs: convergent, sequential explanatory, sequential exploratory, and embedded. Each design serves a specific purpose and is chosen based on the research objectives.

Convergent design (also known as concurrent). In this design, both quantitative and qualitative data are collected simultaneously. The data from these two sources are then analysed independently but brought together during the final analysis phase to compare, thereby providing a comprehensive understanding of the research question. *Sequential explanatory design*. This design involves two distinct phases. Initially, quantitative data are collected and analysed, and the results guide the second phase, which involves qualitative data collection. The qualitative interviews or observations delve deeper into the initial results, helping to explain the "why" and "how" behind the quantitative findings. The insights from both phases are integrated during the interpretation stage to form a cohesive analysis. *Sequential exploratory design.* Here, the process begins with qualitative data collection and analysis, which aims to explore a phenomenon and identify key variables or generate hypotheses. The findings then inform the second phase, involving quantitative research. This design is particularly useful for developing and testing new instruments based on qualitative insights, ensuring that the tools are grounded in real-world observations. *Embedded design (sometimes referred to as nested)*. This design allows for one type of data to be embedded within the other predominant type, either qualitative or quantitative, depending on the researcher's primary focus. Both forms of data are collected simultaneously, but one serves a supportive role to the other, enhancing the depth of analysis without dominating the study’s overall framework (Andrew & Halcomb, 2009; Creswell & Clark, 2017; Creswell & Clark, 2011; Kaur, 2016; Tariq & Woodman, 2013).

This study employed a sequential explanatory mixed methods design to provide a comprehensive description and in-depth understanding of the impact of HF on mental health and HRQoL in Ethiopia. This design is appropriate for this study as it allows for the collection and analysis of quantitative data followed by qualitative data to provide a deeper understanding of the research problem. This approach is suitable because it affords a more complete and broad perspective of the study phenomenon by integrating quantitative and qualitative data (Doyle et al., 2009). The qualitative data collected in the final phase of the project were employed to complement and clarify the quantitative findings from Phase II. During the integration phase, data from the quantitative and qualitative phases were triangulated, compared, and synthesised, to develop a more comprehensive understanding of the phenomenon (Figure 14).

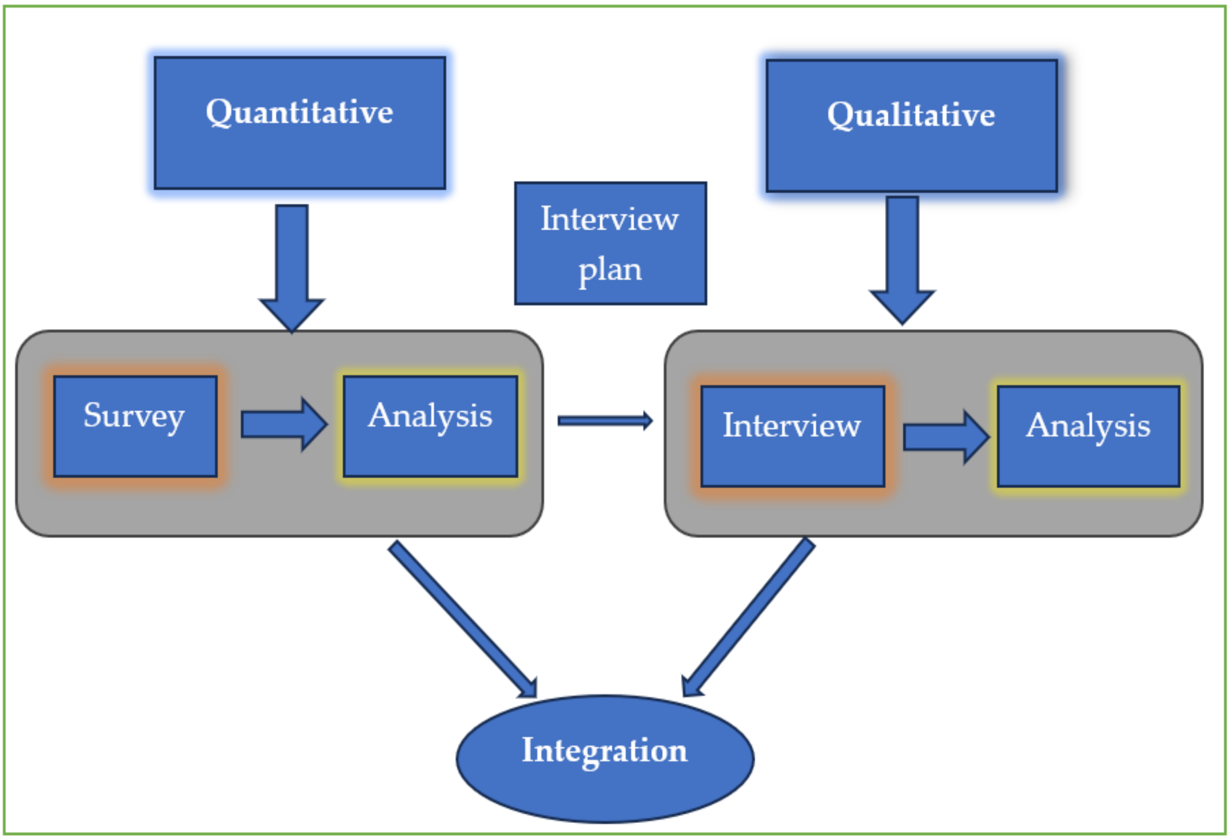


Figure 14: Sequential explanatory mixed method designed for this research

3.5. Theoretical framework

Theoretical frameworks represent the schematic presentation of a theory or model used to better understand a particular phenomenon. These frameworks are integral to research and serve as structured, conceptual guides, outlining and explaining the relationships between variables identified as significant to a study. They are considered a hallmark of quality research because they provide a roadmap for understanding underlying relationships within the context of the research, and assist in framing and interpreting the findings (Imenda, 2014).

This research was guided by two theoretical frameworks: the revised Wilson and Cleary’s model of HRQoL (Ferrans et al., 2005) and the Theory of Symptom Management (TSM) (Dodd et al., 2001). These two frameworks are prominent models used to guide HRQoL research in chronic diseases (Ojelabi et al., 2017; Weiss et al., 2023).

Pragmatism focuses on research that is practical and encourages the use of various models and theories to address complex research problems (Allemang et al., 2022; Kaushik & Walsh, 2019). Employing multiple theories assists the exploration of the philosophical foundations of the research (Scotland, 2012). The use of two theoretical frameworks in this study enabled the research questions to be answered from different perspectives and enabled a more comprehensive understanding of the phenomenon.

The revised Wilson and Cleary’s model presents the complex relationships between many variables grouped into six interrelated domains: characteristics of the individual, biological function, symptoms, functional status, general health perception, and characteristics of the environment, all influencing quality of life outcomes (Ferrans et al., 2005). The model purports that individual and environmental characteristics influence all the other domains, including quality of life (Figure 15). It is the most common and recommended framework for assessing the HRQoL of people with chronic diseases including HF (Bakas et al., 2012) and, consequently, was appropriate to use to evaluate the HRQoL and its influencing factors among people with HF in Ethiopia (Henok Mulugeta, Peter M Sinclair, & Amanda Wilson, 2023a).

In this study, the characteristics that were examined to determine their influence on overall HRQoL include:

- Individual characteristics: age, sex, educational status, marital status, and health insurance coverage
- Biological function: family history of heart failure and comorbid conditions
- Symptoms: presence of depression
- Functional status: severity of the disease, assessed using the NYHA classification

- Environmental characteristics: social support, residence, employment status, duration of illness, history of hospitalisations, and number of medications taken daily.

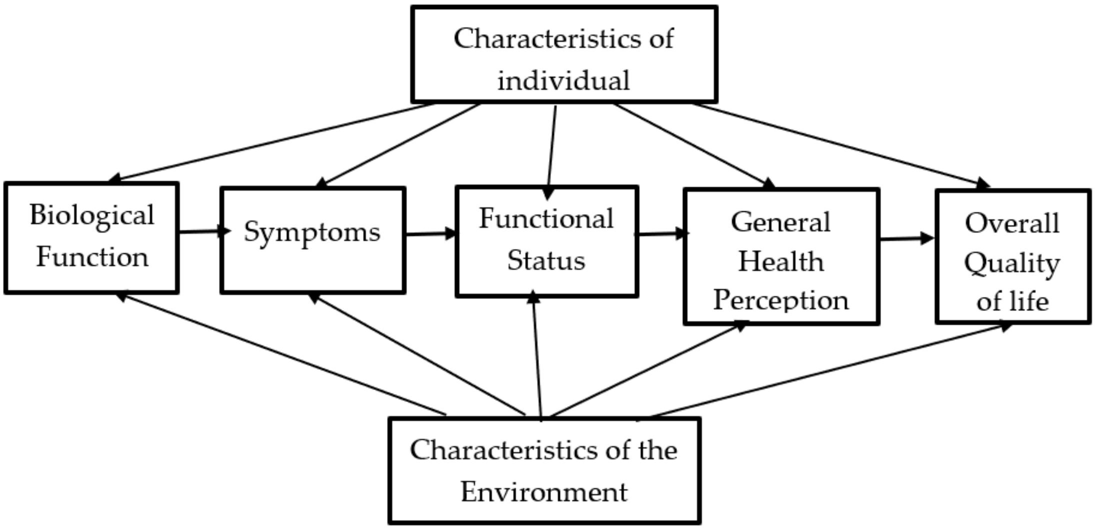


Figure 15: Revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005)

The Theory of Symptom Management (TSM) is a significant framework in nursing research that consists of three concepts: symptom experience, symptom management strategies, and outcomes (Mathew et al., 2021; Silva et al., 2021) (Figure 16). Symptom experience is a simultaneous perception of a symptom, evaluation of the meaning of a symptom, and response to the symptom. Symptom management strategies are efforts to stop or reduce the symptom experience through biomedical, professional, and self-care strategies. Outcomes arise from both symptom management strategies and the symptom experience. These outcomes include improvement in symptom status, which can lead to a better HRQoL (Bender et al., 2018; Seah et al., 2016; Thida et al., 2021). The TSM recognises that symptoms are influenced by multiple factors, including biological, psychological, social, and environmental determinants. This connection highlights its compatibility with the revised Wilson and Cleary model.

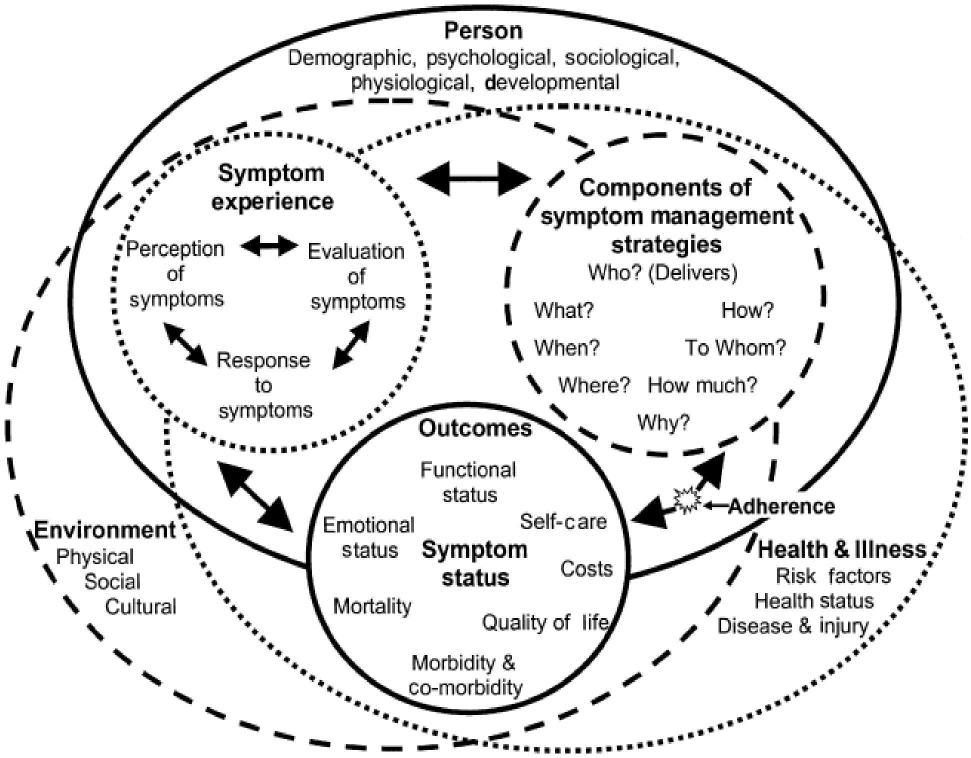


Figure 16 : The revised Theory of Symptom Management (Dodd et al., 2001)

The quantitative survey of this study was guided by the revised Wilson and Cleary's model to assess HRQoL and its influencing factors in people with HF. The TSM was then used in the qualitative semi-structured interviews to explore the symptom experience, symptom management and coping strategies, and the impact on outcomes (HRQoL) from the participant's perspective. This combination provided objective and subjective insight into the impact of HF on mental health and HRQoL, highlighting the benefit of using multiple frameworks in a single research project for a more comprehensive analysis and interpretation of the research findings.

3.6. Study population and eligibility

The study population comprised people with the diagnosis of HF receiving regular follow-up care at the cardiac clinics of the two selected hospitals in Addis Ababa and were available during the data collection period. The inclusion criteria for this study were adults aged 18 years and above, diagnosed with HF, and undergoing a minimum of three months follow-up care at the outpatient cardiac clinic.

3.7. Sampling size and recruitment

For the quantitative survey, a total sample size of 383 was calculated using the single population proportion formula ($N=(Z\alpha/2)^2 * P(1 - P)2 / D^2$) (Suresh & Chandrashekara, 2012) with the assumption of a 95% confidence interval, marginal error (d) of 5.0% and prevalence (P) of low HRQoL/depression. This calculation considered two separate prevalence rates: one for low health-related quality of life (HRQoL), estimated at 51.8% (Seid, 2020), and another for depression at 51% (Yazew et al., 2019), among adults with HF in Northwest Ethiopia. Despite the variation in these prevalence rates, an identical sample size requirement (383) was obtained from both calculations, indicating strong statistical power to investigate the prevalence and impact of these conditions within this specific demographic setting.

Participants were recruited using a consecutive sampling technique. A consecutive sampling technique is one of the non-probability sampling methods in which participants are selected based on their availability and accessibility, in a sequential manner according to the eligibility criteria, until the required sample size is achieved (Bujang & Sa'at, 2016). This technique was chosen as the study focuses on a specific subset of people (those with HF) attending an outpatient department, where attendants come in a sequence, making it more practical and efficient in a busy outpatient department. In addition, it is difficult to prespecify an interval K for a systematic random sampling technique, since the total number of the population is unknown. Therefore, a consecutive sampling technique is easy to implement without the requirement of a sampling frame. Although consecutive sampling was efficient, it may introduce potential biases, such as selection bias (Bujang & Sa'at, 2016), where participants may not represent a broader population of individuals with HF. To address potential biases, the study implemented clear inclusion and exclusion criteria, ensuring a diverse sample across age, gender, and socio-economic status. Participants were also recruited from two hospitals to enhance representativeness and reduce potential bias.

For the qualitative study, eligible participants from the quantitative surveys were invited to participate in the subsequent qualitative interviews. Then, a purposive sampling technique was employed to recruit interested participants for interviews, considering diversity among participants in terms of age, gender, and socioeconomic status. The final sample size was determined to be 14 participants based on a criterion of data saturation. Data saturation is the point at which no new information are observed from participants in qualitative research, indicating that adequate information has been collected to understand the phenomenon under study (Creswell & Creswell, 2017; Doyle et al., 2020; Gill, 2020; Sarfo et al., 2021).

3.8. Rigour in the use of mixed methods

Mixed methods research has emerged as a new and popular scientific approach, which provides a broad and deeper understanding about a complex phenomenon under study (Oliveira et al., 2021). However, ensuring rigour in a mixed methods study is critical to enhance the credibility and validity of the research findings. A clear criterion for validating both quantitative and qualitative components of the study is important to maintain rigour in a mixed methods study. Strategies to ensure the overall validity of mixed methods research include selection of appropriate research design, data collection procedures, rigorous data analysis, and appropriate integration and interpretation of the findings. These strategies are important and should be considered when designing and conducting a mixed methods study (Creswell & Creswell, 2017; Eckhardt & DeVon, 2017; Lavelle et al., 2013).

3.8.1. Achieving rigour in the Phase II study

In quantitative studies, rigour refers to accuracy and is a means of establishing trust or confidence in the findings of the study. It defines the extent to which the researchers have attempted to improve the quality of the study using the measurements of reliability and validity. Validity is defined as the extent to which outcomes are accurately measured in a study (Heale & Twycross, 2015). In quantitative studies, content and construct validity are appropriate for assessing the internal validity of the tool. Content validity of an instrument can be ensured by researchers through careful formulation of the research instrument in line with a theoretical framework and research objectives, which can be verified by experts in the field. Construct validity refers to the extent an instrument measures the core construct it aims to assess and the quality of the instrument against a theoretical framework (Ahmed & Ishtiaq, 2021). Reliability refers to the level of consistency of an instrument in measuring the same outcomes under similar conditions. Reliability is established using internal consistency correlation between different results of the instrument using a Cronbach’s alpha coefficient, where values closer to 1.0 indicate higher reliability of the instrument (Sürücü & Maslakci, 2020).

3.8.2. Achieving rigour in the Phase III study

In qualitative research, rigour is the method of establishing trust or confidence in a study's conclusions. It is the quality of being exact and accurate during a research activity. In qualitative research, the researcher needs to be flexible in developing methodological rigour necessary to attaining trustworthy study results**.** Reflexivity can be helpful in developing the methodological rigour necessary to attain trustworthy qualitative study results (Ghafouri & Ofoghi, 2016; Rettke et al., 2018). Trustworthiness, in qualitative research, is defined as the degree of confidence in the data, interpretation, and methods used (Connelly, 2016).

Lincoln and Guba's trustworthiness framework was used to ensure the quality and rigor of this study. It is the gold standard and widely recognised approach in qualitative research. Lincoln & Guba (1985) propose that four key criteria, which parallel the concepts of validity and reliability in quantitative research, achieve trustworthiness. These are credibility, dependability, confirmability, transferability (Lincoln & Guba, 1985). These criteria were applied throughout the research process.

Credibility of the study, or the confidence in the truth of the study, is concerned with the application of standard procedures used during the qualitative approach, or the presence of an adequate justification provided for variations (Polit & Beck, 2020). Credibility was achieved in this thesis by persistent observation and prolonged engagement such as allocating adequate time for the interviews and using participants' own words during the analysis. Credibility was also achieved by discussing the research process, findings, and interpretations with a peer who is experienced in qualitative research and expert in the research topic. Dependability refers to the stability or consistency of the data over time and over the conditions of the study. In this study, dependability was achieved using inquiry audit, which is the process of validating the data by reviewing the recorded data and the relevant process of the data collection. The researcher documented decisions about aspects of the study such as who to interview and what to observe, data collection, and analysis to ensure transparency and replicability. Dependability was maintained by keeping thorough records and notes of all the research activities for review as necessary and engaging in debriefings with the second author. (Connelly, 2016; Pandey & Patnaik, 2014). Confirmability addresses the neutrality of findings, ensuring they are shaped by participants rather than researcher bias. The researcher not only documents thoughts, decisions and potential biases to establish confirmability, but also continuously checks and rechecks the data throughout the study to address any potential biases. Transferability is the extent to which findings can be applied to people in other contexts. Describing the process of data collection in detail helps the evaluation of the extent to which the conclusion is transferable to other settings (Amankwaa, 2016; Pandey & Patnaik, 2014). Transferability was assured by providing a detailed description of the study participants, context, study setting, and process of data collection, and by maintaining transparency about data analysis, allowing readers to determine if the results are transferable to similar contexts.

3.9. Data collection instruments and procedure

3.9.1. Quantitative data collection

For the quantitative phase, an interviewer-administered, semi-structured questionnaire, prepared in accordance with the revised Wilson and Cleary model of HRQoL, was used to collect data from the participants. The outcome variables of the quantitative survey were depression and HRQoL. The independent variables were formulated from Wilson and Cleary's model. The questionnaire encompassed the sociodemographic and clinical characteristics (biological function) of the participants, the Oslo Social Support Scale (OSSS-3), the Patient health questionnaire (PHQ-9), and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). The quantitative data collection questionnaire is available in Appendices 2 and 3.

Part I: Sociodemographic and clinical characteristics of the participants

The demographic characteristics collected included questions related to age, sex, marital status (social support), educational status, utilisation of community-based health insurance, and socioeconomic status, such as educational level, geographical location, and employment status. The clinical characteristics of the participants included questions related to family history of HF, comorbidities, duration of illness, history of hospitalisation (previous two months), and number of medications taken each day. General health perception was determined using one global question that asked the participants to rate their overall health.

Part II: The Oslo Social Support Scale (OSSS-3)

Social support was assessed using the Oslo Social Support Scale (OSSS-3), which is a brief instrument to assess the level of social support. It consists of three items that ask for the number of close confidants, sense of concern from other people, and relationships with neighbours, with a focus on the accessibility of practical help. The sum score ranges from 3-14, with high values representing strong levels and low values representing poor levels of social support (Kocalevent et al., 2018). It has good construct and predictive validity and a good internal consistency with a Cronbach alpha of 0.91 (Shumye et al., 2019).

Part III: Patient health questionnaire

The Patient Health Questionnaire (PHQ-9) is a 9-item depression screening tool based on DSM-IV criteria that can be scored from 0 (not at all) to 3 (nearly every day). The total score ranges from 0 to 27 to measure depression severity. Each item requires participants to rate the frequency of depressive symptoms experienced in the two weeks prior to assessment. An individual was considered to have depression if their PHQ-9 score was >10, with higher scores indicating more severe depression (Mechili et al., 2022; Moriarty et al., 2015; Nguyen et al., 2022). The PHQ-9 is a reliable and validated instrument for detecting major depressive disorder among Ethiopian adults with chronic conditions in outpatient settings (Degefa et al., 2020; Gelaye et al., 2013).

Part IV: Minnesota Living with Heart Failure Questionnaire

The Minnesota Living with Heart Failure Questionnaire (MLHFQ) was used to assess the HRQoL of the participants. It is the most widely used disease-specific instrument used to measure HRQoL in people with HF (AbuRuz et al., 2016; Jarab et al., 2023). It is a 21-item questionnaire with a 6-point Likert-type scale that ranges from 0 (no effect) to 5 (very much effect). The original questionnaire was developed in the USA by (Rector, 1987). The scores range from 0 to 105 with higher composite scores representing a poorer quality of life (Ahmeti et al., 2016; Audi et al., 2017; Rector, 2017). The MLHFQ provides a total score as well as scores on two dimensions: physical (eight questions, range, 0–40) and emotional (five questions, range, 0–25) (Audi et al., 2017; Rector, 2017).

Many countries have validated the psychometric properties of the MLHFQ, including the UK (Heo et al., 2005), Spain (Bilbao et al., 2016; Garin et al., 2008), the Netherlands (Middel et al., 2001), Taiwan (Hwang et al., 2014), Korea (Moon et al., 2012), Brazil (Saccomann et al., 2007), China (Ho et al., 2007), and Lebanon (Zahwe et al., 2020). However, these studies have reported inconsistencies in its factor structure. Of note, this measure has not been previously validated in the Ethiopian context, prior to this study. To address this research gap, a rigorous translation and cross-cultural adaptation process was undertaken. This process followed the guidelines proposed by Beaton et al. (2000) and involved the following steps: forward translation, synthesis, back translation, expert committee review, and pre-testing (Beaton et al., 2000). A reliability test was conducted to evaluate the internal consistency, in addition to a confirmatory factor analysis to determine the goodness-of-fit of the two-factor structure of the

MLHFQ identified in the original study (Rector & Cohn, 1992). Reliability reflects the extent to which the tool items are interrelated or whether they are consistent in measuring the same construct (Tsang et al., 2017). The details of the translation, cultural adaptation, and validation of the MLHFQ are presented in Chapter 5.

Translation: The standard forward–backward procedure (Borsa et al., 2012; Chen & Boore, 2010) was applied to translate the entire questionnaire from English into the local Ethiopian language, Amharic. The initial translation from English to Amharic was made by two bilingual professional language experts. Discrepancies between the two translators were discussed and resolved by the principal researcher (HM). Then, the initial translation was independently back translated to the English language, to ensure the accuracy of the translation. The original and back translated versions were evaluated and found to be the same with minor editorial corrections. The final version of the translation was checked by language experts familiar with the research topic for its suitability, both culturally and linguistically, in Ethiopia.

Pretest: The prefinal version of the translated questionnaire was pretested on 10% of the intended respondents to ensure there was no confusion about any items in the translated questionnaire. Necessary corrections were made as a result of the preliminary pilot testing. These corrections included changing the wording of questions, changing response options, and adjusting the overall structure.

Before the surveys, one-day training about the questionnaire and the data collection procedure was provided to all research assistants (RAs) (Appendix 5), who were all cardiovascular or mental health nurses working in the hospitals. Two master's level health professionals, with extensive experience in research, supervised the data collection process.

During the study period, an invitation letter and information sheet were distributed to all eligible consecutive clients while they waited for their regular follow-up appointments at the outpatient cardiac clinics. The RAs assisted potential participants by reading the information sheet to those unable to read it themselves (because of a low level of literacy or poor eyesight). If they agreed to participate, a consent form was provided for them to sign. Due to high rates of illiteracy and to ensure consistency, the surveys were administered by the RAs. The surveys were conducted in a private room at the hospital near the cardiac clinics. Two supervisors checked each questionnaire for completeness and clarity. Additionally, the principal investigator also checked the completed questionnaires daily and provided feedback to the supervisors.

3.9.2. Qualitative data collection

During the survey, participants were invited to participate in the next phase of the study, which involve a semi-structured interview. This invitation was extended to participants through an invitation letter (Appendix 6). Those participants who agreed to participate were contacted by phone and scheduled for an interview during their next hospital visit at the cardiac clinic. The principal investigator contacted the consenting participants one day before their monthly appointment, to remind them about the scheduled interview.

The principal investigator (HM), who had been trained and had experience in conducting interviews, conducted the semi-structured interviews using an open-ended interview guide, until data saturation was achieved (Appendix 7). The interview guide was developed based on the TSM (Dodd et al., 2001) and the results of the quantitative survey (Henok Mulugeta, Peter M Sinclair, & Amanda Wilson, 2023a), focusing mainly on participant's symptom experience, perception of their HRQoL, the impact of HF on their HRQoL, and their symptom management and coping strategies (Appendix 8).

Three practice interviews were conducted prior to the main interviews, to evaluate the quality of the interview guide and the interviewer's skills. These interviews were discussed with supervisors and feedback was used to improve the quality of the main interviews.

The actual interviews were conducted in a private room in the hospital. On the day of the interview, the RAs read the information sheet to the participant and the participant was requested to sign the consent form to confirm their agreement to participate. Before the interview, brief sociodemographic and clinical characteristics of the participants were collected. During the interview, the interviewer asked questions slowly according to the interview guide and gave enough time for the participants to respond. Probing questions were used, as needed, to compliment the quantitative findings and to provide deep understanding of their experience of living with HF and how it affected their HRQoL. The interviews were audio-recorded and lasted from 30 to 60 minutes. In this study, the signs of data saturation were observed after 11 interviews. Three additional interviews were conducted to confirm the data saturation point.

3.10. Data analysis

3.10.1. Quantitative data analysis

The collected quantitative data were cleaned and entered into Epi-Data version 3.1 and exported to STATA Version 17 for further analysis (StataCorp, 2020). Descriptive analyses were performed to describe the sociodemographic and clinical characteristics of the participants using frequency, percentage, mean, standard deviation, and cross-tabulation. The results of the descriptive statistics are presented in text, graph, and table. Based on the objectives of the study, two regression models (linear and binary logistic) were used to analyse factors associated with the outcome variables. A linear regression model was employed to identify factors associated with HRQoL, while the binary logistic regression model was used to assess the association between independent variables and depression. First, a bivariable analysis was completed to test the association between each independent variable with the dependent variables (HRQoL and depression) separately. All independent variables with a p-value of less than 0.25 on the bivariate analysis were eligible for further analysis in the multivariable regression model. The results of the two regression analyses are presented separately using text and tables.

3.10.2. Qualitative data analysis

The qualitative interviews were transcribed verbatim in Amharic and then translated into English by a bilingual expert. The candidate (HM) actively participated during the transcription and translation of the interviews, providing the opportunity to become more familiar with the data. The participants were assigned an alphanumeric identification (P01 to P14) to maintain anonymity. The translated transcripts were imported into NVIVO version 12 (QSR International, 2018) statistical software for coding and analysis.

The six phases of Braun and Clark's thematic analysis method were used to analyse the data: data familiarisation, systematic data coding, searching for themes, reviewing themes, defining, and naming themes, and producing the final report (Braun & Clarke, 2006). Although the steps are listed in sequential order, the process is not linear, as the researcher often moves back and forth between these steps to check one aspect of the analysis against one or more of the other steps in the analysis (Figure 17).

Data familiarisation. The researcher repeatedly listened to the audio tapes and read the transcript to gain a deep understanding and comprehensive familiarity with the entire data. The researcher also took memos and annotations to document significant findings and insights.

Systematic data coding. The researcher systematically assigned a descriptive label for significant information from each transcript, aiming to identify related concepts based on the research objective. Both semantic and latent coding were utilised to create codes. Two researchers (HM and PS) independently coded the transcripts, and the third researcher (AW) was consulted as needed to resolve any coding discrepancies. Then, the researchers refined and organised the codes to make categories of related information, to create themes and subthemes from the data.

Searching for themes. The codes were examined systematically based on the three concepts of the TSM and additional patterns of meaning were identified. The researchers combined codes that shared similar concepts, to develop potential themes and eventually subthemes.

Reviewing themes. The researchers reviewed the themes, by discussion, regarding potential themes and subthemes, to ensure their relevance to the research questions. The final identified and emerged themes were critically discussed and approved by all researchers.

Defining and naming themes. After reviewing these themes, the researchers defined and described the characteristics of each theme, and an appropriate name was assigned based on the research questions, objectives, and the TSM theoretical framework.

Producing the final report. The researchers synthesised the key findings by describing the themes, and direct quotations from the transcripts were used to highlight the experiences of the participants.

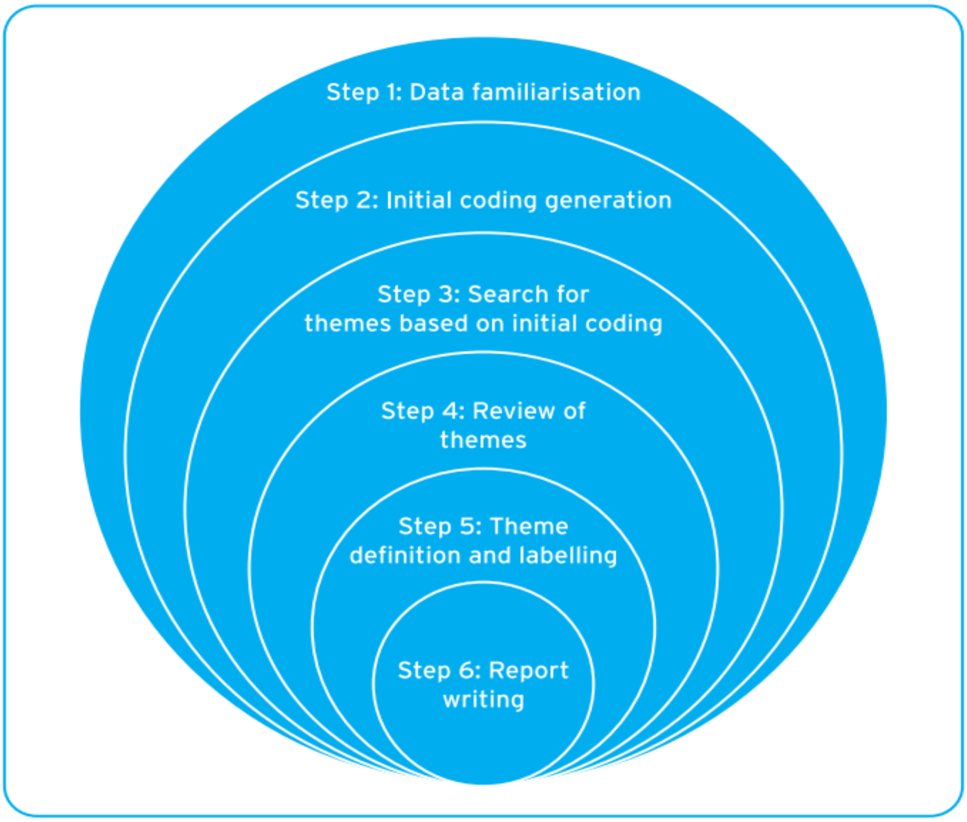


Figure 17: Braun and Clarke's model of thematic analysis (Howitt & Cramer, 2010).

An inductive-deductive hybrid thematic analysis approach was utilised to analyse the data. This approach was chosen because the research questions were strongly linked to existing theory (deductive) and it enabled the exploration of insights within the data, while allowing new themes to emerge from the data (inductive). The validity and rigor of this approach has been well demonstrated previously (Fereday & Muir-Cochrane, 2006; Proudfoot, 2023; Roberts et al., 2019).

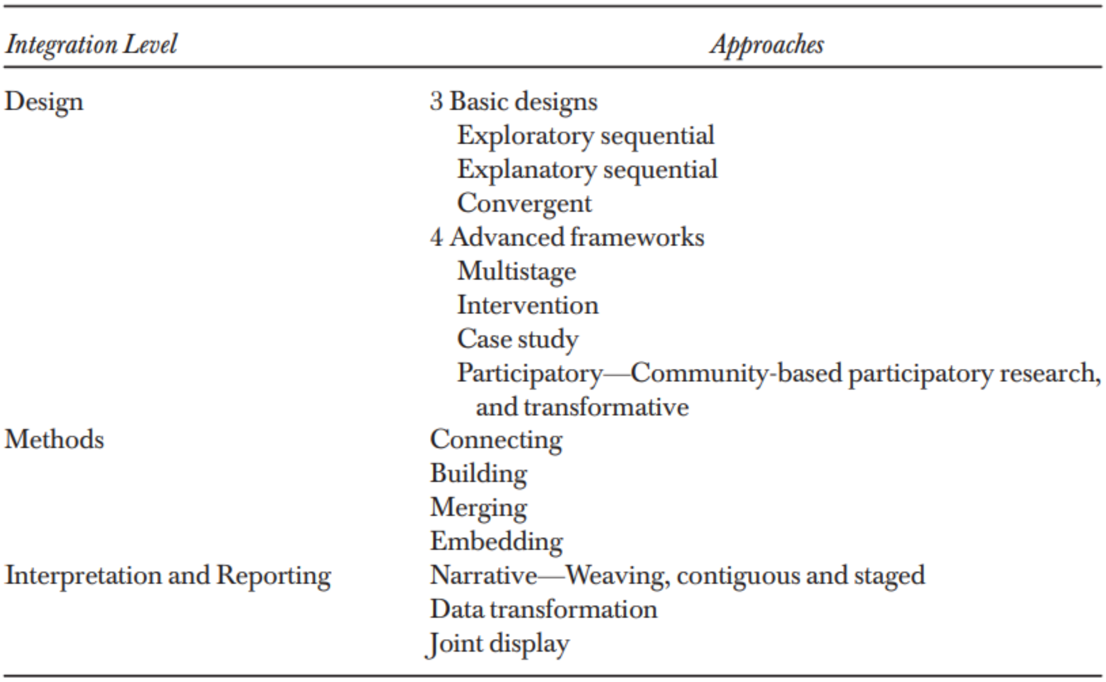
In this thesis, the Consolidated Criteria for Reporting Qualitative Studies (COREQ) guideline was used for comprehensive reporting of the results of the in-depth interviews. COREQ is an internationally recognised guideline consisting of a 32-item checklist to help researchers report study methods, context of the study, findings, analysis, and interpretations (Booth et al., 2014; Tong et al., 2007).

3.11. Data integration

Mixed methods research involves the integration of quantitative and qualitative research procedures and data that can be implemented at the design, methods, and interpretation and reporting levels (Creswell & Clark, 2017; Fetters et al., 2013). Data integration involves merging findings from both quantitative and qualitative components of research, for a better interpretation and to develop a comprehensive understanding of the problem (Creswell et al., 2003; Draucker et al., 2020).

In this study, integration at the design level was accomplished by using the sequential explanatory study design. This design begins with a quantitative survey followed by a qualitative interview that helps to explain the quantitative findings. Furthermore, integration at the methods level occurs through "connecting approaches". This approach is characterised by linking the quantitative data with the qualitative data through the sampling frame, where the interview participants are selected from the population of respondents to the survey. Finally, a narrative approach using a weaving technique was employed to integrate the quantitative and qualitative data at the interpretation and reporting level, which are presented in the discussion section.

Table 11: Levels of integration in mixed method studies (Fetters et al., 2013)



Integration Level	*Approaches*
Design	3 Basic designs Exploratory sequential Explanatory sequential Convergent 4 Advanced frameworks Multistage Intervention Case study Participatory—Community-based participatory research, and transformative
Methods	Connecting Building Merging Embedding
Interpretation and Reporting	Narrative—Weaving, contiguous and staged Data transformation Joint display

3.12. Ethical considerations

This study received ethical approval from the University of Technology Sydney (UTS) Human Research Ethics Committee (UTS HREC REF NO. ETH21-6739) (Appendix 9). Permission to conduct the study was also granted from the institutional review board (IRB) of each hospital (SPHHMC IRB Ref No. PM23/9235/13/10/22, SPSH IRB V561/11/10/22) (Appendix 10). This research was guided by ethical principles and standards to conduct human research. Following these principles protects the dignity, rights, and welfare of the participants. Below are key ethical principles that guided this research work.

Informed and voluntary consent

Informed consent is the process by which the researcher informs the participants about the nature, potential risks, and benefits of the research (Pietrzykowski & Smilowska, 2021). The Participant Information Statement is used to explain the purpose of the research and provide a description of what participants will be required to do, how they will be involved, and how they will be used in the research (Mechili et al.). In this research, the Participant Information Statement was provided to all participants for their perusal, either for them to read it themself or have an RA read it to them in their local language. The Participant Information Statement outlined and informed the participants about the purpose, procedures, risks, and benefits of the study. Subsequently, written informed consent was obtained from each participant, formalising their agreement to participate in the study. This procedure was carried out during both the quantitative and qualitative phases of the study, using distinct Participant Information Statements and Informed Consent Forms. The Participant Information Statements and Informed Consent Forms for both the quantitative survey and qualitative interview were provided in both English and Amharic versions, and are attached in Appendix 11 and Appendix 12, respectively.

