Addis Ababa University

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Department of Pharmaceutics and Social Pharmacy

Validation of the Amharic Version of Multidimensional Fatigue Syndrome Inventory-Short Form for the Assessment of Cancer-Related Fatigue in Patients Receiving Treatment at Tikur Anbessa Specialized Hospital

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Addis Ababa, Ethiopia

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Dinksew Tewuhibo (BPharm)

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This is to certify that the thesis prepared by Dinksew Tewuhibo entitled: *Validation of the Amharic version of Multidimensional Fatigue Syndrome Inventory-Short Form for the Assessment of Cancer-Related Fatigue in Patients Receiving Treatment at Tikur Anbessa Specialized Hospital* and submitted in partial fulfillment of the requirements for the Degree of Master of Science (Pharmacoepidemiology and Social Pharmacy) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Signed by the Examining committee

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Chair of Department

Abstract

Validation of the Amharic Version of Multidimensional Fatigue Syndrome Inventory-Short Form for the Assessment of Cancer-Related Fatigue in Patients Receiving Treatment at Tikur Anbessa Specialized Hospital.

Dinksew Tewuhibo

Addis Ababa University, 2021

Introduction: Multidimensional fatigue syndrome inventory short form (MFSI-SF) is one of the instruments useful for measuring cancer-related fatigue (CRF). However, it was not validated in Ethiopia despite its established reliability and validity in other countries.

Objective: The study was conducted to evaluate the validity and reliability of the Amharic version of MFSI-SF (MFSI-SF-Am) for assessing CRF in Ethiopian cancer patients.

Methods: A hospital-based cross-sectional study was conducted from December 2020 to January, 2021 at the oncology center of Tikur Anbesa Specialized Hospital. Correlation analysis and independent samples t-test were employed to evaluate the construct and known group validity of the tool, respectively. Moreover, confirmatory Factor Analysis was used to assess factorial validity.

Result: A total of 300 patients on cancer treatment were involved in the study. The Cronbach's alpha scores of MFSI-SF-Am subscales vary from 0.79 to 0.90 with overall score of 0.90. A moderate Pearson correlation of MFSI-SF-Am was observed with the Amharic version Brief Fatigue Inventory (BFI-Am) global score (r = 0.64) and the European Organization for Research and Treatment of Cancer Quality of Life

Questionnaire-30 items (EORTC QLQ-C30) fatigue subscale (r = 0.66) suggesting good concurrent validity. MFSI-SF-Am scores were also sensitive to changes across the low and high groupings of Eastern Cooperative Oncology Group Performance Status (ECOG-PS), pain, depression and insomnia which approves a known group validity of MFSI-SF-Am.

Conclusion: The findings confirm the validity and reliability of the MFSI-SF-Am and that the tool can be valuable for CRF measurement in Ethiopian Amharic speaking patients.

Keywords: *Amharic; Cancer; Cancer-related fatigue; MFSI-SF-Am; Psychometric properties; Reliability; Validity.*

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List of Abbreviations /Acronyms

ACRN	African Cancer Registry Network
BFI-Am	Amharic version Brief Fatigue Inventory
CFA	Confirmatory Factor Analysis
CFI	Comparative Fit of Indexes
CRF	Cancer Related Fatigue
ECOG-PS	Eastern Cooperative Oncology Group Performance Status
EDGE	Evidence Database to Guide Effectiveness
EORTCQLQ-C30	European Organization for Research and Treatment of Cancer Quality of Life Questioner-30 items
FMOH	Federal Ministry of Health
GLOBOCAN	Global Cancer Observatory
HRQOL	Health-Related Quality of Life
IFI	Incremental fit of index
ML	Maximum Likelihood
MFSI-SF	Multidimensional Fatigue Symptom Inventory Short Form
NCCN	National Comprehensive Cancer Network
OPD	Out-Patient Department
POM	Patient Outcome Measure
RAMSEA	Root Mean Squared Error of Approximation
SRMR	Standardized Root Mean Squared Residual

TASH	Tikur Anbessa Specialized Hospital
TLI	Tucker-Lewis Index
WHO	World Health Organization

1 Introduction

1.1 Background

Cancer patients may have a variety of chemotherapy side-effects from which cancer related fatigue (CRF) is the frequently encountered side-effect (Jong *et al.*, 2004). The National Comprehensive Cancer Network (NCCN) defined CRF as a severe, subjective and consistent perception of emotional, physical, and cognitive weariness linked with the cancer itself or the treatment that interferes in the usual activity of the patient (Gradishar *et al.*, 2018).

The presence of a persistent fatigue that is not relieved during rest provides a clue for clinicians in the diagnosis of CRF (Fisher *et al.*, 2018). CRF is mostly experienced during and after treatment. It can also have long-lasting effects resulting in higher impact on both quality and daily living conditions of the patient (Weis, 2011). In many cases, CRF is more debilitating and severe compared with usual fatigue in non-cancer populations (Horneber *et al.*, 2012).

CRF may arise before diagnosis or at any point in the course of diagnosis and during treatment. The symptoms may be temporary or persistent and even continues for years after the patient completes the treatment. (Horneber *et al.*, 2012). Studies indicate that despite its adverse impact, CRF is not often assessed or managed in the health care service and its impact on quality of life is underestimated, and remains a largely unrecognized problem in cancer patients (Jones *et al.*, 2016; Molassiotis *et al.*, 2019). As such, the development and application of valid and reliable measurement tools for CRF is crucial.

Currently, different types of tools are available to assess CRF and mainly depend on the use of self-assessment questionnaires (Smets *et al.*, 1996). Among the different measurement tools, the Multidimensional Fatigue Symptom Inventory Short Form (MFSI-SF) is one that is highly recommended by the cancer Evidence Database to Guide Effectiveness (EDGE) task force and is known to be effective in assessing fatigue in different dimensions like: general, physical, emotional, and mental domains (Fisher *et al.*, 2018). This scale contains 30 items, scored on a five-point Likert scale and takes around 5 minutes to complete. While the tool has been established as valid measure of CRF in different parts of the world, information is lacking on its validity in the context of Ethiopia. Thus, this project aimed to evaluate the psychometric properties of the Amharic version of MFSI-SF (MFSI -SF-Am) for use in Ethiopia.

1.2 Statements of the problem

Cancer patients experience fatigue as a result of the disease or the treatment (de Jong *et al.*, 2004; Lacourt *et al.*, 2018). CRF is nearly a universal experience in patients taking chemotherapy, radiation treatment, bone marrow transplantation and biological response modifiers (Minton *et al.*, 2013). Up to 99% of cancer patients commonly report CRF during their treatment time (Bower *et al.*, 2014) and unlike fatigue in non-cancer patients, CRF is moderately more severe, incapacitating, and challenging to get relieved (Jong *et al.*, 2002; NCCN., 2017).

Despite its frequency and negative consequences, the effect of fatigue on the overall life of the cancer patient continues to be largely ignored and poorly handled (Jones *et al.*, 2016). The available studies in Ethiopia also indicates the high prevalence of CRF (66.7%-78.8%) using Brief Fatigue inventory (BFI-Am) (Gebremariam *et al.*, 2018; Nugusse *et al.*, 2021). However, due to the multi-symptom profile of CRF, unidimensional tools like BFI-Am could not able to capture the whole spectrum of CRF. So, effective management of CRF requires reliable and valid multidimensional assessment tools in the respective local contexts as CRF has a complex origin and shows itself in a variety of symptoms across the behavioral, cognitive, physical, and emotional domains (Donovan *et al.*, 2015). In this regard, the 30-item MFSI-SF is highly recommended measure of fatigue because of its multidimensional conceptualization of fatigue and psychometric performance in different contexts (Servaes *et al,* 2002; Stein *et al.*, 2004; Fisher *et al.*, 2018). With a simple 5-point Likert-scale format and being relatively short in length and easy to complete, the MFSI-SF offers a comprehensive investigation of fatigue across various domains like; global, physical, mental, and behavioral manifestations (Stein *et al.*, 1998).

While the MFSI-SF was previously validated in the United States, Germany, China, Italy, Taiwan and Singapore, its psychometric properties are not well documented in the context of Ethiopia (Stein *et al.,* 2004; Krummenacher *et al.,* 2009; Pien *et al.*, 2011; Pino *et al.*, 2015; Chan, Lew, *et al.*, 2018). The absence of such validated tools in the Ethiopian context will have an effect on the ability of clinicians to assess and manage the level of CRF. That was why it was found to be crucial to translate the tool to Amharic and evaluate its psychometric performance among Ethiopian cancer patients.

1.3 Significance of the study

From the existing tools, MFSI-SF is a highly recommended tool to measure CRF. Studies from different countries of the world attest to the excellent psychometric properties of the tool (Servaes *et al,* 2002; Stein *et al.*, 2004; Fisher *et al.*, 2018). However, there is paucity of evidence about the validity and reliability of MFSI-SF in the Ethiopian context.

As proposed in the current study, validation of the Amharic version of MFSI-SF (MFSI-SF-Am) allows clinicians to be able to assess CRF in Amharic speaking patients. If proven valid, the tool will also help clinicians and researchers to evaluate the pattern or/dimension of CRF, design appropriate interventions and measure the effectiveness of interventional therapies on CRF among Ethiopian cancer patients. Furthermore, as MFSI-SF is non-disease specific, the tool can be used for the assessment of fatigue in patients having chronic diseases other than cancer (Stein *et al.*, 2004; Bardwell *et al.*, 2006; Mead *et al.*, 2007; Hawker *et al.*, 2011; Rodrigue *et al.*, 2011; Sadja *et al.*, 2012; Schmidt *et al.*, 2012; Asvat *et al.*, 2014).

2 Literature Review

2.1 Overview of cancer in the World and Ethiopia

In both low- and high-income countries, cancer is a huge burden on society. Because of the population's increase and aging, cancer is becoming more common (FMoH, 2015). From the 2012 Global Cancer Observatory (GLOBOCAN) estimates, 14.1 million cancer cases were newly diagnosed and 8.2 million deaths were reported worldwide. However, according to the 2018 GLOBOCAN's reports, the occurrence and death are rapidly increasing globally, with an estimated 18.1 and 9.6 million new cases and deaths respectively with a 5-year prevalence of 43.8 million worldwide (Bray *et al*., 2018). This data also slightly increased in 2020 and lung cancer, breast cancer, and colorectal cancer ranks the highest in occurrence according to the World Health Organization (WHO) (Sung *et al.*, 2021).

In Ethiopia, according to the report of the National Cancer Control Plan (NCCP) of 2016-2020, cancer holds 5.8% of the total national mortality with a yearly incidence of 60,960 cases and over 44,000 annual mortalities. Based on this report, the most prevalent cancers in the country were; breast cancer (30.2%), cervical cancer (13.4%) and colorectum cancer (5.7%) (FMOH, 2015).

2.2 Concept and burden of Cancer Related Fatigue (CRF)

In normal circumstances, fatigue aids in the maintenance of a healthy balance of activity and rest, and relived after taking proper rest. When there is a disease or medical treatment, however, the degree and persistence of the exhaustion and sleepiness differentiates it from

usual experiences of tiredness and sleepiness, and it cannot be alleviated by rest (Asvat *et al.*, 2014). The symptoms of CRF are multiple and conceptualized as the multidimensional manifestations of fatigue that manifests across physical, affective, cognitive, and functional domains (Stein *et al.*, 2004). These symptoms are begin in pretreatment phase and become worse during the treatment phase (Horneber *et al.*, 2012). Studies reported that among the individuals who experienced CRF, over 80% of them often report a lack of motivation and even they discontinue their chemotherapy regimens due to a reason of poor compliance (Gledhill, 2005; Ancoli-Israel *et al.*, 2014). As a result, CRF has an impact on one's health, mind, social and cultural bonds and spirituality that can last months to years (Pien *et al.*, 2011).

The effects of CRF can begin from temporary illness to insufficient coping in daily activities and social withdrawal which depends on the course and severity of the symptom (Horneber *et al.*, 2012). Hence, patients could be incapable to lead their daily living with significantly reduced Quality of Life (QoL), and leading them to an additional economic burden for the society at large (Spelten, Sprangers and Verbeek, 2002; Liavaag *et al.*, 2007; Oktay *et al.*, 2011).

2.3 Prevalence of CRF

The reported CRF prevalence ranged from 59 to 100% depending the course of the disease and treatment phase (Morrow GR *et al.*, 2002). The severity of fatigue was reported by the level, and type of disease. Based on this, severe fatigue was reported in 15% of newly diagnosed breast cancer, 16% in recently diagnosed with prostate cancer, 50% in lung cancer patients, and 78% with palliative care patients (P. Stone *et al.*, 2000). Regarding

course of treatment, after the last cycle of chemotherapy, patients who received cyclophosphamide, methotrexate and 5-fluorouracil have a significant increased fatigue unlike the patients in doxorubicin where a significant fatigue was reported on the first cycles of chemotherapy (Jong *et al.*, 2004).

Similarly, a review of the study found that fatigue is an issue for most patients undergoing treatment for cancer. Compared to healthy controls, cancer patients have more frequent and severe fatigue and a significant rise of fatigue seen just before treatment and during or immediately after treatment (Servaes *et al.*, 2002). In Germany, CRF was reported among patients who were on admission (32%), discharge (40%) and six months later (36%) from treatment (Shun *et al.*, 2009). Other studies on cancer survivors found that clinically relevant levels of CRF reported up to 6 years of post-treatment (Jones *et al.*, 2016). Studies in Ethiopia also indicates that about 66.7%-78.8% patients were reported experience of significant CRF (Gebremariam *et al.*, 2018; Nugusse *et al.*, 2021). Practice guidelines on cancer-related fatigue management and recently reviewed studies indicating that a severe level of fatigue is a problem for most of patients who received treatment for cancer (Fisher *et al.*, 2018; Gradishar *et al.*, 2018).