Privacy and confidentiality

The privacy and confidentiality of the participants were protected by conducting the interviews in a private room and coding the questionnaire so that no personal information was collected. Participants were treated with the greatest respect and dignity throughout the research process. All collected data, including any identifying information collected during the recruitment, surveys, and interviews process, were stored on a password protected computer accessible only to the researchers. Additionally, any interviews conducted were promptly deleted from the recording device once the files were securely transferred to the password protected computer.

Data storage

All the collected data were stored on a password protected computer and file access was restricted to the research team. The identifiable or re-identifiable data, including audio recordings and survey responses, were stored securely on the UTS provided collaboration space (OneDrive) for a minimum retention period of five years, according to the UTS protocol for disposing of confidential data from general research.

CHAPTER 4: QUANTITATIVE RESULTS I

4.1. Depression among people with heart failure in Ethiopia

4.1.1. Chapter overview

This chapter presents the quantitative findings from Phase II of the study, related to the impact of HF on mental health in Ethiopia. This involves determining the prevalence of comorbid depression and its influencing factors in people with HF.

This chapter begins by introducing the background information about HF and highlighting the growing burden of mental health issues, such as depression, in people with HF. In this phase of the study, the authors identified the research gaps and explained the importance of determining the prevalence of depression and its associated factors in people with HF in the selected study area. The authors have described the methodological procedures and techniques employed, including the study design, participant recruitment, sample size calculation, data collection procedure, and statistical analysis techniques. The findings were used for further quantitative analysis and to develop an interview guide for Phase III of the study. Finally, this chapter interprets the findings, comparing them with the existing literature and discusses the implications of the results for clinical practice, policy, and future research.

The manuscript was submitted to BMC Psychiatry for publication and underwent peer review before being published. The peer review comments were insightful and useful in helping to strengthen the paper.

Publication: Paper Three

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Principal author

Name of principal author	Henok Mulugeta TESHOME	
Contribution to the paper	• *Conceived the study aims and design* • *Performed analysis and interpreted the data* • *Wrote the first draft of the manuscript* • *Revised drafts of manuscript based on comments from co- authors* • *Acted as corresponding author*	
Overall percentage (%)	80% contribution	
Certification	I hereby certify that this paper has been written by me during the period of my higher degree research candidature, and its content is primarily based on my own original work, unless stated otherwise. All references and all sources of information have been appropriately acknowledged.	
Signature	Production Note: Signature removed prior to publication.	Date: 01/05/24

Co-Author contributions.

By signing the Statement of Authorship, each author certifies that:

- *The candidate's stated contribution to the publication is accurate*
- *Permission is granted for the candidate to include the publication in the thesis*
- *The sum of all co-author contributions is equal to 100% less the candidate's stated contribution.*

Name of Co-Author	A/ Professor Peter M. Sinclair
Contribution to the paper	Contributed to the design of the study, validated the data analysis, interpretation of the findings, and reviewed and approved the final manuscript
Signature	Production Note: Signature removed prior to publication. Date: 07.07.24
Name of Co-Author	Professor Amanda Wilson
Contribution to the paper	Contributed to the design of the study, validated the data analysis, interpretation of the findings, and reviewed and approved the final manuscript.
Signature	Production Note: Signature removed prior to publication. Date: 10/7/24

4.1.2. Publication: Comorbid depression among adults with heart failure in Ethiopia: A hospital-based cross-sectional study

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RESEARCH **Open Access**

Comorbid depression among adults with heart failure in Ethiopia: a hospital-based cross-sectional study

Henok Mulugeta[1,2*], Peter M. Sinclair[2] and Amanda Wilson[2]

Abstract

Background Depression is a common comorbidity in adults with heart failure. It is associated with poor clinical outcomes, including decreased health-related quality of life and increased morbidity and mortality. There is a lack of data concerning the extent of this issue in Ethiopia. Consequently, this study aimed to assess the prevalence of comorbid depression and associated factors among adults living with heart failure in Ethiopia.

Methods A hospital-based cross-sectional study was conducted at the cardiac outpatient clinics of two selected specialist public hospitals in Addis Ababa, Ethiopia: St. Paul's Hospital Millennium Medical College and St. Peter Specialized Hospital. An interviewer-administered questionnaire was used to collect data from 383 adults with heart failure who attended the clinics and met the inclusion criteria. Depression was measured using the Patient Health Questionnaire (PHQ-9). A binary logistic regression model was fitted to identify factors associated with depression. All statistical analyses were conducted using STATA version 17 software.

Results The mean age of the participants was 55 years. On average, participants had moderate depression, as indicated by the mean PHQ-9 score of 11.02±6.14, and 217 (56.6%, 95%CI 51.53–61.68) had comorbid depression. Significant associations with depression were observed among participants who were female (AOR: 2.31, 95%CI:1.30–4.08), had comorbid diabetes mellitus (AOR: 3.16, 95%CI: 1.47–6.82), were classified as New York Heart Association (NYHA) class IV (AOR: 3.59, 95%CI: 1.05–12.30), reported poor levels of social support (AOR: 6.04, 95%CI: 2.97–12.32), and took more than five medications per day (AOR: 5.26, 95%CI: 2.72–10.18).

Conclusions This study indicates that over half of all adults with heart failure in Ethiopia have comorbid depression, influenced by several factors. The findings have significant implications in terms of treatment outcomes and quality of life. More research in the area, including interventional and qualitative studies, and consideration of multifaceted approaches, such as psychosocial interventions, are needed to reduce the burden of comorbid depression in this population.

Keywords Depression, Heart failure, PHQ-9, Ethiopia

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Introduction

Heart failure (HF) is a global major public health problem with high prevalence and mortality rates (Russell et al.; Thida et al., 2021). It affects more than 64 million people worldwide (Urbich et al., 2020) and this figure is expected to rise over the next few decades due to ageing and population growth (A. Groenewegen et al., 2020; Lippi & Sanchis-Gomar, 2020). Globally, the annual cost of HF is estimated to be US$108 billion and this cost will continue to grow as the prevalence of HF increases (Cook et al., 2014). Hospital-based studies show that HF is a serious health concern and its prevalence is increasing in sub-Saharan countries, including Ethiopia (Agbor et al., 2020; Gtif et al., 2021).

Living with HF is challenging due to the progressive and unpredictable nature of the disease. Adults with HF are more prone to develop negative emotional conditions compared to the general population (K. S. Lee et al., 2020; Seah et al., 2016). Comorbid depression is a prevalent mental health condition in this population and is associated with negative outcomes. It is characterised by persistent feelings of unhappiness, low self-worth, and lack of interest in daily activity, with symptoms for at least two weeks based on DSM-5 diagnostic criteria (Truschel, 2020). A recent meta-analysis of 149 studies found that 41.9% of adults with HF have any severity of depression and 28.1% have moderate to severe depression (Moradi et al., 2021). Similarly, the pooled prevalence depressive symptoms in adults with HF in China, based on a meta-analysis of 53 studies, was 43% (Lin et al., 2020).

Comorbid depression in HF is five times more common than in the general population and is an independent predictor of repeated hospital admissions and mortality (Sokoreli et al., 2016). Depression can worsen physical symptoms and impair self-care and treatment adherence (Zahid et al., 2018). Many factors contribute to comorbid depression in adults with HF, including age, gender, severity of symptoms, socioeconomic status, social support, and hospitalisation (Chobufo et al., 2020; Graven et al., 2017; Nguyen et al., 2022). Depression is also correlated with poor health-related quality of life (Alemoush et al., 2021; Erceg et al., 2013). It worsens HF symptoms, impairs treatment adherence, reduces self-care practice, and has a double socioeconomic impact (Dastgeer et al., 2016). Despite the high prevalence of depression and its negative impact on adults with HF, it is often unrecognised and under-treated by health professionals (İlhan & Oğuz, 2021; Tran et al., 2022).

While several studies have demonstrated the prevalence of comorbid depression among adults with HF in low- and middle-income countries, there is a notable lack of data regarding the extent of this issue in Ethiopia. The current study not only aimed to provide an updated prevalence estimate using rigorous methodologies, but also examined previously unidentified factors associated with depression among adults with HF attending follow-up appointments at two tertiary-level government hospitals in Addis Ababa, the capital of Ethiopia. The findings will provide evidence for health policymakers to identify effective interventions to improve the mental health of adults with HF, ultimately enhancing the prognosis of HF in this population.

Methods

Study setting and period

The survey was conducted between 21 Nov 2022 to 22 Jan 2023 at two cardiac outpatient clinics of two government hospitals in Addis Ababa, the capital of Ethiopia: St. Paul's Hospital Millennium Medical College and St. Peter Specialized Hospital. St Paul’s Hospital Millennium Medical College was established by a decree of the Council of Ministers in 2010, and the hospital was originally founded by the late Emperor Haile Selassie in 1968. The college has over 2800 clinical, academic, and administrative and support staff who are involved in providing comprehensive tertiary-level care. The hospital boasts over 700 inpatient beds and serves an average of 1200 emergency and outpatient clients daily. St. Peter Specialized Hospital is one of the largest public hospitals in Addis Ababa. The hospital was established in 1963 as the first Tuberculosis (TB) consortium in the country. It offers tertiary-level medical services and education, with around 350 inpatient beds and a catheterisation laboratory (Cath lab) for cardiovascular care and interventions, along with four ICU beds. These hospitals are the largest tertiary-level teaching hospitals in Ethiopia and receive referred cases from many hospitals across the country. Currently, they collaborate to provide care for people with cardiac conditions, and each hospital typically sees an average of 30 adults with HF per week in their outpatient clinics.

Study design

A hospital-based cross-sectional study design was conducted.

Study population

Adults with HF attending a follow-up appointment at the outpatient cardiac clinic in either of the two hospitals during the data collection period.

Eligibility criteria

The inclusion criteria included individuals over the age of 18 years with a confirmed diagnosis of HF (clinically using Framingham criteria or Echocardiography), who attended follow-up appointments at the outpatient cardiac clinic for at least three months, to ensure that they had established ongoing care for their condition, enabling a more holistic assessment of factors affecting depression. Anyone unable or unwilling to provide informed consent was excluded. Additionally, anyone taking antidepressants were also excluded from participating.

Sample size and sampling procedure

The sample size was determined using a single proportion formula for a finite population, given by $N=(Z\alpha/2)^2*P(1-P)^2/D^2)$ (Suresh & Chandrashekara, 2012), with an assumption of a 95% confidence interval, a marginal error (d) of 5 %, and a 51% prevalence (P) of depression among adults with HF in Northwest Ethiopia (Yazew et al., 2019). Therefore, $N= ((1.96)^2*0.511(1-0.511))/0.05^2=383$ adults with HF. A consecutive sampling technique was used to recruit eligible adults with HF attending the outpatient cardiac clinics until the required sample size was achieved.

Variables

Dependent variable:

- *Depression (Yes/No)*

Independent variables:

- *Sociodemographic characteristics, included: age, sex, educational status, marital status, residence, employment status, social support, health insurance*
- *Clinical and other related characteristics included: comorbidity, New York Heart Association (NYHA) class, duration of illness, history of hospitalisation, number of medications taken each day, family history of heart failure, overall health perception.*

Operational definitions and definitions of terms

Adult: over 18 years of age.

Heart failure: the inability of the heart to effectively pump blood as evidenced by either signs and symptoms based on Framingham criteria or reduced ejection fraction (<40%) (Hage et al., 2020; Lofstrom et al., 2019).

General Health Perception: a representation of all health concepts that determine general satisfaction with life, using one global question that asks respondents to rate their overall health on a Likert scale as "excellent", "very good", "fair", or "poor" (Ferrans et al., 2005).

Community health insurance (CHI): a health insurance program in Ethiopia designed to provide affordable healthcare coverage to community members.

The severity of heart failure: The New York Heart Association criteria (NYHA) was used to classify the severity of heart failure as Class I: no limitation during ordinary activity, Class II: slight limitation during ordinary activity, Class III: marked limitation of normal activities without symptoms at rest, or Class IV: unable to undertake physical activity without symptoms and symptoms may be present at rest (Miller-Davis et al., 2006).

Depression: An individual was considered to have depression if their Patient Health Questionnaire (PHQ-9) score was $\geq$10, with higher scores indicating more severe depression (Mechili et al., 2022; Moriarty et al., 2015; Nguyen et al., 2022).

Data collection procedure and instruments

Trained research assistants (RA), who were cardiovascular nurses working at the facilities, contacted eligible adults with HF attending routine follow-up visits at the outpatient cardiac clinic of each hospital. They explained the purpose of the study and obtained informed consent from those who agreed to participate. The RA collected data from each participant using an interviewer-administered questionnaire in a quiet room within the hospital. The questionnaire consisted of three parts: The first part focused on sociodemographic and clinical characteristics, the second part addressed social support, and the third part assessed depression. The sociodemographic and clinical characteristics were assessed using a 19-item questionnaire. This questionnaire asked about age, sex, marital status, employment status, residence, educational level, health insurance, family history of HF, hospitalisation history, comorbidities, duration of illness, NYHA class, number of medications, and general health perception. Data regarding comorbidities and the severity of HF (NYHA class) were extracted from the patient's medical charts. The Oslo Social Support Scale (OSSS-3) was used to assess the level of social support. It consists of three items all focusing on accessibility of practical help: the number of close confidants, the sense of concern from other people, and relationships with neighbours. The total score ranges from 3-14, with high values representing strong support and low values representing poor social support (Kocalevent et al., 2018). It has good construct and predictive validity and a good internal consistency, having a Cronbach alpha of 0.91 (Shumye et al., 2019). Depression was measured using the Patient Health Questionnaire (PHQ-9), which is a 9-item tool based on DSM-IV criteria, where item scores range from 0 (not at all) to 3 (nearly every day). The total score ranges from 0 to 27 to measure depression severity, with higher scores indicating a higher likelihood of depression. Each item requires participants to rate the frequency of a depressive symptom experienced in two weeks prior to the assessment. The PHQ-9 is a reliable and valid instrument for detecting major depressive disorder among Ethiopian adults with chronic conditions in outpatient settings (Degefa et al., 2020; Gelaye et al., 2013). Data collection was carried out by trained health professionals working in the outpatient cardiac clinics of each hospital, with two supervisors overseeing the data collection process. The collected data were reviewed daily to ensure completeness and clarity.

Data analysis

Data were cleaned and entered into Epi-Data version 3.1, and then exported to STATA Version 17 for analysis (StataCorp, 2020). Descriptive analyses, including frequency, mean, and standard deviation, were performed to describe the sociodemographic, clinical, and other characteristics of the participants. A binary logistic regression model was fitted to identify factors associated with depression. A simple bivariable analysis was performed to test the association between each independent variable and the dependent variable. All independent variables with a p-value of less than 0.25 in the bivariable analysis were considered eligible for further analysis in the multivariable logistic regression model. A statistically significant association was declared when the p-value was 0.05 or below. Multicollinearity was assessed by calculating the variance inflation factor, while the adequacy of model fitness was checked using the Hosmer-Lemeshow goodness-of-fit test. The results were presented in text, tables, and graphs based on the data types.

Results

Sociodemographic characteristics of the study participants

A total of 383 adults with HF participated in this study, with a response rate of 100%. Of these, 184 (48.04%) were male, with a mean age of 55.1±15.38 years. A total of 196 (51.17%) participants were married and 184 (48.04%) were employed. Nearly three-fourths, or, 286 (74.67%), resided in urban areas and 114 (29.77%) had low levels or no formal education. Additionally, nearly three-fourths, or 276 (72.06%) of the study participants were enrolled in the community health insurance (CHI) scheme. Details of the sociodemographic characteristics of the participants are summarised in Table 12.

Table 12: Sociodemographic characteristics of people with HF in Ethiopia, 2023 (n=383)

Variables	Category	Frequency (%)
Age	18-39	74 (19.32)
	40-69	222 (57.96)
	≥70	87 (22.72)
Sex	Male	184 (48.04)
	Female	199 (51.96)
Marital status	Single	65 (16.97)
	Married	196 (51.17)
	Divorced	33 (8.62)
	Widowed	69 (18.02)
	Separated	20 (5.22)
Employment status	Employed	184 (48.04)
	Unemployed	199 (51.96)
Residence	Urban	286 (74.67)
	Rural	97 (25.33)
Educational level	Low or no education	114 (29.77)
	Primary education	108 (28.20)
	Secondary education	87 (22.72)
	College and above	74 (19.32)
Community health insurance	Yes	276 (72.06)
	No	107 (27.94)

Clinical characteristics of the study participants

Most participants (87.73%) reported no family history of HF, while 132 (34.46%) had a history of hospitalisation in the previous twelve months. The mean duration of HF among participants was 2.5 years, and the majority, 276 (72.06%) took less than five medications daily. Of the participants, 169 (44.13%) had comorbid hypertension and 80 (20.89%) had comorbid diabetes. Additionally, 135 (35.25%) participants were classified in NYHA class I, and 100 (26.11%) had a poor General Health Perception. The mean social support score of the participants on OSLO-3 was 8.98 ±2.94. Details of the clinical characteristics are summarised in Table 13.

Table 13: Clinical characteristics of people with HF in Ethiopia, 2023 (n=383)

Variables	Category	Frequency (%)
Family history of heart failure	No Yes	336 (87.73) 47 (12.27)
History of hospitalisation in the last 12 months	No Yes	251 (65.54) 132 (34.46)
Comorbidities		
Hypertension	Yes	169 (44.13)
Diabetes	Yes	80 (20.89)
Kidney disease	Yes	29 (7.57)
COPD and asthma	Yes	11 (2.87)
Cancer	Yes	3 (0.78)
HIV/AIDS	Yes	19 (4.96)
Length of time since HF diagnosis	<1year 1–5 years 5–10 years 10–15 years >15 years	65 (16.97) 154 (40.21) 107 (27.94) 34 (8.88) 23 (6.01)
Medications taken daily	<5 ≥5	276 (72.06) 107 (27.94)
NYHA class	Class I Class II Class III Class IV	135 (35.25) 117 (30.55) 93 (24.28) 38 (9.92)
General health perception	Excellent Very good Fair Poor	32 (8.36) 102 (26.63) 149 (38.90) 100 (26.11)
Social support scores (Mean ± SD)		8.98 ±2.94

The PHQ-9 scale scores and the prevalence of depression among participants

Participants were asked about their experiences in the two weeks before the interview: 136 (35.51%) reported little interest or pleasure in doing things for several days, while 117 (30.55%) had trouble falling or staying asleep, or sleeping too much, over several days. Additionally, 103 (26.89%) had poor appetite, and 99 (25.85%) reported trouble falling or staying asleep, or sleeping too much, more than half the days. Only a small percentage (5.48%) thought they would be better off dead or considered hurting themselves. Descriptive statistics for individual items on the PHQ-9 scale scores are summarised in Table 14.

Table 14: Descriptive statistics for individual items of PHQ-9 scale.

PHQ-9 items	Frequency (%)			
How often have you bothered by any of the following problems over the last 2 weeks?	Not at all	Several days	More than half the days	Nearly everyday
Little interest or pleasure in doing things	94 (24.54)	136 (35.51)	109 (28.46)	44 (11.49)
Feeling down, depressed, or hopeless	122 (31.85)	125 (32.64)	72 (18.80)	64 (16.71)
Trouble falling or staying asleep, or sleeping too much	109 (28.46)	117 (30.55)	99 (25.85)	58 (15.14)
Feeling tired or having little energy	16 (4.18)	104 (27.15)	123 (32.11)	140 (36.55)
Poor appetite or overeating	107(27.94)	115 (30.03)	103 (26.89)	58 (15.14)
Feeling bad about yourself or that you are a failure or have let yourself or your family down	130 (33.94)	111 (28.98)	66 (17.23)	76 (19.84)
Trouble concentrating on things, such as reading the newspaper or watching television	175 (45.69)	120 (31.33)	62 (16.19)	26 (6.79)
Moving or speaking so slowly that other people could have noticed	117 (30.55)	120 (31.33)	78 (20.37)	68 (17.75)
Thoughts that you would be better off dead, or of hurting yourself	232 (60.57)	77 (20.10)	53 (13.84)	21 (5.48)

Participants' PHQ-9 scores ranged from 1 to 27 and were categorised as follows: minimal depression (0-4), mild depression (5-9), moderate depression (10-14), moderately severe depression (15-19), and severe depression (20 or higher). The results indicated that 18.28% of participants had minimal depression, 25.07% had mild depression, 28.98% had moderate depression, 19.84% had moderately severe depression, and 7.83% had severe depression (Figure 18). The mean PHQ-9 score of the participants was 11.02±6.14, signifying that, on average, they had moderate depression. In total, 217 (56.66%) of the participants in this study had comorbid depression.

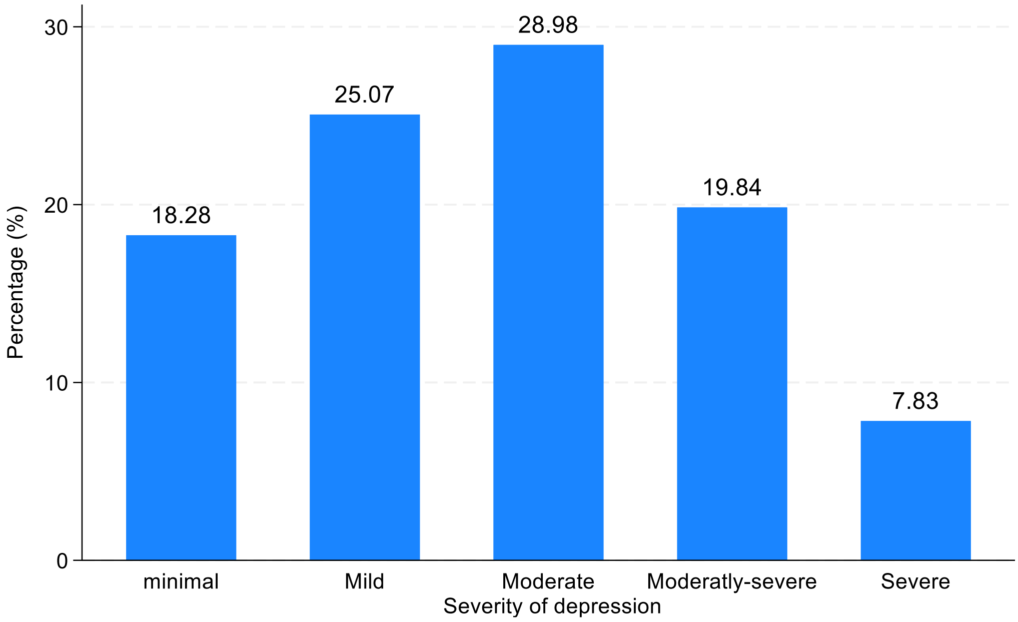

Figure 18: Severity of depression among adults with HF in Ethiopia

Factors associated with comorbid depression in adults with heart failure

The binary logistic regression analysis revealed that several factors, including age, gender, marital status, employment status, educational level, hospitalisation history, diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), number of medications, NYMA class, social support, and general health perception were significant, with a *p*-value of less than 0.20 during the bivariable analysis. Consequently, these variables were included in the final model. However, in the multivariable logistic regression analysis, only six independent variables (gender, comorbid diabetes, NYHA class, social support, number of medications, and general health perception) showed a significant association with depression ($p \leq 0.05$).

The odds of comorbid depression were 2.31 (95% CI 1.30, 4.08) times higher among females compared to males. Participants with HF and diabetes were 3.16 (95% CI 1.47, 6.82) times more likely to be depressed compared to those without diabetes. Additionally, participants taking more than five medications daily had 5.26 (95% CI 2.72, 10.18) times higher odds of comorbid depression compared to those taking fewer medications. The binary logistic regression analysis of factors associated with comorbid depression in adults with HF is summarised in Table 15.

Table 15: Bivariable and multivariable logistic regression analyses of factors associated with depression in adults with HF in Ethiopia, 2023, (n=383).

Variables	Depression		COR (95% CI)	AOR (95% CI)	P-value
	Yes N (%)	No N (%)			
Age					
18-39	38 (17.51)	36 (21.69)	1	1	
40-69	124 (57.14)	98 (59.04)	1.20 (0.71,2.03)	0.71 (0.34,1.46)	0.346
≥70	55 (25.35)	32 (19.28)	1.63 (0.87,3.06)	0.49 (0.19,1.28)	0.145
Sex					
Male	90 (41.47)	94 (56.63)	1	1	
Female	127 (58.53)	72 (43.37)	1.84 (1.22,2.77)	2.31 (1.30,4.08)	0.004*
Marital status					
Single	34 (15.67)	31 (18.67)	0.88 (0.50,1.54)	1.09 (0.53,2.25)	0.808
Married	109 (50.23)	87 (52.41)	1	1	
Divorced	23 (10.60)	10 (6.02)	1.84 (0.83,4.06)	1.53 (0.54,4.29)	0.423
Widowed	41 (18.89)	28 (16.87)	1.17 (0.67,2.04)	0.81 (0.37,1.78)	0.603
Separated	10 (4.61)	10 (6.02)	0.80 (0.32,2.00)	0.51 (0.16,1.65)	0.260
Educational level					
Illiterate	71 (32.72)	43 (25.90)	1	1	
Primary	69 (31.80)	39 (23.49)	1.07 (0.62,1.85)	0.76 (0.37,1.60)	0.458
Secondary	40 (18.43)	47 (28.31)	0.52 (0.29,0.91)	0.62 (0.29,1.30)	0.204
College & above	37 (17.05)	37 (22.29)	0.61 (0.33,1.10)	0.96 (0.41,2.24)	0.928
Diabetes mellitus					
No	150 (69.12)	153 (92.17)	1	1	
Yes	67 (30.88)	13 (7.83)	5.26 (2.79,9.92)	3.16 (1.47,6.82)	0.003*
COPD					
No	208 (95.85)	164 (98.80)	1	1	
Yes	9 (4.15)	2 (1.20)	3.55 (0.76,16.65)	2.43 (0.41,14.49)	0.329
NYHA class					
Class I	62 (28.57)	73(43.98)	1	1	

Class II	62 (28.11)	56(33.73)	1.28 (0.78,2.11)	1.00 (0.54,1.87)	0.997
Class III	62 (28.11)	32(19.28)	2.24 (1.30,3.78)	1.59 (0.78,3.23)	0.204
Class IV	33 (15.21)	5(3.01)	7.77 (2.86,21.12)	3.59 (1.05,12.30)	0.042*
Social support					
Poor	123 (56.68)	35(21.08)	7.14 (4.05,12.57)	6.04 (2.97,12.32)	0.001*
Moderate	62 (28.57)	66(39.76)	1.91 (1.10,3.29)	1.78 (0.89,3.57)	0.103
Strong	32 (14.75)	65(39.16)	1	1	
Employment status					
Employed	87 (40.09)	97(58.43)	1	1	
Unemployed	130 (59.91)	69(41.57)	2.10 (1.39,3.17)	1.18 (0.67,2.09)	0.562
Hospitalisation History					
No	134 (61.75)	117(70.48)	1	1	
Yes	83 (38.25)	49(29.52)	1.48 (0.96,2.28)	1.05 (0.60,1.83)	0.863
Number of medications daily					
<5	133 (61.29)	143(86.14)	1	1	
≥5	84 (38.71)	23(13.86)	3.93 (2.34,6.59)	5.26 (2.72,10.18)	0.001*
Health perception					
Excellent	11 (5.07)	21 (12.65)	1	1	
Very good	36 (16.59)	66 (39.76)	1.04 (0.45,2.40)	1.24 (0.44,3.44)	0.684
Fair	93 (42.86)	56 (33.73)	3.17 (1.42,7.07)	3.50 (1.29,9.52)	0.014*
Poor	77 (35.48)	23 (13.86)	6.39 (2.69,15.19)	4.74 (1.64,13.73)	0.004*

Note. N=Frequency; COPD: Chronic obstructive pulmonary disease**;** CI: Confidence Interval; COR: Crude Odds Ratio; AOR: Adjusted Odds Ratio; NYHA: New York Heart Association.

Discussion

Comorbid depression in adults with HF is a relatively common problem that is associated with increased mortality and morbidity (Di Palo, 2020; Sbolli et al., 2020). Given this context, this study aimed to determine the prevalence of comorbid depression and identify its associated factors among adults with HF in Ethiopia.

This study revealed that the prevalence of comorbid depression was 56.66% (95% CI 51.53, 61.68) among adults with HF, which aligns with a similar study conducted in Northwest Ethiopia (Yazew et al., 2019). Our previous systematic review and meta-analysis also demonstrated a comparable pooled prevalence of depression among adults with HF in low- and middle-income countries (LMICs) (H. Mulugeta et al., 2023). These findings demonstrate that depression in adults with HF is under diagnosed and under-treated in LMICs, including

Ethiopia, indicating a higher prevalence of depression compared to developed countries. For instance, the prevalence of depression in adults with HF was 17.3% in the USA (Chobufo et al., 2020), 28.6 % in the UK (Haworth et al., 2005), 29.7% in Spain (Diez-Quevedo et al., 2013), and 41% in the Netherlands (Lesman-Leegte et al., 2006). The higher prevalence rate in our study could be due limited access to healthcare, including mental health services (Hailemariam et al., 2012; Tsega et al., 2023), which might hinder the early identification and treatment of depression. Developed countries generally have more stable economies, which contribute to reduced stress and anxiety, thereby lowering the risk of depression (Rutledge et al., 2006). Conversely, the prevalence in this study is lower than in similar studies conducted in Jordan (65%) (AbuRuz, 2018), Pakistan (66%) (Husain et al., 2019), South Korea (67.9%) (Son et al., 2012), and Indonesia (85.2%) (Okviasanti et al., 2021). This discrepancy might be due to differences in methodology, measurement tools, the definition of depression, sample size, and the socioeconomic conditions of the study participants. These results support the notion that researchers and the audience should take contextual and methodological factors into consideration while interpreting and comparing prevalence rates across different studies.

In this study, females had a higher prevalence of depression than males. This finding is consistent with the results of other studies (Chobufo et al., 2020; Gottlieb et al., 2004; Kao et al., 2014). A meta-analysis on the global prevalence of depression in adults with HF also found a higher prevalence of depression among women compared to men (Moradi et al., 2021). Females are more susceptible to stressors related to caregiving and family responsibilities, which could contribute to higher rates of depression (Pushkarev et al., 2019). Hormonal differences between men and women may also play a role in the development and severity of depression (Sousa et al., 2017; Thomas & Clark, 2011). This underscores the need to consider gender-specific interventions aimed at reducing the prevalence of depression among female patients with HF.

Our study showed that adults with diabetes had a significantly higher prevalence of depression compared to those without diabetes. Similar findings have been observed in other studies (DeWolfe et al., 2012; Husain et al., 2019). The burden of complications, financial stress, poor glycaemic control, and overall poor health status among adults with both HF and diabetes can be overwhelming and stressful. This can lead to feelings of frustration and hopelessness, which, in turn, may contribute to the development of depression in this population (Bădescu et al., 2016; Chaudhry et al., 2013; Pouwer et al., 2013). Adults with NYHA class IV had significantly higher prevalence of depression compared to those with NYHA class I, which is consistent with previous similar studies (Fan & Meng, 2015; Nguyen et al., 2022; Okviasanti et al., 2021; Tran et al., 2022). Adults with higher NYHA classes experience more severe symptoms and limitations, which can increase the risk of depression (Zhou et al., 2022). These finding collectively emphasise the importance of developing effective interventions for addressing depression for people living with both HF and diabetes, especially those with advanced diseases stages.

Consistent with previous studies (Compare et al., 2013; Graven et al., 2017; Scardera et al., 2020; Yazew et al., 2019), our findings demonstrated a significant association between social support and depression. People with poor social support were more likely to be depressed compared to those with strong social support. A recent systematic review also found that social support serves as a protective factor against depression in Western countries (Gariepy et al., 2016). Social support provides both emotional and practical assistance, helping people to cope with the challenges of HF. Those who lack social support may feel isolated, lonely, and overwhelmed (Gariepy et al., 2016; Scardera et al., 2020), which can contribute to the development of depression. This underscores the importance of incorporating strong social support networks into HF care plans aimed at reducing the burden of depression and improving overall well-being.

There was a significant association between the number of medications taken daily and depression. Participants taking more than five medications daily had a higher prevalence of depression. This finding is in line with a systematic review and meta-analysis which found polypharmacy was significantly associated with an increased risk of depression in adults with HF (Palapinyo et al., 2021). This could be due to increased side effects and adverse reactions, which can lead to negative emotions, including depression (Mastromarino et al., 2014; Palapinyo et al., 2021). Considering this finding, careful monitoring of the patients' medication regimens and educating them about the medication management, including the importance of adherence and potential side effects, are critical for reducing the influence of polypharmacy on mental health outcomes in people with HF.

Determining the prevalence of comorbid depression and associated factors in adults with HF has important clinical implications. It informs healthcare providers regarding the burden of depression on these populations, thereby improving the development of appropriate care strategies. Addressing comorbid depression in adults with HF may lead to improvements in outcomes such as health-related quality of life, morbidity, and mortality. Identification of various sociodemographic and clinical characteristics as a factor affecting depression could be critical in developing interventions aimed to address the specific needs of individuals with HF.

Although this study provides current evidence on comorbid depression in adults with HF in Ethiopia, it has limitations that should be considered when interpreting its results. This study was cross-sectional in nature, which means it cannot establish causality (Savitz & Wellenius, 2023; Setia, 2016) or determine the relationship between depression and sociodemographic and clinical variables. The study used self-reported data to measure depression and other independent variables, which can be subjective to recall bias and social desirability bias (Althubaiti, 2016). Dichotomising PHQ-9 scores may misclassify individuals and ignore small variations in the severity of depression symptoms, which could reduce the sensitivity and depth of the data analysis. Lastly, depressive symptoms may change over time, and this study only captured data at a single point in time. Therefore, longitudinal studies are required to investigate the temporal relationship between variables and to track changes in depressive symptoms over time.

Conclusion

This study found that more than half of all adults with HF in Ethiopia had comorbid depression. Factors such as gender, comorbid diabetes, NYHA class, social support, number of daily medications, and general health perception were significantly associated with comorbid depression in adults with HF. Healthcare providers should be aware of the high prevalence of depression in this population and should incorporate regular depression screening into their routine care practices. Moreover, effective multimodal interventions, such as psychosocial interventions targeting the improvement of mental health, should be carefully developed to reduce the burden of comorbid depression in this population.

List of abbreviations

AOR: Adjusted Odds Ratio; CI: Confidence Interval; COPD: Chronic obstructive pulmonary disease; COR: Crude Odds Ratio; DM: Diabetes Mellitus; DSM-5: Diagnostic and Statistical Manual of Mental Disorders; GHP: General Health Perception; HF: Heart Failure; HRQoL: Health-Related Quality of Life; NYHA: New York Heart Association; OSSS-3: Oslo Social Support Scale; PHQ-9: Patient Health Questionnaire.

Declarations

Ethics approval and consent to participate.

The study was approved by the University of Technology Sydney (UTS) Human Research Ethics Committee (UTS HREC REF NO. ETH21-6739), and local ethical approval was obtained from the institutional review board (IRB) of each hospital where data collection took place. The purpose, risk, and benefit of the study were all thoroughly explained to the participants before conducting data collection. Written informed consent was obtained from participants who agreed to participate, and they were assured of the anonymity and confidentiality of their personal information. The data were collected in a quite area at the hospital.

Consent for publication

Not applicable

Competing interests

The authors report no competing interests.

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Availability of data and materials

All the data analysed in this study are available from the corresponding author upon a reasonable request.

Author contributions

All authors (HM, PS, and AW) were involved in the conception, study design, methods, data collection, analysis, and interpretation. All authors have read and approved the final draft of the manuscript.

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CHAPTER 5: QUANTITATIVE RESULTS II

5.1. Health-related quality of life of people with heart failure in Ethiopia

5.1.1. Chapter overview

This chapter describes one of the key results from the quantitative survey. It begins by presenting the results of the reliability and validity analysis conducted on the Amharic version of the MLHFQ. The analysis includes detailed statistical assessments to ensure that the translated questionnaire maintains the psychometric properties of the original version, such as internal consistency and face, content, and construct validity (CFA).

Next, the chapter investigates HRQoL and its influencing factors among people with HF, utilising the revised Wilson and Cleary model as a conceptual framework. The introduction section describes the burden of HF and its multifaceted impact on affected individuals. The authors also highlight the lack of research addressing HRQoL in people with HF in Ethiopia. The methods section outlines the specific methods conducted during the quantitative survey. The results section presents the overall HRQoL score and its subscales (physical and emotional), and factors influencing the overall HRQoL. The findings were further used to develop an interview guide for Phase III of the study, which involved qualitative interviews. Finally, this chapter discusses and interprets the study findings within the framework, by comparing them with the existing literature and discussing the implications of the results for clinical practice, policy, and future research.

Following peer reviews, the manuscript was published in Scientific Reports (Q1 journal).

5.1.2. Translation, cultural adaptation, and validation of the Amharic version of the MLHFQ

Translation: The standard forward–backward procedure was applied to translate the MLHFQ from English into the local Ethiopian language, Amharic. Two independent translators, fluent in both English and Amharic and familiar with Ethiopian culture, made the initial translation from the original language to the local language. The research team and translators met to synthesise the results of the translations, resolving any discrepancies. Then, the initial translation was independently back translated from the synthesised Amharic version into the original English language to ensure the accuracy of the translation. The original and back translated versions were reviewed by a panel of experts, including researchers, translators, and health professionals in the field, to develop the prefinal version for pre-testing. Finally, the prefinal version was tested on a sample of 40 people with HF to check for understanding, interpretation, and cultural relevance of the translated MLHFQ. The preliminary pre-testing helped identify and address any issues with question comprehension or cultural applicability, resulting in necessary corrections, including wording changes.

Cultural adaptation

A panel of six experts, each a subject matter expert, researcher, and professional in the field (specialised in cardiology and mental health), evaluated the translated MLHFQ for its suitability for the cultural and linguistic context of Ethiopia. Cultural adaptation involves considering the socio-cultural context of the target population in the questionnaire. These experts have examined the clarity, appropriateness, and unambiguousness of the items in the tool about Ethiopian culture. All experts agreed that all items in the tool were culturally appropriate and relevant to the Ethiopian context. However, experts suggested changing the wording of a few questions to allow a better understanding of the items for the respondents. Necessary corrections of wording were made using locally spoken and culturally acceptable words.

Reliability (Internal consistency)

Cronbach’s alpha (α) coefficients were calculated to evaluate the internal consistency of the MLHFQ. It ranges from 0 to 1, with higher values indicating that items are more strongly interrelated with one another (Nawi et al., 2020). The analysis showed that the Cronbach’s α coefficient of the total MLHFQ was 0.90, indicating good internal consistency. There were no inter-item correlations with values greater than 0.80. An inter-item correlation between 0.2 and 0.8 is often considered acceptable for items measuring the same construct (Briggs & Cheek, 1986; Ho, 2006). Additionally, the internal consistencies for the physical and emotional subscales were 0.87 and 0.84, respectively. These findings collectively indicate that the MLHFQ, and its subscales demonstrate adequate internal consistency in measuring the impact of HF on HRQoL.

Validation: Face validity, Content validity, Construct validity (CFA)

Face and content validity

The experts were also asked to evaluate the face and content validity of the translated instrument. Face validity, the subjective judgment of the tool, was evaluated in terms of its clarity, relevance, and appropriateness of the items. A content validity index (CVI) was used to assess the content validity of the tool. The CVI quantifies the degree to which experts agree that the items in the tool are relevant and representative of the construct being measured (Almanasreh et al., 2019). The item-level CVI (I-CVI) and scale-level CVI (S-CVI) were also calculated. The analysis revealed that the overall S-CVI was 0.87. Typically, an S-CVI of 0.83 or higher is considered acceptable for the overall scale (Yusoff, 2019).

Construct validity.

Construct validity was examined through confirmatory factor analysis (CFA). The result of the CFA showed an acceptable overall fit of the data to the model (CFI=0.92, RMSEA=0.10, SRMR=0.10, x2=278.047 with p<0.001). The loadings of items on the corresponding factors were good and positive, ranging 0.50 to 0.84 for all items except for item 2, which was borderline at 0.40 (Figure 19). The factor loadings greater than ±0.33 are considered to meet the minimal level of practical significance (Ho, 2006; Xia & Yang, 2019). In addition, a correlation analysis, as part of the construct validity of the MLHFQ, was conducted to test its hypothesised correlation with other variables. For example, an expected correlation between MLHFQ scores and depression scores (r=0.77, p<0.001) was found, supporting the construct validity of the translated MLHFQ.

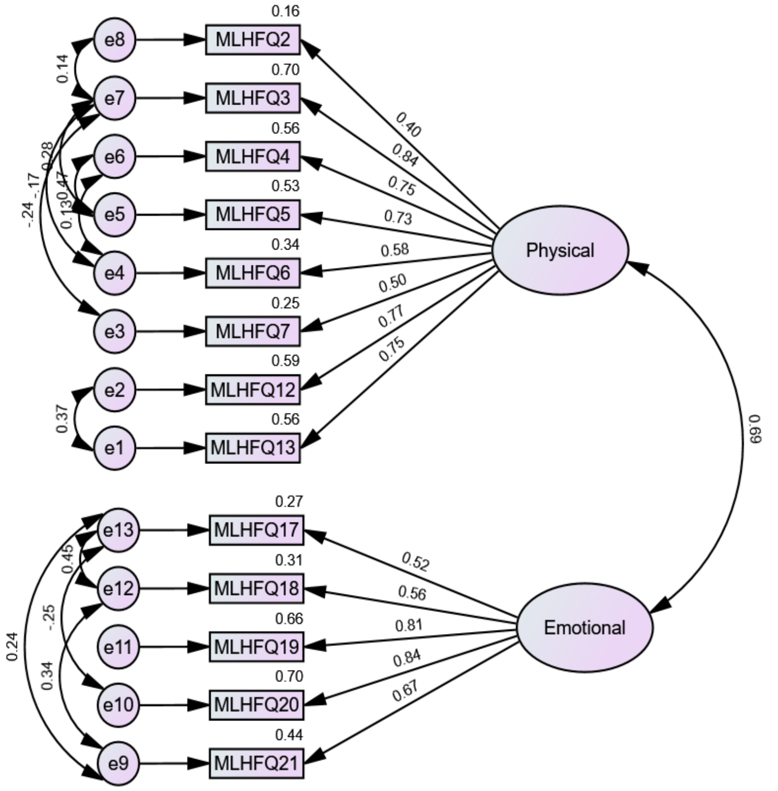

Figure 19: Confirmatory factor analysis of the MLHFQ (N=383)

Although these steps provide preliminary evidence for the reliability and validity of the MLHFQ in the Ethiopian context, it is important to recognize that validation is an ongoing process. While our psychometric analysis results for the tool are acceptable, they indicate areas for improvement. These borderline findings highlight the need for further refinement and testing in larger and more diverse samples to strengthen the psychometric properties of the tool. Additionally, refining the factor structure, such as exploring the potential existence of a third factor, may offer deeper insights into the multidimensional impact of heart failure on HRQoL. Such efforts are essential to ensure that the MLHFQ consistently and accurately measures HRQoL as intended, while accommodating the unique cultural context, language nuances, and social norms of the Ethiopian population.

Publication: Paper Four

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Principal author

Name of principal author	Henok Mulugeta TESHOME
Contribution to the paper	• *Conceived the study aims and design* • *Performed analysis and interpreted the data* • *Wrote the first draft of the manuscript* • *Revised drafts of manuscript based on comments from co- authors* • *Acted as corresponding author*
Overall percentage (%)	80% contribution
Certification	I hereby certify that this paper has been written by me during the period of my higher degree research candidature, and its content is primarily based on my own original work,

	unless stated otherwise. All references and all sources of information have been appropriately acknowledged	
Signature	Production Note: Signature removed prior to publication.	Date: 01/05/24

Co-Author contributions.

By signing the Statement of Authorship, each author certifies that:

- *The candidate's stated contribution to the publication is accurate*
- *Permission is granted for the candidate to include the publication in the thesis*
- *The sum of all co-author contributions is equal to 100% less the candidate's stated contribution.*

Name of Co-Author	A/ Professor Peter M. Sinclair	
Contribution to the paper	Contributed to the design of the study, validated the data analysis, interpretation of the findings, and reviewed and approved the final manuscript.	
Signature	Production Note: Signature removed prior to publication.	Date: 07.07.24
Name of Co-Author	Professor Amanda Wilson	
Contribution to the paper	Contributed to the design of the study, validated the data analysis, interpretation of the findings, and reviewed and approved the final manuscript.	
Signature	Production Note: Signature removed prior to publication.	Date:10/07/24

5.1.3. Publication: Health-related quality of life and its influencing factors among people with heart failure in Ethiopia: Using the revised Wilson and Cleary model

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Health-related quality of life and its influencing factors among people with heart failure in Ethiopia: using the revised Wilson and Cleary model

Henok Mulugeta[1,2]✉, **Peter M. Sinclair**[2] & **Amanda Wilson**[2]

Heart failure is a challenging public health problem associated with poor health-related quality of life (HRQoL). Data on the quality of life of people with heart failure are limited in Ethiopia. This study aimed to assess the HRQoL and its influencing factors in people with heart failure in Ethiopia. A hospital-based, cross-sectional study design was conducted in the cardiac outpatient clinics of two tertiary-level hospitals in Addis Ababa, Ethiopia. Data were collected from people with heart failure who met the inclusion criteria using an interviewer-administered questionnaire. The HRQoL was measured using the Minnesota Living with Heart Failure Questionnaire (MLHFQ). A multiple linear regression model was fitted to identify factors that influenced HRQoL. All statistical analyses were conducted using STATA version 17 software. A total of 383 people with heart failure participated in the study. The mean age of the participants was 55 years. The MLHFQ score was 48.03±19.73, and 54% of participants had poor HRQoL. Multiple linear regression analysis revealed that age (β= 0.12, 95% CI 0.11, 0.28), diabetes mellitus comorbidity (β= 4.47, 95% CI 1.41, 7.54), social support score (β= − 1.48, 95% CI − 1.93, − 1.03), and depression score (β = 1.74, 95% CI 1.52, 1.96) were significant factors influencing overall HRQoL ($p < 0.05$). This study found that people in Ethiopia with heart failure had poor HRQoL, influenced by several factors. The findings can help health professionals identify appropriate interventions to improve the HRQoL of people with heart failure.

Abbreviations

CI	Confidence interval
CVD	Cardiovascular disease
HF	Heart failure
HRQoL	Health-related quality of life
MLHFQ	Minnesota living with heart failure questionnaire
NYHA	New York heart association
NCDs	Non-communicable diseases
OSSS-3	Oslo social support scale
PHQ-9	Patient health questionnaire
SE	Standard error

Heart failure (HF) is a chronic medical condition associated with high morbidity and mortality rates[1]. It is diagnosed in one to two of every 100 adults in the general population, but the actual prevalence is probably around 4%[2]. Its risk factors include age, coronary artery disease, rheumatic heart disease, hypertension, and diabetes mellitus. Heart failure is the most common type of cardiovascular disease (CVD) in Africa and has a great social and economic impact mainly affecting young individuals. Rheumatic heart disease is one of the most prevalent risk factors for HF, occurring in 14 % of people with HF in sub-Saharan Africa[3–5]. According to the international

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Background

Heart failure (HF) is a chronic medical condition associated with high morbidity and mortality rates (Thida et al., 2021). It is diagnosed in one to two of every 100 adults in the general population, but the actual prevalence is probably around 4% (Amy Groenewegen et al., 2020). Its risk factors include age, coronary artery disease, rheumatic heart disease, hypertension, and diabetes mellitus. Heart failure is the most common type of cardiovascular disease (CVD) in Africa and has a great social and economic impact, mainly affecting young individuals. Rheumatic heart disease is one of the most prevalent risk factors for HF, occurring in 14% of people with HF in sub-Saharan Africa (Arrigo et al., 2020; Meijers & de Boer, 2019; Nyaga et al., 2018). According to the International Congestive Heart Failure Study report, the highest annual mortality in people with HF was observed in Africa (Dokainish et al., 2017). In Ethiopia, the in-hospital mortality due to HF is high (Tirfe et al., 2020).

Health-related quality of life (HRQoL) is an individual's perception of their physical, social, emotional, psychological, and mental functioning (Anderson & Ozakinci, 2018; Kang et al., 2016). Measuring HRQoL is often used to assess the effectiveness of HF treatment and the course of the disease (Westlake et al., 2002). Living with HF is challenging as it has a poor prognosis and increased socioeconomic burden due to increased healthcare costs, debilitating symptoms, such as dyspnoea, oedema, fatigue, and sleep disturbance, and frequent hospitalisations, which collectively, significantly impact HRQoL. Poor HRQoL increases the risk of hospitalisation and death (Hobbs et al., 2002).

Many factors influence the HRQoL of people with HF. The revised Wilson and Cleary model is a practical conceptual framework that incorporates the relationship between different health concepts to guide quality of life research (Ferrans et al., 2005). According to this model, HRQoL is affected by individual characteristics, biological function, environmental characteristics, symptoms, functional status, and general health perceptions. Previous studies have identified multiple predictors of poor HRQoL, including gender (female), age (young), marital status (single), income and educational levels (low), presence of depression (high New York Heart Association (NYHA) functional class), tobacco exposure, low ventricular ejection, history of hospitalisation, comorbidity, polypharmacy, poor medication adherence and duration of heart failure (Boombhi et al., 2019; Chu et al., 2014; Demir & Unsar, 2011; Hwang et al., 2014; Shojaei, 2008; Silavanich et al., 2019). Identifying meaningful factors influencing HRQoL is critical to develop effective interventions to improve prognosis in this cohort (AbuRuz et al., 2016).

Improving symptoms and physical functioning are the major aims of heart failure management. Effective means of measuring how much the disease affects this population provides insights into targeted management interventions (AbuRuz et al., 2016; Butler et al., 2021). Both pharmacologic and non-pharmacologic interventions can enhance overall health and reduce poor health outcomes, and are recommended as an integral part of disease management strategies (Lin et al., 2020; Mo et al., 2020). A systematic review and meta-analysis of randomised controlled trials showed significant overall HRQoL improvement after conducting psychosocial interventions for people with HF (Samartzis et al., 2013). In Ethiopia, the government developed a comprehensive guideline for clinical management and care for major non-communicable diseases (NCDs) including HF. This is a major initiative aiming to reduce the increasing burden of NCDs in Ethiopia (Dagnaw et al., 2016).

Heart Failure is a major problem with high prevalence; however, few studies have investigated the impact of HF on HRQoL, especially in Africa. The available data indicates that poor quality of life in people with HF is a challenging problem in Ethiopia (Yazew et al., 2019). Consequently, this study sought to assess HRQoL and its influencing factors in people with HF, based on the revised Wilson and Cleary model of HRQoL. Measuring HRQoL provides information about an individual's overall health status and the impact of health interventions (Tito et al., 2022). The findings from this study will inform healthcare policymakers on effective ways to improve care for this population in Ethiopia.

Methods

Study area and period

The study was conducted at the cardiac outpatient clinics of two tertiary-level public hospitals in Addis Ababa, the capital of Ethiopia. St. Paul's Hospital Millennium Medical College and St. Peter Specialized Hospital are government-owned hospitals in Addis Ababa. They are Ethiopia's largest tertiary-level specialist and teaching hospitals, providing referral services for people from all around the country. Currently, the two hospitals collaborate to provide care for patients with cardiac conditions. Each hospital had a weekly average of 30 people with HF coming to visit outpatient clinics for their routine follow-up care.

The survey was conducted between 21 Nov 2022 to 22 Jan 2023.

Study design

A hospital-based survey using a cross-sectional study design was conducted.

Theoretical framework

This study was guided by the revised version of the Wilson and Cleary model of HRQoL (Ferrans et al., 2005). This model provides a clear understanding of variables influencing HRQoL and clarifies the relationships among them to guide quality of life research (Son et al., 2019). According to this model, HRQoL as the outcome variable is influenced by the characteristics of the individual, biological function, symptoms, functional status, characteristics of the environment, and general health perception (Figure 20). It is the most widely used and the recommended model for HRQoL research (Bakas et al., 2012; Ojelabi et al., 2017). This model, in the context of Ethiopia, provides a significant framework for assessing HRQoL that is adapted to the unique healthcare challenges of the country, such as limited resources, poor healthcare access, and diverse socioeconomic conditions, that influence health outcomes (Ayalneh et al., 2017). By applying this model within this context, we identified factors affecting HRQoL of people with HF in Ethiopia.

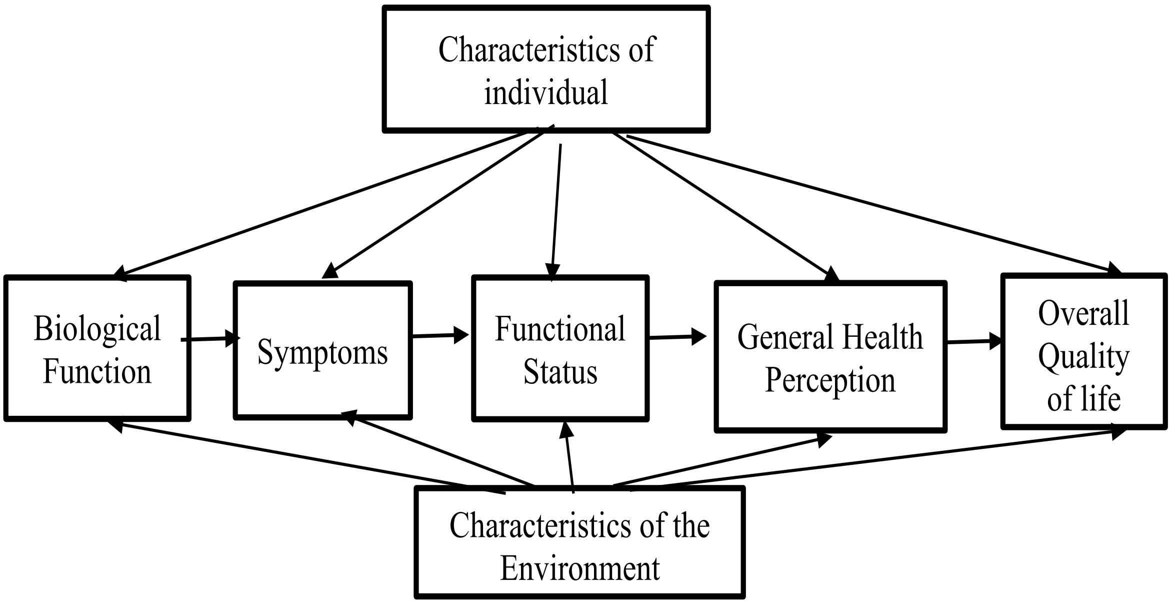

Figure 20: Revised Wilson and Cleary model of HRQoL (Ferrans et al, 2005)

Eligibility criteria and ethics

The following inclusion criteria were considered: 1) adults aged over 18 years of age, 2) diagnosed with heart failure (clinically using Framingham criteria or Echocardiography), 3) receiving follow-up care at the outpatient cardiac clinic for at least three months.

The study was approved by the University of Technology Sydney (UTS) Human Research Ethics Committee (UTS HREC REF NO. ETH21-6739). Local ethical approval was obtained from the institutional review board (IRB) of each hospital where data collection took place. All methods were performed in accordance with the relevant guidelines and regulations.

Sample size and sampling procedure

The sample size was determined using a single proportion formula for finite population, $N=(Z\alpha/2)^{2}*P(1-P)^{2}/D^{2})$ (Suresh & Chandrashekara, 2012), with the assumption of a 95% confidence interval, marginal error (d) of 5.0%, and 51.8% prevalence (P) of low HRQoL among people with HF in Northwest Ethiopia (Seid, 2020). $N=((1.96)^{2}*0.518\ (1-0.518))/0.05^{2}=383$ people with HF.

Consecutive sampling technique was used and all eligible people with HF with an appointment at the outpatient cardiac clinics were invited to participate in the study. Participants who met the inclusion criteria and agreed to provide informed consent were included in this study until the required sample size was achieved.

Variables

Dependent variable:

- *Health-related quality of life*

Independent variables:

- *Characteristics of the individual*
  - *Age, sex, educational status, marital status, health insurance*
- *Biologic function*
  - *Family history of heart failure, comorbidities*
- *Symptoms*

        - *Depression*
- *Functional status*
    - *The severity of heart failure: New York Heart Association (NYHA) class*
- *Characteristics of the environment*
    - *Social support, residence, employment status, duration of illness, history of hospitalisations, number of medications taken each day*
- *Overall health perception*

Operational definitions and definitions of terms

Adult: 18 years and over

Heart failure: inability of the heart to effectively pump blood as evidenced by either signs and symptoms based on Framingham criteria or reduced ejection fraction (<40%) (Hage et al., 2020; Lofstrom et al., 2019).

Health-related quality of life: individuals' perceptions and reactions to the impact of a disease or its treatment on their daily lives. It encompasses many dimensions of life, including physical, functional, emotional, and mental health (Lin et al., 2013). Health-related quality of life of people with HF was measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ). This tool has 21 items or questions that ask participants how their disease has affected their life in the last month. Each question is coded using a six-point Likert-type scale that ranges from 0 (no effect) to 5 (very much effect). These scales are then added together to create a composite score that indicates the participant's overall HRQoL. The scores range from 0 to 105 with higher composite scores representing poorer quality of life. It gives a total score as well as scores on two dimensions: physical (items 2 to 7, 12, and 13, range, 0–40) and emotional (items 17 to 21, range, 0–25). The remaining eight questions (1, 8, 9, 10, 11, 14, 15, and 16) are only considered to calculate the total composite score (Ahmeti et al., 2016; Audi et al., 2017; Rector, 2017). It is a gold standard and widely used disease-specific quality of life measurement instrument that has been validated for use in many countries (Garin et al., 2008; Ho et al., 2007; Hwang et al., 2014; Middel et al., 2001; Moon et al., 2012; Saccomann et al., 2007).

Depression: feelings of unhappiness and lack of interest in daily activities with symptoms for at least two weeks based on DSM-5 diagnostic criteria (Truschel, 2020). Depression was measured using the Patient Health Questionnaire (PHQ-9). This is a 9-item tool based on DSM-IV criteria that can be scored from 0 (not at all) to 3 (nearly every day). Total scores range from 0 to 27, with higher scores indicating a higher likelihood of depression. Each item requires participants to rate the frequency of a depressive symptom experienced in the two weeks prior to assessment. PHQ-9 is a reliable and valid instrument for detecting major depressive disorder among Ethiopian adults with chronic conditions in outpatient settings (Degefa et al., 2020; Gelaye et al., 2013).

The level of social support was measured using the Oslo Social Support Scale (OSSS-3). This scale consists of three items that ask about numbers of close confidants, sense of concern from other people, and relationships with neighbours, with a focus on the availability of practical help. The scores range from 3-14, with high values representing strong levels and low values representing weak levels of social support (Kocalevent et al., 2018). It has good construct and predictive validity and good internal consistency with a Cronbach alpha of 0.91 (Shumye et al., 2019).

General health perception: a representation of all health concepts together which determined overall satisfaction with life using one global question that asks the respondent to rate their overall health on a Likert scale as "excellent", "very good", "fair" or "poor" (Ferrans et al., 2005).

The severity of heart failure: New York Heart Association criteria (NYHA) is used to classify the severity of heart failure as Class I: no limitation during ordinary activity, Class II: slight limitation during ordinary activity, Class III: marked limitation of normal activities without symptoms at rest, Class IV: unable to undertake physical activity without symptoms and symptoms may be present at rest (Miller-Davis et al., 2006).

Data collection procedure and instruments

The questionnaire was adapted from different literature and validated tools, and the process involved translation, cultural adaptation, and validation, which involved professional and language experts and pre-testing. These adaptations were made to ensure that the questionnaire was suitable for the cultural and linguistic context of Ethiopia. The questionnaire consisted of four parts: The first part related to sociodemographic and clinical related characteristics, the second part dealt with social support, the third part measured depression, and the final section evaluated HRQoL. People with HF who met the eligibility criteria were contacted by trained research assistants (RAs) during their routine follow-up visit to the outpatient cardiac clinic of each hospital. RAs collected the data in person using an interviewer-administered questionnaire.

The sociodemographic and clinical characteristics were assessed using a 19-item questionnaire. This questionnaire collected information about age, sex, marital status, employment status, residence, educational level, health insurance, family history of HF, hospitalisation history, comorbidities, duration of illness, NYHA class, number of medications taken each day, and general health perception. The Oslo Social Support Scale (OSSS-3) was used to measure the level of social support, and depression was measured using the Patient Health Questionnaire (PHQ-9). Finally, the Minnesota Living with Heart Failure Questionnaire (MLHFQ) was used to measure the health-related quality of life of participants.

To ensure the quality of data, training on the data collection procedure was provided to the research assistants. The collected data were checked for completeness and clarity daily. Two supervisors supervised the data collection process.

Data management and analysis

Collected data were cleaned and entered into Epi-Data version 3.1 and exported to STATA Version 17 for analysis (StataCorp, 2020). Descriptive analyses were performed to describe the sociodemographic and clinical characteristics of the participants, the OSSS-3, the PHQ-9, and the MLHFQ scores. A linear regression model was fitted to assess the association between independent variables and the dependent variable. First, simple linear regression was performed to test the association between each independent variable with the dependent variable. All independent variables with a p-value of less than 0.25 on the simple linear regression analysis were eligible for further analysis in the multiple linear regression model. The assumptions of linear regression, such as normality, linearity, independence, and homoscedasticity were checked. The results are presented in text, tables, and graphs based on the types of data.

Results

Sociodemographic and clinical characteristics

Three hundred and eighty-three (383) people with heart failure participated in this study with a response rate of 100%. Of these, 199 (51.96%) were female and 184 (48.04%) were male. The mean age of the participants was 55.1 (± 15.38) years. From all participants, 97 (25.33%) came from rural areas and 196 (51.17%) were married. A total of 114 (29.77%) participants did not have any formal education. The Ethiopian Community Health Insurance (CHI) was held by 276 (72.06%) participants and 132 (34.46%) had a history of recent hospitalisation. Concerning comorbidities, 169 (44.13%) and 80 (20.89%) participants had hypertension and diabetes mellitus, respectively. The participants' length of time since HF diagnosis ranged from three months to 22 years, with a mean of 4.80 years. Their mean social support and depression scores were 8.98 ± 2.94 and 11.02 ± 6.14, respectively. In the study, 100 (26.11%) participants had poor general health perception. Other sociodemographic and clinical characteristics are presented in Table 16.

Table 16: Sociodemographic and clinical characteristics of people with HF in Ethiopia, 2023 (n=383)

Variables	Category	N (%) or Mean ± SD
Age (in years)	Mean score	55.1 ± 15.38
Sex	Male	184 (48.04)
	Female	199 (51.96)
Marital status	Single	65 (16.97)
	Married	196 (51.17)
	Divorced	33 (8.62)
	Widowed	69 (18.02)
	Separated	20 (5.22)
Employment status	Employed	184 (48.04)
	Unemployed	199 (51.96)
Residence	Urban	286 (74.67)
	Rural	97 (25.33)
Educational level	Uneducated	114 (29.77)
	Primary education	108 (28.20)
	Secondary education	87 (22.72)
	College and above	74 (19.32)

Health insurance	Yes No	276 (72.06) 107 (27.94)
Family history of heart failure	No Yes	336 (87.73) 47 (12.27)
History of hospitalisation in the last 12 months	No Yes	251 (65.54) 132 (34.46)
Social support scores	Mean score	8.98 ± 2.94
Comorbidities		
Hypertension	Yes	169 (44.13)
Diabetes	Yes	80 (20.89)
Kidney disease	Yes	29 (7.57)
COPD and asthma	Yes	11 (2.87)
Cancer	Yes	3 (0.78)
HIV/AIDS	Yes	19 (4.96)
Duration of illness (in years)	Mean score	4.80 ± 4.65
Number pills taken each day	Mean score	3.98 ± 2.01
NYHA class	Class I Class II Class III Class IV	135 (35.25) 117 (30.55) 93 (24.28) 38 (9.92)
General health perception	Excellent Very good Fair Poor	32 (8.36) 102 (26.63) 149 (38.90) 100 (26.11)
Depression scores	Mean score	11.02 ± 6.14

Health-related quality of life of people with heart failure

In this study, HRQoL of people with HF was assessed with the MLHFQ. The mean of the total MLHFQ score was 48.03 ± 19.73, indicating a poor HRQoL among the study participants. Higher scores on the MLHFQ represent poorer quality of life. The subscale scores of MLHFQ were found to be 21.03 ± 8.46 for the physical scale and 10.12 ± 6.26 for the emotional scale (Table 17).

Table 17: Health-related quality of life scores of people with HF in Ethiopia, 2023 (n=383)

MLHFQ scores	Possible range	Observed range	Mean ± SD
Physical dimension	0-40	0-36	21.03 ± 8.46
Emotional dimension	0-25	0-25	10.12 ± 6.26
Total score	0-105	7-89	48.03 ± 19.73

MLHFQ: Minnesota Living with Heart Failure Questionnaire

The MLHFQ score was used to determine the level of HRQoL as people who score less than 24 labelled as having (good) HRQoL, 24–45 (moderate), and greater than 45 as (poor) HRQoL (Poorshadan et al., 2019). The analysis revealed that 204 (53.26%) participants had a poor HRQoL (Figure 21).

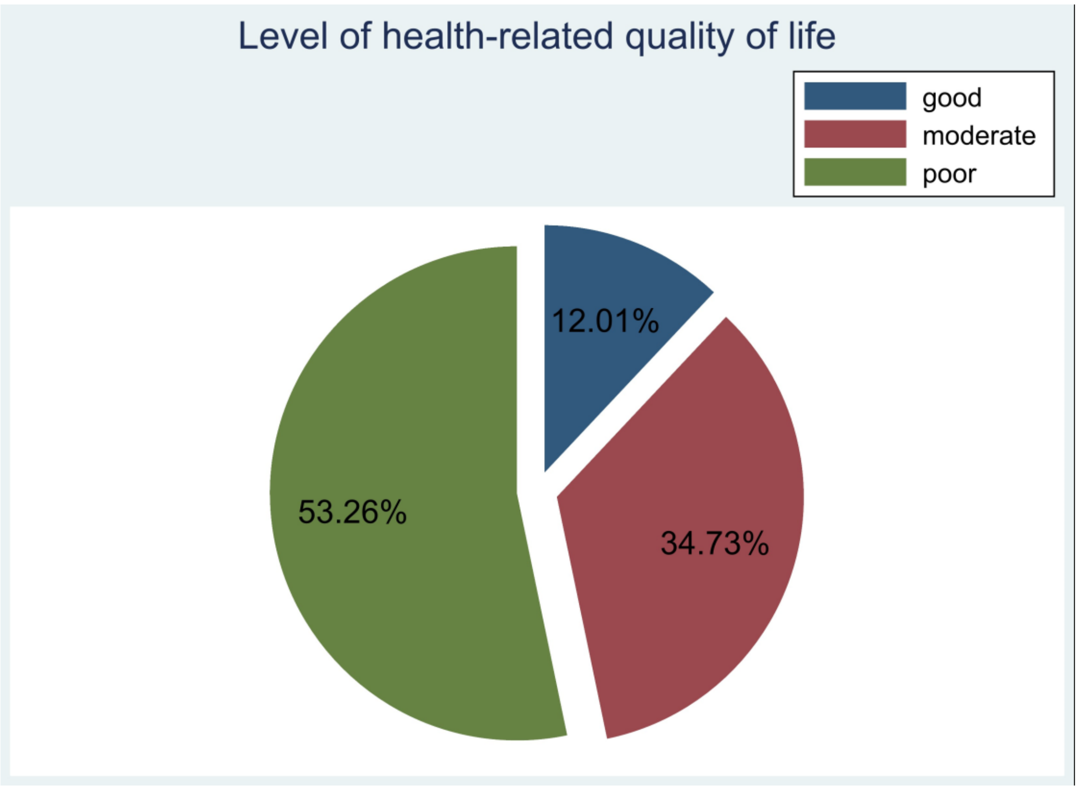

Figure 21: The level of HRQoL among people with heart failure in Ethiopia, 2023.

Factors influencing the HRQoL of people with heart failure

Simple linear regression analysis demonstrated that variables such as age, sex, marital status, employment status, educational level, hospitalisation history, hypertension, diabetes mellitus (DM), Acquired Immune Deficiency Syndrome (AIDS), NYHA class, social support scores, depression scores, and general health perception were factors associated with the MLHFQ score at $p<0.25$ and were eligible for multiple linear regression. The multiple linear regression model revealed that only age, employment status, DM comorbidity, social support scores, NYHA class, depression scores, and general health perception were significantly associated with overall HRQoL of people with heart failure at $p\leq 0.05$. These variables explain 70% of the variation of the overall MLHFQ scores.

Each extra year of age of participants predicts an increase in MLHFQ score by 0.12 (β=0.12, CI= (0.11,0.28), p=0.001). People who were unemployed scored an average 2.73-points higher MLHFQ score than employed people (β=2.73, CI (0.22, 5.24), p=0.033). A 1-unit increase in the Oslo Social Support Score corresponded to a 1.48-unit decrease in MLHFQ score (β=-1.48, CI (-1.93, -1.03), p=0.001). This means that strong social support is positively associated with HRQoL. People with diabetes scored an average 4.47-points higher MLHFQ score than those without diabetes (β=4.47, CI (1.41,7.54), p=0.004). A one unit increase in the PHQ-9 score was associated with an increase in MLHFQ score of 1.744 (β=1.74, CI (1.52,1.96), p=0.001). Compared to participants with NYHA class I, those with class III (β=4.621, CI (1.50,7.74), p=0.004) and IV (β=7.955, CI (3.66,12.25), p=0.001) had a significantly higher HRQoL score, indicating poorer HRQoL as physical limitation or severity increases. The detailed results of the multiple linear regression analysis are presented in Table 18.

Table 18: Multiple linear regression model for factors influencing the HRQoL of people with HF in Ethiopia, 2023 (n=383).

Variables	B	SE	P-value	95% CI
Age	0.120	0.045	0.001*	(0.112, 0.287)
Sex				
Female	0.433	1.272	0.734	(-2.878, 2.935)
Marital status				

Single	2.614	1.608	0.105	(-0.548, 5.777)
Divorced	0.664	2.089	0.751	(-3.444, 4.773)
Widowed	-1.755	1.726	0.310	(-5.150, 1.639)
Separated	1.126	2.567	0.661	(-3.922, 6.174)
Employment status				
Unemployed	2.733	1.277	0.033	(0.223, 5.244)
Educational level				
Primary	1.416	1.548	0.361	(-1.627, 4.460)
Secondary	1.782	1.708	0.298	(-1.578, 5.141)
College and above	1.828	1.826	0.317	(-1.763, 5.420)
Hospitalisation history				
Yes	0.680	1.235	0.582	(-1.749, 3.108)
Hypertension				
Yes	0.906	1.203	0.452	(-1.459, 3.271)
Diabetes mellitus				
Yes	4.472	1.559	0.004*	(1.407, 7.537)
HIV/AIDS				
Yes	5.722	2.670	0.314	(-2.587, 8.031)
Social support score	-1.481	0.228	0.001*	(-1.929, -1.032)
NYHA class				
Class II	1.006	1.417	0.478	(-1.781, 3.793)
Class III	4.621	1.586	0.004*	(1.502, 7.741)
Class IV	7.955	2.182	0.001*	(3.664, 12.245)
Depression score	1.744	0.112	0.001*	(1.524, 1.965)
General health perception				
Very Good	3.914	2.247	0.082	(-0.504, 8.332)
Fair	4.098	2.204	0.064	(-0.237, 8.432)
Poor	4.940	2.349	0.036	(0.321, 9.559)

Note: Model statistics: R^2=0.7023, F (22,360) =42.58, p<0.001
Reference category: male, married, uneducated, employed, NYHA “class I”, “Excellent” health perception, “No” for (hospitalisation history, hypertension, diabetes, HIV/AIDS)
β=standardised beta coefficients, S E =standard error, CI=confidence interval
*Statistically significant

Discussion

Health-related quality of life (HRQoL) is a critically important clinical outcome for people with HF (Kosiborod et al., 2020). This study investigated the HRQoL of people with heart failure and examined its influencing factors using the revised Wilson and Cleary model of HRQoL. In this study, 53.26% (95% CI 48.12, 58.35) of participants had poor HRQoL. This finding is consistent with the result of previous studies conducted in low-middle income countries (An et al., 2022; Molla et al., 2021; Seid, 2020). The mean total MLHFQ scores in the current study was 48.03 (95% CI 46.04, 50.01), which indicates that people with HF have poor physical, emotional, and overall HRQoL. This finding is consistent with the previous similar studies that have shown the negative impact of HF on the physical, emotional, and general aspects of HRQoL (Ahmeti et al., 2016; Molla et al., 2021; Seid, 2020). The mean total MLHFQ score of the current study was higher than similar studies conducted in Brazil (de Sousa et al., 2017; Paz et al., 2019; Sousa et al., 2017), China (J. Zhang et al., 2020), Myanmar (Thida et al., 2021), South Korea (Chu et al., 2014; H. Lee et al., 2020), and Thailand (Silavanich et al., 2019). The higher MLHFQ score in our population could be due to the cohort age, as most participants were aged 40-69 years and had higher rate of depression than reported in studies from other countries. Conversely, the mean of total MLHFQ score in this study was lower than studies conducted in Colombia (Afsharipour et al., 2016), Serbia (Erceg et al., 2013; Jovanic et al., 2018), Georgia (DeWolfe et al., 2012), and South Korea (Jeong et al., 2022). This difference might be due to variations in methodological approaches, sample size, socioeconomic characteristics, and study settings.

The current study identified various sociodemographic and clinical factors influencing the HRQoL of people with HF. Factors such as higher age, unemployment, poor social support, comorbid depression, diabetic comorbidity, higher NYHA class, and poor health perception were significantly associated with low HRQoL in people with HF, after controlling for known confounders, such as gender, hospitalisation history, marital status, educational level, hypertension, and HIV/AIDS.

Sociodemographic factors, such as age and employment, had a strong influence on HRQoL, but gender had a weak influence. Increasing age was significantly associated with an increased MLHFQ score. This was supported by similar studies that reported a decrease in the HRQoL as people aged (Chu et al., 2014; Yaghoubi et al., 2012). This finding can be attributed to the fact that older individuals experience more physical limitations and psychological problems (Audi et al., 2017). A significant negative association between age and HRQoL was observed in other studies; the lower the age, the worse the quality of life (Paz et al., 2019; Sousa et al., 2017). According to the results of previous studies (Chu et al., 2014; Costa et al., 2020; Molla et al., 2021), gender was a significant predictor of poor HRQoL, with women reporting significantly lower quality of life than men. Ahmeti et al. (2016) reported that females had poorer quality of life than males with HF (Ahmeti et al., 2016). However, there was no association between gender and HRQoL in the current study, which is consistent with Erceg and colleagues' (2013) findings. Regarding employment, people who were unemployed had a lower HRQoL than employed people. This finding is supported by previous studies (Chu et al., 2014; Erceg et al., 2013; Pour et al., 2016). This may be attributed to unemployed individuals often having a lower economic status and experience financial hardship due to medication and other health costs, which negatively impact management of HF and reduce their HRQoL (Costa et al., 2020).

Another factor which influenced HRQoL in people with HF was social support. A strong social support network was associated with a better HRQoL. A similar study by Barutcu and Mert (2013) showed that higher levels of social support were significantly associated with better HRQoL in people with HF. In addition, Soleimani et al. (2020) found that people with higher levels of social support had significantly improved HRQoL(Soleimani et al., 2020). Other studies showed that social support improves HRQoL indirectly by enhancing self-care (Jeong et al., 2022; Koirala et al., 2020). This could be because strong social support plays a critical role in helping individuals with emotional support that can help them to cope with the emotional burden of their condition and protect them from harmful outcomes, consequently improving HRQoL (Chung et al., 2013; Jeong et al., 2022).

In the current study, comorbid depression and diabetes mellitus predicted lower HRQoL with a significant association between depression and HRQoL. This finding is consistent with previous studies that reported a strong association between depression and HRQoL (AbuRuz, 2018; Alemoush et al., 2021; Comin-Colet et al., 2020; DeWolfe et al., 2012; Erceg et al., 2013; Son et al., 2012; Tsabedze et al., 2021). Comorbid depression negatively influences an individual's psychosocial well-being and affects self-care practices and treatment adherence (Kato et al., 2011; Loo et al., 2016). Similarly, a significant influence of comorbid diabetes mellitus on the overall HRQoL was observed. The same finding has been reported in previous studies (Alaloul et al., 2017; Fotos et al., 2013; Fritschi & Redeker, 2015). People with diabetes who have poor glycaemic control and associated complications are more likely to experience various health problems that significantly lower their HRQoL (Olivera et al., 2021). In addition, non-cardiovascular comorbidities accelerate disease progression and increase the risk of rehospitalisation, which can lead to additional socioeconomic burden, ultimately reducing HRQoL (Comin-Colet et al., 2020).