2.4 Mechanisms, associated factors and diagnosis of CRF

The tumor itself/treatment, genetic predisposition, mental or physical sickness, behavioral and environmental factors all play a role in the processes of CRF, according to a study. (Horneber *et al.*, 2012). Furthermore, results suggest that cytokine dysregulation has a part in the processes of CRF, since tumor-eradication therapy can activate the proinflammatory

cytokine network, resulting in tiredness symptoms via cytokine signaling in the Central Nervous System (CNS) (Miller *et al.*, 2008; Horneber *et al.*, 2012; Bower *et al.*, 2014).

Regarding to the associated factors, studies indicated that sociodemographic and social classes such as; lower age, female sex, separation/divorce, lower education level and lower social class are among the reported associated factors of CRF (Jong *et al.*, 2005; Lee, 2005; Prue *et al.*, 2006; Jacobsen and Thors, 2008; Kocalevent *et al.*, 2011; Puigpinós-Riera *et al.*, 2020; Nugusse *et al*., 2021).

A review of study revealed that fatigue was also significantly associated with depression /anxiety, insomnia, poor physical activity, pain, dyspnea and appetite loss in cancer patients (Prue *et al.*, 2006). Furthermore, symptoms like; depression, pain, insomnia and dyspnea were frequently reported as symptom clusters of CRF (Prue *et al.*, 2006; Agasi-Idenburg *et al.*, 2017; Puigpinós-Riera *et al.*, 2020). In a mixed retrospective and longitudinal breast cancer study, chronic conditions were also found significant risk factor for CRF (Puigpinós-Riera *et al.*, 2020). Additional to some of the above stated factors, recent studies in Ethiopia also indicated that, Eastern Cooperative Oncology Group Performance Status (ECOG-PS), infection, cancer diagnosis, and treatment variables were significant risk factors of CRF (Gebremariam *et al.*, 2018; Nugusse *et al*., 2021).

Regard to the diagnosis, healthcare practitioners are responsible for assessing and diagnosing CRF (Piper *et al.*, 2008). Experts claim that because CRF is a complicated and subjective experience, self-report evaluation techniques/tools are the only way to measure it (Weis, 2011). Recommendations of NCCN guideline also indicated that for any cancer patient, the symptoms of fatigue should be screened regularly during their treatment and follow up with the help a rating scale (Tishelman *et al.*, 2005; Gradishar *et al.*, 2018).

Among a number of fatigue screening/assessment tools, the Amharic version Brief Fatigue Inventory (BFI-Am) scale rated from zero (no fatigue) to ten (fatigue as bad as you can imagine) was validated in Ethiopia that measures CRF in the past 24 hours (Gebremariam *et al.*, 2018). Despite its intended purpose to one element of the quality of life measuring criteria, the fatigue subscale of the European Organization for Research and Treatment of Cancer Quality of Life Questioner-30 items (EORTC QLQ30) was also available in Ethiopia (Ayana et al., 2016).

However, evidence indicates that CRF symptom is rarely reported by patients and given less attention or remains less treated by the clinicians. The possible barrier of this diagnosis was poor understanding of the CRF mechanism and failure to take the symptoms of fatigue seriously by the clinician or unavailability of validated assessment tools. From the patient's side; fear of complain too much, or considering "normal" for the side effects either the disease or its treatment was some of the barriers of diagnosis (Horneber *et al.*, 2012; Bower *et al.*, 2014). So, in order to have a more comprehensive approach of diagnosis, encouraging the patient for self-behavioral descriptions, additional detail medical and physical examinations, and laboratory data are recommended as sources to diagnose CRF (Weis, 2011; Horneber *et al.*, 2012).

2.5 Management of CRF

A variety of treatment has been approached to address CRF. Among these, counseling, physical activities, psychosocial interventions as well as pharmacological treatment were recommended (Mitchell, 2010; Lim and Melville, 2011; Bourmaud *et al.*, 2017). NCCN guideline states that appropriate fatigue management strategies should be depends on the

clinical situation of the patient and the specific causes and when the causes are not specific (Gradishar *et al.*, 2018). Moderate exercise and psychosocial programs, energy preservation approaches, and nutritional and appropriate sleep are some of the non-pharmacologic treatments as appropriate (Minton *et al.*, 2013; Bower *et al.*, 2014). A review and meta-analysis of 16 studies on 1172 breast cancer participants indicated that exercise is much effective than controls (Cramp and Byron-Daniel, 2012). Pharmacologically, methylphenidate showed greater reductions on fatigue with advanced cancer patients compared to placebo (Minton *et al.*, 2011).

A meta-analysis study from 11,525 participants concludes that exercise and psychological approaches are effective to reduce fatigue in treatment period or after and substantially effective compared to pharmacological treatments (Mustian *et al.*, 2017). In most westerns, the management of CRF is a priority for advanced cancer patients (Weis, 2011) and earlier longitudinal outcome research of CRF also strongly supported the establishment of CRF clinic in the health institutions (Escalante *et al.*, 2010).

2.6 Measurement of CRF

To have an accurate assessment of CRF, there should be validated tools with strong psychometric properties that provide a profound understanding on CRF (Jim and Jacobsen, 2008; Fisher *et al.*, 2018). However, due to the multifactorial causality for CRF, there was a difficulty to define and conceptualizing the problem. This led to the challenge of operationalizing as well as measuring CRF (Asvat *et al.*, 2014). Currently reviewed 136 articles propose that there are five unidimensional and nine multi-dimensional instruments suggested for fatigue measurement (Fisher *et al.*, 2018). With these tools, CRF is

conceptualize either in unidimensional or multidimensional. Unidimensional fatigue measuring scales like; BFI-Am and the fatigue subscale of EORTC QLQ-C30 as part of the quality of life measurement are available in Ethiopia (Ayana *et al.*, 2016; Gebremariam *et al.*, 2018). However, unidimensional measurements are limited ability in capturing the whole spectrum of CRF symptoms particularly in chronically diseased patients with medical therapy (Whitehead, 2009). But multidimensional tools measure CRF over its variety of symptoms (Stein *et al.*, 2004). According to review of studies, MFSI-SF is the mostly used multidimensional assessment of fatigue which measures the multiple dimensions of CRF (Asvat *et al.*, 2014). First, it was published in 1998 in a 30-item self-administered tool evolved from the first 83-items intended to assess multiple dimensions of fatigue (general fatigue, physical fatigue, emotional fatigue, mental fatigue, and vigor).

Strong psychometric qualities, excellent sensitiveness to changes (groups across ECOG-PS, depression, insomnia, pain), comprehensiveness, and shortness are just a few of the advantages of the MFSI-SF over other multidimensional measures (Stein *et al.*, 1998; Pien *et al.*, 2011; Chan, Lew, *et al.*, 2018). The MFSI-SF also provides clinical and research utility because it is not cancer-specific like other fatigue measures as clearly indicated from literatures for different chronic conditions like; fibromyalgia, hypertension, stroke, and osteoarthritis and kidney transplantation (Stein *et al.*, 2004; Bardwell *et al.*, 2006; Mead *et al.*, 2007; Hawker *et al.*, 2011; Rodrigue *et al.*, 2011; Sadja *et al.*, 2012; Schmidt *et al.*, 2012; Asvat *et al.*, 2014). It also highly recommended assessment tool among the different multidimensional tools (Fisher *et al.*, 2018). Hence, validating MFSI-SF-Am, which could be an ideal tool for the measurement and management of fatigue and also encourages clinical research linked to fatigue in the Ethiopian patients. To evaluate the validity of the

MFSI-SF-Am, EORTCQLQC30 and BFI-Am were used as a reference by considering the comprehensiveness of EORTC QLQ-C30 and their established validity and reliability in Ethiopian cancer patients (Ayana *et al.*, 2016; Chan, Lew, *et al.*, 2018; Gebremariam *et al.*, 2018). These instruments were also used for similar validation studies of MFSI-SF in other country contexts (Krummenacher *et al.*, 2009; Pien *et al.*, 2011; Pino *et al.*, 2015; Chan, Lew, *et al.*, 2018).

As a requirement for the validity and reliability tests of MFSI-SF, almost common test studies were conducted across literatures (Donovan *et al.*, 2015). Internal consistency and test-retest investigation were used to ensure the reliability of the instrument. Construct Validity tests like; structural validity, concurrent validity, convergent validity, and divergent validity are indicated for assessing the construct validity of MFSI-SF. Known group validity and discriminant validity were indicated in the studies to measure the sensitivity performance of the MFSI-SF (Stein *et al.*, 1998; Stein *et al.*, 2004; Prue *et al.*, 2006; Pien *et al.*, 2011; Pino *et al.*, 2015; Chan, Lew, *et al.*, 2018).

2.7 Conceptual Framework

The validity and reliability evaluations are required to use MFSI-SF-Am for the assessment of CRF in cancer patients. The MFSI-SF-Am is valid when the total and subscale scores of MFSI-SF-Am are responsive or/correlated ($r \leq$ or $\geq|0.4|$) with the hypothesized subscales of EORTCQLQC30 and BFI-Am for each validity tests (Ayana *et al.*, 2016; Chan, Lew, *et al.*, 2018; Gebremariam *et al.*, 2018). Moreover, validity of MFSI-SF-Am can be established when it has factorial validity revealed by Confirmatory factor analysis (CFA) and sensitiveness to changes with the group categories of ECOG-PS, pain, insomnia, and depression. MFSI-SF-Am also reliable when it has good internal consistency results ($\alpha \geq 0.7$) (Stein *et al.*, 1998; Stein *et al.*, 2004; Asvat *et al.*, 2014; Pino *et al.*, 2015) (Figure 1).

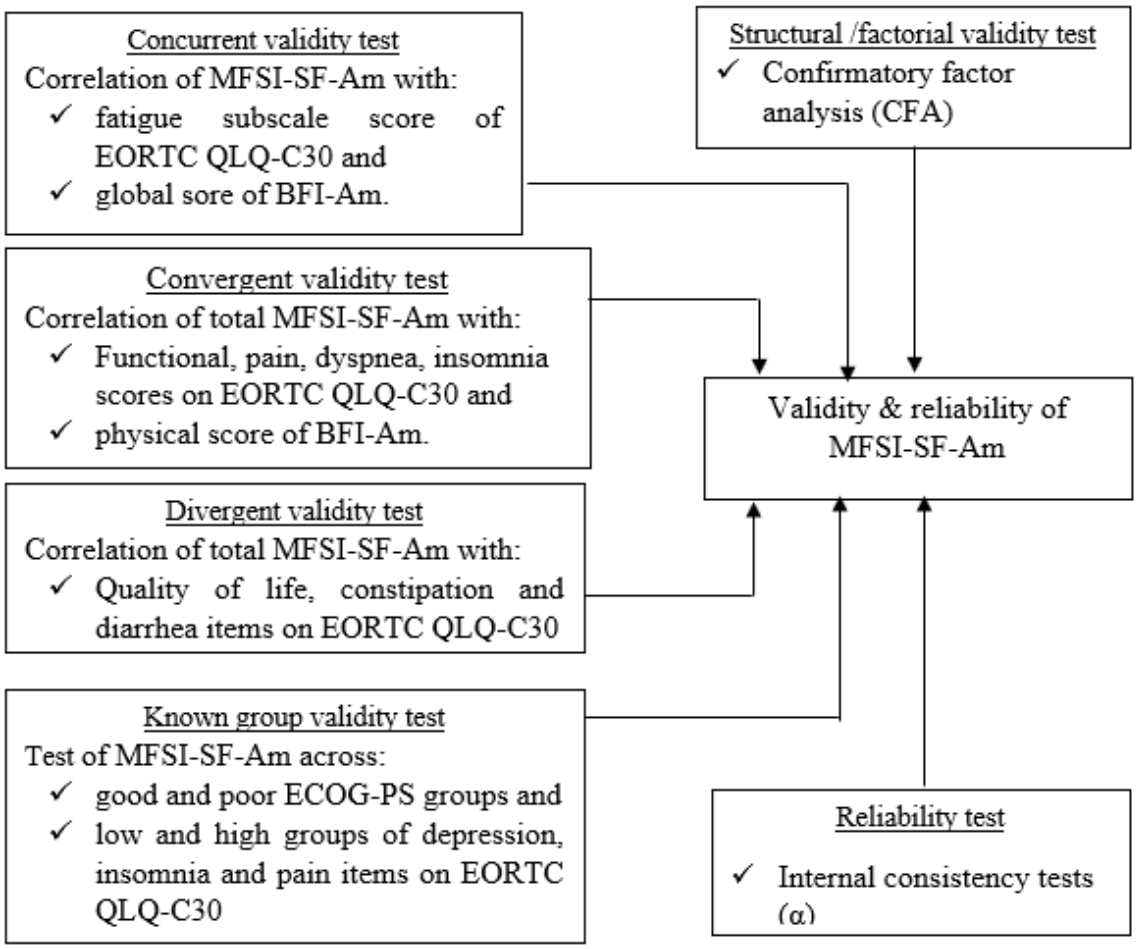

Figure 1:Conceptual framework for the validity and reliability of MFSI-SF-Am.

Note: *BFI-Am: Amharic Version of Brief Fatigue Inventory; ECOG-PS: Eastern Cooperative Oncology Group Performance Status; EORTC QLQ C-30: European Organization for Research and Treatment of Cancer Quality of Life Questioner-30 items.*

3 Objectives

3.1 General objective

The study aimed to evaluate the validity and reliability of the MFSI-SF-Am for the assessment of CRF among Ethiopian patients treated for cancer.

3.2 Specific objectives

The specific objectives were to:

- ✓ Evaluate the validity of the MFSI-SF-Am in the context of Amharic speaking Ethiopian patients
- ✓ Evaluate the reliability of the MFSI-SF-Am in the context of Amharic speaking Ethiopian patients
- ✓ Determine the level of CRF.