In the present study, people with NYHA class III and IV were associated with poor HRQoL. This finding has been reported in many previous studies (Erceg et al., 2013; Eskandari et al., 2016; Polikandrioti et al., 2019). The possible justification for impaired HRQoL being correlated with higher NYHA class could be because the ability to carry out daily activities decreases as the severity of the disease increases, which negatively affects quality of life (Poorshadan et al., 2019).

Limitations and suggestions for future research

The findings of this study have implications for clinical practice. Determining the quality of life of people with HF provides information about the impact of HF on overall perceived well-being. A better understanding of factors influencing HRQoL may help health care professionals to identify effective interventions to improve individuals' HRQoL. This study has several limitations that should be considered when interpreting its results. First, its cross-sectional nature limits its ability to establish cause-and-effect relationships. Therefore, longitudinal studies in this domain are recommended to investigate causal relationships. Second, the use of a self-report questionnaire to collect data in this study could lead to information bias, and participants could be influenced by recall bias or the Hawthorn effect (Perera, 2021). Finally, the influence of critical factors from the Wilson and Cleary model, such as self-care practice, medication adherence, and HF knowledge, were not evaluated in this study. Future research should evaluate these variables to gain a deeper understanding of their influence.

Conclusion

This study reported the impact of HF on the HRQoL in an Ethiopian cohort. The results revealed that more than half of all people living with HF in Ethiopia had a poor HRQoL, as demonstrated by the mean score of total MLHFQ and its subscales. Factors such as age, depression, social support, diabetic comorbidity, and NYHA class were statistically significant in influencing the HRQoL of people with HF. Future interventional studies are recommended with the aim of improving the HRQoL of this population.

List of abbreviations

CI: Confidence Interval; CVD: Cardiovascular Disease; HF: Heart Failure; HRQoL: Health-Related Quality of Life; MLHFQ: Minnesota Living with Heart Failure Questionnaire; NYHA: New York Heart Association; NCDs: Non-communicable Diseases; OSSS-3: Oslo Social Support Scale; PHQ-9: Patient Health Questionnaire; S E =Standard Error

Declarations

Ethics approval and consent to participate.

The study was approved by the University of Technology Sydney (UTS) Human Research Ethics Committee (UTS HREC REF NO. ETH21-6739), and local Ethical approval to conduct the study was obtained from the institutional review board (IRB) of each hospital where the data collection took place. The purpose, risk, and benefit of the study were explained to the participants before conducting data collection. Written informed consent was obtained from participants who agreed to participate, and they were assured of the anonymity and confidentiality of their personal information. The data were collected in a quite area at the hospital.

Consent for publication

Not applicable

Competing interests

The authors report no competing interests.

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Availability of data and materials

All the data analysed in this study are available from the corresponding author upon a reasonable request.

Author contributions

All authors (HM, PS, and AW) were involved in the conception, study design, methods, data collection, analysis, and interpretation. All authors have read and approved the final draft of the manuscript.

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CHAPTER 6: QUALITATIVE INTERVIEW RESULTS

6.1. The experience of people living with heart failure in Ethiopia

6.1.1. Chapter overview

This chapter presents the qualitative findings from Phase III (qualitative interviews) on the experience of people with HF in Ethiopia. The chapter begins by introducing the global burden of HF, its symptoms, treatment, and its multifaceted impact on mental health and HRQoL. The importance of exploring the experiences of people with HF is described, focusing on LMIC like Ethiopia. The comprehensive overview of the qualitative methodology used for the study is discussed, including the study design, the rationale for using the Theory of Symptom Management (TSM) to guide the study, the process of sampling and recruitment, in-depth interview procedure, steps to ensure trustworthiness, and the process of thematic analysis. The results section of the chapter provides the key themes identified deductively from the model and inductively from the data. The results are organised and presented in accordance with the six steps of thematic analysis (Braun & Clarke, 2022), using simple descriptions and direct quotations from the interviews to highlight the experience of the participants. Finally, this chapter contextualises the findings within the existing literature and discusses the relevance of the study for clinical practice, policymaking, and future research.

The manuscript was submitted to PLOS One for publication and have just been accepted for publication after rigorous peer review process.

Publication: Paper Five

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Principal author

Name of principal author	Henok Mulugeta TESHOME
Contribution to the paper	• *Conceived the study aims and design* • *Performed analysis and interpreted the data* • *Wrote the first draft of the manuscript* • *Revised drafts of manuscript based on comments from co- authors* • *Acted as corresponding author*
Overall percentage (%)	80% contribution
Certification	I hereby certify that this paper has been written by me during the period of my higher degree research candidature, and its content is primarily based on my own original work, unless stated otherwise. All references and all sources of information have been appropriately acknowledged.

Signature	Production Note: Signature removed prior to publication.	Date: 01/05/24

Co-Author contributions.

By signing the Statement of Authorship, each author certifies that:

- *The candidate's stated contribution to the publication is accurate*
- *Permission is granted for the candidate to include the publication in the thesis*
- *The sum of all co-author contributions is equal to 100% less the candidate's stated contribution.*

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Contribution to the paper	Contributed to the design of the study, validated the data analysis, interpretation of the findings, and reviewed and approved the final manuscript.	
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6.1.2. Publication: The experience of people living with heart failure in Ethiopia: A qualitative descriptive study

PLOS ONE

RESEARCH ARTICLE

The experience of people living with heart failure in Ethiopia: A qualitative descriptive study

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Abstract

Background

Heart failure is a serious chronic medical condition that negatively impacts daily living. Living with heart failure can be challenging due to the physical symptoms, unpredictable nature of the disease, and lifestyle changes required. The objective of this study was to explore and describe the experiences of people living with heart failure and how it affects their health-related quality of life in Ethiopia.

Methods

A qualitative descriptive design was employed to explore the experience of people living with heart failure, guided by the Theory of Symptom Management. A purposive sample of 14 participants was recruited from the cardiac outpatient clinics at two tertiary-level public hospitals in Ethiopia. Data were collected using a semi-structured interview. The recorded interviews were transcribed verbatim in Amharic, translated into English, and entered NVivo statistical software for analysis. An inductive-deductive hybrid thematic analysis method was used to analyse the data.

Results

Three themes were identified deductively, while an additional three themes emerged inductively:—"Journey from diagnosis to daily life with heart failure"; "Symptom experience"; "Impact of heart failure on health-related quality of life"; "Perception of health-related quality of life and influencing factors"; "Symptom management and coping strategies"; and "Challenges faced in the journey of living with heart failure". Fatigue, and depression were the most frequently reported symptoms. Participants described how their condition affected their overall physical functioning. Participants utilized consistent follow up-care, adhered to their medications, ensured adequate rest, made dietary modifications, sought social support and engaged in spiritual activities to manage their symptoms and cope with their condition.

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Abstract

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Results: Three themes were identified deductively, while an additional three themes emerged inductively: *Journey from diagnosis to daily life with heart failure; Symptom experience; Impact of heart failure on health-related quality of life; Perception of health-related quality of life and influencing factors; Symptom management and coping strategies; and Challenges faced in the journey of living with heart failure*. Fatigue, and depression were the most frequently reported symptoms. Participants described how their condition affected their overall physical functioning. Participants utilised consistent follow-up-care, adhered to their medications, ensured adequate rest, made dietary modifications, sought social support, and engaged in spiritual activities to manage their symptoms and cope with their condition. Challenges they faced included financial difficulties, unavailability of medications, and a lack of continuity of care.

Conclusion: People living with heart failure in Ethiopia experience various symptoms. The impact of heart failure on various aspects of their lives, combined with the challenges they face while living with heart failure, significantly affect their health-related quality of life. Health care providers caring for these people need to understand their experiences and the impact on their daily life. Effective multimodal interventions are needed to reduce the impact of heart failure and improve health-related quality of life in this population.

Keywords: Experience, Heart failure, HRQoL, Symptoms, Ethiopia

Background

Heart failure (HF) is a major cardiovascular problem that affects about 2% of the general population in developed countries, however, there is little quality HF data from developing countries (A. Groenewegen et al., 2020; Olano-Lizarraga et al., 2022). It is a significant public health challenge in low-resource settings, including Ethiopia, where it is associated with poor health-related quality of life (HRQoL). In Ethiopia, HF is a serious issue and the most common reason for hospitalisation. It primarily affects middle-aged adults (45 to 65 years old) who are typically the most productive in terms of their roles within family and community (Molla et al., 2021; Tigabe Tekle et al., 2022). As a result, there is a significant economic impact at an individual and family, as well as national, level. HF leads to physical, emotional, and social disruption throughout its disease trajectory (Polikandrioti et al., 2019; Tsega & Demissei, 2018).

The experience of people with HF failure is significant due to the debilitating and unpredictable nature of the disease. They experience a wide range of symptoms and psychosocial challenges compared to healthy individuals (Arrigo et al., 2020; Nordfonn et al., 2021). Common symptoms associated with HF include severe fatigue, dyspnoea, orthopnoea, oedema, chest pain, cough, and palpitations. Additionally, these people frequently experience mental health issues, such as depressive symptoms and anxiety (Celano et al., 2018). These symptoms, which are responsible for 90% of global hospitalisation among adults with HF, worsen HRQoL by adversely affecting physical, emotional, social, and physiological functioning (Arrigo et al., 2020; Hobbs et al., 2002; Seah et al., 2016).

Treatment options for HF includes pharmacological therapy, symptom management, and lifestyle changes, as it is not considered to be a curable condition (Jaarsma et al., 2021). People with HF integrate various approaches to cope with their illness (Bender et al., 2018). These include taking prescribed medications, embracing spirituality, seeking social support, and engaging in self-management (Seah et al., 2016; Sousa & Santos, 2019; Thida et al., 2021). In addition, sharing ideas and experiences with others and being flexible to changing circumstances are ways people with HF cope with their condition (Jeon et al., 2010; Mahoney, 2001).

Exploring the symptom experiences of people living with heart failure and understanding how they adapt, along with the coping strategies they employ, is important for comprehending the impact of HF on HRQoL (Seah et al., 2015). Addressing symptoms and improving HRQoL are the major aims of HF management (Thida et al., 2021). Heart failure is a significant problem in Ethiopia (Bloomfield et al., 2013; Molla et al., 2021; Tsega & Demissei, 2018), however, little is known about the impact of this condition from the patient perspective. The aim of this study was to explore and describe the experiences of Ethiopian people living with HF, and how it affects their HRQoL, using the Theory of Symptom Management. The findings will provide high-quality evidence for developing interventions to effectively support this population and improve their HRQoL.

Methods

Study setting and period

The study was conducted at the cardiac outpatient clinics in two governmental hospitals, St. Paul's Hospital Millennium Medical College and St. Peter Specialized Hospital, in Addis Ababa, the capital of Ethiopia. These settings were selected because they are the largest tertiary-level hospitals, providing cardiology services and treatment for people from all around the country. The hospitals collaborate to provide care for people with cardiac conditions.

The interviews were conducted between 1 February to 31 March 2023.

Study design

A qualitative descriptive design was used to explore the experiences of people living with HF, following a quantitative survey.

Theoretical framework

This study was guided by the Theory of Symptom Management (TSM), a middle-range nursing theory to guide research and practice (Mathew et al., 2021; Silva et al., 2021). The TSM is a framework primarily used for nursing research that focuses on three domains (person, environment, and health/illness) and examines the relationship between them. The three essential concepts of the TSM are symptom experience, symptom management strategies, and outcomes (Figure 22). A symptom is a subjective experience reflecting changes in the biopsychosocial functioning, sensations, or cognition of an individual. Symptom experience is a simultaneous perception of a symptom, evaluation of the meaning of a symptom, and response to the symptom. Symptom management strategies are efforts to avert, delay, or minimise the symptom experience through biomedical, professional, and self-care strategies. Outcomes arise from both symptom management strategies and the symptom experience. These outcomes include obvious improvement in symptom status, which can lead to enhanced physical and mental functioning, and an improved quality of life (Bender et al., 2018; Seah et al., 2016; Thida et al., 2021). The TSM was utilised in this study as it provides a robust framework for understanding the multifaceted experiences of people living with HF, particularly symptom experience, symptom management strategies, and the impact on HRQoL. This theory was used to formulate the research questions and guide the data analysis.

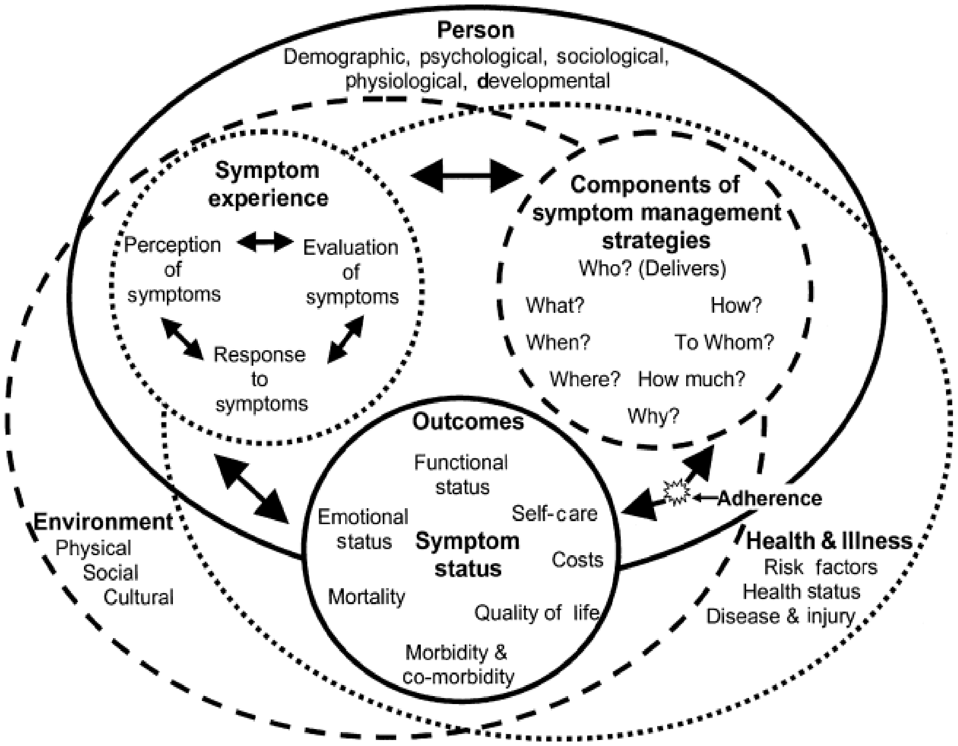


Figure 22: The revised Theory of Symptom Management (Dodd et al., 2001)

Sampling and recruitment

Participants were adults (aged 18 years or older) who had received a clinical diagnosis of HF by a specialist medical doctor and had been receiving regular follow-up care at a cardiac outpatient clinic for at least three months. Invitation letters were distributed to all eligible participants during the earlier phase of the project (quantitative survey) (Henok Mulugeta, Peter M Sinclair, & Amanda Wilson, 2023a) to involve them in the subsequent phase (semi-structured interviews) and, if interested, they were asked to provide their phone number to be contacted for a qualitative interview. Subsequently, the principal researcher (HM) contacted the eligible participants by telephone and invited them to participate in an interview. If they agreed, an appointment was scheduled at their convenience. Participants were recruited using a purposive sampling technique, considering a balanced representation in terms of gender, age, geographical location (urban/rural), and disease severity. Information power was used to determine the final sample size (Malterud et al., 2016).

Data collection

The first author (HM), who had undergone rigorous training and gained experience in conducting qualitative interviews, conducted the interviews using a semi-structured interview guide developed using the TSM (Dodd et al., 2001) and the findings of the quantitative survey published in Scientific Reports (Henok Mulugeta, Peter M Sinclair, & Amanda Wilson, 2023a). The interviews took place in a private room at the hospital when participants were attending an outpatient cardiac clinic appointment. Prior to the interview, brief demographic and clinical information was collected. The audio-recorded interviews were conducted in the local language (Amharic) and notes were taken. The interview guide covered four main topics: sociodemographic and clinical characteristics, symptom experience, concept of HRQoL and impact of HF on it, and symptom management and coping strategies (Table 19). Probing questions were used, as needed, to explore the impact of participants' symptoms on their HRQoL and how they coped with this. The interviewer transcribed each participant's interview verbatim in Amharic. Signs of information power were observed after 11 interviews. An additional three interviews were conducted to confirm that no significant new information emerged, solidifying the data saturation point. The interviews varied in duration between 30 and 60 minutes.

Table 19: Interview guide exploring the experiences of people with heart failure in Ethiopia

No.	Primary Question	Optional prompt questions
1	*To begin with, I'm going to ask you some sociodemographic and clinical questions*	Age, sex, residence, education, marital status, New York Heart Association (NYHA) class, employment status, duration of HF, known comorbidity.

2	*Tell me about living with HF?*	When were you diagnosed and how did you feel at the time? What kind of symptoms do you have? What makes you feel better or worse? What management/treatment strategies do you use? What about non-medical interventions?
3	*Now, I want to discuss the concept of HRQoL.*	What does the term HRQoL mean to you? What is the quality of your life since having HF? Are there things you can't do so well? What do you do to feel better? How do you deal with feeling down or depressed? What are the best and worst aspects of your life now?
4	*Now, I would like to ask you about the impact of HF on your HRQoL.*	How is it living with heart failure? How does it affect your family or friends? What about work? Income? Sleep? What about social activities and relationships? What factors most affect your HRQoL? Why? What are the most difficult aspects of HF? How do you deal with these? What strategies do you use to improve your HRQoL?

Ethical consideration

The study was approved by the University of Technology Sydney (UTS) Human Research Ethics Committee (UTS HREC REF NO. ETH21-6739). Permission to conduct the study was also granted from the institutional review board (IRB) of each hospital (SPHHMC IRB Ref No. PM23/9235/13/10/22, SPSH IRB V561/11/10/22) where the study was conducted. Prior to participation, an information sheet prepared in local language was provided and, if required, read out to participants. Written consent was obtained from each participant for their interview to be audio-recorded, transcribed, and for the findings to be shared through presentations and publications. Privacy and confidentiality of the participants was maintained throughout the study. Personal details were systematically removed during the transcription process.

Data quality and trustworthiness

Three pretest interviews were conducted before the main interview process. These pretest interviews were used to refine the interview guide, ensuring that the questions were clear and relevant. The data from these interviews were not included in the analyses. To ensure trustworthiness of the data, criteria of credibility, dependability, confirmability, and transferability were applied throughout the research process (Connelly, 2016). Credibility was achieved by allocating adequate time for the interviews and using participants' own words during analysis. Dependability was maintained by keeping thorough records and notes of all the research activities, for review when necessary, and engaging in debriefings with the second author. To establish confirmability, data were continuously checked and rechecked throughout the study to address any potential biases. Transferability was assured by providing a detailed description of the study population, context, study area, the process of data collection, and by maintaining transparency about data analysis.

Data analysis

Interviews were transcribed verbatim in Amharic and then translated into English by a bilingual expert. One of the authors (HM) actively participated during transcription and translation of the interviews, providing the opportunity to become more familiar with the data. The participants were assigned identification (P01 to P14) to maintain anonymity. The interviews were imported into NVivo Version 12 statistical software for analysis (2018). An inductive-deductive hybrid thematic analysis approach was utilised to analyse the data. This approach was chosen because the research questions were strongly linked to the existing theory (deductive), and it enabled the exploration of insights within the data while allowing new themes to emerge from the data (inductive). The validity and rigour of this approach has been well demonstrated previously (Fereday & Muir-Cochrane, 2006; Proudfoot, 2023; Roberts et al., 2019). The overall analysis was undertaken across six phases following Braun and Clark's thematic analysis method: data familiarisation, systematic data coding, searching for themes deductively using TSM, creating new themes inductively, reviewing themes, defining, and naming themes, and producing the final report (Braun & Clarke, 2022). Before the analysis, the authors read and re-read the transcribed/translated data to immerse themselves and become familiar with the concepts, for a holistic understanding of the data. During data familiarisation, memos and annotations were taken to document important findings and insights. After data familiarisation, both semantic and latent coding were utilised to generate codes for significant information from each transcript. To enhance the validity of coding, two authors (HM and PS) independently coded the transcripts, and the third author (AW) was consulted as needed to resolve any coding discrepancies. As coding progressed, similar or related codes were grouped into categories, and these categories were used to identify and generate themes and subthemes. The final identified and emerged themes were critically discussed and approved by all authors.

Results

Sociodemographic and clinical characteristics of the study participants

A total of 14 people (eight male and six female) with HF were recruited and completed the study. The age range of the participants was 32 to 73 years, with a mean age of 52.92 years. Over half (57.14%) of participants were married and half (50.00%) had completed primary education. Half (50.00%) were employed, 21.43% were retired, and 28.57% were unemployed. Duration of HF varied with 28.6% of participants having lived with the condition for more than five years. The New York Heart Association (NYHA) classification was used to determine the severity of HF, revealing 43.00% of participants classified as class III or IV. Details of sociodemographic and clinical characteristics are summarised in Table 20.

Table 20: Sociodemographic and clinical characteristics of participants (Phase III).

Participants	Age	Sex	Marital status	Employment status	Education	Duration of HF	Known comorbidity	NYHA class
P1	71	M	Married	Unemployed	Primary	6 years	DM	II
P2	73	M	Widowed	Retired	Secondary	3 years	No	III
P3	52	M	Married	Employed	Degree	1 year	DM	I
P4	60	M	Married	Employed	Primary	11 years	Asthma	IV
P5	32	F	Single	Employed	Primary	3 years	No	II
P6	48	F	Married	Unemployed	Primary	8 years	No	III
P7	62	M	Married	Retired	Degree	1 year	HTN, DM	II
P8	40	M	Married	Employed	Primary	1 year	No	III
P9	65	F	Widowed	Unemployed	Primary	2 years	No	I
P10	70	F	Widowed	Retired	Primary	4 years	DM, HTN	IV

P11	35	F	Single	Employed	Diploma	3 years	No	I
P12	42	F	Married	Employed	Secondary	8 years	No	I
P13	43	M	Single	Unemployed	Diploma	2 years	Epilepsy	III
P14	48	M	Married	Employed	Secondary	1 year	HTN	II

DM: Diabetes mellitus, HTN: Hypertension, NYHA: New York Heart Association

The experience of people living with heart failure

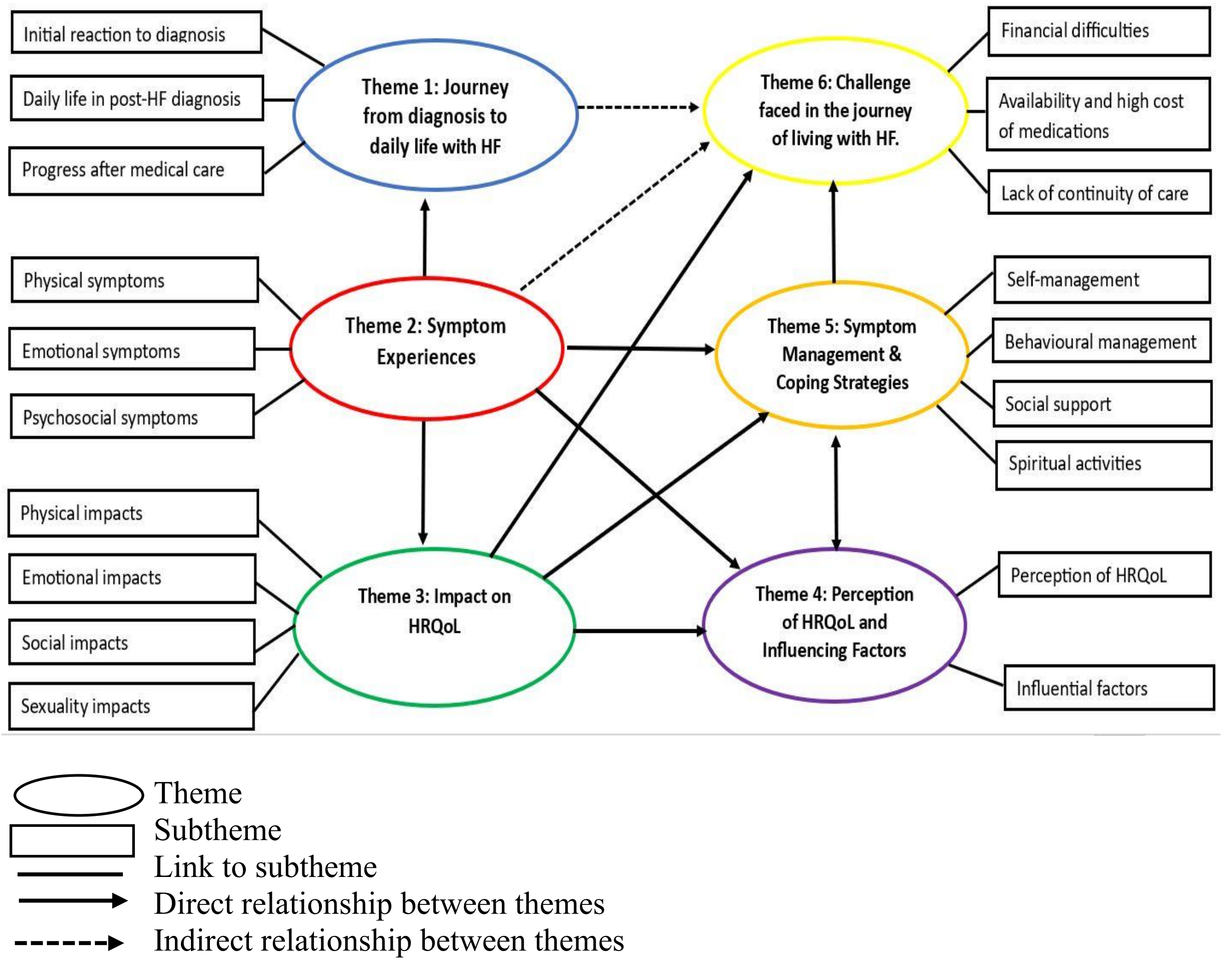
The inductive-deductive hybrid thematic analysis method revealed three themes (Themes 2, 3, and 5) that were identified deductively, while an additional three themes (Themes 1, 4, and 6) emerging inductively, all containing related subthemes (Table 21).

Table 21: Themes and subthemes in the study on experiences of people with HF in Ethiopia

No	Theme title	Subtheme	Origin
1	Journey from diagnosis to daily life with HF	• *Initial reaction to diagnosis* • *Daily life in post-HF diagnosis* • *Progress after medical care*	Emerged
2	Symptom experience	• *Physical symptoms* • *Emotional symptoms* • *Psychosocial symptoms*	Identified
3	Impact of HF on HRQoL	• *Physical impact* • *Emotional impact* • *Social impact* • *Sexuality impact*	Identified
4	Perception of HRQoL and influencing factors	• *Perception of HRQoL* • *Influential factors*	Emerged
5	Symptom management and coping strategies	• *Self-management* • *Behavioural management*	Identified

		- *Social support* - *Spiritual activities*	
6	Challenges faced in the journey of living with HF	- *Financial difficulties* - *Availability and high cost of medications* - *Lack of continuity of care*	Emerged

While these six themes are presented separately, they were all inextricably linked. Analysing the relationship between these themes provides insights into the holistic experience of people living with heart failure in Ethiopia (Figure 23).



HF: Heart failure; HRQoL: Health-related quality of life

Figure 23: Thematic map indicating the relationship between the six themes.

Theme 1: "Journey from diagnosis to daily life with HF"

This theme encompasses participants' initial feelings and thoughts following their life-altering diagnosis. Participants described their experiences after receiving the diagnosis and their progress after medical care was initiated.

Subtheme 1.1: "Initial reaction to diagnosis"

Participants reported feeling shocked, anxious, and hopeless upon receiving their diagnosis.

> *"I was shocked to hear the diagnosis and thought I wouldn't be able to survive." (P05)*
>
> *"After I learned about my condition, I was anxious. I couldn't sleep at night due to my anxiety. I thought I would die." (P12)*

Some participants voiced concerns about their children's future, while others expressed a feeling that their condition was part of a divine plan.

> "*I was shocked when I heard of my diagnosis since I have two kids and felt like how they would survive if I'm leaving them; I was worried about them, not about myself". (P14)*
>
> *"I wasn't shocked to hear of my diagnosis, it happened as per God's will". (P10)*

Subtheme 1.2: "Daily life in post-HF diagnosis"

Most of the participants reported that their lives had changed significantly post-diagnosis, especially compared to their pre-diagnosis lives.

> *"My lifestyle is not as it was before. You should deal with it. I was doing all sorts of activities without difficulty…you know what...I did everything at home, but now I have limitations, a heavy activity makes me to feel tired." (P11)*

Subtheme 1.3: "Progress after medical care"

Many of the participants reported noticing positive changes post-medication and after follow-up care. Adherence to medications and the self-care recommendations had contributed significantly to their overall good progress.

> *"I thought I wouldn't improve at all. But I have seen positive changes in my health status after I started taking medication and received follow-up care in this hospital." (P07)*

Theme 2: "Symptom experience"

Participants described their symptoms, including physical, emotional, and psychosocial symptoms. Every participant reported having at least one symptom, with physical symptoms being the most frequently mentioned.

Subtheme 2.1: "Physical symptoms"

Many participants mentioned several physical symptoms, with fatigue and exhaustion being the most frequently cited symptoms.

> *"Currently, I have chest pain, fatigue, dyspnoea, abdominal pain, leg swelling, and decreased appetite. I have difficulty breathing and I can't walk for long distances." (P04)*

Subtheme 2.2: "Emotional symptoms"

Participants often described experiencing depressed or anxious feelings as a result of the diagnosis and attributed them to physical limitations and lifestyle changes post-diagnosis.

> *"I feel down because I can't work as hard as I used to…I become fatigued after working hard…you know...in that case I feel depressed. I asked God…why is this happening to me?" (P05)*

Subtheme 2.3: "Psychosocial symptoms"

Participants expressed experiencing a range of psychosocial symptoms, including sadness, frustration, isolation, worry, and sudden mood changes.

The feeling of worry was commonly described due to the unpredictable nature of the disease, which made them feel unsure about what might happen next.

> *"I am scared of falling asleep because I feel like I'm going to die, and I worry a lot that one day my heart may stop beating." (P12).*

Some participants experienced sudden mood changes upon realising the impact of their condition on daily functioning.

> *"Your mood suddenly changes when you realise that you have physical limitations. I usually want to be alone…I require silence; I don't want to be disturbed by any noise, not even by the voices of my children." (P06)*

Theme 3: "Impact of HF on HRQoL"

Participants reported how HF had impacted their everyday lives. They described a multifaceted experience, and four subthemes emerged from the data: physical impact, emotional impact, socioeconomic impact, and impact on sexual relationships.

Subtheme 3.1: "Physical impact"

Many of the participants described how their condition affected their daily activities, work, and overall physical functioning. Activities that were simple and taken for granted were now difficult for them.

> *"I can't walk far, and I can't finish what I start....it is even hard for me to come from home to this hospital for my regular follow-up. You can't do what others are doing; you have limitations. When you go to do something, and you realise that you can't do it. For instance, one day I was walking fast to take the bus. I saw 70-year-old women pass me for the bus, but I was late to reach the bus, and it left. At that moment, I really felt like I was worthless. I became panicked, wondering why this was happening to me." (P08)*

Similarly, Participant 11, a 35-year-old female, reiterated: *"I can't do things like I used to. I have difficulty walking long distances at a fast pace. I find it challenging to go shopping because I can only lift and carry up to five kilograms."*

Subtheme 3.2: "Emotional impact"

Many participants expressed feeling negative emotions, including depression and anxiety, as a result of the physical impact of their condition.

> *"I feel down when I get tired of doing ordinary activities at home…when I feel depressed, I have nothing to do...just nothing, I just sit down and take a rest and there is no other solution. I can't eat what I want. When I see someone else eating something delicious, I become frustrated because I can't. My life right now is very miserable. I'm angry that I can't go out and come back as I want. This is the worst. I might seem in good physical condition, but my body is weak, which depresses me." (P04)*

Subtheme 3.3: "Social impact"

Many participants indicated that HF led to social isolation and challenges in maintaining relationships.

> *"I used to actively engage in social activities, visit my relatives on holidays, visit sick people, and have fun with my friends. But now, due to my illness, I stopped everything... I mean, I can't do that now. People may also isolate you; for example, when you cough, they may treat you differently and think you have COVID 19. You find this upsetting." (P07)*

A 52-year-old male shared a workplace experience in which he faced challenges with his colleagues.

> *"At work, my co-workers are more frustrated with my condition than I am. They feel that people with heart failure are more vulnerable to sudden death. For instance, if you need to have a loan of money, nobody wants to take the risk by giving it to you because they worry that you might die suddenly before paying them back." (P03)*

Subtheme 3.4: "Sexuality impact"

Two participants indicated that they had experienced reduced sexual desire and the inability to perform sexual intercourse with their partners. Both participants were concerned about whether it was due to the disease process itself or the side effects of medications.

> *"This illness has also had an impact on my marriage because I feel less motivated to engage in sexual activities. I used to have a good sexual relationship with my wife, but now it has impaired my entire sexual desire. My wife thinks that I am having a*

> *relationship with another woman because of my lack of interest in intimacy with her. I'm not sure if this is due to the side effects of the medications or something else." (P08)*

Theme 4: "Perception of HRQoL and influencing factors"

Participants described their perception of their HRQoL and evaluated their overall well-being in the context of their physical health, mental health, and social functioning. This perception varied from participant to participant and was influenced by various factors.

Subtheme 4.1: "Perception of HRQoL"

Some participants perceive HRQoL primarily in terms of emotional well-being, happiness, and physical activity; they feel that feeling content, balanced emotionally, and engaging in regular physical activity are essential aspects of living a life of good quality. Others, however, focus more on financial aspects when considering HRQoL; they feel that financial stability leads to a sense of security and facilitates access to resources that can improve overall well-being.

> *"Health-related quality of life means the physical ability to do what you want and being physically healthy, no illness." (P03)*

> *"I think staying healthy and financially secure are key components of health-related quality of life. If I have adequate income, I could be happy and comfortable with my life…. I think that is quality of life." (P07)*

Subtheme 4.2: "Influential factors"

Many participants described the influence of several factors on their HRQoL, including age, symptoms, comorbid conditions, income, social support, and general health perception.

Participants perceived that life slows down as age increases, which impacts their overall health status.

> *"Everything slows down as you age; the presence of heart failure exacerbates this and has a substantial impact on my day-to-day activities, which influenced my quality of life." (P03)*

Physical and emotional symptoms, such as chest pain and depression, had a negative effect on HRQoL.

> *"The presence of symptoms affects your quality of life since you can't work even though you want to, and when you try to work, it makes you feel exhausted, incapacitated, and possibly weaker than you once were, so I sit down. Yes, obviously, it has a significant influence." (P06)*

Participants perceived that the presence of comorbid conditions also had a negative impact on their physical and mental health.

> *"I have additional diabetes and high blood pressure…so I am scared…what is going to happen? You become dissatisfied with your life when you have many comorbid conditions." (P10)*

Some participants had lost their job due to their physical limitations, which reduced their income. Unemployment and financial hardship led to anxiety and depression.

> *"My condition prevents me from working as I did before, so I reduced on my working hours. When I start working, you know…I feel fatigue and tired. I can't work the whole day, so I get frustrated with not being able to work and not having the energy as before. So, I am not working as before because of my illness, and it affects my income. In this case, you feel dissatisfied with your life and feel down." (P14)*

Participants highlighted that living without social support was quite challenging, with some emphasising the need for someone to provide physical and/or financial support while living with HF.

> "Social support has an impact on my quality of life because when I'm away from my family, I'm anxious, but when they're nearby, I feel relaxed and safe. They support me in all my home activities, and without them I would not be alive at the time." (P12)

Many of the participants perceived themselves as being in poor health status, which contributed to feelings of depressive symptoms, thereby reducing their HRQoL.

> *"…. here I am, as you can see, a critically ill and weak person. I asked God if my time is over; I don't want to suffer anymore, and I am not scared of dying. The fatigue is overwhelming; I can't even do simple tasks without difficulty. It's been really challenging. I am exhausted with everything, and I feel like my health is deteriorating.*

> *I am not a happy person now because I am not feeling well. I never thought I would have to go through all this..." (P10)*

Theme 5: "Symptom management and coping strategies"

Participants reported strategies they use to manage their symptoms and cope with their condition. This theme includes four subthemes: self-management, behavioural management, social support, and spiritual activities.

Subtheme 5.1: "Self-management"

Several self-management strategies were reported, including medication adherence, getting adequate rest, attending regular follow-up care, making dietary modifications, engaging in exercise and weight monitoring, use of herbal products, and avoiding harmful habits.

> *"When I feel tired, I sit down and take a rest. This makes me to feel better." (P03)*

> *"I monitor what I eat; I avoid salt; and I am using a sunflower oil instead of eating fatty foods. Of course, I reduced salt and avoid fatty foods." (P07)*

> *"I'm taking my medicines properly as prescribed. After I started taking the medicines, my symptoms have improved." (P09)*

Subtheme 5.2: "Behavioural management"

Behavioural strategies included acceptance of condition, distraction, maintaining a positive emotional state, and avoiding stress. Participants indicated that accepting their condition helped them cope with it.

> *"It is a matter of accepting your condition. If you do not accept it, you will be depressed. Although I have heart failure, this does not necessarily mean that I am going to die. I accepted my condition and am following the instructions from the doctors." (P07)*

Some participants reduced their symptoms and managed their condition by entertaining themselves using various techniques.

> *“I have always tried to feel happy, and I don't want to feel down. I watch television, I play and talk with my family members so that I can forget about my depression.” (P01)*

Subtheme 5.3. “Social support”

Many participants mentioned the importance of social support from family and others to cope with this condition. This view emphasises how important social support may be for people with chronic conditions. Social support from friends, family, and loved ones can provide a sense of belonging, and physical and emotional support—all of which are essential for navigating challenges associated with HF and improving HRQoL.

> *“... my husband and children are helping me a lot, and I feel comfortable. My brothers who live abroad also provide me with support, assisting me in managing my health and sometimes sending me money and medications. Their support has been crucial to my survival, and I would find it difficult to live without them.” (P06)*

Participants indicated that sharing experiences with other patients helped them to cope.

> *“I shared ideas with other people while I came here for my appointment. We shared strategies for dealing with our symptoms and other problems, which helped me to reduce my depression and made me feel good.” (P12)*

Subtheme 5.4: “Spiritual activities”

Several participants emphasised the importance of spirituality in coping with the emotional and physical challenges of living with HF. Attending church regularly and praying to God were part of their day-to-day activities.

> *“I am coping with the help of my God. I feel I have a good relationship with God. I am always praying and reading the Bible. I might not be able to do things I used to do, but I believe God is with me...I am not afraid of dying.” (P13)*

Theme 6: “Challenges faced in the journey of living with heart failure”

Participants mentioned a wide range of challenges they faced during their journey of living with HF, including financial difficulties and the availability of medications and their high costs, as well as a lack of continuity of care.

Subtheme 6.1: "Financial difficulties"

The high cost of medical care and medications posed a significant financial strain for almost all participants. They reported that medical expenses were hard to afford, and for those who could not afford, it felt like a death sentence.

> *"…it's a death sentence if you have a cardiac condition, don't have enough money, or can't afford it." (P03)*
>
> *"The expenses related to managing heart failure are high, and there are several costs involved, including those for medications, blood tests, and diagnostic procedures. Thus, if you can't afford them, you'll feel miserable, your symptoms will get worse, and you might even die." (P12)*

Subtheme 6.2: "Availability and high costs of medications"

Many participants reported that unavailability and the high costs of prescription medicines were extremely challenging.

> *"Purchasing medicines on the open market can be challenging and expensive. I buy what I need if it is within my budget, however, if it is not affordable, I will not purchase that medication. In such instances, not having the medication makes my symptoms worse." (P08)*

Subtheme 6.3: "Lack of continuity of care"

Some participants expressed their frustration regarding the lack of continuity of care during their monthly hospital visits. They indicated that inconsistent physician involvement and inadequate communication between healthcare providers were significant concerns.

> *"…. when I arrived for my appointment, the physicians occasionally changed. I never saw the same physician twice. Due to the doctors' poor handwriting, I have noticed them getting confused about my most recent medical history when reading my chart.*

> *Their colleagues' handwriting was also difficult for them to read. Consequently, they just continued prescribing the same medication. They responded to my concerns quickly, didn't fully consider my complaints, and seemed eager to rush through the appointment to move on to the next waiting patient." (P02)*

> *"Since starting follow-up care in this hospital, I've started taking medications and have regular appointments every month. However, no doctor has consistently examined me. I expect doctors to provide adequate information about my progress, but they often ask questions quickly and then hand you a prescription. I once provided a blood sample, but they haven't returned the results. I continue to come here simply to take my medications." (P08)*

Discussion

Heart failure is a serious chronic medical condition that has an adverse impact on HRQoL (Thida et al., 2021). To our knowledge, there needs to be more data regarding the experience of people with HF in Ethiopia and how it affects their HRQoL. A recently published study conducted in Northwest Ethiopia during the same data collection period as our study, but with a two-month gap, revealed the physical, social, and emotional impacts of HF and the challenges associated with HF treatment (Mengistu et al., 2024). Expanding upon these findings, the current study delves deeper into these issues, providing additional insights regarding symptoms experience, symptom management and coping strategies, and perception of HRQoL and influencing factors in this population. These additional insights are critical for a comprehensive understanding of the phenomenon.

In this study, six main themes were identified and emerged from the data. Under "Journey from diagnosis to daily life with HF", participants described initial shock and anxiety post-diagnosis, followed by significant lifestyle changes and a gradual adaptation to living with HF. The "Symptom experience" theme revealed struggles with physical, emotional, and psychosocial symptoms, such as fatigue, chest pain, depressive symptoms, and anxiety. "Impact of HF on HRQoL" encompassed the extensive physical limitations, emotional distress, social challenges, and disruptions in sexuality. In "Perception of HRQoL and influencing factors", participants' views on quality of life were shaped by age, symptoms, comorbidities, income, health perception, and social support. The "Symptom management and coping strategies" theme highlighted approaches such as medication adherence, lifestyle modifications, and seeking social and spiritual support. Lastly, "Challenges faced in the journey of living with HF" underscored financial difficulties, medication accessibility issues, and inconsistencies in healthcare. Overall, this study provides a holistic view of the complex and multifaceted impact of HF on individuals in Ethiopia.

The findings emphasise the significant psychological distress accompanying an HF diagnosis, echoing results from UK-based research (Thornhill et al., 2008). Participants commonly experienced shock and sadness, stemming from fears about mortality and potential physical limitations (Harris et al., 2021; Taylor et al., 2017). This emotional impact might be exacerbated by a lack of prior HF knowledge (Rodriguez et al., 2008), highlighting the need for improved education and early intervention strategies. Consistent with other studies (Fry et al., 2016; Nordfonn et al., 2019; Walsh et al., 2018), the diagnosis necessitated lifestyle changes and presented new challenges, reinforcing the notion that HF affects multiple life dimensions (Kyriakou et al., 2020; Liljeroos et al., 2023). These findings further highlight the need to develop patient education programs to help people understand their condition, manage symptoms, and adapt to new lifestyle requirements effectively.

The categorisation of symptoms into physical, emotional, and psychosocial domains provides a comprehensive understanding of the participants' health challenges. Commonly reported physical symptoms, such as fatigue, tiredness, shortness of breathing, and chest pain, align with previous findings (Niklasson et al., 2022; Nordgren & Sorensen, 2003; Seah et al., 2016). Predominantly, fatigue affects the daily activities of participants and causes frustration. This aligns with existing literature (Hägglund et al., 2008; Hayeah et al., 2017; Walthall et al., 2019) and underscores the need for targeted management strategies. The association between fatigue and emotional distress (Liljeroos et al., 2023), particularly depressive symptoms (Walthall et al., 2019), shows the importance of holistic care addressing both physical and emotional health. Emotional symptoms align with prior studies (Bennett et al., 2000; Dekker et al., 2009; Zambroski, 2003), highlighting the impact of financial difficulties, uncertainty about their condition, and physical limitations as major contributors to depressive symptoms (Harris et al., 2021). This emphasises the need to consider not only physical, but also financial and psychosocial aspects in the management of people with HF.

Participants echoed concerns found in previous studies about the restriction of daily activities and social participation due to HF (Aldred et al., 2005; McHorney et al., 2021; Niklasson et al., 2022). These limitations, coupled with fatigue and weakness (Del Buono et al., 2019), not only diminish physical capacity but also lead to social isolation (Aldred et al., 2005) and emotional distress (Checa et al., 2020; Li et al., 2019; Ryan & Farrelly, 2009; Thornhill et al., 2008). The impact of HF on sexual intimacy, as noted by some participants, highlights the broad-ranging effects of the condition on personal relationships (Jaarsma et al., 2014). Two participants described how their condition impacted their sexual intimacy with their partners. This might be due to physical limitations, medication side effects, and emotional factors (Jaarsma et al., 2014). To address these issues, interventions should focus on tailored exercise programs to improve physical functioning and provide emotional support for adapting to lifestyle changes.

Perceptions of HRQoL, consistent with definitions found in previous research (Hayeah et al., 2017; Heo et al., 2009), focusing on happiness, income, and health, diverge from standard definitions, potentially due to lower educational levels affecting comprehension (Checa et al., 2020). This finding suggests a need for healthcare providers to contextualise HRQoL in appropriate terms for people with varied educational backgrounds. The influence of age, comorbid conditions, depression, income, health perception, and social support on HRQoL (Barutcu & Mert, 2013; Chu et al., 2014; Yaghoubi et al., 2012) indicates that a multifaceted approach that accounts for the diverse factors affecting HRQoL is essential in managing HF.

Participants utilised multiple strategies for symptom management and coping. This study aligns with previous research (Bennett et al., 2000; Checa et al., 2020; Li et al., 2019) in highlighting the prevalence of self-management strategies like medication adherence and lifestyle modifications. The importance of behavioural strategies, including acceptance and seeking social support (Bennett et al., 2000; Checa et al., 2020; Mahoney, 2001; Seah et al., 2016), is evident. These findings reinforce the role of comprehensive patient education and support systems in enhancing coping mechanisms and self-care. Social connections play a pivotal role, with participants stressing the positive impact of social support (Heo et al., 2009; Seah et al., 2016; Thornhill et al., 2008) and shared experiences (Gregory et al., 2006; Lockhart et al., 2014) on coping abilities, and the need for holistic care that addresses psychosocial well-being. Additionally, spiritual activities, which have also been reported in the previous research (Hopp et al., 2012; Seah et al., 2016; Sepehrian et al., 2020), were identified as significant coping mechanisms, highlighting the potential benefits of integrating spiritual support into HF care plans.

Financial constraints were a significant challenge for participants, with concerns about out-of-pocket healthcare costs highlighting the broader socioeconomic factors influencing HF management. The unavailability of medication in the open market, coupled with financial difficulties, was associated with poor outcomes, such as depression and poor HRQoL (Guan et al., 2022; Malhotra et al., 2021). These challenges are probably due to insufficient health care financing and a lack of adequate insurance coverage (Ali, 2014; Tsega et al., 2023). This emphasises the necessity of policy interventions, including the enhancement of healthcare infrastructure, improvement of medication supply chains, and provision of financial support for HF patients, to effectively address the identified challenges. Participants expressed frustration at the lack of continuity of care and poor interprofessional communication. This could be because most of the doctors in the study hospitals' cardiac clinics were resident physicians who rotate on a monthly basis. This issue, consistent with findings in other studies (Chester et al., 2021; Nordfonn et al., 2019; Ryan & Farrelly, 2009), illustrates the importance of consistent and effective care for individuals with chronic conditions. The reported poor communication with healthcare providers (Al-Azri et al., 2011; Fry et al., 2016) shows the importance of establishing strong patient-provider relationships to improve outcomes and HRQoL.

This study provides insight into the multifaceted impact of HF in Ethiopia, from initial diagnosis to ongoing management. It highlights the need for holistic care approaches that address physical, emotional, and social needs, and the importance of patient education, consistent healthcare provision, and support systems in improving the HRQoL for individuals living with HF. The findings have significant policy implications, particularly in resource-limited settings. Further research to understand cultural and contextual influences on HF management, particularly in settings like Ethiopia could help in developing culturally sensitive and contextually appropriate intervention strategies.

Limitations

There are some limitations that should be considered for future research. Potential for selection bias may arise as people who chose to participate in the study might have different experiences or views compared to non-participants. The identification and interpretation of themes may be influenced by the researchers' perspectives, potentially leading to biased conclusions. Cultural and geographical characteristics of the sample may limit the transferability of findings to other contexts, reducing generalisability. Furthermore, language and interpretation issues may risk losing nuanced meanings in translation.

Conclusion

This study provides in-depth descriptions of the experiences of people living with HF. The diverse symptoms experienced by participants and their impacts on various aspects of life highlight the profound impact of HF on HRQoL, and the pervasive influence of this condition on individuals' lives. Notably, financial difficulties and medication unavailability emerged as significant challenges, significantly affecting HRQoL. Symptom management and coping strategies, such as medication adherence, self-care, spirituality, consistent follow-up care, and social support, underscore the multifaceted approach individuals employ to cope with HF. In response to these findings, there is a clear call for effective multimodal and context-specific interventions, such as psychosocial, educational, and lifestyle changes, to mitigate the multifaceted impacts of HF and improve HRQoL in this population.

List of abbreviations

DM: Diabetes Miletus; HF: Heart Failure; HRQoL: Health-Related Quality of Life; HTN: Hypertension; IRB: Institutional Review Board; NYHA: New York Heart Association; TSM: Theory of Symptom Management; UK: United Kingdom; UTS: University of Technology Sydney.

CHAPTER 7: DISCUSSION AND IMPLICATIONS

7.1. Introduction

This body of work sought to assess the impact of heart failure on mental health and HRQoL in Ethiopia. A sequential explanatory mixed methods study design was used to achieve the following research objectives:

1) To determine the prevalence of comorbid depression and identify the associated factors among adults living with HF

2) To evaluate the HRQoL and its influencing factors among adults living with HF

3) To explore and describe the experiences of people living with HF and how it affects their HRQoL.

This study was conducted in three phases: systematic reviews, a quantitative cross-sectional study, and a subsequent qualitative descriptive study. The systematic reviews and meta-analyses synthesised the existing literature on depression and HRQoL among people with HF in LMICs. Data from the cross-sectional study were analysed using descriptive statistics and regression models, while data from the qualitative descriptive study were analysed using thematic analysis using the six steps of the Braun and Clarke approach. The revised Wilson and Cleary model and the Theory of Symptom Management were integrated to create a broad framework for a better understanding of how HF affects mental health and HRQoL. These frameworks guided the research design, data collection, data analysis, and interpretation of the findings. In this chapter, a comprehensive analysis and interpretation of the findings are provided by integrating the quantitative and qualitative data using a narrative approach.

This chapter starts by summarising the key findings from each phase of the study that were reported in Chapters Two, Four, Five, and Six. It will then integrate and compare the quantitative and qualitative findings to provide a comprehensive understanding of the research problem, and then interpret and report on how the qualitative data expands on the quantitative results.

In addition, it discusses how the findings align with, or diverge from, the existing literature, and implications will be made for clinical practice and policy. The study limitations are discussed along with the recommendations for future research. Finally, conclusions will be presented by summarising the key findings and implications.

7.2. Summary of key findings

7.2.1. Key findings from the systematic reviews and meta-analyses

Two systematic reviews were undertaken to achieve the first aim of this body of work using the JBI methodology. The first systematic review (Henok Mulugeta, Peter Sinclair, & Amanda Wilson, 2023) reported the pooled prevalence of depression in people with HF and its association with HRQoL in LMICs. The meta-analysis demonstrated that the pooled prevalence of depression in this region was 51.5% and that depression was positively associated with HRQoL. The second systematic review (Henok Mulugeta, Peter M Sinclair, & Amanda Wilson, 2023b) estimated the pooled HRQoL score of people with HF in LMICs and the results showed that people with HF had poor HRQoL. Both Systematic reviews revealed that depression was highly prevalent in people with HF in LMICs and is associated with poor HRQoL, thus indicating the need to assess for depressive symptoms and implement evidence-based management in this population to improve HRQoL.

7.2.2. Key findings from the mixed methods study

This was the first study in Ethiopia that used the Wilson and Cleary model to understand HRQoL and its influencing factors using the MLHFQ. Comorbid depression was also measured using the PHQ-9 questionnaire. In addition, the experiences of people living with HF and how it affects their HRQoL were explored using qualitative interviews guided by the Theory of Symptom Management (TSM). Understanding the impact of HF on mental health and HRQoL can provide valuable information to guide clinical decision-making process.

The key findings of the mixed methods study can be summarised as follows: -

1. *Many of the respondents were female, married, unemployed, resided in urban areas, and had no formal education. Many participants had comorbid hypertension (44.13%) and diabetes (20.89%), reported no family history of HF (87.73%), took fewer than five medications daily (72.06%), reported poor social support (41.25%), and were classified in NYHA class I (35.25%).*
2. *The mean of the total MLHFQ score of the study participants was 48.03±19.73, indicating a poor mental and physical HRQoL. In addition, over half of the participants (56.6%) had comorbid depression.*

3. *Age, diabetes mellitus comorbidity, a low social support score, and higher depression score were significant factors influencing overall HRQoL. There were significant positive relationships between depression and HRQoL.*
4. *Significant associations with depression were observed among participants who were female, had comorbid diabetes mellitus, were classified as NYHA class IV, reported poor levels of social support, and took more than five medications per day.*
5. *HF diagnosis and treatment changed participants' perceptions of their HRQoL. It was challenging and impacted upon their daily activities, work, income, sleep, family, social activities, and relationships.*
6. *Symptom experience: Fatigue, and depression were the most frequently reported symptoms.*
7. *Participants explained how age, comorbid conditions, such as depression and diabetes, income, and social support influenced their HRQoL.*
8. *Participants reported the strategies they used to manage their symptoms and cope with their condition. These strategies include medication adherence, adequate rest, acceptance of their condition, attending regular follow-up care, making dietary modifications, and finding comfort through prayer.*
9. *Financial difficulties and stress, unavailability of medications in the open market and their high costs, as well as a lack of continuity of care, were the major challenges faced by the participants while living with HF.*

7.3. Integration of quantitative and qualitative results

7.3.1. Impact on mental health

Heart failure has a significant impact on mental health. This thesis evaluated the impact of HF on mental health by determining the prevalence of depression and identifying associated factors. Previous research have similarly evaluated the impact of HF on mental health by assessing the depressive symptoms experienced by participants (Bang et al., 2013; Carmin et al., 2024). Depression, the most common mental health condition in people with HF, exhibits a significantly higher prevalence rate among this population compared to the general population (Celano et al., 2018). Mental health conditions, including depression, in people with chronic diseases such as HF appear to be a neglected and unrecognised public health problem in Ethiopia. Although a significant proportion of the Ethiopian population is affected by a mental illness, particularly depression, the rate is higher among people with chronic conditions like HF (Kassa & Abajobir, 2018; Umer et al., 2019).

Evidence such as the prevalence of comorbid depression in people with HF is lacking in Ethiopia or not well studied. The quantitative results of the third paper profiled in this thesis revealed that depression affects a significant portion of Ethiopian people living with HF, with over one in two people with HF experiencing comorbid depression (56.66%, 95% CI 51.53, 61.68). This finding is consistent with the current systematic review and meta-analysis, which estimated 51.50% prevalence of depression among people with HF in LMICs (H. Mulugeta et al., 2023).

The finding of 56.66% prevalence of depression among people with HF in Ethiopia is higher than the global prevalence of 41.9% reported by Moradi et al. (2021). This discrepancy might be attributed to several factors. Firstly, Moradi's meta-analysis mostly included studies from high-income countries, where access to mental health services is generally better (Nugent, 2008; Zhou et al., 2023). Secondly, the current study was conducted during the COVID-19 pandemic, which may have exacerbated mental health issues. Lastly, socioeconomic factors, such as unemployment and poverty, along with cultural factors, such as stigma around mental health conditions, comorbidities, political unrest, and conflict, all exist in Ethiopia, which might have influenced the results (Alemayehu et al., 2022; Anbesaw et al., 2024; Bitew, 2014; Gebreyesus et al., 2024; Molla et al., 2016). In addition, the current study (Mulugeta et al., 2024) revealed that the prevalence of depression among people with HF exceeds that reported in Ethiopian people with cancer (40.4%) (Abraham et al., 2022) and those with diabetes (34.61%) (Tegegne et al., 2023). The higher prevalence of depression in people with HF could be due to the unpredictable nature of HF symptoms, physical limitations, the constant threat of acute exacerbations, and the significant lifestyle changes required for management (Eisele et al., 2017; Sbolli et al., 2020). Unlike cancer, which may have periods of remission, or diabetes, which can often be managed with medication and diet, HF presents ongoing challenges that may contribute to a higher risk of depression (Celano et al., 2018; Radha & Lopus, 2021; Wong et al., 2021).

The qualitative findings provide context and depth of the quantitative findings as the participants described the impact of HF on their mental health. During the interviews, depressive symptoms were apparent among many participants. For example, participants explained the experience of distress due to the psychological shock and fear of death following a HF diagnosis. This finding is congruent with a UK-based qualitative study (Thornhill et al., 2008), in which the participants also described their struggles with the overwhelming nature of their condition, including the feelings of tiredness or fatigue, physical limitations, the challenges associated with accessing medications, and financial burdens. This finding is consistent with the findings in the literature (Guan et al., 2022; Harris et al., 2021; Malhotra et al., 2021; Taylor et al., 2017).

Across participants, negative thinking patterns were prevalent and served to reinforce anxiety and persistent depressed mood (Dekker et al., 2009). For instance, one participant shared, *"After I learned about my HF diagnosis, I was anxious. I couldn't sleep at night due to my anxiety. I thought I would die". Another participant said, "I feel down because I can't work as hard as I used to. . . I become fatigued after working hard . . .you know. . . in that case I feel depressed.* This narrative is not only aligned with the high prevalence of depression reported in the quantitative data but also supported by findings from the existing literature, where individuals living with HF have described experiencing both emotional and somatic symptoms of anxiety and depression (Bennett et al., 2000; Dekker et al., 2009; Zambroski, 2003). Participants reported that the physical limitations and the inability to perform daily activities contributed to their increased feelings of depression. These findings are consistent with a similar study conducted in Ireland, where participants described the causes of their depressive symptoms (Ryan & Farrelly, 2009). These physical limitations can lead to a sense of helplessness in the Ethiopian context, which highly values social roles and family responsibilities. These findings support the notion that HF has a significant impact on mental health, shedding light on the importance of early screening of depressive symptoms and the need for psychosocial support for this populations in Ethiopia.

The research identified a significant association between depression and various sociodemographic and clinical factors. For example, females are more likely to be depressed compared to males. This finding is consistent with Al Shamiri et al. (2023), who reported a higher prevalence of depression among females with HF in Saudi Arabia, and Allabadi, Probst-Hensch et al. (2019), who found a similar conclusion in Palestine. This finding is supported by the qualitative data, where many female participants expressed feelings of sadness, hopelessness, and an increased sense of responsibility for their families. This perspective is supported by the conclusion of a systematic review of qualitative studies (Dekker, 2014). In the Ethiopian context, depressive symptoms among females with HF may be caused by biophysiological factors, economic hardship, gender inequality, multiple roles, and caregiving responsibilities (Lesman-Leegte et al., 2008; Molla et al., 2016; Moller-Leimkuhler, 2007). Combined, these findings emphasise the vulnerability of females as a high-risk group for depression among people with HF and, therefore, highlights the need for gender-specific interventions.

In the current research, people with HF and diabetes had noticeably higher prevalence of depression compared to people without diabetes. This finding is supported by other studies (DeWolfe et al., 2012; Fetahu et al., 2021; Husain et al., 2019), which report higher prevalence of depression among people living with HF and diabetes. This could be due to the presence of diabetic complications, persistent poor glycaemic control, and polypharmacy (Egede et al., 2005; Oladeji & Gureje, 2013). These factors may lead to frustration and stress, which may worsen depression symptoms. The qualitative data provide context for this finding by explaining how comorbid diabetes exacerbates depression in this population. Participants living with HF and diabetes shared their experience of dealing with the burden of living with HF and diabetes. For instance, one participant shared, *"I have additional diabetes and high blood pressure…so I am scared…what is going to happen? You become dissatisfied with your life when you have many comorbid conditions".* For these individuals, living with two chronic conditions led to frustration and psychological distress due to additional financial strain, and presented challenges in managing medication adherence and schedules (Dekker, 2014; Jani et al., 2013; Nagelkerk et al., 2006). This underscores the dual impact on psychological well-being, highlighting the need for this population to receive special attention and an integrated approach to manage their HF and diabetes effectively.

Participants taking more than five medications daily had a higher prevalence of depression. This finding is consistent with previous evidence, which demonstrated that polypharmacy was significantly associated with an increased risk of depression in people with HF (Mastromarino et al., 2014; Palapinyo et al., 2021). This was echoed by the participants interviewed in the qualitative arm of this thesis, who received prescriptions for more than five medications daily. This cohort described the challenges they faced while managing multiple medications daily, including scheduling their pills and coping with potential side effects. They expressed feelings of frustration and stress when they forget to take their medications, which in turn contributed to an exacerbation of their depression. These findings are consistent with the reports of other similar qualitative studies (Jani et al., 2013; Nagelkerk et al., 2006). The findings reinforce the importance of monitoring patient medication adherence, co-designing medication routines to encourage adherence, educating patients about the importance of adherence, and managing potential side effects, which are critical for reducing the influence of polypharmacy on depression.

7.3.2. Impact on health-related quality of life (HRQoL)

HRQoL is considered to be an important measurement of overall well-being and health status, especially in people with chronic conditions like HF, where the impact on various aspects of life is significant (Khajavi et al., 2023; Romero et al., 2013). The symptoms of HF, such as fatigue and shortness of breath, combined with the physical limitations imposed by the disease, can significantly impact the HRQoL of affected individuals (Roalfe et al., 2023). Poor HRQoL is associated with an increased risk of morbidity and mortality in people with HF. Therefore, improving their HRQoL is one of the major goals of HF therapy (Lewis et al., 2017). In Ethiopia, HF imposes a unique impact on HRQoL on affected individuals due to socioeconomic and healthcare system factors (Ludwick et al., 2022; Memirie et al., 2022).

The quantitative and qualitative findings of this study revealed the multifaceted impact of HF on HRQoL in Ethiopian people living with HF. The quantitative cross-sectional study of HRQoL (Henok Mulugeta, Peter M Sinclair, & Amanda Wilson, 2023a), using the MLHFQ, indicated that people with HF in Ethiopia had poor physical, emotional, and overall HRQoL. The overall mean MLHFQ score was 48.03±19.73, and 54% of participants had poor HRQoL, highlighting the profound physical and emotional burden of HF on the affected individuals. This finding is consistent with previous studies conducted in northwest Ethiopia (Seid, 2020), China (J. Zhang et al., 2020), and Brazil (Paz et al., 2019), where the majority of participants reported significantly lower scores in both the physical and emotional domains of HRQoL. The qualitative data of this study provide valuable additional insights into the impact of HF on physical, emotional, and social functioning, as well as a rich context for why this happens. In this case, many participants consistently described the challenges they faced, mainly due to the physical symptoms such as fatigue and an inability to live a normal life (Hägglund et al., 2008; Hayeah et al., 2017; Walthall et al., 2019). Many of the participants shared their experiences of limitations on daily physical activities, including difficulty performing their jobs and walking long distances. Participants described how physical symptoms, such as fatigue, affect their daily activities, work, and sleep. Participants also described how their physical limitations affected their employment, leading to frustration and emotional distress (Checa et al., 2020; Li et al., 2019; Ryan & Farrelly, 2009; Thornhill et al., 2008). All participants emphasised the relationship between physical limitations and mental distress, particularly depression (Liljeroos et al., 2023; Walthall et al., 2019). In addition, they shared feelings of loneliness as their physical limitations affected their social activities and relationships (Aldred et al., 2005; McHorney et al., 2021; Niklasson et al., 2022). These findings underscore the need for effective strategies and multifaceted interventions, such as psychosocial interventions aimed at improving the overall well-being of this population.

7.3.3. Factors influencing the HRQoL of people with HF

The revised Wilson and Cleary model and the Theory of Symptom Management (TSM) were integrated to provide a broad comprehensive understanding of HRQoL and its influencing factors in people with HF in Ethiopia. According to the revised Wilson and Cleary model, HRQoL, as the outcome variable, is influenced by six interrelated domains: characteristics of the individual, biological function, symptoms, functional status, characteristics of the environment, and general health perception. The three essential concepts of the TSM are symptom experience, symptom management strategies, and outcomes (HRQoL). Both models emphasise the importance of individual and environmental factors, with symptom experience being central to both, and both approaches share the ultimate goal of improving HRQoL (Figure 24).

The integrated theoretical framework provides both support and expansion to the Wilson and Cleary model of HRQoL. While the quantitative data aligned with the model's proposed relationships between the six interrelated domains, and overall HRQoL, the qualitative findings highlight the importance of patients' illness perceptions and coping strategies, which are not explicitly included in the original model. This suggests a need for a more comprehensive theoretical framework that incorporates both objective measures and subjective experiences in understanding HRQoL in HF.

The integrated framework from the revised Wilson and Cleary model along with the taxonomy of the TSM shows how the domains and concepts are interrelated and, collectively, influence the overall quality of life of people with HF. Each of these factors influence overall HRQoL in different ways, highlighting the need to consider them when developing interventions aiming to improve HRQoL. The impact of these factors on HRQoL is discussed below by integrating the qualitative findings.

While this integration provides a broad framework for this study, it also presents challenges. The linear nature of the six domains affecting HRQoL, as presented by the Wilson and Cleary model, may not adequately represent the cyclical structure in the TSM. Further research exploring more dynamic models that better capture the cyclical nature of HF symptoms and their effect on HRQoL may prove beneficial in future studies.

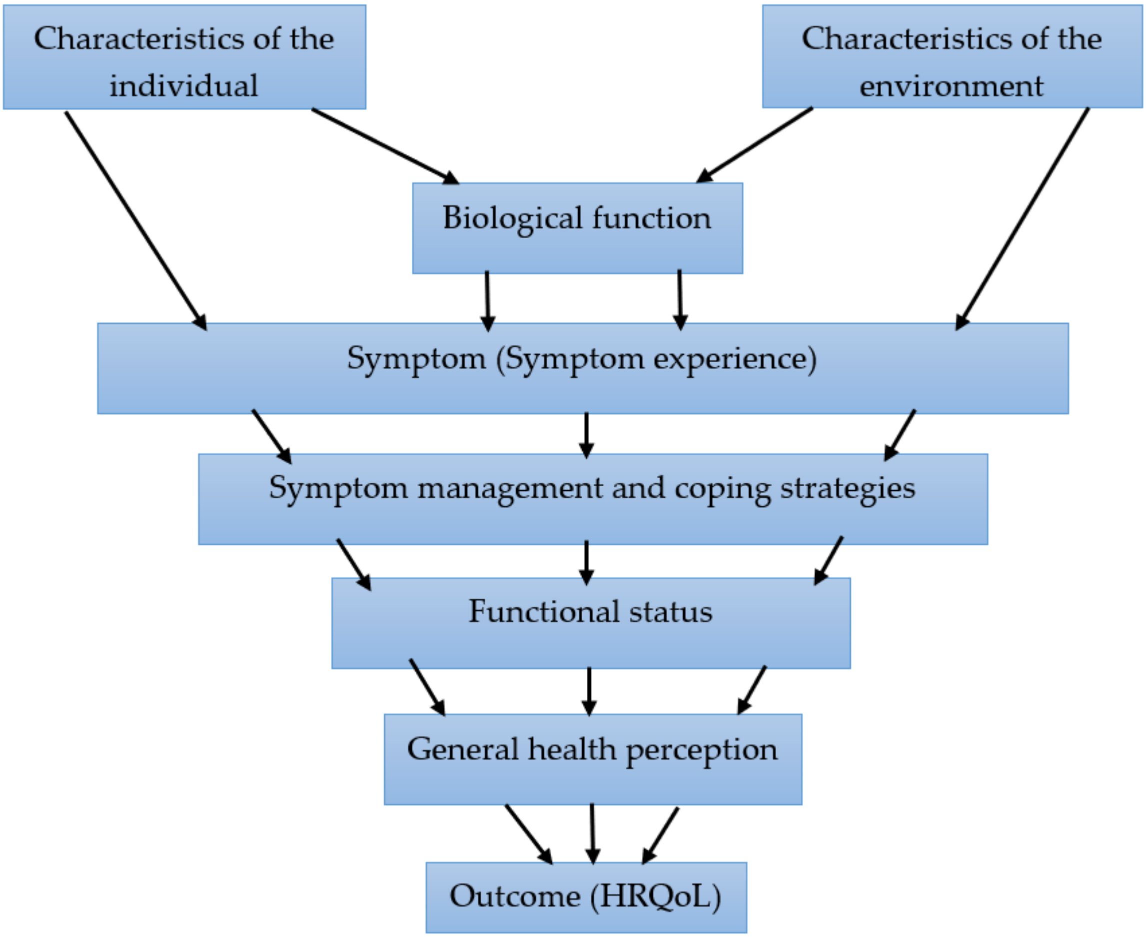


Figure 24: The integrated theoretical framework for understanding HRQoL and its influencing factors in people with HF, adapted from Ferrans et al. (2005) and Dodd (2001)

A) Characteristics of the individual

The findings of the cross-sectional study showed a significant association between age and MLHFQ scores. The MLHFQ has a score range of 0-105, where higher scores indicate poorer HRQoL. This significant association between age and HRQoL aligns with the 'characteristics of the individual' component in the integrated framework. This finding suggests that age, as a non-modifiable individual characteristic, plays a crucial role in shaping the overall HRQoL experience of people with HF in Ethiopia.

Each year increase in age of participant predicts an increase in MLHFQ score by 0.12 ($\beta=0.12$, $p=0.001$), holding all other variables constant. This suggests that increasing age is associated with a lower HRQoL. This decline in HRQoL with age is similar to the reports of other quantitative studies (Chu et al., 2014; Lawson et al., 2023; Yaghoubi et al., 2012). This might be due to the presence of more comorbidities with age, reduced physical capacity, and age-related physiological changes, like muscle strength and tone, which lead to physical limitations among older individuals with HF (Collamati et al., 2016; Regan et al., 2019). This relationship is also observed in the general population (Anjum et al., 2024). The 0.12-point decrease in HRQoL score per year of increase in age is statistically significant but may not be clinically meaningful on its own over short time periods. However, its cumulative effect over longer periods could become clinically relevant. For instance, over a 10-year period, this would equate to a 1.2-point decrease in HRQoL score ($10*0.12=1.2$). For a 20-year difference in age, we would expect a 2.4-point difference in HRQoL score, all else being equal. The significant negative association between age and HRQoL identified in the quantitative analysis was contextualised by the qualitative data, where older participants described age-related challenges that significantly influence their quality of life, including the progression of their HF, comorbidities, functional decline, and psychological conditions. For instance, one 73-year-old participant stated, *"I used to be quite physically active, but I'm not now, it's become harder to manage my HF, which could be related to ageing"*. This finding suggests that HRQoL in people with HF declines steadily with age, emphasising the need for holistic and age-specific interventions that can address age-related factors and prioritise the unique needs of older individuals with HF.

B) Characteristics of the environment

The cross-sectional study revealed the significant influence of employment status and social support on the overall HRQoL. This significant association aligns with the 'characteristics of the environment' component in the integrated framework. In agreement with previous studies (Chu et al., 2014; Erceg et al., 2013; Pour et al., 2016), the significant association between employment status and HRQoL in the quantitative analysis indicates that unemployed individuals are more likely to experience low HRQoL. An inability to pay for medications contributes to physical decline and subsequent depression. This finding was supported by the qualitative data, in which unemployed participants described how the impact of their health condition contributed to losing their job, which leads to financial hardship and depression. They expressed concern about unaffordable out-of-pocket healthcare expenses. In addition, participants reported challenges in finding their prescriptions on the open market, with the high costs of medications significantly impacting their ability to manage symptoms effectively (Guan et al., 2022; Malhotra et al., 2021). This finding underscores the profound economic impact of HF, highlighting the negative consequences of financial hardship in managing HF. The serious financial stress in this population could be attributed to limited health care funding, as the Ethiopian health care system prioritises funding infectious diseases, such as TB and HIV, over non-communicable disease like HF (Debie et al., 2022). Therefore, enhanced interventions by the government or NGOs, including a strong insurance coverage program and targeted financial assistance initiatives, are critical to effectively address the financial demands associated with managing HF.

Social support scores were significantly associated with HRQoL, indicating that people with lower levels of social support networks had poorer overall HRQoL. This finding is consistent with other similar quantitative studies (Al Shamiri et al., 2023; Barutcu & Mert, 2013; Compare et al., 2013; Soleimani et al., 2020). This strong association between social support and HRQoL found in the quantitative data is explained deeper from the personal experiences of the participants in the qualitative data. The participants frequently described how social support, including emotional, physical, and economic assistance from families and significant others, helped them to cope with their condition. Participants reported that support may involve anything from daily practical assistance at home to attending follow-up appointments. This is consistent with other studies (Checa et al., 2020; Mahoney, 2001; Seah et al., 2016), where participants highlighted the importance of social support for maintaining their mental well-being while coping with the challenges of living with HF in their daily lives. Some participants described how excessive support from family members led to feelings of dependence and frustration, potentially negatively impacting their HRQoL. For instance, an older woman who recently lost her husband shared her struggle with depressive symptoms, which directly impacted her HRQoL. She linked these emotions to a lack of support, on which she had previously depended. Strong social and emotional support increases the sense of autonomy and self-worth of people with chronic conditions, leading to a significant improvement in their HRQoL (American Psychological Association, 2019). Social connections and supports are highly valued in Ethiopia. For instance, traditional social support systems, such as ‘Idir’, provide a wide range of supports for individuals in need to improve social support, which ultimately leads to a better HRQoL (Diress et al., 2022). Therefore, strong social support connections should also be included in HF care plans to enhance the overall well-being of individuals.

C) Biological function and symptoms (symptom experience)

In the quantitative cross-sectional study, comorbid diabetes (DM) was a significant predictor of poor HRQoL, aligning with the 'biological function' component in the integrated framework. This finding is consistent with the reports of previous studies. For instance, Alaloul et al. (2017), in a study conducted in Jordan on factors associated with quality of life of people with HF, reported that the presence of diabetes significantly affected the HRQoL of people with HF. Similarly, Fotos et al. (2013) evaluated the HRQoL of people with HF in a population in Greece and reported that people with HF and diabetes had significantly lower quality of life compared to those without diabetes. Comorbid diabetes in people with HF is associated with poorer health outcomes, including a higher risk of rehospitalisation, poor HRQoL, and mortality (Elendu et al., 2023; Reeves et al., 2015). In the qualitative descriptive study, participants with comorbid diabetes shared their experiences on the challenges of managing two chronic conditions, particularly the need to take more medication and the additional financial burden that was associated with it (Forsyth et al., 2023). They described how DM exacerbates their symptoms and physical limitations, affecting their HRQoL. They also expressed a great sense of fear and uncertainty about their future health, feeling that their health was declining because of having DM and HF together, echoing the findings of a comparable qualitative study conducted in Spain (Checa et al., 2020).

People with HF experience various physical and emotional symptoms that can affect their HRQoL (Blinderman et al., 2008; Hwang et al., 2014). While the quantitative cross-sectional study of this thesis did not evaluate the physical symptoms and their influence on HRQoL, the qualitative descriptive study arm did explore participants’ experiences of physical symptoms and their effects on HRQoL. Participants reported that physical symptoms, particularly fatigue, had a significant effect on their daily activities and caused emotional distress (depression). This finding is consistent with the findings reported in other studies (Hägglund et al., 2008; Hayeah et al., 2017; Walthall et al., 2019). Similarly, using a mixed methods design, Rubio et al. (2021) found that physical symptoms were strong predictors of poor HRQoL in people with HF in Spain. Additionally, their quantitative data revealed a strong positive association between depression and HRQoL (Rubio et al., 2021).

In the cross-sectional study, comorbid depression was significantly associated with HRQoL. The qualitative data, where participants described how depression causes a lack of energy and exacerbates feelings of social isolation, supports the quantitative finding of a significant association between depression and HRQoL. Similar findings are widely reported in the literature. For instance, a significant association between depression and HRQoL has been reported in Jordan (AbuRuz, 2018; Alemoush et al., 2021), Serbia (Erceg et al., 2013), Georgia (DeWolfe et al., 2012), South Korea (Son et al., 2012), and South Africa (Tsabedze et al., 2021). The findings of the qualitative descriptive study reinforce the findings of a significant association between depression and HRQoL in the cross-sectional study, as many participants frequently described how depression affects their physical, emotional, and social well-being. They reported that consistent fatigue often hinders their ability to perform daily activities, which leads to feelings of sadness and hopelessness. The COVID-19 epidemic and civil war in Ethiopia, during the data collection period, may have further exacerbated these emotional feelings of the participants, thereby affecting their HRQoL. Participants also expressed that the physical limitations imposed by their condition result in a lack of energy or motivation to engage with others, which can further exacerbate the physical limitations and social isolation. This is consistent with the reports of other similar studies (Dekker, 2014; Heo et al., 2009; Jeon et al., 2010). In addition, symptom severity and symptom distress were found to be the strongest predictors of HRQoL in a cross-sectional study conducted in Myanmar (Thida et al., 2021). These findings emphasise the significant influence of physical and emotional symptoms on the HRQoL of people with HF, indicating the need to develop focused nursing interventions that can effectively reduce symptom experiences to enhance the HRQoL of these population.