4 Methods

4.1 Study area and period

This study was carried out starting from December, 2020 in the Tikur Anbessa Specialized Hospital (TASH) oncology center and was continued to January, 2021 to meet the required sample size. TASH is the leading referral and teaching hospital in the country which is managed by Addis Ababa University, in Addis Ababa, Ethiopia. The hospital has been in operation since 1972 and now has 800 beds, providing diagnostic and therapeutic services to approximately 500,000 patients each year through inpatient, outpatient, and specialized clinics (Ngusse, 2019).

As the country's main referral unit, the oncology clinic of TASH gives comprehensive inpatient and outpatient cancer care (chemotherapy, radiotherapy, surgery and palliative care) for more than 60,000 cancer patients per year (Ngusse, 2019).

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4.2 Study design

A hospital-based cross-sectional study was carried out at the oncology center of TASH.

4.3 Source and study population

As a source population, all adult patients diagnosed and treated at TASH's outpatient and inpatient oncology centers were included. Patients who were diagnosed with cancer and treated in the oncology clinic during the study period and met the eligibility criteria were included in the study population.

4.4 Inclusion and exclusion criteria

The following were the inclusion criteria:

- ✓ Patients with diagnosis of cancer of any stage,
- ✓ Patients treated during the study period,
- ✓ Patients who were able to speak or read and write the Amharic language and
- ✓ Patients who were 18 and above years of age.

The exclusion criteria were:

- ✓ Critically ill patients,
- ✓ Patients with mental health problem that could impede or negatively impact on data collection.

4.5 Sampling

4.5.1 Sample Size Determination

The sample size estimation to perform factor analysis for patient outcome measurement tools is different across studies. Literatures suggest that the required estimated sample size to perform factor analysis is estimated using the ratio of a sample size to the number of free parameters. In this case, the ratio of at least 10:1 is recommended as appropriate (Bentler and Chou, 1987; Bollen, 1989). By taking this ratio and the 25 free parameters of MFSI-SF (one variable from each of the five construct is fixed to one), the sample size for the current study would give us 250 patients. On the other hand, Hutcheson and Sofroniou's recommendation also states that sample size of 150 to 300 patients should be required to

perform factor analysis (Hutcheson and Sofroniou, 1999). So, by reconciling the above two ideas and to improve the estimation, the maximum required sample size of 300 cancer patients was used (excluding incomplete data).

4.5.2 Sampling Technique

The participants were recruited using convenience sampling strategy. The recruitment process was approached on eligible participants treated at the oncology clinic of TASH. The recruitment period was prolonged until the sample size required was met.

4.6 Data collection procedure

Data collection was conducted in both outpatient and inpatient oncology clinics. Inpatient participants were contacted on the admission rooms. After checking their eligibility, the participants were asked for informed consent. After obtaining informed consent, then patients were asked to answer the questionnaires and finally, their medical chart was reviewed to fill the medical characteristics part of the questionnaire.

Outpatient participants were contacted during their follow up visit at the reception desk. Then participants were checked for the fulfillment of eligibility criteria upon reviewing the medical chart and informed consent was obtained to proceed the interview upon completion of their assessments. After getting the questionnaires filled by the participants, the patient's card was reviewed to extract the medical characteristics of the patient.

4.7 Data collection instruments

General data abstraction checklist was used to collect information on patient medical and demographic characteristics. The checklist included demographic data such as age, sex,

marital status, place of residence, religion, educational status and employment status. The patient's medical chart was reviewed to collect medical information like; admission status, cancer stage, time since diagnosis, treatment related variables (treatment history, current type of cancer treatment, type of prescribed chemotherapy regimens, current cycle of chemotherapy and treatments prescribed for pain and emesis), comorbid condition and current hemoglobin level. Symptom, quality of life and fatigue related information were collected by using MFSI-SF-Am, EORTC-QLQ30 version-three, BFI-Am and ECOG-PS which are described as follows.

A) The Multidimensional Fatigue Syndrome Inventory Short Form (MFSI-SF) Amharic Version

MFSI-SF comprises 30-items constructed to measure the multidimensional feature of fatigue. Each item is rated from zero to four (zero = not at all; four = extremely) to which respondents indicated their extent of symptoms and experience during the previous one-week period. Items are grouped in to five subscales(six-items each): physical, general, emotional, vigor, and mental (Stein *et al.,* 1998). To get total fatigue score, the vigor sub-scale score was subtracted from the summation of the rest of other subscales score. By considering the possibilities of minimum and maximum scores, each subscale has a range of zero to 24 points. The MFSI-SF total score ranges from -24 to 96, with the higher number indicating higher levels of CRF for the patient experienced.

To use it in the study's context, the tool was translated into Amharic (MFSI-SF-Am) based on good practice guidelines on the translation and cultural adaptation of patient outcome measures (Wild *et al.*, 2005). Two bilingual translator members of the research team, both

fluent in English and Amharic first translated the tool to Amharic. Then, backward translation of the Amharic version was performed by two other independent bilingual members of the research team. Then comparison was performed to check the uniformity of two English Versions. The inconsistencies with translation were fixed through discussion and consensus.

B) European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)

The EORTC QLQ-C30 is a cancer-specific instrument that assess a patient's health-related quality of life (HRQOL) over the previous week (Uwer *et al.*, 2011). It has 30-items which are grouped in different sub-scales that include; global QoL, functional subscales (physical, role, emotional, cognitive, and social), symptom domains (fatigue, nausea/vomiting, and pain), and single items organized into separate sub-scales (dyspnea, insomnia, loss of appetite, constipation, diarrhea and financial difficulty). All items are assessed on a four-point Likert scale, with one indicating "not at all," two; "a little," three; "quite a bit," and four indicating "very much." The last two-items that assess QoL, on the other hand, employ a seven-point rating scale.

First, the scores of each domain were transformed to 100% (Fayers P. M. et al, 2001). A greater score of the functional scales and QoL indicates greater in functioning and QoL, respectively and greater symptom scale score indicates a worsening of symptoms. Since the EORTC QLQ-C30 was validated in Ethiopia, the subscales in the EORTC QLQ-C30 were used in this study for establishing the validity of MFSI-SF-Am (Ayana *et al.*, 2016).

C) Brief Fatigue Inventory (BFI)

BFI consists nine items assessing the patient's unusual fatigue or tiredness in the last 24 hrs. Three of the first items assess worst fatigue, usual fatigue, and fatigue now during the previous 24 hours, and rated from zero (no fatigue) to ten (fatigue as bad as you can imagine) (Mystakidou *et al.,* 2008). The rest of six items assess the extent of interference of fatigue with general activities, and rated from a scale of zero (no interference) to ten (complete interferences). The average of these six-items gives composite interference score (Fisher *et al.,* 2018). BFI was adapted in Ethiopia with Amharic version (BFI-Am) (Gebremariam *et al.,* 2018) and used as an additional reference for the validation process of MFSI-SF-Am.

D) Eastern Cooperative Oncology Group (ECOG) performance status

The ECOG PS scale was used to evaluate the patient's functional status (Anshabo *et al.,* 2016). The ECOG-PS scale has five levels, ranging from zero to five. Level zero implies that a person is totally active, level four indicates that they are unable to care for themselves and are completely bedridden, and level five indicates death. Patients' ratings of zero and one are grouped as good performance whereas the rest from two to five are grouped as bad performance. In this study, the physician evaluations of ECOG-PS were collected to evaluate the known group validity of MFSI-SF-Am.

4.8 Data quality management

To assure the data quality, structured questionnaires /tools were used. A pretest was done with 15 patients who were not included in the final sample. This step was intended to obtain feedback from the participants and their medical charts about the questionnaire and

modifications were made accordingly. The data were collected by two oncology nurses who received a half-day training about the purpose of the study, contents of the questionnaire, identification of participants using inclusion/exclusion criteria, and ways of approaching or getting consent from the patient. For those who were unable to read and write the Amharic language, items were read out loud by the data collectors repeatedly (without giving further explanation about the statement) until the patient properly understood the statement. The introductory /instruction part of each questionnaire was slightly modified in such a way that is suitable to read for the participants without changing its original message integrity. If the participant was unable to understand, the statement was left as incomplete. The collected data were checked for accuracy and completeness by the primary investigator on a daily basis.

4.9 Data analysis

Data analysis was done using the statistical package for social sciences (SPSS) version 23. Descriptive statistics was employed for summarizing the data in frequencies, percentages, mean and standard deviation (SD). Amos version three software was used to perform the CFA of MFSI-SF-Am. Raw scores of EORTCQL Q-C30 Version-three were transformed in to percentages based on the established formula across the subscales (Fayers P. M. et al, 2001). The continuous variable data were checked for normality by Shapiro Wilk test. Pearson correlation tests were used to examine the relationship of MFSI-SF-Am subscales with the subscales of EORTC QLQ-C30 and BFI-Am. A statistically significant correlation was considered with a $P\text{-}value < 0.05$. Correlation values of <0.4 were considered poor; 0.4 to 0.7 moderate; and 0.7 or above were considered strong correlations (Brogden, 1946).

Independent samples t-test was employed to investigate the known group validity of MFSI-SF-Am with the ECOG-PS groups, and the three known symptom items of EORTC QLQ-C30 associated with Fatigue (depression, Pain and insomnia). All statistical tests were two-sided with *p-value<0.05* considered significant.

The following validity and reliability tests were carried out to assess the psychometric properties of MFSI-SF-Am:

- **Reliability**

Internal consistency of MFSI-SF-Am was assessed using Cronbach's alpha coefficient (α). It was proposed that an α value of 0.7 and above is regarded as a satisfactory indicator for internal consistency or reliability of measurement tool (Taber, 2018). Moreover, the Cronbach's alpha score if item deleted was assessed to identify inconsistent or varying items across MFSI-SF-Am subscales.

- **Validity**

Structural validity of MFSI-SF-Am- Structural or factorial validity entails the extent of reproducibility of the original factor structure of the MFSI-SF when translated in to other contexts (Donovan *et al.*, 2015). CFA was performed to assess the factorial validity of MFSI-EF-Am. The model (Model-one) of CFA included 30 items of the MFSI-SF-Am and based on the theory developed in the preceding study, factor loadings were constrained so that each item could only load on the scale with which it was associated (Stein *et al.*, 1998). Firstly, Chi-square test (χ^2) goodness of fit statistic was used to evaluate the adequacy of the model fit in relation to the observed sample matrix with Maximum Likelihood

estimation (ML) method. The model would be considered adequate and well fitted regard to χ^2-test statistic if *p-value > 0.05*. However; studies indicate that χ^2 is affected with larger sample size and the distribution of variables making it insufficient test alone to evaluate the model fit. To avoid this doubt, fit of indices with ML are reliable for model fit evaluations regardless of the problems with sample size and distribution especially for sample size ≥ 200 (Bentler and Chou, 1987). In this case, standardized root mean squared residual (SRMR) and root mean squared error of approximation (RMSEA) are among the recommended general rule of thumb and were used for this study along with other frequently used model fit measures like; the ratio of chi-square test and degree of freedom (χ2/df), incremental fit of index (IFI), comparative fit of indexes (CFI) and Tuckers-Lewis's index (TLI) (Bentler and Chou, 1987; Hu & Bentler, 1995; Hu and Bentler, 1999).

Concurrent validity- A moderate to high correlation would be expected on the total and subscale MFSI-SF-Am score with a fatigue subscale score of EORTC QLQ-C30 and global sore of BFI-Am.

Convergent validity- A correlation analysis was employed between the total score of MFSI-SF-Am with its related constructs on the domains of EORTC QOQ-C30 (physical, emotional, cognitive, role) and sub-scales conceptually related to fatigue (pain, dyspnea, insomnia) (Theobald, 2004). A similar procedure was also employed on the physical composite score of BFI-Am. The MFSI-SF-Am domains (physical, emotional, mental and vigor subscale) could also be expected to correlate moderate to high with the physical, emotional, cognitive and role functioning subscales on EORTC QLQ-C30 (Chan, Lew, *et al.*, 2018).

Divergent validity- Indicates the degree of correlation of the MFSI-SF-Am fatigue score i.e., either negatively correlated with constructs conceptually related to fatigue or did not correlate with constructs that are not related to fatigue (Donovan *et al.*, 2015). Studies revealed that CRF negatively predicts the QoL of the patients and it would be expected that the total score of MFSI-SF-Am could be negatively correlated ($|r| \geq 0.4$) with the global QoL scale on the EORTC QLQ-C30 (Lukas *et al.*, 2009; Charalambous and Kouta, 2016) and constipation and diarrhea items on EORTC QLQ30 thought to be conceptually unrelated to fatigue and expected to be poorly correlated with the total MFSI-SF-Am score ($|r| < 0.4$) (Chan, Lew, *et al.*, 2018).

Known group validity– Known group validity was employed to evaluate the ability of MFSI-SF-Am to differentiate groups that have known characteristics that affect fatigue levels across these groups. CRF is generally expected to be sensitive to changes across good (zero and one) and poor (two to four) performance status measured by ECOG-PS (Stein *et al.*, 1998). Thus, patients with good ECOG-PS could be expected to have lower level of CRF on the total and subscale MFSI-SF-Am compared to those with poor ECOG-PS.

CRF is associated with depression, insomnia and pain (Theobald, 2004; Prue *et al.*, 2006). So, patients who scored three and four on these items of EORTC QLQ-C30 would have higher level of CRF on the total and domains of MFSI-SF-Am compared to patients who scored one and two.

4.10 Ethical Consideration

To use the MFSI-SF, permission was obtained via e-mail confirmation from the University of South Florida and the H. Lee Moffitt Cancer Center & Research Institute. Ethical clearance was obtained from Addis Ababa university, School of Pharmacy Ethical Review Committee (reference number: ERB/SOP/230/11/2020). Then, permission for the study was also obtained from the Oncology department of TASH. Finally, a written informed consent was obtained from each study participant and confidentiality was maintained through anonymity.