D) Functional status

The cross-sectional quantitative study showed that people with NYHA classes III and IV scored statistically significantly higher MLHFQ scores than class I and II, indicating poorer HRQoL. The better HRQoL reported by people with NYHA classes I and II could be due to better physical functioning and less severe symptoms, compared to people with NYHA classes III and IV. Several studies have reported a decline in HRQoL as severity of HF increases. For example, quantitative studies by Erceg et al. (2013) in Serbia and Eskandari et al. (2016) in Iran found that higher NYHA classes were independent predictors of poor HRQoL in people with HF. The association between higher NYHA class and impaired HRQoL may be due to the decline in daily activity ability as disease severity escalates, thereby negatively impacting quality of life (Poorshadan et al., 2019). The qualitative data supports this finding, showing that individuals with a higher NYHA class describe overwhelming pain and fatigue, which significantly limit their daily physical activities and leave them feeling hopeless. They also discuss emotions such as anxiety and depression, due to fear of disease progression and death. The high cost of medical care and the unavailability of medications in Ethiopia, as identified in the qualitative descriptive study conducted for this thesis, exacerbate their emotional distress, especially for those with advanced HF, reducing their HRQoL. The results also demonstrate a complex interplay between symptom status and functional status, as proposed in the Wilson and Cleary model. For instance, the qualitative data revealed how fatigue (a key symptom of HF) directly impacts participants' ability to perform daily activities (functional status), which, in turn, influences their overall perception of HRQoL.

E) General health perceptions

A significant influence of general health perception on HRQoL was observed in the quantitative cross-sectional study of this thesis, where respondents who reported lower levels of health perception had poorer HRQoL. This finding is comparable with the findings of a cross-sectional study conducted in Eastern Norway, which highlighted that the participant’s perception of their illness significantly affected their overall well-being (Lerdal et al., 2019). This finding is supported in the qualitative interviews, where many of the participants perceived themselves as being in poor health status, which contributes to feelings of depression, thereby reducing their HRQoL, emphasising the emotional impact of general health perception on HRQoL. This is consistent with the findings of a similar study, where participants expressed the belief that their general health status influenced their HRQoL (Heo et al., 2009). In addition, many participants in the current study had a lesser understanding of the standard definition of HRQoL, compared to participants in previous research (Hayeah et al., 2017; Heo et al., 2009). In Ethiopia, people may not be able to separate HRQoL from overall life satisfaction due to a lack of awareness and poor health literacy. Furthermore, understanding and expressing the concept of HRQoL in Ethiopian cultures can be challenging due to a lack of direct or easily understandable translation in local languages. According to the WHO, HRQoL is an individual's 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 (WHO, 2024). Evaluating participants' perceptions of HRQoL may be critical for assessing how the disease and its treatment affect their overall sense of well-being (Calvert et al., 2005).

7.3.4. Symptom management and coping strategies

Symptom management and coping strategies are considered one of the essential treatment options for HF, with people often integrating various approaches to manage their symptoms to cope with their condition (Bender et al., 2018; Jaarsma et al., 2021). The integrated framework, which was created by combining the revised Wilson and Cleary model and the TSM, shows how effective symptom management and coping strategies, supported by individual and environmental factors, can alleviate symptoms and improve functional status, leading to improved HRQoL.

Although symptom management and coping strategies were not investigated in the quantitative cross-sectional study, the findings of the qualitative descriptive study expand the current knowledge regarding the symptom management and coping strategies used by people with HF. Participants described the strategies they use, with most participants using more than one strategy. Consistent with previous research (Bennett et al., 2000; Checa et al., 2020; Li et al., 2019), almost all participants use self-management strategies including medication adherence, dietary modifications, regular exercise, and weight monitoring. Alternative approaches have been reported by participants in other studies as their preferred symptom management strategies (Bennett et al., 2000; Niklasson et al., 2022), such as undertaking physical activities more slowly and avoiding heavy exertion. In addition, the participants in this research reported using a variety of behavioural management strategies, including accepting their condition, engaging in distraction, such as reading books and watching television, and adjusting to cope with it. These results are in line with those of other qualitative studies (Bennett et al., 2000; Checa et al., 2020; Mahoney, 2001; Seah et al., 2016), which all found that behavioural management strategies help people to reduce their symptoms and cope with their condition. Participants also reported that having social support networks (Heo et al., 2009; Seah et al., 2016; Thornhill et al., 2008) and sharing experiences with others facing a similar condition

(Gregory et al., 2006; Lockhart et al., 2014) helped them improve their ability to cope. Moreover, spiritual activities, such as the use of holy water, prayer, and reading the Bible, which have been reported in previous research (Hopp et al., 2012; Seah et al., 2016; Sepehrian et al., 2020), were also reported to be important coping mechanisms for many of the participants in this study. These insights provide additional understanding of how people with HF manage and cope with their symptoms. The results underscore the importance of symptom management strategies, a key component of the TSM, in improving the overall HRQoL of people living with HF. This suggests that interventions targeting symptom management education and support could be particularly effective in enhancing the HRQoL for people with HF in Ethiopia. Health professionals should also consider these strategies when developing care plans for people with HF.

7.4. Implications for clinical practice and policy

The following sections discuss the implications of the research findings in relation to recommendations for clinical practice and policy.

7.4.1. Clinical practice

The quantitative findings demonstrate the significant burden of depression and poor HRQoL among people with HF. The qualitative data support the quantitative findings by providing the context and a deeper insight into how HF and its symptoms affect the emotional and physical functioning of affected individuals. This knowledge can help clinicians incorporate early screening for comorbid depression and regular HRQoL assessment into their routine clinical practice, and plan effective interventions aimed at improving the overall well-being of this population. People with HF who are older, unemployed, depressed, diabetic, have low levels of social support, or are with advanced disease stage may need enhanced assessment of HRQoL. Identifying these critical factors helps clinicians to develop individualised care plans aimed to address both clinical and psychosocial aspects of HF and develop specific interventions targeting the identified factors. Mental health professionals should collaborate with cardiovascular health professionals for comprehensive management of people with heart failure. They should prioritise their efforts in managing comorbidities, like depression and diabetes, and improving social networks.

7.4.2. Policy

The quantitative study demonstrates the high prevalence of depression in people with HF and its significant impact on their HRQoL. The qualitative study, on the other hand, showed the specific experiences and challenges that affect their mental health, such as financial difficulties, unavailability of medications, and lack of continuity of care. These findings could lead to policy changes that promote the integration of mental health screening and psychosocial interventions within the clinical guidelines for managing HF in Ethiopia. Policymakers in Ethiopia, such as the Ministry of Health, should allocate adequate resources for mental health services aimed at reducing depression and improving the HRQoL of Ethiopian people with HF. The evidence of financial difficulties faced by the participants may serve as leverage for policy implementation, to ensure that HF medical care is accessible and affordable. The qualitative study explored how participants manage their symptoms and the strategies they use to cope with their condition, which was not examined in the quantitative study. These additional insights can inform policymakers to consider these strategies that are implemented by individuals while developing interventions aimed at improving the outcomes of HF.

7.5. Strength and limitations of the study

7.5.1. Strengths of the study

This study is one of the first to comprehensively examine the impact of HF on mental health and HRQoL in Ethiopia. By focusing on this understudied population, this research contributes valuable insights to the global understanding of HF in diverse contexts. The use of a sequential explanatory mixed methods design is a key strength. This design had a distinct advantage to the previous studies as it combined the quantitative investigation of depression and HRQoL with qualitative insights from individuals' perspectives. The integration of both quantitative and qualitative methods has provided a more comprehensive and nuanced knowledge of the impact of HF in Ethiopia. For instance, while the quantitative data showed a high prevalence of depression, the interviews revealed the complex relationship between physical symptoms, social isolation, and financial stress that contribute to this depression. This insight would not have been possible with a single methodological approach. In addition, the qualitative part of this thesis has contributed to the limited evidence from Ethiopia related to the qualitative exploration of the experiences of people with HF and its impact on their HRQoL, as highlighted in the literature review. This research used a combination of two theoretical frameworks, providing the best evidence through the integration of these frameworks. The integrated framework provides a strong theoretical foundation for the study, as well as a more comprehensive understanding of HRQoL and its influencing factors in people with HF.

7.5.2. Limitations of the study

This mixed methods research provides valuable insight on the prevalence of depression and level of HRQoL, as well as the impact on physical, emotional, and social aspects of life, following the diagnosis of HF. However, there are some limitations that should be considered for future research.

Potential for selection bias: The systematic reviews provide comprehensive summaries and syntheses of the existing literature but may be subject to selection bias introduced by restricting inclusion to research published after 2012 and English language articles, and there was significant heterogeneity across the included studies. Likewise, while the qualitative study provided rich, in-depth insights into the experiences of people living with HF in Ethiopia, it is important to acknowledge the contextual nature of the findings. The experiences shared by the participants reflect their unique perspectives and circumstances, which may differ from those of other individuals living with HF in different contexts or settings (Neergaard et al., 2009).

Generalisability: The results of this mixed methods study might not be generalised to all other low- and middle-income countries or culturally unique contexts. The analysis was limited in its generalisability by the specific social, economic, and healthcare characteristics of Ethiopia. While the quantitative findings provide valuable insights into the prevalence of depression and factors affecting HRQoL in HF patients in Ethiopia, the scope of generalisation has to be carefully considered. The sample, drawn from the cardiac outpatient departments, may not fully represent the diverse Ethiopian population, particularly those in rural areas or without access to specialist care. The qualitative findings offer a rich, contextual understanding of living with HF in Ethiopia. The transferability of the findings should be considered, noting the specific context of the study. While the themes and experiences identified may resonate with other settings, the unique cultural, social, and healthcare context of Ethiopia should be taken into account when considering the applicability of the findings to other populations or settings.

Potential for response bias: The use of self-report questionnaires to measure depression and HRQoL during the quantitative phase of the study may be subject to recall bias and social desirability bias (Althubaiti, 2016). Participants might have under- or over-reported their symptoms due to social desirability or other factors.

Temporal causality: The study provides a snapshot of the outcomes (depression and HRQoL) rather than tracking changes over time due to the cross-sectional nature of the quantitative phase, which measured the outcomes among the study participants simultaneously at a single point in time, making it challenging to establish causal relationships (Savitz & Wellenius, 2023; Setia, 2016).

Potential researcher bias: Despite efforts to maintain objectivity, the qualitative data collection, analysis, and interpretation process may be influenced by the researchers' experiences and perspectives. Member checking and peer debriefing were performed to mitigate the researcher' bias, while acknowledging the possibility of alternative interpretations of the data.

7.6. Directions for future research

Several directions for future research are recommended to enhance the robustness and generalisability of the findings in this area, building on the identified limitations.

To provide more reliable evidence, future research should use a combination of self-report and digital medical record data, as well as conduct a longitudinal study, to better understand the dynamic relationships between symptoms, functional status, and HRQoL over time throughout the course of HF, as proposed in the integrated theoretical framework.

This study assesses the impact of HF on mental health by determining the prevalence of depression in people with HF. However, it did not extensively examine other mental health conditions, which could influence HRQoL in this population. Future research should assess other mental health conditions, such as anxiety and stress, in people with HF for a more comprehensive understanding of the impact of HF on mental health.

Although the integrated framework provides a comprehensive view of factors influencing the overall HRQoL of people with HF, some components, particularly those related to biological function and functional status, were not as thoroughly assessed quantitatively in this study due to resource constraints. However, the qualitative phase touched on some aspects of medication adherence and self-care practices. Future studies could further validate this framework and provide additional insights by incorporating more detailed variables from physiological measures of biological function, such as data from physical exams and laboratory tests, as well as functional status, including medication adherence and self-care practices.

While specific results may not be directly generalisable to all populations, the analytical approaches used, and the patterns identified can be applied more broadly. For instance, researchers could adopt a mixed methods approach to understand the multifaceted nature of HRQoL in HF for studying other chronic conditions or in different cultural contexts. Furthermore, these findings, while specific to the study context, highlight the need for similar investigations in other regions of Ethiopia and other low- and middle-income countries.

Such research would help to build a more comprehensive understanding of HF experiences across diverse settings, allowing for more confident generalisation of findings and the development of broadly applicable interventions.

CHAPTER 8: CONCLUSIONS

The global prevalence of HF is increasing, making it a major cause of mortality. A HF diagnosis results in a wide range of emotional and social distress due to its physical symptoms, debilitating health conditions, and the required lifestyle changes, significantly impacting mental health and HRQoL. Depression is a common mental health condition affecting a considerable proportion of people with HF and is a significant predictor of negative outcomes in this population, such as poor HRQoL (Carmin et al., 2024; Patel et al., 2022).

This thesis has demonstrated the impact of HF on mental health and HRQoL. Phase I of this thesis (the systematic reviews) revealed that depression is highly prevalent among people living with HF in LMICs, compared to high-income countries, and it is positively associated with HRQoL. The HRQoL of people with HF in these counties is poor. These findings emphasise the importance of early detection and management of depression to improve the HRQoL of people living with HF in LMICs.

Phase II of the research (quantitative cross-sectional study) provided valuable information into the prevalence of depression and levels of HRQoL among Ethiopian adults with HF, as well as the factors influencing these outcomes. This phase of the thesis revealed a high prevalence of comorbid depression and poor HRQoL (both physical and emotional), with several sociodemographic and clinical factors contributing to these outcomes. These findings highlight the importance of addressing these multidimensional factors to improve overall HRQoL.

Phase III of the research (qualitative descriptive study) enriched the quantitative findings by providing a comprehensive understanding of the participants' experiences of living with HF and its profound impact on their HRQoL. Participants reported initially feeling shocked to receive an HF diagnosis and expressed anxiety about their future. Symptoms of HF, such as fatigue and associated physical limitations, adversely affect their work, sleep, and social activities. However, many participants reported good progress after beginning medical care and employing their own symptom management strategies. This study also describes the major challenges faced by participants, including financial difficulties, medication availability, and a lack of continuity of care.

This mixed methods study provides both objective and subjective insights on the impact of HF on mental health and HRQoL particularly in the Ethiopian context. Integrating quantitative and qualitative data has provided a comprehensive picture of the challenges faced by this population, from physical symptoms to psychosocial struggles. These findings highlight the need for integrated models that address both the physical and mental health needs of people living with HF in a LMIC- setting like Ethiopia. Stakeholders, including healthcare providers, policymakers, and researchers, must act on these findings to implement comprehensive care strategies that can improve the health outcomes for this vulnerable population. This study also lays the groundwork for future interventions aimed at improving the holistic well-being of people with HF in Ethiopia and similar contexts.

Although this study is contextualised within Ethiopia, the findings contribute to the broader theoretical understanding of how chronic illnesses like HF impact individuals in low- and middle-income countries. The relationships observed between physical symptoms, psychological well-being, and socioeconomic factors may inform more general models of chronic disease management in LMICs.

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APPENDICES

8.1. Appendix 1. Supplementary information of systematic reviews

Supplement 1: The protocol for Systematic Review 1

Prevalence of depression and its association with health-related quality of life in people with heart failure in low- and middle-income countries: a protocol for systematic review

Authors

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Abstract

Background: Heart failure is a serious clinical burden with variety of physical and emotional symptoms such as fatigue, reduced functional capacity, edema, dyspnea and depression. These symptoms limit patients' daily physical and social activities, which reduce their health-related quality of life. The objective of this systematic review is to estimate the prevalence of depression and its association with HRQoL in people living with heart failure in LMICs.

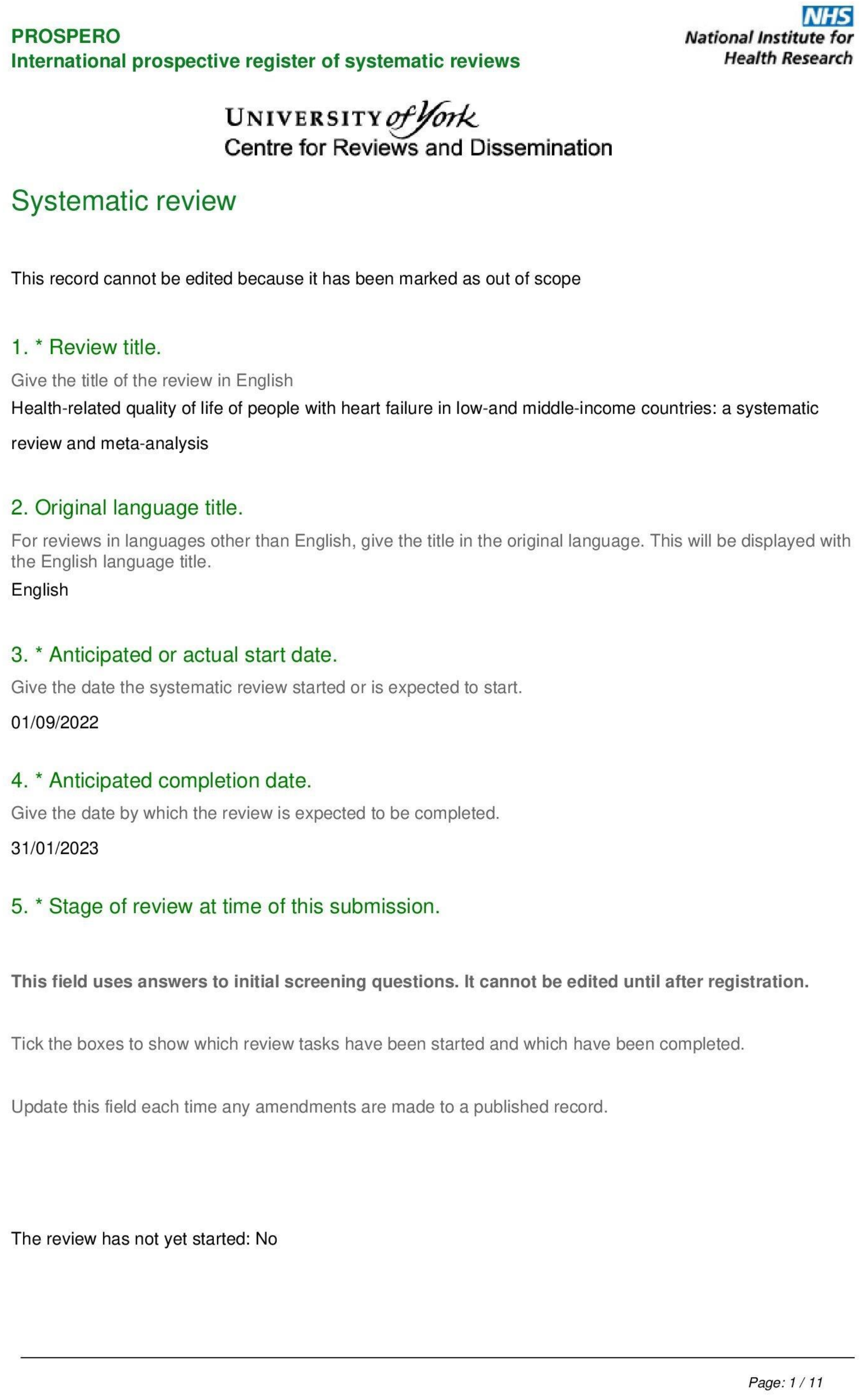
Methods: The primary outcome is the prevalence of depression in people with heart failure. The secondary outcome is association of depression with health-related quality of life. Comprehensive search of MEDLINE, PsycINFO, EMBASE, CINAHL, Web of Science, Scopus and JBI EBP databases will be conducted to identify relevant studies. The methodological quality of each article will be assessed using a JBI critical appraisal instruments. A random-effects model using the DerSimonian and Laird method will be employed to estimate the regional prevalence. Heterogeneity across the studies will be assessed by Cochrane Q test and I^2 statistic. A funnel plot and Egger's test will be used for assessing publication bias. This protocol is developed in accordance with the JBI methodology for systematic reviews. All statistical analyses will be performed using STATA version 17 software. The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines 2020 will be followed for reporting the results.

Discussion: This systematic review will provide up-to-date high-quality evidence on the impact of depression and inform healthcare policymakers on effective ways to improve care for this population in LMICs. The results will be published in a peer-reviewed journal.

Systematic review registration: PROSPERO CRD42022361759.

Keywords: Heart failure, depression, HRQoL, systematic review, LMICs

Supplement 2: PROSPERO registration for Systematic Review 2



PROSPERO
International prospective register of systematic reviews

NHS
National Institute for Health Research

UNIVERSITY of York
Centre for Reviews and Dissemination

Systematic review

This record cannot be edited because it has been marked as out of scope

1. * Review title.

Give the title of the review in English

Health-related quality of life of people with heart failure in low-and middle-income countries: a systematic review and meta-analysis

2. Original language title.

For reviews in languages other than English, give the title in the original language. This will be displayed with the English language title.

English

3. * Anticipated or actual start date.

Give the date the systematic review started or is expected to start.

01/09/2022

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

31/01/2023

5. * Stage of review at time of this submission.

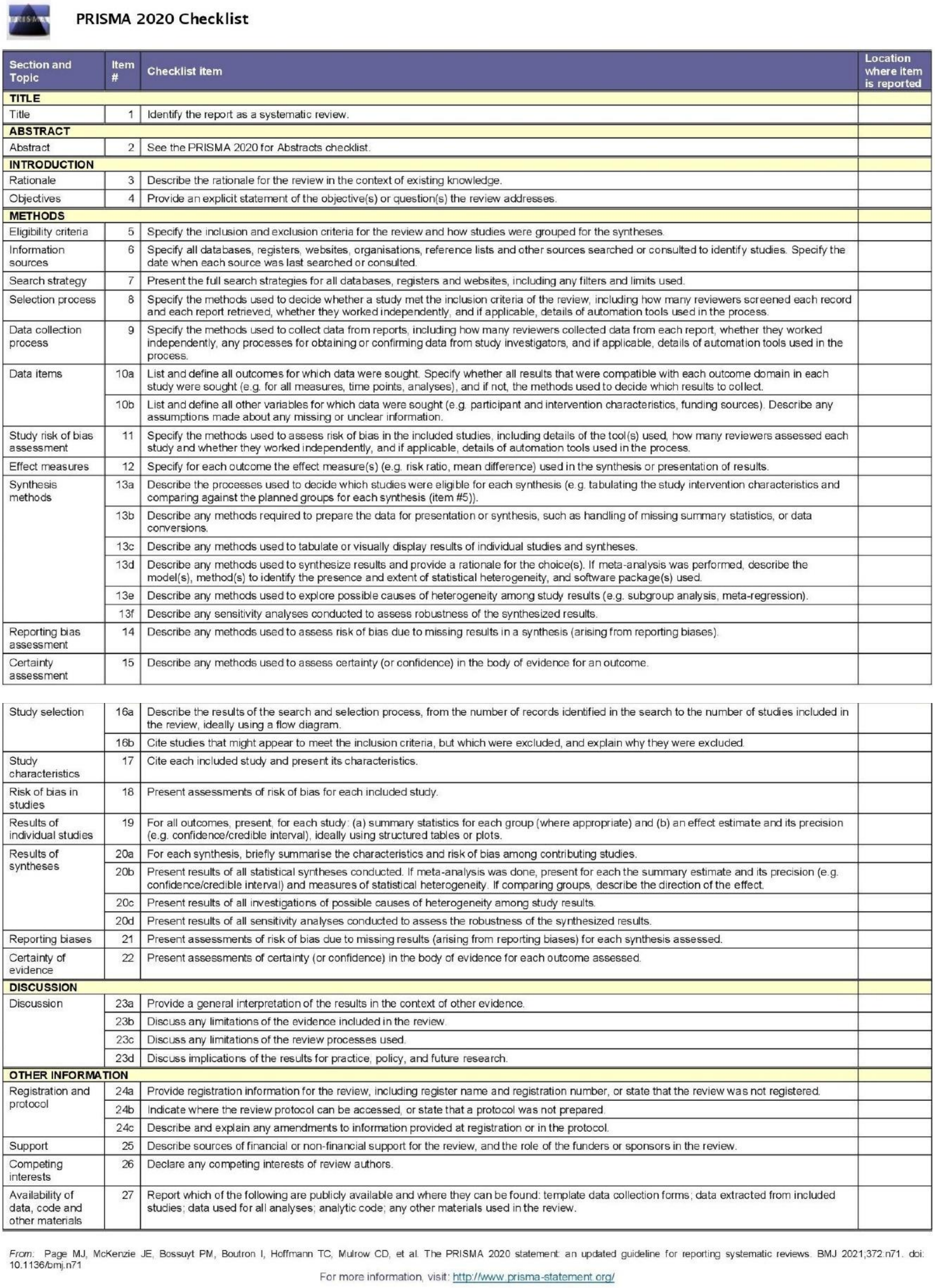
This field uses answers to initial screening questions. It cannot be edited until after registration.

Tick the boxes to show which review tasks have been started and which have been completed.

Update this field each time any amendments are made to a published record.

The review has not yet started: No

Supplement 3: PRISMA 2020 checklist



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	
Study characteristics	17	Cite each included study and present its characteristics.	
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	
	23b	Discuss any limitations of the evidence included in the review.	
	23c	Discuss any limitations of the review processes used.	
	23d	Discuss implications of the results for practice, policy, and future research.	
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

Supplement 4: Search strategy for Systematic Review 1

Search strategy of databases from January 2012 to August 2022 for systematic review titled "Prevalence of depression and its association with health-related quality of life in people with heart failure in low-and middle-income countries".

Medline		
No	**Query**	**Records retrieved**
1	Depression/ or Depression.tw.	413590
2	Quality of life.tw. or "Quality of Life"/	391275
3	Health-related quality of life.tw.	51063
4	HRQoL.tw.	19568
5	QoL.tw.	45371
6	Heart failure.tw. or Heart Failure/	227166
7	heart disease*.tw. or heart diseases/	236293
8	cardiac failure.tw.	12328
9	#1 OR #2 OR #3 OR #4 OR #5	765187
10	Low-middle-income countries*	1809560
11	#6 OR #7 OR #8	446521
12	#9 AND #10 AND #11	1230
13	limit #12 to "all adult (19 plus years)"	754
14	Limit #13 to English, yr="2012 -Current	508
Embase		

No	**Query**	**Records retrieved**
1	Depression/ or Depression.tw.	695337
2	Quality of life.tw. or "Quality of Life"/	688384
3	Health-related quality of life.tw.	75596
4	HRQoL.tw.	32656
5	QoL.tw.	87373
6	Heart failure.tw. or Heart Failure/	406054
7	heart disease*.tw. or heart diseases/	336758
8	cardiac failure.tw.	17910
9	#1 OR #2 OR #3 OR #4 OR #5	1308642
10	Low-middle-income countries*	2111652
11	#6 OR #7 OR #8	704966
12	#9 AND #10 AND #11	2544
13	limit #12 to (adult <18 to 64 years> OR aged <65+ years>)	1578
14	limit #13 to English, yr="2012 -Current"	1119
JBI database		
No	**Query**	**Records retrieved**
1	Depression.mp.	1323
2	Health-related quality of life.mp.	381

3	HRQoL.mp.	75
4	quality of life.mp.	1816
5	QoL.mp.	221
6	Heart failure.mp.	310
7	heart disease*.mp.	377
8	cardiac failure.mp.	55
9	#1 or #2 or #3 or #4 or #5	2507
10	Low-middle-income countries*	1468
11	#6 or #7 or #8	593
12	#9 and #10 and #11	138
13	limit #12 to English, yr="2012 -Current"	53
Web of science		
No	**Query**	**Records retrieved**
1	**TS=(Depression OR "Quality of life" OR "Health-related quality of life" OR HRQoL OR QoL)**	1061448
2	**TS=("Heart failure" OR "heart disease*" OR "cardiac failure")**	574654
3	Low-middle-income countries*	4199317
4	**#1 OR #2**	1703
5	**#3 AND #4**	1426
6	**Limit 5 to English** (Languages), yr="2012 -Current"	1236

PsycINFO

No	Query	Records retrieved
1	**DE "Major Depression" OR DE "Depression" OR "Depression"**	530173
2	**DE "Health-related quality of life” OR DE "Health-related quality of life" Quality of life" OR HRQoL OR QoL)**	123199
3	**DE "Heart disorders" OR "Heart failure" OR "heart disease*" OR "cardiac failure"**	26789
4	Low-middle-income countries*	581990
5	**#1 OR #2**	416168
6	**#3 AND #4 AND #5**	863
7	Limit #**6 to English** (Languages), yr="2012 -Current"	661

Low-middle-income countries*

=(afghanistan or albania or algeria or american samoa or angola or argentina or armenia or azerbaijan or bangladesh or belarus or belize or benin or bhutan or bolivia or "bosnia and Herzegovina" or botswana or brazil or bulgaria or burkina faso or burundi or cabo verde or cambodia or cameroon or central african republic or chad or china or colombia or comoros or congo or costa rica or "cote d'ivoire" or cuba or djibouti or dominica or ecuador or egypt or arab republic or el salvador or equatorial guinea or eritrea or eswatini or ethiopia or fiji or gabon or gambia or georgia or ghana or grenada or guatemala or guinea or guinea bissau or guyana or haiti or honduras or india or indonesia or iran or iraq or jamaica or jordan or kazakhstan or kenya or kiribati or korea or kosovo or kyrgyz republic or lebanon or lesotho or liberia or libya or madagascar or malawi or malaysia or maldives or mali or marshall islands or mauritania or mauritius or mexico or micronesia or moldova or mongolia or montenegro or morocco or mozambique or myanmar or namibia or nepal or nicaragua or niger or nigeria or north macedonia or pakistan or panama or papua new guinea or paraguay or peru or philippines or romania or russia* or rwanda or samoa or "sao tome and principe" or senegal or serbia or sierra leone or solomon islands or somalia or south africa or south sudan or sri lanka or "st. lucia" or "st. vincent and the grenadines" or sudan or suriname or syrian arab republic or tajikistan or tanzania or thailand or timor leste or togo or tonga or tunisia or turkey or turkmenistan or tuvalu or uganda or ukraine or uzbekistan or vanuatu or vietnam or west bank or gaza or yemen or zambia or zimbabwe or low income countr* or middle income countr* or developing countr*).ti,ab,sh,kf.

Supplement 5: Search strategy for Systematic Review 2

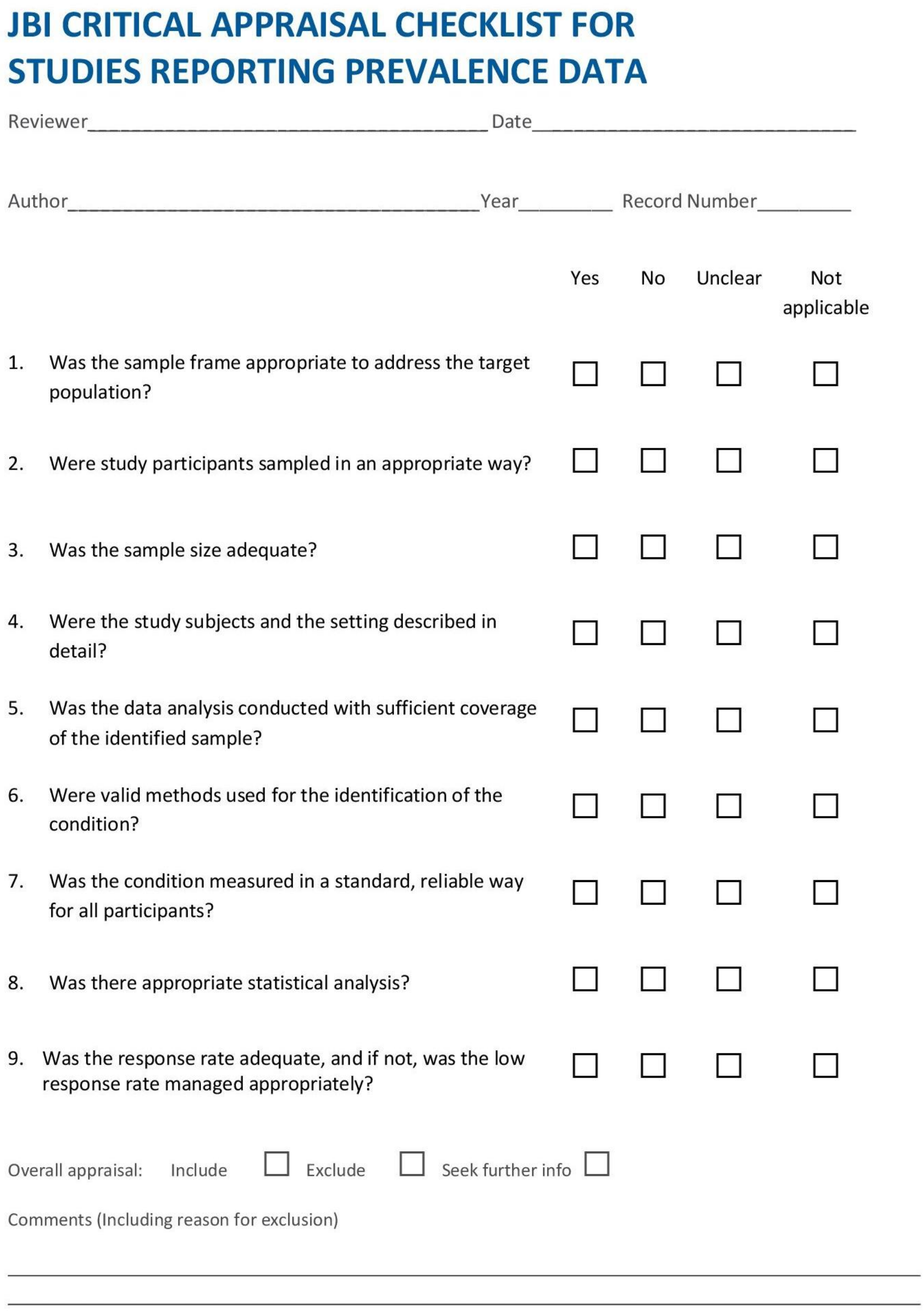
Search strategy of databases from January 2012 to November 2022 for systematic review titled "Health-related quality of life of people with heart failure in low-and middle-income countries".

Medline		
No	**Query**	**Records retrieved**
1	Quality of life.mp. or "Quality of Life"/	417881
2	QoL.mp.	48319
3	HRQoL.mp.	20894
4	Heart failure.mp. or Heart Failure/	240178
6	cardiovascular diseases/ or heart diseases/	243191
7	cardiac failure.mp.	12636
8	Low-middle-income countries*	1965571
9	**#1 OR** #2 **OR** #3	419431
10	#4 **OR** #5 **OR** #6	473322
11	#7 AND #8 AND #9	819
12	limit #10 to (English language and yr="2012 -Current" and "all adult (19 plus years)")	368
Embase		
No	**Query**	**Records retrieved**
1	Quality of life.mp. or "Quality of Life"/	739110
2	QoL.mp.	92192
3	HRQoL.mp.	34611
4	Heart failure.mp. or heart failure/	470791
6	heart disease*.mp. or heart disease/	452269
7	cardiac failure.mp.	18716
8	Low-middle-income countries*	2412464
9	**#1 OR** #2 **OR** #3	745678
10	#4 **OR** #5 **OR** #6	859719
11	#7 AND #8 AND #9	2159

12	limit #11 to (human and English language and yr="2012 -Current" and adult <18 to 64 years>)	928
JBI database		
No	**Query**	**Records retrieved**
1	Quality of life.mp.	1850
2	QoL.mp.	227
3	HRQoL.mp.	75
4	Heart failure.mp	315
6	heart disease*.mp.	377
7	cardiac failure.mp.	55
8	Low-middle-income countries*	1485
9	**#1 OR** #2 **OR** #3	1855
10	#4 **OR** #5 **OR** #6	597
11	#7 AND #8 AND #9	117
12	limit #10 to yr="2012 -Current"	85
Web of science		
No	**Query**	**Records retrieved**
1	**"Quality of life" OR QoL OR HRQoL**	680, 492
2	**"Heart failure" OR "heart disease*" OR "cardiac failure"**	1,335, 789
3	Low-middle-income countries*	6,360,850
4	**#1 AND #2 AND #3**	2,163
6	**Limit 4 to English** (Languages), yr="2012 -Current"	1,173
PsycINFO		
No	**Query**	**Records retrieved**
1	**DE "Health-related quality of life" OR DE "quality of life" OR "Quality of life" OR HRQoL OR QoL**	112, 125
2	**"Heart failure" OR "heart disease*" OR "cardiac failure"**	26,775
3	Low-middle-income countries*	633, 930
4	**#1 AND #2 AND #3**	336

5	Limit #4 **to English** (Languages), yr="2012 -Current", 18 years and older (Age)	190
CINAHL		
No	**Query**	**Records retrieved**
1	(MH “Quality of life”) OR “Quality of life” OR QoL OR HRQoL	136, 107
2	(MH “Heart failure”) OR “Heart failure” OR “heart disease*” OR “Cardiac failure” OR (MH “heart diseases”)	66, 637
3	Low-middle-income countries*	567, 367
4	**#1 OR** #2 **OR** #3	242
5	limit #4 to English language and yr="2012 -Current" and all adult)	114
Scopus		
No	**Query**	**Records retrieved**
1	**“Quality of life” OR QoL OR HRQoL**	637,893
2	**"Heart failure” OR “heart disease*” OR “cardiac failure”**	772,806
3	Low-middle-income countries*	5,690,216
4	**#1 AND #2 AND #3**	1,714
6	**Limit 4 to English** (Languages), yr="2012 -Current"	1,268
Low-middle-income countries*		
=(afghanistan or albania or algeria or american samoa or angola or argentina or armenia or azerbaijan or bangladesh or belarus or belize or benin or bhutan or bolivia or "bosnia and Herzegovina" or botswana or brazil or bulgaria or burkina faso or burundi or cabo verde or cambodia or cameroon or central african republic or chad or china or colombia or comoros or congo or costa rica or "cote d'ivoire" or cuba or djibouti or dominica or ecuador or egypt or arab republic or el salvador or equatorial guinea or eritrea or eswatini or ethiopia or fiji or gabon or gambia or georgia or ghana or grenada or guatemala or guinea or guinea bissau or guyana or haiti or honduras or india or indonesia or iran or iraq or jamaica or jordan or kazakhstan or kenya or kiribati or korea or kosovo or kyrgyz republic or lebanon or lesotho or liberia or libya or madagascar or malawi or malaysia or maldives or mali or marshall islands or mauritania or mauritius or mexico or micronesia or moldova or mongolia or montenegro or morocco or mozambique or myanmar or namibia or nepal or nicaragua or niger or nigeria or north macedonia or pakistan or panama or papua new guinea or paraguay or peru or philippines or romania or russia* or rwanda or samoa or "sao tome and principe" or senegal or serbia or sierra leone or solomon islands or somalia or south africa or south sudan or sri lanka or "st. lucia" or "st. vincent and the grenadines" or sudan or suriname or syrian arab republic or tajikistan or tanzania or thailand or timor leste or togo or tonga or tunisia or turkey or turkmenistan or tuvalu or uganda or ukraine or uzbekistan or vanuatu or vietnam or west bank or gaza or yemen or zambia or zimbabwe or low income countr* or middle income countr* or developing countr*).ti,ab,sh,kf.		

Supplement 6: JBI critical appraisal checklist for studies reporting prevalence data.



JBI CRITICAL APPRAISAL CHECKLIST FOR STUDIES REPORTING PREVALENCE DATA

Reviewer______________________________________ Date_______________________________

Author_______________________________________Year_________ Record Number_________

	Yes	No	Unclear	Not applicable
1. Was the sample frame appropriate to address the target population?	☐	☐	☐	☐
2. Were study participants sampled in an appropriate way?	☐	☐	☐	☐
3. Was the sample size adequate?	☐	☐	☐	☐
4. Were the study subjects and the setting described in detail?	☐	☐	☐	☐
5. Was the data analysis conducted with sufficient coverage of the identified sample?	☐	☐	☐	☐
6. Were valid methods used for the identification of the condition?	☐	☐	☐	☐
7. Was the condition measured in a standard, reliable way for all participants?	☐	☐	☐	☐
8. Was there appropriate statistical analysis?	☐	☐	☐	☐
9. Was the response rate adequate, and if not, was the low response rate managed appropriately?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

____

____

8.2. Appendix 2. English version of quantitative data collection questionnaire

Part I: Questions to assess demographic, socioeconomic, and clinical characteristics.
Instructions: Please write the answer or circle the number in front of the option you choose

Q. N<u>o</u>	**Questions**	**Responses**
101	Age	________
102	Sex	1. Male 2. Female
103	Marital status	1. Single 3. Divorced 2. Married 4. Widowed 5. Separated
104	Employment status	1. Employed 2. Unemployed
105	Geographical location	1. Urban 2. Rural
106	Educational status	*1. Not attended formal education* *2. Primary education (1-8)* *3. Secondary education (9-12)* *4. College and above*
107	Government health cover (health insurance)	1. Yes 2. No
108	Family history of heart failure	1. Yes 2. No
109	History of hospitalisation in the last 12 months	1. Yes 2. No
Comorbidities		
110	Hypertension	1. Yes 2. No
111	Diabetes	1. Yes 2. No
112	Kidney disease	1. Yes 2. No
113	COPD	1. Yes 2. No
114	Cancer	1. Yes 2. No
115	Other	……………………………....
116	Duration of illness	………………. months or years
117	Number medication taken each day	……………………………….
118	NYHA class	*1. Class I*

		2. Class II *3. Class III* *4. Class IV*
General health perception		
119	How do you perceive your overall health	1. Excellent 2. Very good 3. Fair 4. Poor

Part II: The Oslo Social Support Scale (OSSS-3)

Instructions: Read each statement carefully and circle the number in front of the option you choose

Q. No	**Questions**	**Responses**
201	How many people are so close to you that you can count on them if you have great personal problems?	*1. ‘none’* *2. ‘1–2’* *3. ‘3–5’* *4. ‘5+’*
202	How much interest and concern do people show in what you do?	*1. ‘none’* *2. ‘little’* *3. ‘uncertain’* *4. ‘some’* *5. ‘a lot’*
203	How easy is it to get practical help from neighbours if you should need it?	*1. ‘very difficult’* *2. ‘difficult’* *3. ‘possible’* *4. ‘easy’* *5. ‘very easy’*

Part III: Patient Health Questionnaire (PHQ-9)

Instructions: Over the last 2 weeks, how often have you been bothered by any of the following problems? Mark the box in the response that is closest to how you have been feeling in the past 2 weeks. 0 = Not at all, 1 = Several days, 2 = More than half the days, 3 = Nearly everyday

No	**Questions**	Responses			
301	Little interest or pleasure in doing things	0	1	2	3
302	Feeling down, depressed, or hopeless	0	1	2	3
303	Trouble falling or staying asleep, or sleeping too much	0	1	2	3
304	Feeling tired or having little energy	0	1	2	3
305	Poor appetite or overeating	0	1	2	3
306	Feeling bad about yourself or that you are a failure or have let yourself or your family down	0	1	2	3
307	Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
308	Moving or speaking so slowly that other people could have noticed. Or the opposite being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
309	Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3

Part IV: The Minnesota Living with Heart Failure Questionnaire (MLHFQ)

Instructions: Read each statement and indicate how much your HF affected your life during the past month (4 weeks). 0 = No (Never), 1 = Very little, 2 = Little, 3 = Somewhat (moderate), 4 = Much, 5 = Very much

No	**Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by-**	**Response**					
401	causing swelling in your ankles or legs?	0	1	2	3	4	5
402	making you sit or lie down to rest during the day	0	1	2	3	4	5
403	making your walking about or climbing stairs difficult?	0	1	2	3	4	5
404	making your working around the house or yard difficult?	0	1	2	3	4	5
405	making your going places away from home difficult?	0	1	2	3	4	5
406	making your sleeping well at night difficult?	0	1	2	3	4	5

407	making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
408	making your working to earn a living difficult?	0	1	2	3	4	5
409	making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
410	making your sexual activities difficult?	0	1	2	3	4	5
411	making you eat less of the foods you like?	0	1	2	3	4	5
412	making you short of breath?	0	1	2	3	4	5
413	making you tired, fatigued, or low on energy?	0	1	2	3	4	5
414	making you stay in a hospital?	0	1	2	3	4	5
415	costing you money for medical care?	0	1	2	3	4	5
416	giving you side effects from treatments?	0	1	2	3	4	5
417	making you feel you are a burden to your family or friends	0	1	2	3	4	5
418	making you feel a loss of self-control in your life?	0	1	2	3	4	5
419	making you worry?	0	1	2	3	4	5
420	making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
421	making you feel depressed?	0	1	2	3	4	5

8.3. Appendix 3. Amharic version of quantitative data collection questionnaire

ክፍል 1፡ የማህበራዊ፤ ክሊኒካል፤ የሕክምና እና ሌሎች ባህሪያት

መመሪያ፡ እባክዎ መልስዎትን በክፍት ቦታው ወይም ቁጥሮቹን በማክብበ ያስቀምጡ፡፡

ተ.ቁ	**ጥያቄዎች**	**ምላሽ**
101	ዕድሜዎ ስንት ነው?	________
102	ፆታ	1. ወንድ 2. ሴት
103	የጋብቻ ሁኔታዎ?	1. ያላገባ 3. የተፋታ 5. ተለያይቶ የሚኖር 2. ያገባ 4. የሞተባት/በት
104	የስራ ሁኔታዎ	1. ስራ ያለው 2. ስራ የሌለው
105	የሚኖሩት የት ነው?	1. ከተማ 2. ገጠር
106	የትምህርት ደረጃዎ ምንድን ነው?	*1. መደበኛ ት/ት ያልተማረ/ች* *2. የመጀመሪያ ደረጃ ትምህርት (1-8)* *3. ሁለተኛ ደረጃ ትምህርት(9-12)* *4. ዲፕሎማ እና ከዛ በላይ*
107	የጤና መድህን አሎዎት?	1. አዎ 2. የለም
108	በቤተሰብዎ የልብ ድካም ህመምተኛ አለ	1. አዎ 2. የለም
109	ባለፉት 12 ወራት ውስጥ ሆስፒታል ተኝተው ያውቃሉ	1. አዎ 2. የለም
ተጓዳኝ ህመሞች		
110	የደም ብዛት	1. አዎ 2. የለም
111	ስኳር	1. አዎ 2. የለም
112	የኩላሊት ህመም	1. አዎ 2. የለም
113	የሳንባ ህመም(COPD)	1. አዎ 2. የለም
114	ካንሰር	1. አዎ 2. የለም
115	ሌላ	……………………
116	ህመሙ ከጀመርዎት ምን ያህል ጊዜ ይሆናል?	…………………… ወር/ አመት
117	በቀን የሚወስዱት መድሃኒቶች ቁጥር ስንት ነው?	……………………
118	የ NYHA ደረጃ	*1. ደረጃ I* *2. ደረጃ II*

		3. ደረጃ III *4. ደረጃ IV*
119	አጠቃላይ የጤንነትዎን ሁኔታ እንዴት ይገልፁታል?	1. እጅግ በጣም ጥሩ 2. በጣም ጥሩ 3. በቂ 4. ዝቅተኛ

ክፍል 2፡ አስሎ ማኅበራዊ ድጋፍ መለኪያ (oslo-3)

***መመሪያ*፡ እባክዎ ስለ እያንዳንዱ ሃሳብ ምን እንደሚሰማዎት ቁጥሮቹን በማክብበ ይግለጡ፡፡**

ተ.ቁ	**ጥያቄዎች**	ምላሽ
201	ከባድ የግል ችግር ቢያጋጥምዎ በጣም የሚቀርብዎትና ሊረዳዎት የሚችል ካጠገብዎ ምን ያህል ሰዎች አሉ?	*1. ምንም* *2. ከ 1-2 ሰዎች* *3. ከ 3-5 ሰዎች* *4. ከ 5 በላይ ሰዎች*
202	ሰዎች ስለእርሶ እንደሚያስቡና ጤናዎ እንደሚያሳስባቸው ምን ያህል ያሳያሉ?	*1. ምንም* *2. ትንሽ* *3. እርግጠኛ አይደለሁም* *4. መካከለኛ* *5. ብዙ*
203	የሚያስፈልግዎ ከሆነ ከጎረቤትዎ እርዳታ ማግኘት ምን ያህል ቀላል ነው?	*1. በጣም ከባድ* *2. ከባድ* *3. እርግጠኛ አይደለሁም* *4. ቀላል* *5. በጣም ቀላል*

ክፍል 3፡ ድባቴ(ቁዘማ) *መገምገሚያ* (Patient Health Questionnaire (PHQ-9))

***መመሪያ*፡ ባለፈው ሳምንት የተሰማዎትን ትክክለኛ ስሜት መሰረት በማድረግ የጤና ባለሙያው ቅጥሎ ለሚጠይቁዎት ጥያቄ ተገቢውን ምልስ ይስጡ፡፡** 0 = ኧረ በጭራሽ, 1 = በርካታ ቀናት, 2 = ከግማሽ ቀን በላይ, 3 = በየቀኑ ማለት ይቻላል

ተ.ቁ	**ጥያቄዎች**	**ምላሽ**			
301	ነገሮችን ለማከናወን እምብዛም ፍላጎት አለመኖር	0	1	2	3
302	የመንፈስ ጭንቀት ወይም ተስፋ የመቁረጥ ስሜት	0	1	2	3

303	እንቅልፍ ለመተኛት መቸገር ወይም ከመጠን በላይ መተኛት	0	1	2	3
304	የድካም ስሜት ወይም የጉልበት ማነስ	0	1	2	3
305	የምግብ ፍላጎት ማጣት ወይም ከመጠን በላይ መብላት	0	1	2	3
306	ስለ ራስዎ መጥፎ ስሜት መሰማት ወይም ስኬታማ ያለመሆን ስሜት ወይም ራስዎንም ሆነ ቤተሰብዎን እንዳሳዘኑ መሰማት	0	1	2	3
307	ጋዜጣ ማንበብ ወይም ቴሌቪዥን በትኩረት ለመመልከት መቸገር	0	1	2	3
308	ሌሎች ሰዎች ሊያስተውሉ እስኪችሉ ድረስ ቀስ ብሎ መንቀሳቀስ ወይም መናገር ። ወይም ደግሞ ከወትሮው የበለጠ እረፍት ማጣት ወይም አለመረጋጋት	0	1	2	3
309	ብሞት ወይም እራሴን ብጎዳ ይሻላል የሚል አስተሳሰብ መሰማት	0	1	2	3

ክፍል 4፡ የሚኒሶታ ከልብ ድካም ህመም ጋር የመኖር መጠይቅ (MLHFQ)

እባክዎ እያንዳንዱን መግለጫ ያንብቡና የልብ ድካም ህመምዎ ባለፈው አንድ ወር በሕይወትዎ ላይ ምን ያህል ተጽዕኖ እንዳሳደረብዎት ይጠቁሙ፡፡ 0 = ምንም የለም (በፍፁም), 1 = በጣም ትንሽ , 2 = ትንሽ, 3 = በመጠኑ, 4 = ብዙ, 5 = በጣም ብዙ

ተ.ቁ	የልብ ድካም ህመምዎ ባለፈው አንድ ወር (4 ሳምንታት) ውስጥ እንደፈለግከው እንዳትኖር ምን በማድረግ እንቅፋት ሆኖብሃል/ሻል?	ምላሽ					
401	ቁርጭምጭሚትዎ ወይም እግርዎት ላይ እብጠት በማስከተል?	0	1	2	3	4	5
402	ቀን ላይ ዕረፍት እንዲወስዱ ቁጭ ወይም ጋደም በማስደረግ?	0	1	2	3	4	5
403	በእግር መሄድ ወይም ደረጃ መውጣትን አስቸጋሪ እንዲሆንብዎ በማድረግ?	0	1	2	3	4	5
404	በቤት ውስጥ ወይም በግቢ ውስጥ ስራ መሥራት አስቸጋሪ እንዲሆንብዎ በማድረግ?	0	1	2	3	4	5
405	ከቤትዎ ርቀው መሄድን አስቸጋሪ እንዲሆንብዎ በማድረግ?	0	1	2	3	4	5
406	ማታ ማታ ጥሩ እንቅልፍ መተኛትን አስቸጋሪ እንዲሆንብዎ በማድረግ?	0	1	2	3	4	5
407	ከጓደኞችዎ ወይም ከቤተሰብዎ ጋር ያለዎትን ግንኙነት ወይም ከነሱ ጋር የሆነ ነገር ለማድረግ አስቸጋሪ በማድረግ?	0	1	2	3	4	5
408	መተዳደሪያ ሥራዎን ለመስራት አስቸጋሪ እንዲሆንብዎ በማድረግ?	0	1	2	3	4	5
409	የመዝናኛ ጊዜዎትን፣ ስፖርትን ወይም የትርፍ ጊዜ ማሳለፊያዎችዎን አስቸጋሪ እንዲሆንብዎ በማድረግ?	0	1	2	3	4	5
410	የጾታዊ ግንኙነት ለመፈጸም አስቸጋሪ እንዲሆንብዎ በማድረግ?	0	1	2	3	4	5
411	የሚወዱትን ምግብ ትንሽ ብቻ እንዲመገቡ ወይም የምግብ ፍላጎትዎን በመቀነስ?	0	1	2	3	4	5
412	ትንፋሽ እንዲያጥርዎ በማድረግ?	0	1	2	3	4	5

413	ድካም በመጨመር ወይም አቅም በማሳጣት?	0	1	2	3	4	5
414	ሆስፒታል ብዙ ጊዜ እንዲቆዩ በማድረግ?	0	1	2	3	4	5
415	ለሕክምና ብዙ ገንዘብ በማስወጣት?	0	1	2	3	4	5
416	ከሕክምና ጋር ተያይዞ የሚመጡ የጎንዮሽ ጉዳቶች በማስከተል?	0	1	2	3	4	5
417	ለቤተሰብዎ ወይም ለጓደኞችዎ ሸክም እንደሆኑ እንዲሰማዎት በማድረግ?	0	1	2	3	4	5
418	ራስዎን የመቆጣጠር ችግር እንዳለብዎት እንዲሰማዎ በማድረግ?	0	1	2	3	4	5
419	እንዲፍሩ ወይም እንዲጨንቅዎ በማድረግ??	0	1	2	3	4	5
420	ነገሮችን በትኩረት መከታተል ወይም ማስታወስ እንዳይችሉ በማድረግ?	0	1	2	3	4	5
421	ድባቴ ወይመ ድብርት እንዲሰማዎ በማድረግ?	0	1	2	3	4	5

8.4. Appendix 4: The Content Validity Index (CVI) to assess the content validity of the Minnesota Living with Heart Failure Questionnaire (MLHFQ)

N<u>o</u>	**Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by-**	E1	E2	E3	E4	E5	E6	I-CVI
401	causing swelling in your ankles or legs?	4	3	3	4	4	4	1
402	making you sit or lie down to rest during the day	3	3	3	4	4	4	1
403	making your walking about or climbing stairs difficult?	4	3	4	3	4	3	1
404	making your working around the house or yard difficult?	3	2	3	3	3	3	.83
405	making your going places away from home difficult?	4	3	4	4	4	4	1
406	making your sleeping well at night difficult?	3	3	3	4	3	4	1
407	making your relating to or doing things with your friends or family difficult?	3	3	2	3	2	3	.66
408	making your working to earn a living difficult?	3	3	2	4	4	3	.83
409	making your recreational pastimes, sports or hobbies difficult?	4	2	2	2	3	3	.5
410	making your sexual activities difficult?	3	3	3	2	2	3	.66
411	making you eat less of the foods you like?	4	3	3	3	4	3	1
412	making you short of breath?	4	3	3	4	3	4	1
413	making you tired, fatigued, or low on energy?	4	4	4	4	4	4	1
414	making you stay in a hospital?	3	2	3	3	2	3	.66
415	costing you money for medical care?	4	3	3	3	4	3	1
416	giving you side effects from treatments?	3	3	3	3	3	3	1
417	making you feel you are a burden to your family or friends	3	4	3	3	3	4	1

418	making you feel a loss of self-control in your life?	3	3	2	2	2	3	.5
419	making you worry?	4	3	3	3	4		1
420	making it difficult for you to concentrate or remember things?	3	3	3	2	2	3	.66
421	making you feel depressed?	3	4	3	3	4	4	1
	Scale-level CVI (S-CVI)							0.85

8.5. Appendix 5: Pictorial representation of the training session for research assistants regarding the questionnare and the data collection procedure

8.6. Appendix 6: Invitation letter for qualitative interview

Subject: Invitation to qualitative interview

Dear…………

Hello! Good afternoon/ Good evening. My name is_______________. I am working as data collector in a study conducted by Henok Mulugeta who is PhD student at one of the public universities in Australia (University of Technology Sydney. Along with this survey, the study has next phase of qualitative interview on your experience of living with heart failure, and you are purposively selected to participate in the next phase of study. If you are willing to participate in the next phase of the study, the principal investigator will contact you by phone to schedule an interview during your next hospital visit.

Please find below more information on the study and the interview setting

Purpose: The purpose of this research is to explore and describe the experiences of Ethiopian people living with HF, and its impact on their HRQoL. The results will be helpful for improving the mental health and health-related quality of life and recommending ways to improve them.

Scope: If you decide to participate, you will be invited to respond to questions related to your experiences of living with heart failure and will be audio-recorded.

Duration: the interview will take 30 to 60 minutes and will be audio-recorded.

Privacy and anonymity: The interview will be conducted in a private room for your privacy and your personal details will not be included in the data. All the information collected from you will be treated confidentially.

If you decide to participate in the study, we will provide participant information sheet for more information and invite you to sign a consent form.

Are you willing to participate in the next phase of the study?

1. If yes, provide the phase two information sheet and continue with consent form
2. If No, Skip to the next participant

Subject: Invitation to qualitative interview (Amharic version)

ጉዳዩ፡ ቃለ መጠይቅ መጋበዝን ይመለከታል

ውድ…………

ሰላም! እንደምን አረፈዱ። ስሜ.................................ይባላል፡፡ በአውስትራሊያ ሀገር በሚገኝ ዩኒቨርሲቲ የ3ኛ ዲግሪ ተማሪ የሆነው አቶ ሄኖክ ሙሉጌታ ተሾመ ለሚያደረገው ጥናት መረጃ በመሰብሰብ ላይ እገኛለሁ፡፡ከዚህ ጥናት በተጨማሪ ጥናቱ ቀጣይ የሆነ ከልብ ድካም ህመም ጋር የመኖር ተሞክሮዎትን በተመለከተ ቃለ መጠይቅ አለው እርስዎም በሚቀጥለው የጥናቱ ምዕራፍ ላይ እንዲካፈሉ ተመርጠዋል ። በሚቀጥለው የጥናቱ ክፍል ለመሳተፍ ፈቃደኛ ከሆኑ ዋናው መርማሪው በሚቀጥለው የሆስፒታል ጉብኝትዎ ሲመጡ ቃለ መጠይቅ ለማድረግ በስልክ ለማስታወስ ያነጋግርዎታል።

እባክዎ ጥናቱን እና ቃለ መጠይቁን በተመለከተ ተጨማሪ መረጃ ከዚህ በታች ያግኙ

የምርምሩ ኣላማ፡ በኢትዮጵያ የልብ ድካም ያለባቸው አዋቂዎች ከህመሙ ጋር አብሮ የመኖር ተሞክሮን እንዲሁም ህመሙ በ ከጤና ጋር የተያያዘ የኑሮ ደረጃቸው ላይ የሚያሳድረውን ተፅዕኖ ለመቃኘትና ጥናት ማድርግ፡፡ የጥናቱ ውጤቱ የአዕምሮ ጤና እና ከጤና ጋር የተያያዘ የኑሮ ደረጃን ለማሻሻል የሚረዳ ከመሆኑም በላይ እነዚህን ችግሮች ለማሻሻል የሚያስችሉ መንገዶችን ይመክራል።

የምርምሩ ስፋት፡- በቃለ መጠይቁ ተሳትፎ ለማድረግ ፍቃደኛ ከሆኑ ከልብ ድካም ህመም ጋር የመኖር ተሞክሮዎትን እና ተያያዥ ጉዳዮችን እንዲያካፈሉን ይጋበዛሉ፡፡

የሚፈጀው ቆይታ፡- ቃለ መጠይቁ ከ30 እስከ 60 ደቂቃ የሚወስድ ሲሆን ቃለ መጠይቁም በድምፅ የሚቀዳ ይሆናል።

ሚስጥራዊነት እና ማንነት፡- ቃለ መጠይቁ ለብቻ በተዘጋጀ ክፍል ውስጥ ይካሄዳል። የግል መረጃዎም በመረጃው ውስጥ አይካተትም። ከእርስዎም የተሰበሰበው መረጃ ሁሉ በሚሥጥር ይያዛል ።

በጥናቱ ለመሳተፍ ፍቃደኛ ከሆኑ ለበለጠ መረጃ የተሳታፊ መረጃ ወረቀት እናቀርባለን እንዲሁም የስምምነት ቅጽ እንዲፈርሙ ይጋበዛሉ።

በሚቀጥለው ቃለ መጠይቅ ላይ ለመሳተፍ ፈቃደኛ ኖት?

1. አዎ ከሆነ፤ የመረጃ ወረቀትን ይሰጥዎትና በስምምነት ፎርም ይቀጥላሉ
2. አይደለም ከሆነ ፤ወደ ቀጣዩ ተሳታፊ

8.7. Appendix 7: Pictorial representation of the study area

A. *St. Paul's Hospital Millennium Medical College*

B. *St. Peter Specialized Hospital*

8.8. Appendix 8: Interview guide for semi-structured interviews

A: English version

The participants will be reminded that they can stop the interview at any time if they feel distressed. Thank you for taking the time to speak to me today. I am interested in hearing about your experiences in living with heart failure and how it affects your quality of life. To begin, I'm going to ask you for some demographic information.

No	**Topic to explore**	**Optional** prompt questions
1	Demographics	-Age, sex, residence, education, marital status NYHA class, employment status, duration of HF, comorbidity
2	Heart failure diagnosis and symptom experience?	-When were you diagnosed and what were you feeling and thinking after the initial diagnosis? -What kind of symptoms? -What makes you feel better or worse? -What management/treatment strategies do you use? How many medications? -What about non-medical interventions?
3	Now, I want to discuss the concept of HRQoL.	-What do you understand by the term HRQoL? -How is it living with HF? What is the quality of your life since having HF? -Are there things you can't do so well? (severity) -How do you deal with feeling down or depressed? -What are the best and worst aspects of your life at the moment?
4	Now, I would like to ask you the impact of HF on your health-related quality of life.	-What are the most difficult aspects of living with HF? -How does it affect your family or friends? -What about work? Daily activities? Money? Sleep? -What about social activities and relationships? -Do you think HRQoL is affected by physical symptoms, age, negative emotion (depression), income, having

		comorbid condition (DM), social support, severity of symptoms? How? -What strategies and coping mechanisms do you use to improve your HRQoL?
5	Do you have any questions for me?	
6	Would you like to see a copy of the transcript of this interview?	If they say yes, then ask for address to send a hardcopy (if they don't have email).

B: Amharic version

የቃለ መጠይቅ መመሪያ

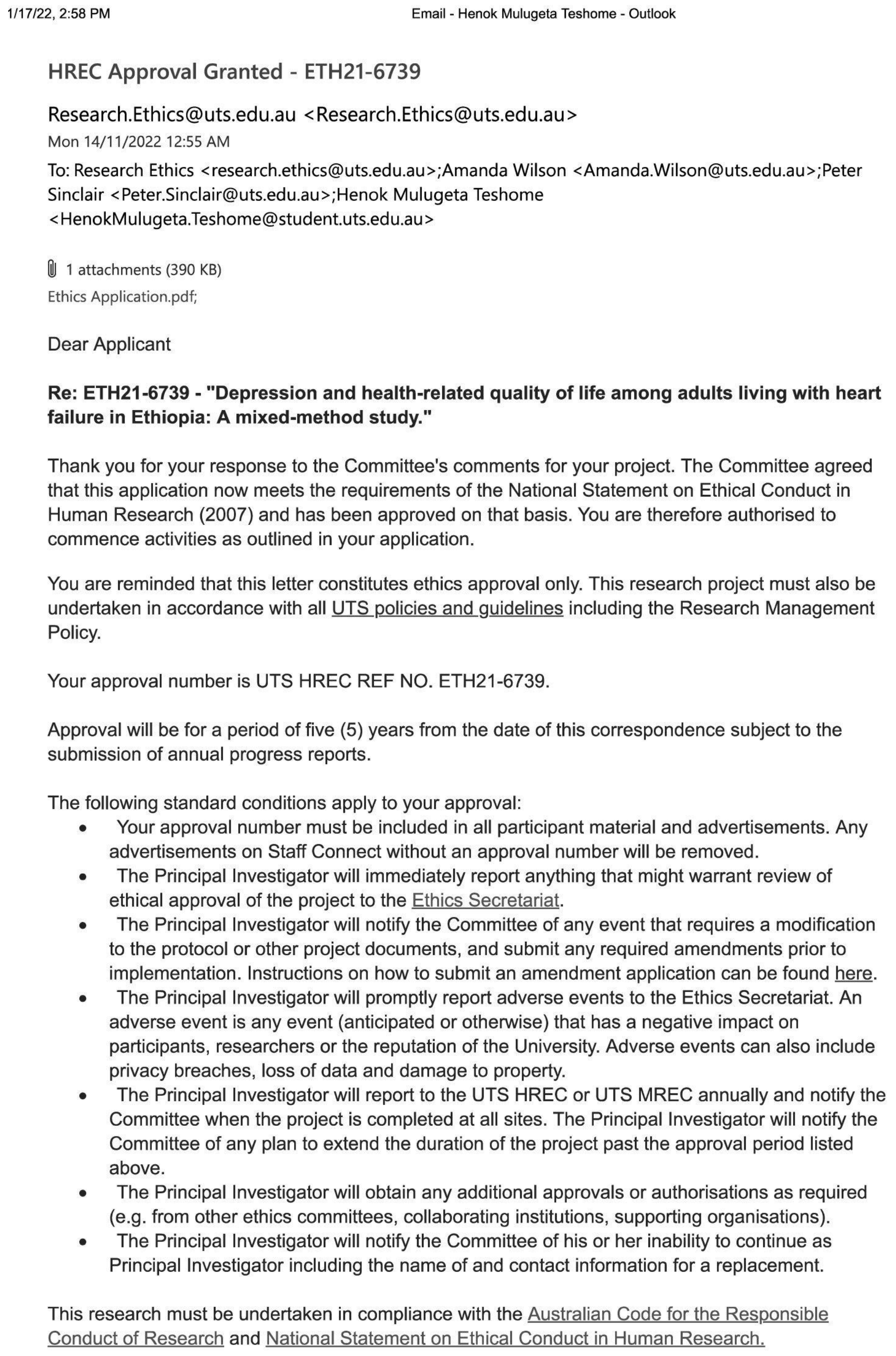
ተሳታፊዎቹ ጭንቀት ከተሰማቸው በማንኛውም ጊዜ ቃለ መጠይቁን ማቆም እንደሚችሉ ይነገራቸዋል።

ለቃለ መጠይቁ ፍቃደኛ ስለሆኑ ለጊዜዎት አመሰግናለሁ ። እርስዎ የልብ ድካም ህመምተኛ መሆንዎ ይታወቃል በመሆኑም ከህመሙ ጋር አብሮ የመኖር ተሞክሮዎትን እንዲሁም ህመሙ ከጤና ጋር የተያያዘ የኑሮ ደረጃዎት ላይ ያሳድረውን ተፅዕኖ በቃለ መጠይቁ ለመቃኘት እንሞክራልን፡፡

ተ ቁ	**ርዕሰ ጉዳይ**	**አማራጭ ጥያቄዎች**
1	የማህበራዊና ስነ ህዝብ ባህሪያት	-እድሜ፣ ጾታ፤ መኖሪያ ቦታ፣ ትምህርት፣ ገቢ፣ ቤተሰብ፤ስራ፤ NYHA ደረጃ፤ ተጨማሪ ህመም; የህመሙ ቆይታ
2	ከልብ ድካም ህመም ጋር ስለ መኖር?	• *የልብ ድካም እንዳለብዎ በምርመራ የተረጋገጠልህ መቼ ነው? ከዛስ በኋላ ምን ተሰምቶህና ታስብ ነበር?* • *ምን ዓይነት የሕመሙ ምልክቶች አሉህ?* • *የተሻለ ወይም የከፋ ስሜት እንዲሰማህ የሚያደርገው ምንድን ነው?* • *ምን ዓይነት ሕክምና እየተደረገልህ ነው? ከሕክምና ውጪ ሌላ ምን ትጠቀማለህ?*
3	አሁን ስለ **ከጤና ጋር የተያያዘ የኑሮ ደረጃ** ጽንሰ ሐሳብ መወያየት እፈልጋለሁ.	• *ከጤና ጋር የተያያዘ የኑሮ ደረጃ (ጥራት) የሚለው ቃል ለእርስዎ ምን ትርጉም አለው?* • *የልብ ድካም ካለብህ ጊዜ አንስቶ ሕይወትህ (የኑሮ ሁኔታህ) ምን ዓይነት ነው?* • *በደንብ ልታደርገው የማትችላቸው ነገሮች አሉ?* • *የተሻለ ስሜት እንዲሰማህ ምን ታደርጋለህ?* • *የመንፈስ ጭንቀት ወይም ድባቴ ሲሰማህ ምን ታደርጋልህ?* • *በአሁኑ ጊዜ በሕይወትህ ውስጥ ከሁሉ የተሻሉና መጥፎ ገጽታዎች ምን ምን ናቸው?*
4	የኑሮ ሁኔታህ ላይ ተጽዕኖ ያሳደረው ምንድነው?	• *በቤተሰብህ ወይም በጓደኞችህ ላይ ምን ተጽዕኖ ያሳድራል? በስራ ላይስ? በገቢህ ላይስ? እንቅልፍ ላይስ? ማኅበራዊ እንቅስቃሴዎችና ግንኙነቶችስ ላይ?*

		• *በጣም አስቸጋሪ የሆኑት የልብ ድካም ገጽታዎች ምንድን ናቸው?* • *እነዚህን ችግሮች እንዴት ነው እየተቋቋምክ ያለሀው?* • *የህመሙ ምልክቶች፣ እድሜ፣ ድባቴ ፣ የገቢ መጠን፣ ተጨማሪ ህመም መኖር፤ እና ማኅበራዊ ድጋፍ ከጤና ጋር የተያያዘ የኑሮ ደረጃህ(ጥራት) ላይ ተጽዕኖ የሚያሳድሩ ይመስልሃል? እንዴት?*
5	ማንኛውም አይነት ጥያቄ አለህ?	
6	የዚህን ቃለ መጠይቅ ጽሑፍ አንድ ቅጂ ማየት ትፈልጋለህ?	አዎ! የሚሉ ከሆነ ሃርድ ኮፒ ለመላክ አድራሻ ይጠይቁ (ኢሜይል ከሌለዎት).

8.9. Appendix 9: UTS Human Reseach Ethics Committee approval letter



HREC Approval Granted - ETH21-6739

Research.Ethics@uts.edu.au <Research.Ethics@uts.edu.au>
Mon 14/11/2022 12:55 AM
To: Research Ethics <research.ethics@uts.edu.au>;Amanda Wilson <Amanda.Wilson@uts.edu.au>;Peter Sinclair <Peter.Sinclair@uts.edu.au>;Henok Mulugeta Teshome <HenokMulugeta.Teshome@student.uts.edu.au>

1 attachments (390 KB)
Ethics Application.pdf;

Dear Applicant

Re: ETH21-6739 - "Depression and health-related quality of life among adults living with heart failure in Ethiopia: A mixed-method study."

Thank you for your response to the Committee's comments for your project. The Committee agreed that this application now meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and has been approved on that basis. You are therefore authorised to commence activities as outlined in your application.

You are reminded that this letter constitutes ethics approval only. This research project must also be undertaken in accordance with all UTS policies and guidelines including the Research Management Policy.

Your approval number is UTS HREC REF NO. ETH21-6739.

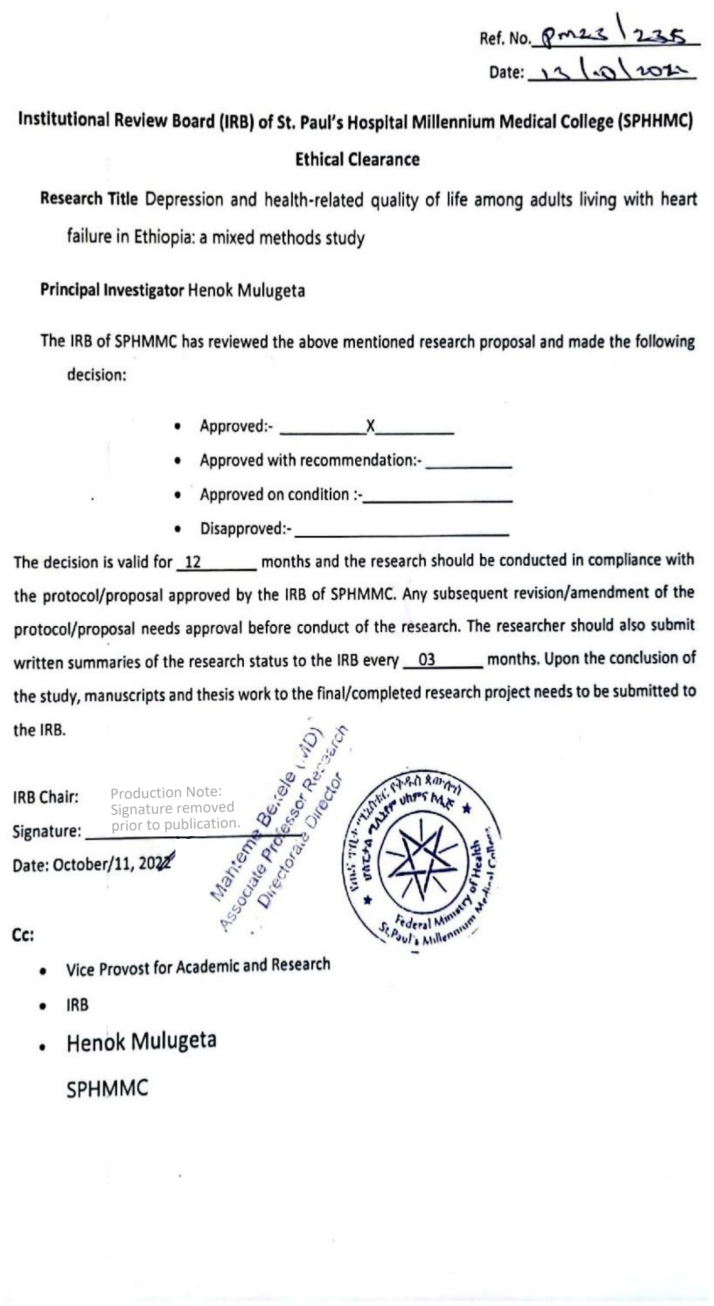
Approval will be for a period of five (5) years from the date of this correspondence subject to the submission of annual progress reports.

The following standard conditions apply to your approval:

- Your approval number must be included in all participant material and advertisements. Any advertisements on Staff Connect without an approval number will be removed.
- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project to the Ethics Secretariat.
- The Principal Investigator will notify the Committee of any event that requires a modification to the protocol or other project documents, and submit any required amendments prior to implementation. Instructions on how to submit an amendment application can be found here.
- The Principal Investigator will promptly report adverse events to the Ethics Secretariat. An adverse event is any event (anticipated or otherwise) that has a negative impact on participants, researchers or the reputation of the University. Adverse events can also include privacy breaches, loss of data and damage to property.
- The Principal Investigator will report to the UTS HREC or UTS MREC annually and notify the Committee when the project is completed at all sites. The Principal Investigator will notify the Committee of any plan to extend the duration of the project past the approval period listed above.
- The Principal Investigator will obtain any additional approvals or authorisations as required (e.g. from other ethics committees, collaborating institutions, supporting organisations).
- The Principal Investigator will notify the Committee of his or her inability to continue as Principal Investigator including the name of and contact information for a replacement.

This research must be undertaken in compliance with the Australian Code for the Responsible Conduct of Research and National Statement on Ethical Conduct in Human Research.

8.10. Appendix 10: Local ethical approval letter obtained from the Institutional Review Board (IRB) of each hospital



Ref. No. PM23\235

Date: 13\10\2022

Institutional Review Board (IRB) of St. Paul's Hospital Millennium Medical College (SPHHMC)

Ethical Clearance

Research Title Depression and health-related quality of life among adults living with heart failure in Ethiopia: a mixed methods study

Principal Investigator Henok Mulugeta

The IRB of SPHMMC has reviewed the above mentioned research proposal and made the following decision:

- Approved:- ____X____
- Approved with recommendation:- ________
- Approved on condition :- ________
- Disapproved:- ________

The decision is valid for 12 months and the research should be conducted in compliance with the protocol/proposal approved by the IRB of SPHMMC. Any subsequent revision/amendment of the protocol/proposal needs approval before conduct of the research. The researcher should also submit written summaries of the research status to the IRB every 03 months. Upon the conclusion of the study, manuscripts and thesis work to the final/completed research project needs to be submitted to the IRB.