4.11 Operational Definitions

Cancer-related fatigue: A severe, subjective, and long-term feeling of physical, emotional, and mental weariness that is unrelated to present activities and interferes with normal functioning and is linked to cancer or cancer treatment (Gradishar *et al.*, 2018).

Cut off value for CRF: Patients who scored greater than 0.85 on MFSI-SF-Am are considered as significantly fatigued (Stein *et al.*, 1998).

Clinically significant CRF: Patients who scored ≥ 11 across groups on MFSI-SF-Am(Chan, Yo, *et al.*, 2018).

Chemotherapy only treatments: includes cytotoxic drugs for cancer treatment other than hormonal therapy and zoledronic acid.

5 Results

5.1 Socio-demographic characteristics of the participants

A total of 314 patients were approached and five were unwilling to participate and nine were excluded due to the incompleteness of MFSI-SF-Am items, and then a total of 300 participants were included in the analysis. The MFSI-SF-Am completion rate was 97.1% (9/309) with the average time to complete of 6.28 minutes (range from three to sixteen minutes). Among the participants 194(64.7%) were female with the mean (±SD) age in years of 44.7 (12.96). Majority of the participants 191(63.7%) were married. Around half (153, 51%) were from Addis Ababa and 76 (25.3%) and 34 (11.3%) were from the Oromia and Amhara regions, respectively. Orthodox, Protestant and Muslim accounted for 211 (70.3%), 46(15.3%) and 37(12.3%) religious affiliations of participants, respectively.

Regarding the educational status, 243(81%) attended formal education while 40(13.3%) were unable to read and write. On employment status, 72 (24%) were house wife and government organization employee 57(19%). Majority of participant's 168 (56.0%) health care service charge was covered by government insurance (Table 5:1).

Table 5:1: Socio-demographic summary of the participants in TASH oncology center, from December 2020 to January 2021 (n = 300).

Variables		Number of participants n (%)
Sex:	Male	106 (35.3)
	Female	194 (64.7)
Marital status:	Single	49 (16.0)
	Married	191 (63.7)
	Divorced	37 (12.3)
	Widowed	23 (7.7)
Region:	Addis Ababa	153 (51.0)
	Oromia	76 (25.3)
	Amhara	34 (11.3)
	SNNPR	26 (8.7)
	Benshangul Gumz	3 (1.0)
	Dire Dawa	2 (0.7)
	Afar	2 (0.7)
	Hararai	1 (0.3)
	Sidama	1 (0.3)
	Tigray	1 (0.3)
	Somali	1 (0.3)
Place of Residence:	Urban	258 (86.0)
	Rural	42 (14.0)
Religion:	Orthodox	211 (70.3)
	Muslim	37 (12.3)
	Protestant	46 (15.3)
	Catholic	3 (1.0)

	Other (Adventist and Hawariyat)	3 (1.0)
Level of education /Completed:	Unable to read and write	40 (13.3)
	Able to read and write (non-formal educations)	17 (5.7)
	Primary School (1-4th)	6 (2.0)
	Primary school (5-8th)	57 (19.0)
	Secondary school (9_10th)	49 (16.3)
	Secondary school (11-12th)	42 (14.0)
	Higher Education (> 12th)	89 (29.7)
Employment status:	Governmental employee	57 (19.0)
	Employee of private company	41 (13.7)
	Farmer	23 (7.7)
	Student	8 (2.7)
	House wife	72 (24.0)
	Unemployed	32 (10.7)
	Retired	29 (9.7)
	Merchant	33 (11.0)
	Other (laborer, NGO)	5 (1.7)
Payment of medical service:	Government insurance	168 (56.0)
	Out of pocket payment	109 (36.3)
	Fully reimbursement from the working organization	13 (4.3)
	Partially reimbursement from the working organization	4 (1.3)
	Private insurance	6 (2.0)

5.2 Participants' medical characteristics

Majority (175, 58.3%) of the study participants were ambulatory patients. Regarding the primary diagnosis, a greater number of patients were diagnosed and treated for Breast cancer (117, 39.0%) followed by gastrointestinal cancer (69, 23.0%) and gynecologic cancers (32, 10.5%). During the study, 194 (64.7%) of the participants had less than one year since the diagnosis was made. Performance status of 246 (82%) participants was ECOG one and 42 (14%) had a status of ECOG two. Patients with cancer stages III and IV accounted for 76 (25.3%) and 125 (41.7%) of the total, respectively.

During the study period, 285 (95%) participants were on active cancer treatment from which chemotherapy only (236, 82.8%) accounts the highest percentage. From the participants treated with chemotherapy, AC-T (Adriamycin + Cyclophosphamide +Paclitaxel) 47(18.9%), FOLFOX (5-FU+ Leucovorin + Oxaliplatin) 28 (11.2%), Cisplatin + gemcitabine 24(9.6%), and Cisplatin + paclitaxel 24(9.6%) were the most frequently prescribed chemotherapy regimens.

Only 52 (17.3%) participants had known comorbid conditions, and majority of them have HIV/AIDS 18(34.6%) and hypertension 15(28.8%). The mean level of hemoglobin (±SD) amongst the 284 participants was 12.83(±1.64) gm/ dl, which ranged from 8 to 17.8.

Less than half of the participants 123 (41%) have experienced unusual fatigue within the last seven days and more than two-third 86 (69.9%) of them told the physician as they were fatigued (Table 5.2). Among who were not told to the physician, "I am not fatigued" 50 (40.0%) and "It is due to chemotherapy" 45 (36.0%) were the common reasons of the participants.

Table 5:2 Medical summary of the participants in TASH oncology center, from December 2020 to January 2021 (n = 300).

Characteristics		**n (%)**
Patient admission status:	Outpatient	175 (58.3)
	Inpatient	125 (41.7)
Primary cancer diagnosis:	Breast Cancer	117 (39.0)
	Gastrointestinal Cancer	69 (23.0)
	Gynecologic Cancer	32 (10.7)
	Head and neck Cancer	28 (9.3)
	Sarcoma	20 (6.7)
	Genitourinary Cancer	12 (4.0)
	Lung cancer	10 (3.3)
	Endocrine Cancer	7 (2.3)
	Other (Skin Cancer, Hematologic malignancy)	5 (1.7)
Time since diagnosis (in months):	<12	194 (64.7)
	12-60	90 (30.0)
	>60	16 (5.3)
ECOG performance scale:	Fully active (ECOG-0)	8 (2.7)
	Restricted but ambulatory (ECOG-1)	246 (82.0)
	Ambulatory, capable of self-care (ECOG-2)	42 (14.0)
	Capable of only limited self-care (ECOG-3)	4(1.3)
Current cancer stage:	Stage I	37 (12.3)
	Stage II	52 (17.3)
	Stage III	76 (25.3)
	Stage IV	125 (41.7)
	Stage not mentioned	10 (3.3)
Treatment history:	Chemotherapy plus surgery	85 (28.3)
	Surgery only	52 (17.3)
	Chemotherapy only	47 (15.7)
	No treatment received	41 (13.7)

	Chemotherapy plus surgery plus radiotherapy	20 (6.7)
	Radiotherapy only	20 (6.7)
	Chemotherapy plus radiotherapy	13 (4.3)
	Chemotherapy plus surgery plus hormonal therapy	9 (3.0)
	Chemotherapy plus hormonal therapy	3 (1.0)
	Others	10 (3.3)
Current cancer treatment (in data collection period):	Chemotherapy only	236 (78.7)
	Hormonal therapy	16 (5.3)
	Follow up only	15 (5.0)
	Zoledronic acid	10 (3.3)
	Chemotherapy plus surgery	6 (2.0)
	Chemotherapy plus zoledronic acid	4 (1.3)
	Chemotherapy plus radiotherapy	3 (1.0)
	Surgery only	2 (0.7)
	Radiotherapy only	1 (0.3)
	Others	7 (2.3)
Total		300 (100)
Current cycle of chemotherapy:	1st cycle	59 (23.7)
	2nd cycle	53 (21.3)
	3rd cycle	53 (21.3)
	4th cycle	34 (13.7)
	5th cycle	27 (10.8)
	6th cycle	14 (5.6)
	Above 6th cycle	9 (3.6)
Current regimen:	AC-T (Adriamycin + Cyclophosphamide + Paclitaxel)	47 (18.9)
	FOLFOX (5-FU + Leucovorin + Oxaliplatin)	28 (11.2)
	Cisplatin + gemcitabine	24 (9.6)
	Cisplatin+ paclitaxel	24 (9.6)
	AC (Adriamycin + Cyclophosphamide)	19 (7.6)
	Gemcitabine	16 (6.4)
	Paclitaxel	15 (6.0)
	Cisplatin+5-FU	14 (5.6)
	Carboplatin + paclitaxel	9 (3.6)
	Capecitabine, Oxaliplatin (CAPOX)	8 (3.2)
	FOLFIRI (Irinotecan+5-Fu+leucovorin)	8 (3.2)
	Adriamycin + dacarbazine (AD)	6 (2.4)

	Adriamycin + Cisplatin	4 (1.6)
	Cisplatin	4 (1.6)
	Bleomycin + Etoposide + Cisplatin	3 (1.2)
	Idarubicin + Cytarabine (IA)	3 (1.2)
	Others	17 (6.8)
Total		249 (83.0)
Known comorbid condition:	Yes	52 (17.3)
	No	248 (82.7)
Type of comorbid condition:	Hypertension (HTN)	15 (28.8)
	Type 2 Diabetes Meletus (DM_2)	6 (11.5)
	HIV/AIDS	18 (34.6)
	Both DM_2 and HTN	7 (13.5)
	Others	6 (11.5)
Presence of infection (reported during data collection period):	Yes	13 (4.3)
	No	287 (85.7)
Opioids use for pain treatment:	Yes	36 (12.0)
	No	264 (88.0)
Use of antiemetics:	Yes	242 (80.7)
	No	58 (19.3)
Feeling of unusual fatigue in the last seven days:	Yes	123 (41.0)
	No	177 (59.0)
Report to the physician about the feeling of fatigue:	Yes	175 (58.3)
	No	125 (41.7)
Reason for not to tell the physician:	I am not fatigued	50 (40.0)
	It is due to chemotherapy	45 (36.0)
	It is due to the disease	22 (17.6)
	Other (I feel but the physician was not asked me)	8 (6.4)

Others for treatment history: *Hormonal Therapy, Chemotherapy + Radiotherapy + Hormonal therapy, Surgery + Radiotherapy, Chemotherapy + Surgery + Hormonal therapy, Thyroxine.* ***Others for current cancer treatment:*** *Hormonal Therapy + zoledronic acid, Thyroxine.* ***Others for type of Regimen:*** *Docetaxel, Capecitabine, Carboplatin+5-FU, Cisplatin + Etoposide, Adriamycin, cyclophosphamide + methotrexate + 5-FU, Oxaliplatin, Cyclophosphamide + Docetaxel, Oxaliplatin + Irinotecan, Dacarbazine, Iso-phosphamide + Etoposide, Vincristine + Dactinomycin + Cyclophosphamide.* ***Others for type of comorbid condition:*** *Hepatitis B, Deep vein thrombosis (DVT), HIV/AIDS + DVT, HIV/AIDS + hypertension, HIV/AIDS + DM2.*

5.3 Assessment of CRF Using MFSI-SF-Am

The previous study defined CRF as a mean MFSI-SF score of >0.85. (Stein *et al.*, 1998). The total mean score of MFSI-SF-Am was 19.11 ±18.6 and by using the above cut off value, 246 (82%) of the cancer patient participants were above 0.85. Patients were highly fatigued on the general subscale and least fatigued on mental subscale i.e., 8.71 ±5.35 and 4.80±4.35 respectively (Table 5.3).

Table 5:3: Total and subscale MFSI-SF-Am scores from the participants in TASH oncology center, December 2020 to January 2021.

Total and subscale fatigue	**Number of items**	**n**	**Mean ±SD**
Genera scale fatigue score	6	300	8.71 ±5.35
Physical fatigue score	6	300	7.04 ±4.62
Emotional fatigue score	6	300	6.90 ±5.26
Mental fatigue score	6	300	4.80 ±4.35
Vigor score	6	300	8.34 ±4.49
MFSI-SF-Am fatigue total Score		300	19.11 ±18.60

5.4 Validity and reliability of MFSI-SF-Am

5.4.1 Structural validity

As shown in Table 5.4, the results of the CFA model indicates that; all goodness of fit measuring indices were near or in range with the proposed cut-off values. The model was significant at *p value* of *0.001* with χ^2 of 764.1 and degree of freedom (*df*) 395. As the significance level of χ^2 is an indicator of poor model fitness, the model was not well fitted with this result.

Upon examination of the model fit indices, higher covariances between few error terms and cross loadings were observed on item one, eleven and twenty-two (loaded other than their underlying factor). The results of model re-estimation were indicated under model-two (Table 5.4) after constraints made on the error terms and deleting the three cross loading items, item-one “I have trouble remembering things”, item-11 “I’m confused”, and item-22 “I feel refreshed”.

Table 5:4: Summary of the model fit results on the factorial validity of MFSI-SF-Am from the participants in TASH oncology center, December 2020 to January 2021.

Measurements	Indices	Test standards	Result of 1st model	Result of 2nd model	Model fit verification
Absolute fit indices	RMSEA	$\leq$ 0.06	0.056	0.05	Good fit
	SRMR	$\leq$ 0.08	0.05	0.04	Good fit
	χ2/df	Between 1&3	1.93	1.68	Good fit
Incremental fit indices	CFI	$\geq$ 0.95	0.92	0.94	Acceptable
	IFI	$\geq$ 0.95	0.92	0.94	Acceptable
	TLI	$\geq$ 0.95	0.91	0.94	Acceptable

RMSEA: Root mean squared error of approximation); SRMR: Standardized Root Mean Squared Residual; χ2: chi-square test; df: degree of freedom; CFI: Comparative fit of index; IFI: Incremental fit of index; TLI: Tucker-Lewis Index.