IRB Chair:

Signature: ________ Production Note: Signature removed prior to publication.

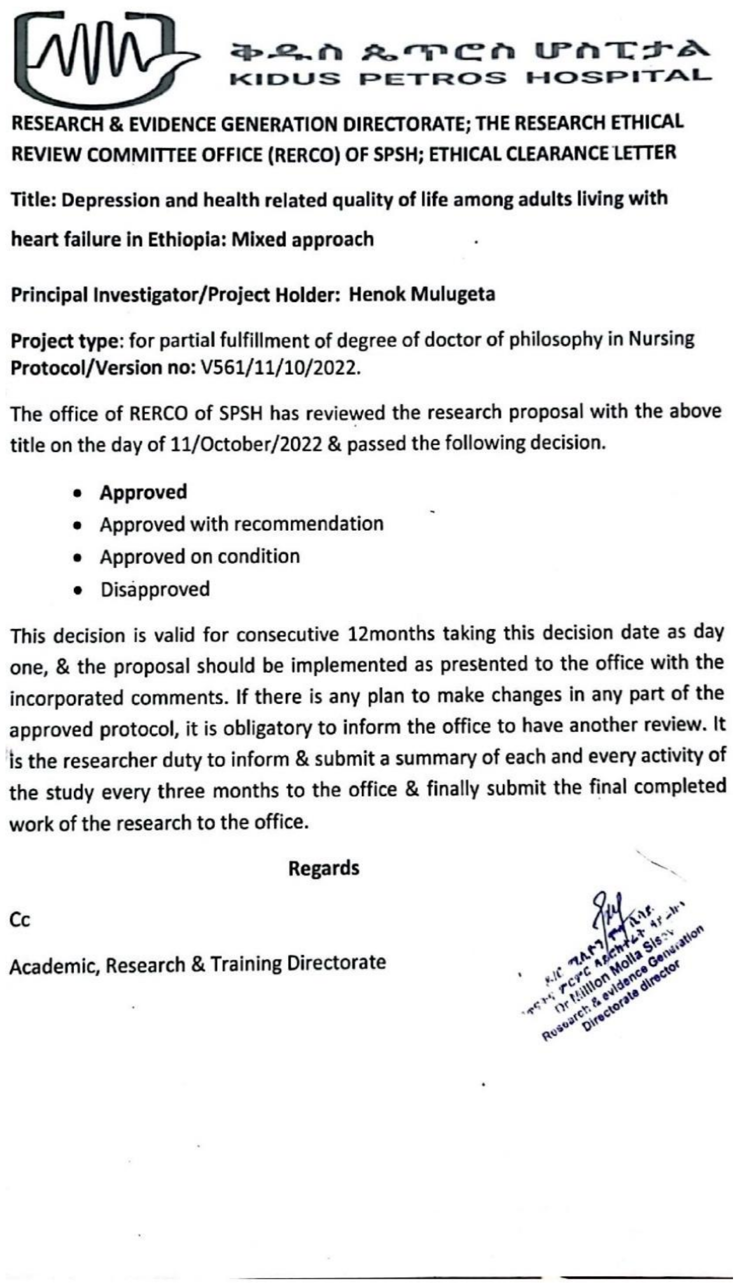
Date: October/11, 2022

Manteme Bekele (MD)
Associate Professor Research
Directorate Director

Cc:

- Vice Provost for Academic and Research
- IRB
- Henok Mulugeta

  SPHMMC



ቅዱስ ጴጥሮስ ሆስፒታል
KIDUS PETROS HOSPITAL

RESEARCH & EVIDENCE GENERATION DIRECTORATE; THE RESEARCH ETHICAL REVIEW COMMITTEE OFFICE (RERCO) OF SPSH; ETHICAL CLEARANCE LETTER

Title: Depression and health related quality of life among adults living with heart failure in Ethiopia: Mixed approach

Principal Investigator/Project Holder: Henok Mulugeta

Project type: for partial fulfillment of degree of doctor of philosophy in Nursing
Protocol/Version no: V561/11/10/2022.

The office of RERCO of SPSH has reviewed the research proposal with the above title on the day of 11/October/2022 & passed the following decision.

- **Approved**
- Approved with recommendation
- Approved on condition
- Disapproved

This decision is valid for consecutive 12months taking this decision date as day one, & the proposal should be implemented as presented to the office with the incorporated comments. If there is any plan to make changes in any part of the approved protocol, it is obligatory to inform the office to have another review. It is the researcher duty to inform & submit a summary of each and every activity of the study every three months to the office & finally submit the final completed work of the research to the office.

Regards

Cc

Academic, Research & Training Directorate

Dr Million Molla Sisay
Research & evidence Generation
Directorate director

8.11. Appendix 11: Participant Information Sheet and Informed Consent form for Phase II of the study

A. English version

PARTICIPANT INFORMATION SHEET: PHASE II

[UTS HREC REF NO. ETH21-6739] – Health-related quality of life and influencing factors among adults living with heart failure in Ethiopia.

WHO IS CONDUCTING THIS RESEARCH?

My name is Henok Mulugeta Teshome ([redacted]@student.uts.edu.au) and I am a nursing lecturer and a higher degree research student at UTS. My supervisors are Professor Amanda Wilson (Amanda.Wilson@uts.edu.au) and Associate professor Peter Sinclair (Peter.Sinclair@uts.edu.au).

WHAT IS THE RESEARCH ABOUT?

The purpose of this research is to assess the prevalence of depression and the level of health-related quality of life, and to gather information about factors affecting adults living with heart failure in Ethiopia. The results may help improve outcomes for people with heart failure and depression in Ethiopia.

WHY HAVE I BEEN INVITED?

You have been invited to participate because you are a person living with heart failure. We would like you to complete an interviewer-administered questionnaire about your mental health status and health-related quality of life.

FUNDING

Funding for this project has been received from University of Technology Sydney.

WHAT DOES MY PARTICIPATION INVOLVE?

If you decide to participate, we will invite you to complete an interviewer-administered questionnaire about your mental health status and health-related quality of life which will take 30 to 40 minutes.

ARE THERE ANY RISKS/INCONVENIENCE?

Participation in this study will focus on the impact of heart disease on depression and quality of life and reflecting on these subjects may have the potential to cause distress. If you experience any distress during the questionnaire, we will pause the interview. Your interviewer will be a qualified nurse and they can in obtaining counselling services if needed. You can choose whether to continue the questionnaire or stop participating at any time during the study.

DO I HAVE TO TAKE PART IN THIS RESEARCH PROJECT?

Participation in this study is voluntary. It is completely up to you whether or not you decide to take part.

If you decide not to participate, or to withdraw from the study, it will not affect your relationship with the researchers or your hospital care in any way.

WHAT IF I WITHDRAW FROM THIS RESEARCH PROJECT?

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason, by contacting Henok Mulugeta ([redacted]@student.uts.edu.au). Any information you have provided will be deleted from the study. However, as the information you provide will be de-identified for analysis once analysis occurs it may not be possible to delete this data.

WHAT WILL HAPPEN TO INFORMATION ABOUT ME?

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. All this information will be treated confidentially. This information will be treated as confidential and stored securely. All data will be kept in password protected folders and only the researchers will have access to the data. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

WHAT IF I HAVE ANY QUERIES OR CONCERNS?

If you have queries or concerns about the research that you think I, or my supervisors, can help you with, please feel free to contact me on +251[redacted] or ([redacted]@student.uts.edu.au). You will be given a copy of this form to keep.

NOTE: This study has been approved in line with the University of Technology Sydney Human Research Ethics Committee [UTS HREC] guidelines. If you have any concerns or complaints about any aspect of the conduct of this research that you wish to raise independently of the research team, please contact the Ethics Secretariat on ph.: +61 2 9514 2478 or email: Research.Ethics@uts.edu.au] and quote the UTS HREC reference number. Any matter raised will be treated confidentially, investigated and you will be informed of the outcome.

CONSENT FORM: PHASE II

[UTS HREC REF NO. ETH21-6739] - Prevalence of depression and level of health-related quality of life and influencing factors among adults living with heart failure in Ethiopia.

I ____________________ agree to participate in the research project being conducted by Henok Mulugeta Teshome ([redacted]). I understand that funding for this research has been provided by the University of Technology Sydney.

I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research as described in the Participant Information Sheet.

I have had an opportunity to ask questions, and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time without affecting my relationship with the researchers, the University of Technology Sydney *or* my hospital.

I agree for possible publication of the information gained from the survey.

I understand that I will be given a signed copy of this document to keep.

I am aware that I can contact Henok Mulugeta Teshome (+251[redacted]) if I have any concerns about the research.

____ ____/____/____

Name and Signature [participant] Date

____ ____/____/____

Name and Signature [researcher] Date

B. Amharic version

የተሳታፊዎች የመረጃ መስጫ ሰነድ፡ ክፍል ሁለት

[UTS HREC REF NO. ETH21-6739] – በኢትዮጵያ የልብ ድካም ያለባቸው አዋቂዎች ድባቴ እና ከጤና ጋር የተያያዘ የኑሮ ደረጃቸውን ጥናት ማድርግ፡፡

ጥናቱን ማን ነው የሚያጠናው?

ይህ ጥናት በአውስትራሊያ ሀገር በሚገኝ ዩኒቨርሲቲ የ3ኛ ዲግሪ ተማሪ በሆኑት በአቶ ሄኖክ ሙሉጌታ ተሾመ የሚካሄድ ነው፡፡ ጥናቱም የዶክትሬት ዲግሪ ማሟያ ሲሆን በፕሮፌሰር ኤማንዳ ዊልሰን (Amanda.Wilson@uts.edu.au) እና በተባባሪ በፕሮፌሰር ፒተር ሲንክሌር (Peter.Sinclair@uts.edu.au) አማካሪነት የሚሰራ ነው፡፡

ምርምሩ ስለ ምንድነው?

የምርምሩ ኣላማ በኢትዮጵያ የልብ ድካም ያለባቸው አዋቂዎች ድባቴ እና ከጤና ጋር የተያያዘ የኑሮ ደረጃቸውን እንዲሁም ተዛማች ሁኔታዎችን ጥናት ማድርግ ነው፡፡፡ የምርምሩ ውጤት ከልብ ድካም ጋር የሚኖሩ ሰዎችን የኣእምሮ ጤና እና ከጤና ጋር የተያያዘ የኑሮ ደረጃቸውን ለማወቅ እንዲሁም እንዴት ማሻሻል እንደሚቻል ለመጠቆም ነው፡፡፡ በመሆኑም ጠቀሜታው ለታካሚዎች እና ለጤና ተቋማት የላቀ ነው፡፡

እኔ ለምን በጥናቱ ተሳታፊ እንድሆን ተጋበዝኩኝ?

የልብ ድካም ህክምና በመከታተል ላይ ያሉትን ሰዎች በመጋበዝ ላይ እንገኛለን፡፡ እናም እርሰዎ ላለፉት 3 ወራት ህክምና እየተከታተሉ ስለሆነ በጥናቱ እንዲሳተፉ ተጋብዘዋል፡፡ ይሁን እንጂ የእርስዎ ተሳትፎ ሙሉ በሙሉ በፈቃደኝነትዎ ላይ የተመሰረተ ነው፡፡

የገንዘብ ድጋፍ

የምርምሩ ወጪ University of Technology Sydney በሚባል በአውስትራሊያ ሀገር በሚገኝ ዩኒቨርሲቲ ይሸፈናል፡፡

ተሳትፎዬ ምን ነገሮችን ይጨምራል?

ለመሳተፍ ፍቃደኛ ከሆኑ ስለእርስዎ የአእምሮ ጤና እና ከጤና ጋር የተያያዘ የኑሮ ደረጃዎትን በተመለከተ ከ30 እስከ 40 ደቂቃ የሚወስድ በመጠይቅ እንጠይቆታልን፡፡ በተጨማሪም በሁለተኛ ዙር ቃለ-መጠይቅ ላይ ለመሳተፍ ፍቃደኛ ከሆኑ የመገኛ አድራሻዎን ለመረጃ ሰብሳቢ ባለሙያው መስጠት ይችላሉ፡፡ ለመሳተፍ ፍቃደኛ ከሆኑ ስለምርምሩ ጠለቅ ያለ ምረጃ ለማግኘት የሚያስችል የመረጃ መስጫ ወረቀት ይሰጥዎታል እንዲሁም የፍቃደኝነት ፎርም ይሞላሉ፡፡

ምርምሩ ውስጥ ከመሳተፍ ጋር ተያይዘው የሚመጣ ችግር ይኖራል?

ጥናቱ በቃለ መጠየቅ የሚደረግ ስሆን ከዚህ ጋር ተያይዘው በአንዳንድ ተሳታፊዎች ላይ የድካም እና የመረበሽ ስሜት ሊታይ ይችላል፡፡ በመሆኑም መረጃ የሚሰበሰበው የምክር አግልግሎት መስጫ ክፍል ውስጥ ብቻ ነው: በተጨማሪም በማንኛውም ጊዜ ተሳትፎዎን ማቆም ይችላሉ:: የመጨነቅ ስሜት ከተሰማዎ መረጃ ሰብሳቢ ባለሙያዎች በሆስፒታሉ ውስጥ የምክር አገልግሎት እንዲያገኙ ይረዱዎታል::

ምርምሩ ውስጥ መሳተፍ ግዴታ ነው ?

ምርምሩ ላይ መሳተፍ ሙሉ በሙሉ በእርስዎ ፈቃደኝነት ላይ የተመሰረተ ይሆናል:: ቢሳተፉም ባይሳተፉም ከተመራማሪው ወይም ከሆስፒታሉ ጋር ያልዎትን ግኑኝነት በምንም መንገድ አያውከውም፡፡

ከምርምሩ መውጣት ወይም ማቋረጥ እችላለሁ?

በዚህ ኘሮጀክት መሳተፍ በፈቃደኝነት ላይ የተመሠረተ እንዲሁም ለመሳተፍ ከተስማሙ በኃላ በማንኛውም ጊዜ ያለምንም ቅድመ ሁኔታ ከጥናቱ ማቋረጥ ይችላሉ፡፡ ከጥናቱ በማቋረጠዎ አሁንም ሆነ ወደፊት ህክምናዎ ላይ ምንም ተጽእኖ አይኖረውም፡፡ ከጥናቱ ማቋረጥ ከፈለጉ ተጨማሪ መረጃ መውሰድ እናቆማልን፡፡

የምሰጠው መረጃ እንደት ይያዛል?

እርስዎ የሰጡት መረጃ ለምርምር ብቻ የሚውል ነው፡፡ ከእርስዎ መረጃ ሲሰበሰብ ምንም አይነት የግል መለያ ስምዎ፤ ቁጥርዎ አይካተትም፡፡ሁሉም መረጃ በይለፍ ቃል ይታሰራል፡፡ የተሰበሰበውን መረጃ ዋናው ተመራማሪ እና የምርመሩ አማካሪዎች ብቻ የሚያውቁት ሲሆን የተሳታፊዎች መረጃ ከፍቃዳቸው ውጭ ለማንም ማሳየት አይቻልም፡፡ የምርምሩ ውጤት ሊታተም ወይም በተለያዩ ስብሰባዎች ላይ ሊቀርብ ይችላል፡፡ስለሰጡት መረጃ በማንኛውም ጌዜ መጠየቅም ማስተካከልም ይችላሉ፡፡

ስለ ምርምሩ ጥያቄ ቢኖረኝ ማንን ልጠይቅ እችላለሁ?

ስለምርምሩ ማንኛውም ጥያቄ ካለዎት አቶ ሄኖክ ሙሉጌታን በስልክ ቁጥር +251[redacted]፤ ኢሜል [redacted]@student.uts.edu.au ይደውሉ፡፡

የዚህ ቅጽ አንድ ቅጂ ይሰጥዎታል።

ማስታወሻ: ይህ ጥናት በዩኒቨርስቲ ኦፍ ቴክኖሎጂ ሲድኒ የሰው ምርምር ሰነምግባር ኮሚቴ ተቀባይነት አግኝቶ በፍቃድ ቁጥር **UTS HREC REF NO. ETH21-6739** ጸድቋል፡፡ በፕሮጀክቱ ውስጥ ከተሳተፉዋቸው ተግባራዊ ጠቀሜታዎች ጋር የተዛመዱ ጥያቄዎች ወይም ችግሮች ካጋጠሙዎት ወይም ስለ ፕሮጀክቱ ጉዳይ ወይም አቤቱታ ለማቅረብ ከፈለጉ ከፈለጉ የሰብአዊ ምርምር ሥነ-ምግባር ኮሚቴ ጽ/ቤ በስልክ ቁጥር፡ +61 2 9514 2478 ወይም በ ኢሜል: Research.Ethics@uts.edu.au ያማክሩ፡፡

የፍቃደኝነት ማረጋገጫ ሰነድ፡ ክፍል ክፍል ሁለት

[UTS HREC REF NO. ETH21-6739] - በኢትዮጵያ የልብ ድካም ያለባቸው አዋቂዎች ድባቴ እና ከጤና ጋር የተያያዘ የኑሮ ደረጃቸውን ጥናት ማድርግ፡፡

እኔ______________________ በአቶ ሄኖክ ሙሉጌታ ለሚደርገው ምርምር ለመሳተፍ ፍቃደኛ ሆኜ ተስማምቻለሁ፡ ፡ የምርምሩ ወጪም University of Technology Sydney በሚባል በአውስትራሊያ ሀገር በሚገኝ ዩኒቨርሲቲ እንደሚሸፈን ተረድቻለሁ፡፡

የተሳታፊዎች የመረጃ መስጫ ወረቀትን አንብቤያለሁ ወይም አንድ ሰው በሚገባኝ ቋንቋ አንብቦልኛል።

የምርምሩን ዓላማ፣ አሰራር እና አደጋዎች (ተፅእኖ) በተሳታፊዎች መረጃ ወረቀት ላይ እንደተገለጸው ተረድቻለሁ።

ጥያቄ የመጠየቅ እድል አግኝቻለሁ ፤ እንዲሁም ባገኘኋቸው መልሶች ረክቻለሁ ።

ከምርምሩ በማንኛውም ጊዜ ለመውጣት ነፃ እንደሆንኩና ይህም ከተመራማሪዎቹ ወይም ከሆስፒታሉ ጋር ያለኝን ግንኙነት ላይ ምንም አይነት ተፅእኖ እንደማይኖረው ተረድቻለሁ፡፡

ከጥናቱ የተገኘው መረጃ ሊታተም እንደሚችል ተስማምቻለሁ፡፡

ይህን የስምምነት ሰነድ በተፈረመ ቅጂ እንደሚሰጠኝ ተረድቻለሁ ።

ለቀጣይ የምርምሩ ደረጃዎች ከተፈለኩ ወደፊት በአድራሻዬ እንዲያገኙኝ ተስማምቻለሁ፡፡

ስለ ምርምሩ የሚያሳስበኝ ነገር ካለ አቶ ሄኖክ ሙሉጌታን (+251[redacted]) ማነጋገር እንደምችል ተረድቻለሁ ።

____ ____/____/____

የተሳታፊው ስም እና ፊርማ ቀን

____ ____/____/____

የተመራማሪው ስም እና ፊርማ ቀን

8.12. Appendix 12: Participant Information Sheet and Informed Consent form for Phase III of the study

A. English version

PARTICIPANT INFORMATION SHEET: PHASE THREE

[UTS HREC REF NO. ETH21-6739] – Experiences of Ethiopian people living with heart failure. A qualitative study

WHO IS CONDUCTING THIS RESEARCH?

My name is Henok Mulugeta Teshome ([redacted]@student.uts.edu.au) and I am a higher degree research student at UTS. My supervisors are Professor Amanda Wilson (Amanda.Wilson@uts.edu.au) and Associate professor Peter Sinclair (Peter.Sinclair@uts.edu.au).

WHAT IS THE RESEARCH ABOUT?

The purpose of this research is to explore and describe the experiences of Ethiopian people living with Heart Failure, and its impact on their health-related quality of life. The results may help improve the mental health and health-related quality of life for adults with heart failure in Ethiopia.

WHY HAVE I BEEN INVITED?

You have been invited to participate because you are a person living with heart failure. We would like to interview you about your experience of living with heart failure. The face-to-face interview will be held during your next appointment at the hospital or another place convenient to you.

FUNDING

Funding for this project has been received from University of Technology Sydney.

WHAT DOES MY PARTICIPATION INVOLVE?

If you decide to participate, you will be invited to take part in an interview related to your experiences of living with heart failure which will take 30 to 60 minutes and will be audio-recorded. If you decide to participate in the study, we will invite you to sign a consent form.

ARE THERE ANY RISKS/INCONVENIENCE?

Participation in this study will focus on the impact of heart disease on depression and quality of life and reflecting on these subjects may have the potential to cause distress. If you experience any distress during the questionnaire, we will pause the interview. Your interviewer will be a qualified nurse, and they can in obtaining counselling services if needed.

You can choose whether to continue the questionnaire or stop participating at any time during the study.

DO I HAVE TO TAKE PART IN THIS RESEARCH PROJECT?

Participation in this study is voluntary. It is completely up to you whether or not you decide to take part.

If you decide not to participate, or to withdraw from the study, it will not affect your relationship with the researchers or your hospital care in any way.

WHAT IF I WITHDRAW FROM THIS RESEARCH PROJECT?

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason, by contacting Henok Mulugeta ([redacted]@student.uts.edu.au). Any information you have provided will be deleted from the study. However, as the information you provide will be de-identified for analysis once analysis occurs it may not be possible to delete this data.

WHAT WILL HAPPEN TO INFORMATION ABOUT ME?

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. All this information will be treated confidentially. This information will be treated as confidential and stored securely. All data will be kept in password protected folders and only the researchers will have access to the data. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

WHAT IF I HAVE ANY QUERIES OR CONCERNS?

If you have queries or concerns about the research that you think I or my supervisors can help you with, please feel free to contact me on +251[redacted] or ([redacted]@student.uts.edu.au).

You will be given a copy of this form to keep.

NOTE: This study has been approved in line with the University of Technology Sydney Human Research Ethics Committee [UTS HREC] guidelines. If you have any concerns or complaints about any aspect of the conduct of this research that you wish to raise independently of the research team, please contact the Ethics Secretariat on ph.: +61 2 9514 2478 or email: Research.Ethics@uts.edu.au] and quote the UTS HREC reference number. Any matter raised will be treated confidentially, investigated and you will be informed of the outcome.

CONSENT FORM: PHASE III

[UTS HREC REF NO. ETH21-6739] - Experiences of Ethiopian people living with heart failure. A qualitative study

I ____________________ agree to participate in the research project being conducted by Henok Mulugeta Teshome ([redacted]). I understand that funding for this research has been provided by the University of Technology Sydney.

I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research as described in the participant information sheet.

I have had an opportunity to ask questions, and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time without affecting my relationship with the researchers or the University of Technology Sydney *or* my hospital.

I understand that the interview will be audiotaped, and I agree to this.

I agree for possible publication of the information gained from the interview but understand that any information I provide will not be presented in such a way that I will not be able to be identified.

I understand that I will be given a signed copy of this document to keep.

I am aware that I can contact Henok Mulugeta Teshome (+251[redacted]) if I have any concerns about the research.

____	____/____/____
Name and Signature [participant]	Date
____	____/____/____
Name and Signature [researcher]	Date

Amharic version

የተሳታፊዎች የመረጃ መስጫ ሰነድ፡ ክፍል ሶስት

[UTS HREC REF NO. ETH21-6739] – የምርምሩ ርዕስ፡ በኢትዮጵያ የልብ ድካም ያለባቸው አዋቂዎች ከህመሙ ጋር የመኖር ተሞክሮን ጥናት ማድርግ፡፡

ጥናቱን ማን ነው የሚያጠናው?

ይህ ጥናት በአውስትራሊያ ሀገር በሚገኝ ዩኒቨርሲቲ የ3ኛ ዲግሪ ተማሪ በሆኑት በአቶ ሄኖክ ሙሉጌታ ተሾመ የሚካሄድ ነው፡፡ ጥናቱም የዶክትሬት ዲግሪ ማሟያ ሲሆን በፕሮፌሰር ኤማንዳ ዊልሰን (Amanda.Wilson@uts.edu.au) እና በተባባሪ በፕሮፌሰር ፒተር ሲንክሌር (Peter.Sinclair@uts.edu.au) አማካሪነት የሚሰራ ነው፡፡

ምርምሩ ስለ ምንድነው?

የምርምሩ ኣላማ በኢትዮጵያ የልብ ድካም ያለባቸው አዋቂዎች ከህመሙ ጋር አብሮ የመኖር ተሞክሮን እንዲሁም ህመሙ በ ከጤና ጋር የተያያዘ የኑሮ ደረጃቸው ላይ የሚያሳድረውን ተፅዕኖ ለመቃኘትና ጥናት ማድርግ፡፡ የጥናቱ ውጤቱ የአዕምሮ ጤና እና ከጤና ጋር የተያያዘ የኑሮ ደረጃን ለማሻሻል የሚረዳ ከመሆኑም በላይ እነዚህን ችግሮች ለማሻሻል የሚያስችሉ መንገዶችን ይመክራል።

እኔ ለምን በጥናቱ ተሳታፊ እንድሆን ተጋበዝኩኝ?

የልብ ድካም ህክምና በመከታተል ላይ ያሉትን ሰዎች በመጋበዝ ላይ እንገኛለን፡፡ እናም እርሰዎ ላለፉት 3 ወራት ህክምና እየተከታተሉ ስለሆነ በጥናቱ እንዲሳተፉ ተጋብዘዋል፡፡ ይሁን እንጂ የእርስዎ ተሳትፎ ሙሉ በሙሉ በፈቃደኝነትዎ ላይ የተመሰረተ ነው፡፡ ከልብ ድካም ጋር የመኖር ተሞክሮትን እና ተያያዥ ጉዳዮችን በተመለከተ ቃለ መጠይቅ ልናደርግላችሁ እንፈልጋለን።

የገንዘብ ድጋፍ

የምርምሩ ወጪ University of Technology Sydney በሚባል በአውስትራሊያ ሀገር በሚገኝ ዩኒቨርሲቲ ይሸፈናል፡፡

ተሳትፎዬ ምን ነገሮችን ይጨምራል?

ለመሳተፍ ፍቃደኛ ከሆኑ ከልብ ድካም ጋር የመኖር ተሞክሮትን እና ተያያዥ ጉዳዮችን በተመለከተ ከ30 እስከ 60 ደቂቃ የሚወስድ በድምፅ የሚቀዳ ቃለ መጠይቅ ልናደርግልዎ እንፈልጋለን። ለመሳተፍ ፍቃደኛ ከሆኑ ስለምርምሩ ጠለቅ ያለ ምረጃ ለማግኘት የሚያስችል የመረጃ መስጫ ወረቀት ይሰጥዎታል እንዲሁም የፍቃደኝነት ፎርም ይሞላሉ፡፡

ምርምሩ ውስጥ ከመሳተፍ ጋር ተያይዘው የሚመጣ ችግር ይኖራል?

ጥናቱ በቃለ መጠየቅ የሚደረግ ስሆን ከዚህ ጋር ተያይዘው በአንዳንድ ተሳታፊዎች ላይ የድካም እና የመረበሽ ስሜት ሊታይ ይችላል፡፡ በመሆኑም ጭንቀትን ለመቀነስ መረጃ የሚሰበሰበው የምክር አግልግሎት መስጫ ክፍል ውስጥ ብቻ ነው:: በተጨማሪም በማንኛውም ጊዜ ተሳትፎዎን ማቆም ይችላሉ:: የመጨነቅ ስሜት ከተሰማዎ መረጃ ሰብሳቢ ባለሙያዎች በሆስፒታሉ ውስጥ የምክር አገልግሎት እንዲያገኙ ይረዱዎታል::

ምርምሩ ውስጥ መሳተፍ ግዴታ ነው ?

ምርምሩ ላይ መሳተፍ ሙሉ በሙሉ በእርስዎ ፈቃደኝነት ላይ የተመሰረተ ይሆናል:: ቢሳተፉም ባይሳተፉም ከተመራማሪው ወይም ከሆስፒታሉ ጋር ያልዎትን ግኑኝነት ላይ በምንም መንገድ ተፅዕኖ አይኖረውም፡፡

ከምርምሩ መውጣት ወይም ማቋረጥ እችላለሁ?

በዚህ ፕሮጀክት መሳተፍ በፈቃደኝነት ላይ የተመሠረተ እንዲሁም ለመሳተፍ ከተስማሙ በኃላ በማንኛውም ጊዜ ያለምንም ቅድመ ሁኔታ ከጥናቱ ማቋረጥ ይችላሉ፡፡ ከጥናቱ በማቋረጠዎ አሁንም ሆነ ወደፊት ህክምናዎ ላይ ምንም ተጽእኖ አይኖረውም፡፡ ከጥናቱ ማቋረጥ ከፈለጉ ተጨማሪ መረጃ መውሰድ እናቆማልን፡፡

የምሰጠው መረጃ እንደት ይያዛል?

እርስዎ የሰጡት መረጃ ለምርምር ብቻ የሚውል ነው፡፡ ከእርስዎ መረጃ ሲሰበሰብ ምንም አይነት የግል መለያ ስምዎ፤ ቁጥርዎ አይካተትም፡፡ሁሉም መረጃ በይለፍ ቃል ይታሰራል፡፡ የተሰበሰበውን መረጃ ዋናው ተመራማሪ እና የምርመሩ አማካሪዎች ብቻ የሚያውቁት ሲሆን የተሳታፊዎች መረጃ ከፈቃዳቸው ውጭ ለማንም ማሳየት አይቻልም፡፡ የምርምሩ ውጤት ሊታተም ወይም በተለያዩ ስብሰባዎች ላይ ይቀርባል፡፡ስለሰጡት መረጃ በማንኛውም ጌዜ መጠየቅም ማስተካከል ይችላሉ፡፡

ስለ ምርምሩ ጥያቄ ቢኖረኝ ማንን ልጠይቅ እችላለሁ?

ስለምርምሩ ማንኛውም ጥያቄ ካለዎት አቶ ሄኖክ ሙሉጌታን በስልክ ቁጥር +251[redacted]፤ ኢሜል [redacted]@student.uts.edu.au ይደውሉ፡፡

የዚህ ቅጽ አንድ ቅጂ ይሰጥዎታል።

ማስታወሻ: ይህ ጥናት በዩኒቨርስቲ ኦፍ ቴክኖሎጂ ሲድኒ የሰው ምርምር ሰነምግባር ኮሚቴ ተቀባይነት አግኝቶ በፍቃድ ቁጥር **UTS HREC REF NO. ETH21-6739** ጸድቋል፡፡ በፕሮጀክቱ ውስጥ ከተሳተፉዋቸው ተግባራዊ ጠቀሜታዎች ጋር የተዛመዱ ጥያቄዎች ወይም ችግሮች ካጋጠሙዎት ወይም ስለ ፕሮጀክቱ ጉዳይ ወይም አቤቱታ ለማቅረብ ከፈለጉ ከፈለጉ የሰብአዊ ምርምር ሥነ-ምግባር ኮሚቴ ጽ/ቤ በስልክ ቁጥር፡ +61 2 9514 2478 ወይም በ ኢሜል: Research.Ethics@uts.edu.au ያማክሩ፡፡

የፍቃደኝነት ማረጋገጫ ሰነድ፡ ክፍል ሶስት

[UTS HREC REF NO. ETH21-6739] - የምርምሩ ርዕስ፡ በኢትዮጵያ የልብ ድካም ያለባቸው አዋቂዎች ከህመሙ ጋር የመኖር ተሞክሮን ጥናት ማድርግ፡፡

እኔ______________________ በአቶ ሄኖክ ሙሉጌታ ለሚደርገው ምርምር ለመሳተፍ ፍቃደኛ ሆኜ ተስማምቻለሁ፡ ፡ የምርምሩ ወጪም University of Technology Sydney በሚባል በአውስትራሊያ ሀገር በሚገኝ ዩኒቨርሲቲ እንደሚሸፈን ተረድቻለሁ፡፡

የተሳታፊዎች የመረጃ መስጫ ወረቀትን አንብቤያለሁ ወይም አንድ ሰው በሚገባኝ ቋንቋ አንብቦልኛል።

የምርምሩን ዓላማ፣ አሰራር እና አደጋዎች (ተፅእኖ) በተሳታፊዎች መረጃ ወረቀት ላይ እንደተገለጸው ተረድቻለሁ።

ጥያቄ የመጠየቅ እድል አግኝቻለሁ ፤ እንዲሁም ባገኟኋቸው መልሶች ረክቻለሁ ።

ከምርምሩ በማንኛውም ጊዜ ለመውጣት ነፃ እንደሆንኩና ይህም ከተመራማሪዎቹ ወይም ከሆስፒታሌ ጋር ያለኝን ግንኙነት ላይ ምንም አይነት ተፅእኖ እንደማይኖረው ተረድቻለሁ፡፡

ቃለ ምልልሱ በድምጽ እንደሚቀዳ ተነግሮኛል። በዚህም ተስማምቻለሁ።

ከጥናቱ የተገኘው መረጃ ሊታተም እንደሚችል ተስማምቻለሁ፡፡

ይህን የስምምነት ሰነድ በተፈረመ ቅጂ እንደሚሰጠኝ ተረድቻለሁ ።

ስለ ምርምሩ የሚያሳስበኝ ነገር ካለ አቶ ሄኖክ ሙሉጌታን (+251[redacted]) ማነጋገር እንደምችል ተረድቻለሁ ።

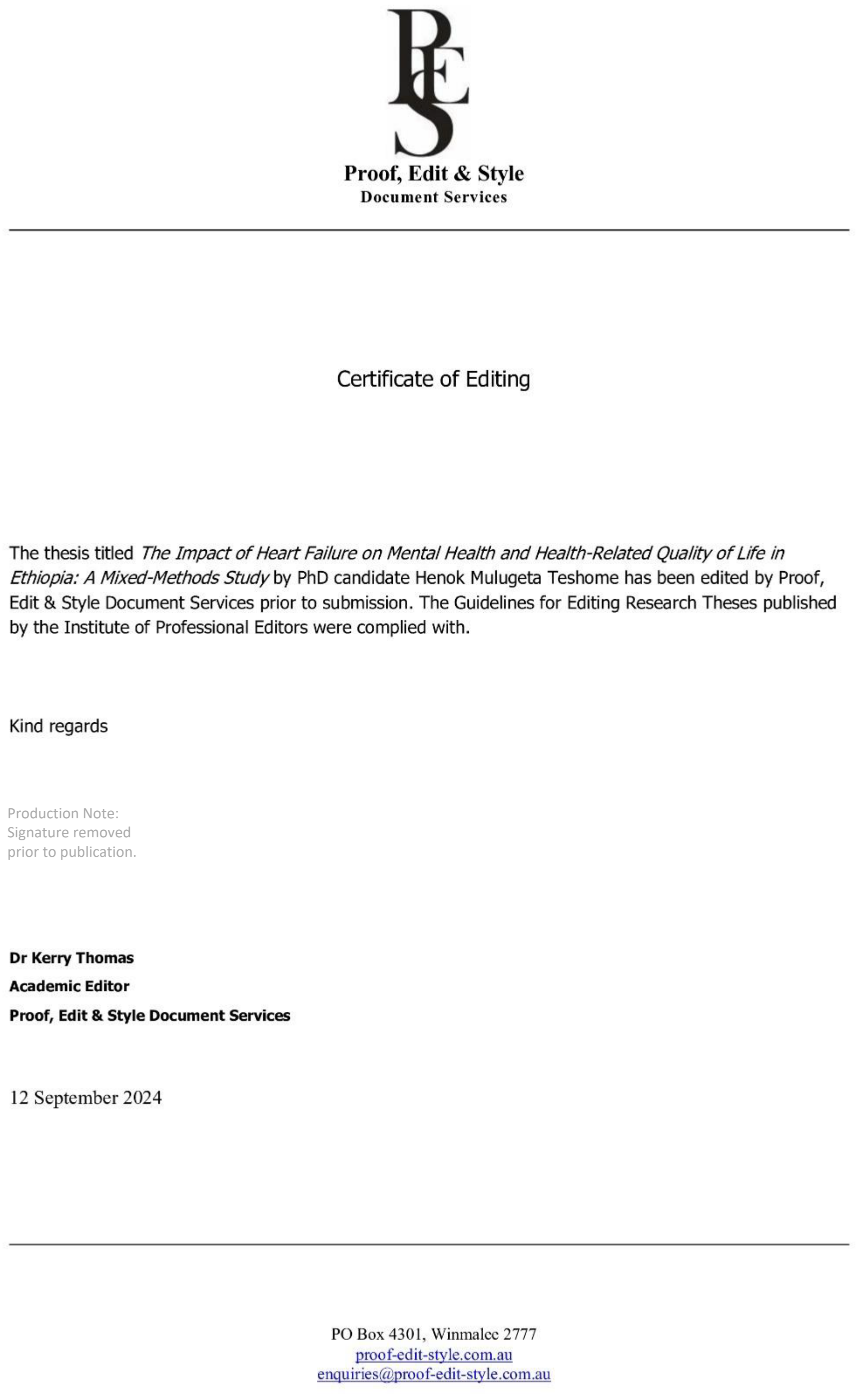
____ _____/_____/_____

የተሳታፊው ስም እና ፊርማ ቀን

____ _____/_____/_____

የተመራማሪው ስም እና ፊርማ ቀን

8.13. Appendix 13: Certificate of Professional Editing



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8.14. Appendix 14: Certificate of attendance for *JBI Comprehensive Systematic Review Training Program*

JBI

CERTIFICATE

OF ATTENDANCE

This is to certify that

Henok Mulugeta Teshome

Attended

Comprehensive Systematic Review Training Program

Adelaide, Australia
25 October 2021 – 29 October 2021

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Prof Zoe Jordan, PhD
Executive Director
JBI, University of Adelaide
Adelaide, South Australia

8.15. Appendix 15: Certificate of completion for *Qualitative Research Methods for Public Health*

MONASH University

MONASH
MEDICINE
NURSING AND
HEALTH SCIENCES

CERTIFICATE OF COMPLETION

THIS IS TO CERTIFY THAT

Henok Teshome

HAS SUCCESSFULLY COMPLETED

Qualitative Research Methods for Public Health
29-31 May 2024

AND HAS ACHIEVED AN OVERALL PASS RESULT IN THE ASSESSMENT MODULES

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Associate Professor Darshini Ayton
Course Facilitator
School of Public Health and Preventive Medicine
Monash University

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