The items in each factor were loading significantly at *p-value of 0.0001* with their respective factors starting from 0.72 to 0.80 for general factor, 0.72 to 0.84 for emotional factor, 0.52 to 0.87 for mental factor, 0.51 to 0.73 for vigor factor and 0.53 to 0.81 for physical factor (Figure 2).

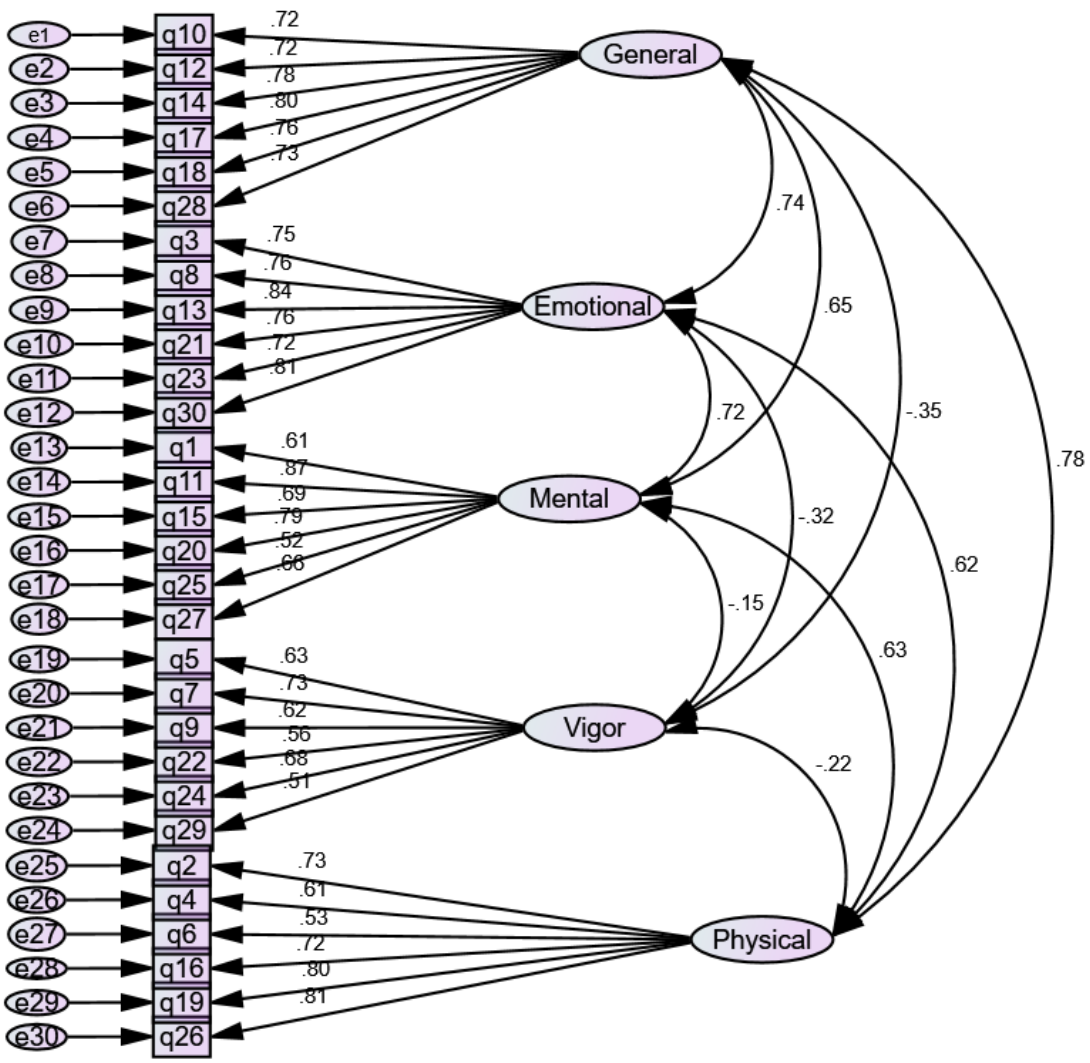

Figure 2: Structural model of the five factors of MFSI-SF-Am.

5.4.2 Validity of MFSI-SF-Am with EORTC QLQ30 and BFI-Am

In addition to structural/factorial validity, concurrent validity, convergent validity, divergent validity and known group validity were assessed to establish the construct validity and sensitiveness of MFSI-SF-Am. Assessment of concurrent validity was conducted using the previously validated Amharic versions of EORTC QLQ-C30 and BFI-Am (Tables 5.5). Moderate correlation was observed between the total and subscale score of MFSI-SF-Am and total score of BFI-Am (r = 0.52 to 0.64) except the mental and vigor subscales (r = 0.32 and -0.33 respectively; *p-value = 0.01*). Similarly, a positive moderate correlation was demonstrated between the fatigue subscale of EORTC QLQ-C30 and the total MFSI-SF-Am (r = 0.66). The fatigue subscale EORTC QLQ-C30 also correlated strongly with the general subscale of MFSI-SF-Am (r = 0.71), and moderately correlated with the physical and emotional subscales (r = 0.53 and 0.54 respectively) confirming the concurrent validity of MFSI-SF-Am. However, like BFI-Am, poor correlation was observed with the mental and vigor subscale (r = 0.35 and -0.31 respectively; *p-value = 0.01*) (Table 5.5).

In the process of assessing convergent validity, the total fatigue score of MFSI-SF-Am was correlated moderately with pain, dyspnea and insomnia subscales of EORTC QLQ-C30 (r = 0.59, 0.4, & 0.39, respectively; *p-value = 0.01*). The total MFSI-SF-Am was also moderately correlated with physical (r = -0.41), emotional (r = -0.72), role (r = -0.45) and cognitive (r = -0.57) functioning subscale of EORTC QLQ-C30 and the interference composite score of BFI-Am (r = 0.61; *p-value 0.01*). The physical, emotional, role and cognitive functioning subscale of EORTC QLQ-C30 were also correlated significantly

with the constructs of the physical, emotional, vigor, and mental fatigue subscale of MFSI-SF-Am (r = -0.60, -0.76, 0.295, and -0.54 respectively; *p-value = 0.01*) (Table 5.5).

With respect to divergent validity, the total MFSI-SF-Am fatigue score was correlated negatively as expected with the global quality of life scale of EORTC QLQ-C30 (r = -0.44). Constipation and diarrhea constructs of EORTC QLQ-C30 were correlated with the total scores of MFSI-SF-Am (r = 0.25 and 0.18, respectively) (Table 5.5).

Table 5:5:Pearson's correlations between subscale and total MFSI-SF-Am fatigue score across EORTC QLQ-C30 and BFI-Am domains from the participants in TASH oncology center, December 2020 to January 2021.

EORT QLQ-C30 subscales	**MFSI-SF-Am Subscales**					
	General fatigue	Physical fatigue	Emotional fatigue	Mental fatigue	Vigor fatigue	Total MFSI-SF-Am score
Global health status/QoL	-0.426**	-0.308**	-0.406**	-0.179**	0.318**	**-0.443****
Physical functioning	-0.468**	**-0.601****	-0.307**	-0.169**	0.233**	**-0.413****
Emotional functioning	-0.602**	-0.473**	**-0.758****	-0.514**	0.307**	**-0.716****
Role functioning	-0.448**	-0.359**	-0.371**	-0.179**	**0.295****	**-0.447****
Cognitive functioning	-0.501**	-0.405**	-0.444**	**-0.537****	0.242**	-0.568**
Social functioning	-0.318**	-0.309**	-0.347**	-0.211**	0.242**	-0.383**
Fatigue	**0.713****	**0.525****	**0.538****	**0.349****	**-0.306****	**0.659****
Nausea and vomiting	0.385**	0.329**	0.320**	0.186**	-0.160**	0.374**
Pain	0.605**	0.492**	0.472**	0.267**	-0.355**	**0.592****
Dyspnea	0.448**	0.364**	0.325**	0.215**	-0.134*	**0.400****
Insomnia	0.368**	0.299**	0.349**	0.227**	-0.203**	**0.390****
Appetite loss	0.430**	0.311**	0.306**	0.135*	-0.333**	0.409**
Constipation	0.257**	0.239**	0.188**	0.109	-0.153**	**0.255****
Diarrhea	0.166**	0.146*	0.172**	0.050	-0.141*	**0.182****
Financial difficulties	0.258**	0.247**	0.295**	0.297**	-0.181**	0.340**
BFI-Am						
BFI-Am score interference (6 items)	0.613**	0.501**	0.521**	0.321**	-0.310**	**0.613****
BFI-Am global mean score	**0.644****	**0.520****	**0.537****	**0.319****	**-0.327****	**0.635****

BFI-Am: Brief Fatigue Inventory-Amharic version; MFSI-SF-Am: The Amharic Version of Multidimensional Fatigue Symptom Inventory Short Form; EORTC QLQ-C30- European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire 30; ** Correlation is significant at the 0.01 level (2-tailed); * Correlation is significant at the 0.05 level (2-tailed); Unmarked correlations were not significant at the 0.05 level.

Known group validity- The total and subscale mean fatigue scores of MFSI-SF-Am was significantly higher on participants grouped as poor ECOG PS (two and three) compared to those with good ECOG-PS (zero and one). Similarly, significantly higher mean difference was also observed across each group of the three known items of EORTC QLQ-C30 associated with fatigue (item twenty-four; "Did you feel depressed?", item eleven; "have you had trouble sleeping?" and item-nine; "have you had pain?"). Those who were scored three and four in each item had higher total and subscale mean scores of MFSI-SF-Am than participants who scored one and two (Table 5.6). All total MFSI-SF-Am mean differences were clinically significant (score difference $\geq$ 11) and all results support the known group validity of MFSI-SF-Am and confirms its sensitiveness to changes across groups.

Table 5:6: Known group validity of total and subscale mean scores of MFSI-SF-Am across ECOGPS, and the three known EORTC QLQ-C30 items from the participants in TASH oncology center, December 2020 to January 2021.

MFSI-SF-Am subscales	**ECOGPS Mean (SD)**			**Did you feel depressed? (Item 24th) ** mean (SD)**			**Have you had trouble sleeping? (Item 11th) ** mean (SD)**			**"Have you had pain" (Item 9th) ** mean (SD)**		
	Good (n=254)	Poor (n=46)	MoD	Score [a] (n=208)	Score [b] (n=92)	MoD	Score [a] (n=183)	Score [b] (n=117)	MoD	Score [a] (n=134)	Score [b] (n=166)	MoD
General fatigue	8.05 (5.24)	12.33 (4.47)	-4.27*	7.21 (5.04)	12.98 (4.43)	-4.88*	7.19 (5.14)	11.08 (4.80)	-3.89*	5.54 (4.36)	11.26 (4.67)	-5.72*
Physical Fatigue	6.68 (4.52)	9.04 (4.70)	-2.37*	6.04 (4.35)	9.29 (4.44)	-3.25*	5.92 (4.30)	8.78 (4.57)	-2.86*	4.62 (3.67)	3.67 (4.38)	-4.37*
Emotional Fatigue	6.49 (5.18)	9.15 (5.19)	-2.66*	5.06 (4.35)	11.05 (4.77)	-5.99*	5.41 (4.85)	9.21 (5.06)	-3.79*	4.59 (4.29)	8.75 (5.25)	-4.16*
Mental Fatigue	4.56 (4.36)	6.15 (4.08)	-1.59*	3.62 (3.65)	7.48 (4.64)	-3.86*	3.89 (3.85)	6.23 (4.71)	-2.34*	3.83 (3.69)	5.58 (4.68)	-1.75*
Vigor	8.63 (4.57)	6.74 (3.67)	1.89*	8.97 (4.5)	6.91 (4.16)	2.06*	8.91 (4.63)	7.44 (4.13)	1.47*	9.66 (4.77)	7.27 (3.95)	2.39*
Total MFSI-SF-Am score	17.15 (17.85)	29.93 (16.07)	-12.78*	12.96 (15.78)	33.01 (15.35)	-20.05*	13.51 (17.10)	27.87 (16.26)	-14.36*	8.93 (14.69)	27.33 (16.48)	-18.39*

t-test is significant with a p value < 0.05 level (2-tailed); **Item from EORTC QLQ30 questionnaire; ECOGPS: Eastern Cooperative Oncology Group Performance Status; Good ECOGPS: Participants who rated as 0 & 1 on ECOGPS scale; Poor ECOGPS: Participants who rated as 2&3 on ECOGPS scale; MoD: Mean of difference; Score [a]: participants scored 1&2 on each of items; score [b]: participants scored 3&4 on each of items.

5.4.3 Reliability of MFSI-SF-Am

Cronbach's alpha (α) values were in acceptable ranges showing that MFSI-SF-Am has good internal consistency. The overall consistency of MFSI-SF-Am if items deleted was 0.90 (ranged from 0.89 to 0.91). For each of the five sub-scales; the internal consistency of general sub-scale (0.90), physical (0.85), emotional (0.90), mental (0.85) and vigor (0.79) (Table 5.7).

Table 5:7: Internal consistency of MFSI-SF-Am evaluated by Cronbach's alpha from the participants in TASH oncology center, December 2020 to January 2021.

Sub-scales	Item Number	Item name	Cronbach's Alpha if Item is Deleted	Cronbach's Alpha
General scale				**0.884**
	10	I feel pooped	0.867	
	12	I am worn out	0.869	
	14	I am fatigued	0.859	
	17	I feel sluggish	0.859	
	18	I feel run down	0.862	
	28	I feel tired	0.866	
Physical sub-scale				**0.844**
	2	My muscles ache	0.804	
	4	My legs feel weak	0.838	
	6	My head feels heavy	0.851	
	16	My arms feel weak	0.816	
	19	I ache all over	0.802	
	26	My body feels heavy all over	0.800	
Emotional sub-scale				**0.897**
	3	I feel upset	0.881	
	8	I feel nervous	0.878	
	13	I feel sad	0.867	
	21	I feel depressed	0.882	
	23	I feel tense	0.886	
	30	I am distressed	0.875	
Mental subscale				**0.846**
	1	I have trouble remembering things	0.827	

	11	I am confused	0.799	
	15	I have trouble paying attention	0.826	
	20	I am un able to concentrate	0.807	
	25	I make more mistakes than usual	0.846	
	27	I am forgetful	0.818	
Vigor sub-scale				**0.788**
	5	I feel cheerful	0.752	
	7	I feel lively	0.738	
	9	I feel relaxed	0.754	
	21	I feel refreshed	0.769	
	24	I feel energetic	0.746	
	29	I feel calm	0.777	

6 Discussion

In this study, we determined the psychometric properties of MFSI-SF-Am in Ethiopian Cancer patients. The findings indicate that MFSI-SF-Am had a good construct validity and reliability to be used for Ethiopian cancer patients.

The translation process followed the guidelines on Translation and Cultural Adaptation-Principles of Good practice for patient outcome measures (POM) (Wild *et al.*, 2005). The completion rate of MFSI-SF-Am was 97.1% and the average time to complete the questionnaire was 6.28 minutes, which was similar with its' earlier study (Stein *et al.*, 2004). These findings support the acceptability and usefulness of the MFSI-SF-Am tool for assessing CRF in Ethiopian cancer patients.

CFA was applied to evaluate the model fit of the five-factor structure of MFSI-SF-Am by using the theory from the earlier study (Stein *et al.*, 1998). For testing the hypothesized model; $\chi 2$ goodness of fit statistics, absolute fit of indices (RMSEA, SRMR and $\chi 2/df$) and comparative indices (IFI, CFI & TLI) were used (Hu and Bentler, 1999). However, $\chi 2$ goodness of fit statistics was not insignificant and this result also similarly happened on its earlier study in USA (Stein *et al.*, 2004) and China (Pien *et al.*, 2011) which could be affected as the sample size gets larger (Bentler and Chou, 1987). This was confirmed by other in range values that are not affected by the sample size and distribution ($\chi 2/df = 1.93$; less than 3, RMSEA = 0.056, below 0.06, and SRMR = 0.05 below the cutoff value 0.08). Furthermore, the values of CFI(0.92), IFI(0.92) and TLI (0.91) were in acceptable ranges (Hu and Bentler, 1999) and in agreement with a study done in USA where similar results of CFI and IFI were reported (Stein *et al.*, 2004) and better fits to be used in Ethiopian

cancer patients compared to the study done among African Americans (Asvat *et al.*, 2014) and China (Pien *et al.*, 2011).This revealed that the model was in a good fit implying that the hypothesized model accounted most of the variance of observed sample data and identifies the five-factor structure of MFSI-SF-Am.

Despite the strong inter factor correlations observed between general factor with physical and emotional factors, and between emotional and mental factor; the inter factor correlations were in the recommended range ($r<0.85$) suggesting the distinctness of the five factor structure of MFSI-SF-Am (Byrne, 2010). This finding was also similar with its earlier study showing the general factor to be correlated with the physical (Stein *et al.*, 2004). Moreover, factor loading were lie above 0.5 (Hair *et al*., 2010) indicating that each item were well explained by their respective factors and further confirms the factorial validity of MFSI-SF-Am.

Re-estimation was employed in two ways from Model-one to Model-two to improve $\chi 2$ test statistics and to improve the fit of the three comparative indices (≥ 0.95). First, constraints were made between the error terms that have higher model indices improvement. Secondly; due to the minimal difference from the error term covariation, items that had cross loadings were removed. However; the second model (Model two) was slightly improved with respect to CFI, IFI and TLI and no difference was observed on $\chi 2$ test. As a result, model-two was not more satisfactory compared to model-one and deleting items (items-one; “I have trouble remembering things”, item eleven; “I’m confused” and item twenty-two; “I feel refreshed”) in fact is not desirable either in research or clinical perspective as it provides additional symptom profiles in cancer patients (Bentler and Chou, 1987).

Further construct validity assessments were performed using previously validated Amharic versions of EORTC QLQ-C30 and BFI. The concurrent validity results of total MFSI-SF-Am with BFI-Am and the fatigue subscale of EORTC QLQ-C30 were excellent and suggest that MFSI-SF-Am is capable of measuring similar constructs as other fatigue measuring instruments like BFI-Am and the fatigue subscale of EORTC QLQ-C30. The finding was consistent with a study done in Italy with BFI-Am (r = 0.68) (Pino *et al.*, 2015) and higher correlation coefficient compared to a study done in Singapore (0.48) (Chan, Lew, *et al.*, 2018).

As expected, the total MFSI-SF-Am was moderately correlated with the related concepts or constructs (pain, dyspnea and insomnia) of EORTC QLQ-C30 that are associated with fatigue (Agasi-Idenburg *et al.*, 2017). The findings were supportive for the convergence validity of MFSI-SF-Am and in agreement with a study from Singapore (Chan, Lew, *et al.*, 2018). The total MFSI-SF-Am moderately and significantly correlated with the physical, emotional, cognitive, and role functioning's of EORTC QLQ-C30 and the physical interference score of BFI-Am further asserting the convergence validity of MFSI-SF-Am and in line with the validity test study in USA (Stein *et al.*, 2004).

Furthermore, the study demonstrated that the physical, emotional, vigor, and mental fatigue subscale of MFSI-SF-Am were also correlated significantly with their related constructs of the physical, emotional, role and cognitive functioning subscale of EORTC QLQ-C30 except vigor (r = 0.295). This indicates that the related constructs in MFSI-SF-Am were measuring similarly and further confirms convergent validity and consistent with the validity study in Singapore (Chan, Lew, *et al.*, 2018) and similar with a study in USA (Leeuw, Studts and Carlson, 2005). Despite the poor correlation of the vigor subscale with

the role functioning subscales, the positive relationship further magnifies the validity of MFSI-SF-Am as both the vigor and functional ability of the patients were decrease with CRF.

As CRF affects patient's quality of life; the total MFSI-SF-Am also moderately correlated negatively with global QoL subscale and poorly correlated with diarrhea and constipation symptom scales of EORT QLQ-C30 as expected. The finding were in agreement with the study in Singapore and suggesting its divergent validity (Chan, Lew, *et al.*, 2018)

Known group validity was demonstrated based on the way of previous similar validation studies. Participants' ECOG-PS classified in good and poor, and the three known items from EORTC QLQ-C30 (depression, insomnia and pain) each grouped by lower (score one and two) and higher (three and four) symptom were used to assess the sensitivity to changes of MFSI-SF-Am across these groups. The finding demonstrates that, the MFSI-SF-Am fatigue subscales were significantly higher with poor ECOG-PS, more depression, insomnia and pain. Statistically and clinically significant score differences were also observed on total MFSI-SF-Am across all of these group categories as the mean difference > 11 established by the previous studies (Chan, Yo, *et al.*, 2018). The findings were in line with a stud in USA (Stein *et al.*, 1998) and in agreed with other similar studies in Singapore (Chan, Lew, *et al.*, 2018). Thus, MFSI-SF-Am has good construct validity as explained by the correlation with the concepts or constructs of EORTC QLQ-C30 and BFI-Am and sensitive to changes confirming its known group validity.

The alpha coefficient values demonstrated that each subscale of MFSI-SF-Am had good internal consistency (general sub-scale (0.90), physical (0.85), emotional (0.90), mental (0.85) and vigor (0.79)). The overall consistency of MFSI-SF-Am was 0.90 indicating that

all the subscales were testing the same data. The findings were almost similar with the previous validation study by stein and his colleagues (general fatigue (0.96), emotional fatigue (0.92), physical fatigue (0.87), mental fatigue (0.91), and vigor (0.90)) and consistent in terms of overall consistency with the study in China (0.9) and in Singapore (0.749 to 0.944) (Stein *et al.*, 2004; Pien *et al.*, 2011; Ke *et al.*, 2017). So, the study evidenced that MFSI-SF-Am had good internal consistency and is reliable to use in Ethiopian cancer patients.

6.1 Limitation of the study

Despite the fairly large number of participants and the comprehensive nature of the study questionnaires (which enabled us to evaluate various aspects of the validity and reliability of the MFSI-SF-Am questionnaire), the study had few limitations. While the study established the validity and reliability (in the form of internal consistency) of the tool, aspects such as test-retest reliability were not studied due to the cross-sectional nature of the study. Moreover, the cut point level of CRF to define fatigue in the context of Ethiopian patients was not established in this study as this would have required the inclusion of healthy individuals in the study which was not possible in our case given the time and financial constraints.

7 Conclusion and Recommendations

7.1 Conclusion

Generally, MFSI-SF-Am had valid and reliable psychometric properties with good internal consistency and construct validity with well identified five factor structures. In addition, the tool had low burden to patients with reduced performance status as it has 30 items with short form of statement completed within few minutes. As Amharic is the official language in Ethiopia, the tool can have a widespread use in clinical practice and research towards CRF.

7.2 Recommendations

- As the MFSI-SF-Am tool was found to have a reasonably good level of reliability and validity, clinicians are encouraged to apply in the assessment and management of CRF in Ethiopian cancer patients.
- Researchers are also recommended to use this tool for future studies to examine the pattern of CRF and its dimensionality across the course of the disease and its treatment in Ethiopia cancer patients.
- It is also recommended to expand the evidence base for the reliability of the tool by conducting longitudinal studies to establish test-retest reliability of MFSI-SF-Am as an additional psychometric property.
- It was recognized that fatigue is subjective experience and affected by the patient's financial capacity, psychological symptoms like; anxiety and depression and habit of physical exercise. So, future studies should include healthy control group to establish

the cut point vale of fatigue in Ethiopian cancer patients between the healthy control group and cancer patients.

- As non-specific to any type of disease, the tool can be used for the assessment and management of fatigue symptom associated with any type of chronic disease. The performance of the tool with in other chronic diseases should also be studied well.

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Informed Consent Form

Addis Ababa University College of health sciences School of Pharmacy

Department of Pharmaceutics and Social pharmacy

Data collection Questionnaire prepared for Cancer patients receiving care at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia 2020/21

Study Title: Validation of the Amharic version of multidimensional fatigue syndrome inventory short form (MFSI-SF) on Cancer patients receiving care at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia 2020/21

Introduction and study objective

Hello, my name is _____, and I am contacting you from Addis Ababa university school of pharmacy; for the fulfillment of master's program in pharmaco-epidemiology and social pharmacy department. The data you generate will be aggregated and used to develop valid and reliable Multidimensional Fatigue Syndrome Inventory-Short Form tool for accurate fatigue assessment tools in Ethiopian cancer patients. In addition to its future research purpose, it will also help to ease the measurement and treatments process of cancer related fatigue in clinical settings. Your responses will be strictly anonymous, meaning that your name or any personalized information will not be used or appear in any documents, communications, or analysis related to these data. Participation is strictly voluntary, and you do not have to answer all questions you do not wish to. You can opt to withdraw consent at any time. There is no guarantee of immediate benefit from your

participation, yet, if the tool will be found valid and reliable, it will help the Ethiopian cancer patients in the assessment and treatment of CRF by clinicians upon measuring the level of cancer related fatigue by the tool. To participate, you are requested to: 1) collaborate with our data collectors to respond to questions 2) authorize the use of these data while maintaining anonymity
Confidentiality
The data collectors will maintain complete confidentiality during the interview. The other members of the assessment team or viewers of the report will NOT be told your name or any other personally identifiable information.
Risks
Although our team will never, under any circumstances, disclose your name or personal details about you being contacted to anyone. If users of the data guess (based on your location) or if you choose to disclose your identity to anyone, there may be a risk that your identity is revealed and linked to the results of the assessment.
Benefits
The benefit of your participation is helpful in validation of the cancer related fatigue assessment tool so that measurement and treatment of fatigue will be advanced in future Ethiopian cancer patients. Furthermore, researches regarding to cancer related fatigue will be initiated in Ethiopia as such validated tools will be available.
Who to contact

If you decide to participate in this exercise and you have additional doubts or questions, you can communicate with the principal investigator **Ato Dinksew Tewuhibo**. at **0932153592** and/or with the main supervisor **Dr Eskinder Eshetu Ali at *0911944218.***
Verbal consent and agreement
If you would like to participate, please confirm that you understood everything I have told you about this exercise. Do you have any questions? (Let the participant ask any questions they have).
Do you agree to allow us to start the anonymous partner tracing process? (Interviewer to fill out part below and sign and give the participant a copy.)
Agrees to participate: _____
Does NOT agree to participate: _____
I understand the study aims and objectives and have decided to allow the partner tracing process to go forward.
Name:
Signature: Day/Month/Year: _____/_____/_____
Person Obtaining Consent:
Name:
Signature: Day/Month/Year: _____/_____/_____

Annexes

Annex I: Socio-demographic and clinical characteristics of Cancer patients at TASH oncology center in Addis Ababa, Ethiopia 2020/21.

Section 1- Socio-demographic characteristics of respondents

1.1.	**Sex:**	**Male** ☐ **Female** ☐
1.2.	**Age: ____**	
1.3.	**Marital status:** **Single** ☐ **Married** ☐ **Divorced** ☐ **Widowed** ☐	
1.4.	**Region (specify): _____**	
1.5.	**Place of residence:** **Urban** ☐ **Rural** ☐	
1.6.	**Religion:**	**A) Orthodox** **B) Muslim** **C) Protestant** **D) Catholic** **E) Other(specify)**
1.7.	**Level of education**	**A) Able to read and write (from informal educations)** **B) Unable to read and write**

		C) Primary School (1-4th) **D) Primary school (5-8th)** **E) Secondary school (9-10th)** **F) Secondary school (10-12th)** **G) Higher Education (First degree &above)**
1.8.	**Employment Status**	**A) Governmental employee** **B) Employee of private company** **C) Farmer** **D) House wife** **E) Student** **F) Unemployed** **G) Retired** **H) Merchant** **I) Other, please Specify_____**
1.9.	**Payment for Medical Service**	**A. Fully reimbursed from the working organization** **B. Partially reimbursement from the working organization**

		C. Government Insurance **D. Private Insurance** **E. Health care fee** **F. Out of pocket payment** **G. Other (specify)_____**

3. Did you report to your physician as you feel fatigued?

Yes_____ No_____

4. If you say no, what are the possible reasons?

Section 2: Medical Characteristics (to be filled through chart review by data collectors)		
2.1.	Level of admission:	Outpatient level__☐_ Inpatient level___☐__
2.2.	Primary cancer diagnosis	_____
2.3.	Time since diagnosis (in month):	_____
2.4.	Current Cancer Stage:	A) Stage I B) Stage II C) Stage III D) Stage IV E) Stage not mentioned
2.5.	Current cycle of chemotherapy	A) 1st cycle B) 2nd cycle C) 3rd cycle D) 4th cycle E) 5th cycle F) 6th cycle

		G) 7^{th} cycle H) 8^{th} cycle I) 9^{th} cycle
2.6.	History of anti-cancer treatment (before the data collection period):	A) Surgery only B) Radiation only C) On chemotherapy only D) Chemotherapy plus surgery E) Chemotherapy plus radiotherapy F) Chemotherapy plus hormonal therapy G) Chemotherapy plus surgery plus radiotherapy H) Chemotherapy plus surgery plus hormonal therapy I) No treatment received J) Other_____

2.7.	Current type of anticancer treatment (within a period of the data collection):	A) Surgery only B) Radiotherapy only C) Hormonal therapy D) Chemotherapy only, please write the regimen here_____ _____ E) Chemotherapy plus surgery F) Chemotherapy plus radiotherapy G) Chemotherapy plus surgery plus radiotherapy H) No treatment received I) Others (Zoledronic acid)
2.8.	Any known comorbid Condition:	Yes (specify)_____ No _____ No

2.9.	Presence of current infection:	YES (please specify) _____ NO
2.10.	Use of opioids to treat pain:	A) YES B) NO
2.11.	Use of anti-emetic:	A) YES B) NO
2.12.	Current Hemoglobin level (reported during data collection period): _____	
2.13.	Eastern Cooperative Oncology Group Performance scale (ECOG PS) _____	

Annex II: Multidimensional fatigue syndrome inventory short form (MFSI-SF-Am)

Below is a list of statements that describe how people sometimes feel. Please read each item carefully, then circle the one number next to each item which best describes how true each statement has been for you in the past 7 days.

Study ID number: _____

S. No		Not at all	A little	Moderately	Quite a bit	Extremely
1	I have trouble remembering things	0	1	2	3	4
2	My muscles ache	0	1	2	3	4
3	I feel upset	0	1	2	3	4
4	My legs feel weak	0	1	2	3	4
5	I feel cheerful	0	1	2	3	4
6	My head feels heavy	0	1	2	3	4
7	I feel lively	0	1	2	3	4
8	I feel nervous	0	1	2	3	4
9	I feel relaxed	0	1	2	3	4
10	I feel pooped	0	1	2	3	4
11	I am confused	0	1	2	3	4
12	I am worn out	0	1	2	3	4
13	I feel sad	0	1	2	3	4
14	I feel fatigued	0	1	2	3	4
15	I have trouble paying attention	0	1	2	3	4
16	My arms feel weak	0	1	2	3	4
17	I feel sluggish	0	1	2	3	4
18	I feel run down	0	1	2	3	4

19	**I ache all over**	**0**	**1**	**2**	**3**	**4**
20	**I am unable to concentrate**	**0**	**1**	**2**	**3**	**4**
21	**I feel depressed**	**0**	**1**	**2**	**3**	**4**
22	**I feel refreshed**	**0**	**1**	**2**	**3**	**4**
23	**I feel tense**	**0**	**1**	**2**	**3**	**4**
24	**I feel energetic**	**0**	**1**	**2**	**3**	**4**
25	**I make more mistakes than usual**	**0**	**1**	**2**	**3**	**4**
26	**My body feels heavy all over**	**0**	**1**	**2**	**3**	**4**
27	**I am forgetful**	**0**	**1**	**2**	**3**	**4**
28	**I feel tired**	**0**	**1**	**2**	**3**	**4**
29	**I feel calm**	**0**	**1**	**2**	**3**	**4**
30	**I am distressed**	**0**	**1**	**2**	**3**	**4**

Annex-III: EORTC-QLQ 30 Version 3

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Study ID No_____

		Not at all	**A little**	**Quite a bit**	**Very much**
1	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2	Do you have any trouble taking a long walk?	1	2	3	4
3	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4	Do you need to stay in bed or a chair during the day?	1	2	3	4
5	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
	During the past week	**Not at all**	**a little**	**Quite a bit**	**Very much**
6	Were you limited in doing either your work or other daily activities?	1	2	3	4
7	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8	Were you short of breath?	1	2	3	4

9	Have you had pain?	1	2	3	4
10	Did you need to rest?	1	2	3	4
11	Have you had trouble sleeping?	1	2	3	4
12	Have you felt weak?	1	2	3	4
13	Have you lacked appetite?	1	2	3	4
14	Have you felt nauseated?	1	2	3	4
15	Have you vomited?	1	2	3	4
16	Have you been constipated?	1	2	3	4
	During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very much**
17	Have you had diarrhea?	1	2	3	4
18	Were you tired?	1	2	3	4
19	Did pain interfere with your daily activities?	1	2	3	4
20	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21	Did you feel tense?	1	2	3	4
22	Did you worry?	1	2	3	4
23	Did you feel irritable?	1	2	3	4
24	Did you feel depressed?	1	2	3	4
25	Have you had difficulty remembering things?	1	2	3	4
26	Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27	Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4

28	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29 How would you rate your overall <u>health</u> during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30 How would you rate your overall <u>quality of life</u> during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

Annex IV: Brief Fatigue Inventory (BFI English version)

Study Id No _____

Throughout our lives, most of us have times when we feel very tired or fatigued in the last week? Yes ------ No -------

1. **Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your fatigue right NOW.**

0 1 2 3 4 5 6 7 8 9 10

No fatigue as bad as you can imagine

2. **Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your USUAL level of fatigue in the past 24 hours.**

0 1 2 3 4 5 6 7 8 9 10

No fatigue as bad as you can imagine

3. **Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your WOREST level of fatigue in the past 24 hours.**

0 1 2 3 4 5 6 7 8 9 10

No fatigue as bad as you can imagine

4. **Circle the one number that describes how, during the past 24 hours, fatigue has interfered with your:**

A. General activity

0 1 2 3 4 5 6 7 8 9 10

Does not interfere completely interfere

B. Mood

0 1 2 3 4 5 6 7 8 9 10

Does not interfere completely interfere

C. Walking ability

0 1 2 3 4 5 6 7 8 9 10

Does not interfere completely interfere

D. Normal work (includes both work outside the home and daily chores)

0 1 2 3 4 5 6 7 8 9 10

Does not interfere completely interfere

E. Relation with other people

0 1 2 3 4 5 6 7 8 9 10

Does not interfere completely interfere

F. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10

Does not interfere completely interfere

Annex-V: The Eastern Cooperative Oncology Group Performance Scale

Grade ECOG	**Grade ECOG**
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking Hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

ዕውቀት ላይ የተመሠረተ የፍቃደኝነት ስምምነት ቅጽ

በአዲስ አበባ ዩኒቨርሲቲ ፋርማሲ ትምህርት ቤት እና ህክምና ትምህርት ቤት

ጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል ውስጥ በመታከም ላይ በሚገኙ የካንሠር ታማሚዎች ስለህመማቸው ሁኔታ መረጃ ለመሰብሰብ የተዘጋጀ መጠይቅ፣ 2013 ዓ.ም

የጥናቱ ርዕስ፦ ዘርፈ ብዙ የድካም ምልክቶች መገምገሚያ አጭር የአማርኛ መጠይቅ ከካንሰር ጋር ተያይዞ የሚመጣዉን ድካም ለመለካት፤ በካንሰር ህሙማን ላይ የሚደረግ የመለኪያነት ማሰረገጫ

መግቢያና የጥናት ዓላማዎች

ጤና ይስጥልኝ፣ ሥሜ _____ይባላል። የማናግርዎት ከአዲስ አበባ ዩኒቨርሲቲ፣ በፋርማሲ ትምህርት ቤት የማስተርስ ማሟያ ጥናት ለማካሄድ ነው። ጥናቱ የካንሠር ህሙማንን የድካም ሁኔታ ለመገምገም የሚያስችል መጠይቅ ማዘጋጀት ነው። የሚሰጡን መረጃ መጠይቁ ከካንሰር ጋር ተያይዘው የሚታዩ የድካም ምልክቶች መለኪያነቱን ለማረጋገጥ ይረዳናል። ይህም ወደፊት በኢትዮጲያ ካንሰር ታማሚዎች ላይ በካንሰሩ ምክንያት የሚመጣውን ድካም ከማጥናትም ባለፍ በተማሚዎች ዘንድ የሚታውን የድካም ሁኔታ በቀላሉ ለመለካትና ህክምና ለመስጠት ይረዳል። ምላሾችዎ በማን የተሰጡ እንደሆኑ በፍጹም አይታወቅም፤ ማለትም፣ ሥምዎ ወይም ግላዊ መረጃዎችዎ ከዚህ መረጃ ጋር በሚገናኙ በማናቸውም ዶክመቶች፣ የመረጃ ልውውጦች፣ ወይም ትንተናዎች ውስጥ አይታዩም። ተሳትፎዎ ፍጹም በፍቃደኝነት ላይ የተመሠረተ ነው፤ እናም መመለስ የማይፈልጓቸውን ሁሉንም ጥያቄዎች አለመመለስ ይችላሉ። ፍቃደኝነትዎንም በማንኛውም ጊዜ ማንሳት ወይም መከልከል ይችላሉ። በመሳተፍዎ ምክንያት ወዲያውኑ የሚያገኙት ጥቅም አይኖርም፤ ነገር ግን፣ የጥናቱ ውጤት፣የወደፊት የአትዮጵያ ካንሰር ታማሚዎች ላይ የሚታየውን ድካም መጠንና ደረጃውን በመለካት የህክምናውን ደረጃ ያሻሽለዋል፤ በበሽታው ዙሪያ ጥናት በማካሄድ ኢትዮጲያ ውስጥ ተጨባጭ የሆነ ሃተታና ግንዛቤ እንድኖር ያስችላል።

ለመሳተፍ የሚከተሉትን ይጠየቃሉ፦

1) ጥያቄዎችን ለመመለስ ከመረጃ ሰብሳቢዎቻችን ጋር መተባበር፣

2) ይህ መረጃ ማንነትዎን በማይገልጽ መልኩ ጥቅም ላይ እንዲውል ፍቃደኛ መሆን።

ሚስጥራዊነት

በቃለመጠይቁ ጊዜ መረጃ ሰብሳቢዎች ምሥጢራዊነትን ሙሉ በሙሉ ይጠብቃሉ። ሌሎች የጥናት ቡድኑ አባላት ወይም ገምጋሚዎች የግል ማንነትዎን ሊገልጹ የሚችሉ መረጃዎች በፍጹም አይነገራቸውም።
ሊኖሩ የሚችሉ ያልተፈለጉ ውጤቶች
ሥምዎንም ሆነ ከማን ጋር እንደተገናኙ የሚያሳዩ የግል ዝርዝር መረጃዎች ቡድናችን በፍጹም የማያሳውቅ ወይም የማይገልጥ ሲሆን፣የጥናቱ ውጤት ተጠቃሚዎች ስላሉበት ቦታ ያለውን መረጃ መሠረት በማድረግ ማንነትዎን ቢገምቱ ወይም ማንነትዎን ለማንኛውም ሰው ቢገልጹ፣ ማንነትዎ ሊታወቅና ከጥናቱ ውጤቶች ጋር ሊያያዝ የሚችልበት ዕድል አለ።
ጥቅሞች
የአትዮጵያ ካንሰር ታማሚዎች ላይ የሚታየውን ድካም መጠንና ደረጃውን በመለካት ህክምና እንዲያገኙ ይረዳል፤ካንሰርን ተከትሎ ሚመጣዉን የድካም ሁኔታ ዘርፈ ብዙ በሆነ መንገድ ለመግለጽ ያስችላል፤ በበሽታው ዙሪያ ጥናት በማካሄድ ኢትዮጲያ ውስጥ ተጨባጭ የሆነ ሃተታና ግንዛቤ እንድኖር ያስችላል
መረጃ ቢፈልጉ
በዚህ ጥናት ለመሳተፍ ከወሰኑና ተጨማሪ ጥርጣሬዎች ወይም ጥያቄዎች ካሉዎት፣ ዋና ኢንቨስቲጌተር ከሆኑት ከ አቶ **ድንቅሰው ተውህቦ** ጋር ስልክ ቁጥር፡ ***0932153592*** ወይም ከዋና ረዳት ኢንቨስቲጌተር ከዶ/ር ***እሰክንድር እሸቱ አሊ*** ጋር በሥልክ ቁጥር ***0911944218*** መነጋገር ይችላሉ።
በቃል የሚገለጽ የፍቃደኝነት ስምምነት
መሳተፍ የሚፈልጉ ከሆነ፣ እባክዎ ስለዚህ ጥናት የተነገረዎትን ነገር በሙሉ መረዳትዎን ያረጋግጡ። ጥይቄ አለዎት?
የመረጃው ባለቤት ማንነት የማይገለጽበትን ይህን የጥናት ሂደት እንድንጀምር ፍቃደኛ ነዎት? (ሠራተኞች ከታች ያሉትን ሞልተው ይፈረምባቸውና አንድ ቅጂ ለተሳታፊዎች ይሰጣሉ)
ለመሳተፍ ይስማማሉ: -------
ለመሳተፍ አይስማሙም: _____
የጥናቱን ዓላማዎችና ግቦች ተረድቻለሁ፤ እናም የአጋሮች ጥናት ሂደቱ ላይ ለመሳተፍ ወስኛለሁ።
ሥም፦

ፊርማ፦	ቀን/ወር/ዓ.ም: _____/_____/_____
ፍቃደኝነቱን ያገኘው ሰው፦	
ሥም፦	
ፊርማ፦	ቀን/ወር/ዓ.ም፡ _____/_____/_____

1. እርስዎን በተመለከተ አጠቃላይ መጠይቅ

ቀን ……/…. ./….. መለያ ቁጥር……

1.1.	ፆታ:	ወንድ ☐	ሴት ☐
1.2.	እድሜዎት:	_____	
1.3.	የጋብቻ ሁኔታ:	ያላገባ/ች ☐ ባለትዳር ☐ አግብተው የፈቱ ☐ የትዳር ጓደኛን በሞት ያጡ ☐	
1.4.	የመጡበት ክልል፡	_____	
1.5.	የመኖሪያ ቦታ:	ገጠር ☐ ከተማ ☐	
1.6.	ሃይማኖት:	ሀ) ኦርቶዶክስ ለ) ሙስሊም ሐ) ፕሮቴስታንት መ) ካቶሊክ ሠ) ሌሎች፣ይገለጽ_____	

1.7.	የትምህርት ደረጃ	ሀ) ማንበብና መፃፍ አልችልም ለ) ማንበብና መፃፍ እችላለሁ (መደበኛ ያልሆነ ትምህርት/የሃይማኖት ትምህርት) ሐ) አንደኛ ደረጃትምህርት (ከ1ኛ-4ኛ ክፍል) መ) አንደኛ ደረጃትምህርት (ከ5ኛ-8ኛ ክፍል) ሠ) ሁለተኛ ደረጃ/መሰናዶትምህርት (ከ9ኛ-10ኛ ክፍል) ረ) ሁለተኛ ደረጃ/መሰናዶትምህርት (ከ11ኛ-12 ኛክፍል) ሸ) ከፍተኛ ትምህርት (ሰርተፍኬት፣ ዲፕሎማ፣ የመጀመሪያ ዲግሪና ከዚያ በላይ)
1.8.	የስራ ቅጥር ሁኔታ	ሀ) የመንግስት ሰራተኛ ለ) የግል መሥሪያ ቤት ተቀጣሪ ሐ) አርሶ አደር መ) ተማሪ ሠ) የቤት እመቤት ረ) ሥራ አጥ ሰ) ጡረተኛ/ በጡረታ ከሥራ የተገለሉ ሸ) ነጋዴ (በግል የንግድ ሥራ የተሰማሩ) ቀ) ሌሎች፣ይገለጽ
1.9.	የክፍያ ሁኔታ	ሀ) ሙሉ በሙሉ መስሪያ ቤቱ ይከፍላል ለ) በከፊል መስሪያ ቤቱ ይከፍላል ሐ) የመንግስት ጤና መድን ይሸፍናል

		መ) የግል ጤና መድን ይሸፍናል ሠ) ነጻ ታካሚ ረ) ከራስ ኪስ የሚከፈል ሰ) ሌሎች(ይገለጽ) _____

3. ለቀናት የሚቆይ ከባድ የድካም ስሜት እየተሰማዎት እንደሆነ ለሀኪሞት ተናግረዋል?

   አዎ_____ አይ_____

4. አይ ካሉ, ምክንያትዎን

   ይግለጹ?_____

   _____

2. MFSI-SF (Amharic version): Self-Administered

ከዚህ በታች የተዘረዘሩት አረፍተ ነገሮች ሰዎች አንዳንድ ጊዜ ምን እንደሚሰማቸው የሚገልጹ ናቸው፡፡ እባክዎ እያንዳንዱን ጥያቄ በጥንቃቄ ያንብቡ ከዚያም ባለፉት ሰባት ቀናት ውስጥ ስሜቱን በደንብ ይገልጸኛል የሚሉትን መልስ ከጥያቄው ቀጥሎ ካሉት አማራጮች አንድ ቁጥር መርጠው ያክብቡ ፡፡

ቀን፡___/___/____ ሰአት፡ _____ መለያ ቁጥር/ካርድ ቁጥር፡_____

	ባለፉት ሰባት ቀናት ዉስጥ	በጭራሽ	በትንሹ	መካከለኛ	በጣም	እጅግ በጣም
1	ነገሮችን ለማስታዎስ እቸገራለሁ	0	1	2	3	4
2	ጉንቻዎቸን ያመኛል	0	1	2	3	4
3	ብስጭት ይሰማኛል	0	1	2	3	4
4	እግሮቸን የመዛል ስሜት ይሰማኛል	0	1	2	3	4
5	ደስ የሚል ስሜት ይሰማኛል	0	1	2	3	4
6	ጭንቅላቴን ይከብደኛል	0	1	2	3	4
7	የመነቃቃት ስሜት ይሰማኛል	0	1	2	3	4
8	የመረበሽ ስሜት ይሰማኛል	0	1	2	3	4
9	ዘና ያለ ስሜት ይሰማኛል	0	1	2	3	4
10	ከባድ የድካም ስሜት ይሰማኛል	0	1	2	3	4
11	ግራ ተጋብቻለሁ	0	1	2	3	4

12	ጉልበቴ እንደተሟጠጠ ይሰማኛል	0	1	2	3	4
13	ሀዘን ይሰማኛል	0	1	2	3	4
14	ለቀናት የሚቆይ ከባድ የድካም ስሜት ይሰማኛል	0	1	2	3	4
15	ትኩረት የመስጠት ችግር አለብኝ	0	1	2	3	4
16	ክንዶቼን የመዛል ስሜት ይሰማኛል	0	1	2	3	4
17	የመንቀራፈፍ ስሜት ይሰማኛል	0	1	2	3	4
18	አቅም እንዳጣሁ ይሰማኛል	0	1	2	3	4
19	መላ አካሌን ያመኛል	0	1	2	3	4
20	ሃሳቤን መሰብሰብ ያቅተኛል	0	1	2	3	4
21	የድብርት ስሜት ይሰማኛል	0	1	2	3	4
22	የመታደስ ስሜት ይሰማኛል	0	1	2	3	4
23	የውጥረት ስሜት ይሰማኛል	0	1	2	3	4
24	የመበርታት ስሜት ይሰማኛል	0	1	2	3	4
25	ከተለመደዉ በላይ ስህተት እሰራለሁ	0	1	2	3	4
26	አጠቃላይ አካሌን ክብድ የሚል ስሜት ይሰማኛል	0	1	2	3	4
27	የመርሳት ችግር አለብኝ	0	1	2	3	4
28	የድካም ስሜት ይሰማኛል	0	1	2	3	4

29	**የመረጋጋት ስሜት ይሰማኛል**	**0**	**1**	**2**	**3**	**4**
30	**ተጨናንቂያለሁ**	**0**	**1**	**2**	**3**	**4**

2.1. MFSI-SF (Amharic version)- for interviewer administered version

ከዚህ በታች የተዘረዘሩት አረፍተ ነገሮች ሰዎች አንዳንድ ጊዜ ምን እንደሚሰማቸው የሚገልጹ ናቸው፡፡ እባክዎ እያንዳንዱን ጥያቄ ሳነብልዎት በጥንቃቄ ያዳመጡኝ ከዚያም ባለፉት ሰባት ቀናት ውስጥ ስሜቴን በደንብ ይገልጸኛል የሚሉትን መልስ ከጥያቄው ቀጥሎ ካሉት አማራጮች አንድ ቁጥር መርጠው ይንገሩኝ፡፡

ቀን፡___/___/_____ ሰአት፡ _____ መለያ ቁጥር/ካርድ ቁጥር፡_____

	ባለፉት ሰባት ቀናት ዉስጥ	በጭራሽ	በትንሹ	መካከለኛ	በጣም	እጅግ በጣም
1	ነገሮችን ለማስታወስ እቸገራለሁ	0	1	2	3	4
2	ጉንቻዎቸን ያመኛል	0	1	2	3	4
3	ብስጭት ይሰማኛል	0	1	2	3	4
4	እግሮቸን የመዛል ስሜት ይሰማኛል	0	1	2	3	4
5	ደስ የሚል ስሜት ይሰማኛል	0	1	2	3	4
6	ጭንቅላቴን ይከብደኛል	0	1	2	3	4
7	የመነቃቃት ስሜት ይሰማኛል	0	1	2	3	4
8	የመረበሽ ስሜት ይሰማኛል	0	1	2	3	4
9	ዘና ያለ ስሜት ይሰማኛል	0	1	2	3	4
10	ከባድ የድካም ስሜት ይሰማኛል	0	1	2	3	4
11	ግራ ተጋብቻለሁ	0	1	2	3	4

12	ጉልበቴ እንደተሟጠጠ ይሰማኛል	0	1	2	3	4
13	ሀዘን ይሰማኛል	0	1	2	3	4
14	ለቀናት የሚቆይ ከባድ የድካም ስሜት ይሰማኛል	0	1	2	3	4
15	ትኩረት የመስጠት ችግር አለብኝ	0	1	2	3	4
16	ክንዶቼን የመዛል ስሜት ይሰማኛል	0	1	2	3	4
17	የመንቀራፈፍ ስሜት ይሰማኛል	0	1	2	3	4
18	አቅም እንዳጣሁ ይሰማኛል	0	1	2	3	4
19	መላ አካሌን ያመኛል	0	1	2	3	4
20	ሃሳቤን መሰብሰብ ያቅተኛል	0	1	2	3	4
21	የድብርት ስሜት ይሰማኛል	0	1	2	3	4
22	የመታደስ ስሜት ይሰማኛል	0	1	2	3	4
23	የውጥረት ስሜት ይሰማኛል	0	1	2	3	4
24	የመበርታት ስሜት ይሰማኛል	0	1	2	3	4
25	ከተለመደዉ በላይ ስህተት እሰራለሁ	0	1	2	3	4
26	አጠቃላይ አካሌን ክብድ የሚል ስሜት ይሰማኛል	0	1	2	3	4
27	የመርሳት ችግር አለብኝ	0	1	2	3	4
28	የድካም ስሜት ይሰማኛል	0	1	2	3	4

29	**የመረጋጋት ስሜት ይሰማኛል**	**0**	**1**	**2**	**3**	**4**
30	**ተጨናንቂያለሁ**	**0**	**1**	**2**	**3**	**4**

3. EORTC QLQ C-30 (እትም -3): Self-Administered

እርስዎንና ጤንነትዎን በተመለከተ የተወሰኑ ነገሮችን ለማወቅ እንፈልጋለን። እባክዎትን የሚከተሉትን ጥያቄዎች በሙሉ እርስዎ ትክክለኛ ነው ብለው ያመኑበትን በማክበብ ይመልሱ። «ትክክለኛ» መልስ ወይም « የተሳሳተ» መልስ የሚባል የለም። የሚሰጡት መረጃ ሁሉ ምስጢራዊነቱ በደንብ የተጠበቀ ይሆናል።

ቀን፡___/___/_____ መለያ ቁጥር/ካርድ ቁጥር፡_____

		በጭራሽ	**በትንሹ**	**በመጠኑ**	**በጣም በብዛት**
1	**እንደ ከባድ ዘንቢል ወይም ሻንጣ ለመሸከም የመሳሰሉ ጉልበት የሚጠይቁ እንቅስቃሴዎችን ለማድረግ ችግር አለብዎት?**	1	2	3	4
2	**<u>ረዥም</u> የእግር ጉዞ ለማድረግ ችግር አለብዎ**	1	2	3	4
3	**ከቤትዎ ውጭ <u>አጭር</u> የእግር ጉዞ ለማድረግ ችግር አለብዎ?**	1	2	3	4
4	**በህመምዎ የተነሳ በቀን አልጋ ላይ ወይም ወንበር ላይ ሆነው ረዘም ላለ ሰዓት ያሳልፍሉ?**	1	2	3	4
5	**ሲመገቡ፣ ሲለብሱ፣ ሲታጠቡ፣ ወይም ሽንት ቤት ሲጠቀሙ እገዛ ያስፈልገዎታል?**	1	2	3	4
	ባለፈው ሳምንት ውስጥ፡-	**በጭራሽ**	**በትንሹ**	**በመጠኑ**	**በጣም በብዛት**

6	**ስራዎትን ወይም የዕለት ተለት እንቅስቃሴዎን ለማከናወን ተገድበው ነበር?**	1	2	3	4
7	**በትርፍ ጊዜ የሚከናወኑ ስራዎችን ወይንም ሌሎች የመዝናኛ ጊዜዎችን ለማሳለፍ ገድቦዎት ነበር?**	1	2	3	4
8	**ሲተነፍሱ የትንፋሽ ማጠር አጋጥሞት ነበር?**	1	2	3	4
9	**የህመም ስሜት ነበረብዎ?**	1	2	3	4
10	**ከወትሮው የተለየ ዕረፍት አስፈልጎዎት ነበር?**	1	2	3	4
11	**የእንቅልፍ ችግር ነበረብዎ?**	1	2	3	4
12	**አቅም ያንስዎት ነበር?**	1	2	3	4
13	**የምግብ ፍላጎትዎ ቀንሷል?**	1	2	3	4
14	**የማቅለሽለሽ ስሜት ነበረብዎ?**	1	2	3	4
15	**አስመልሶዎት ነበር?**	1	2	3	4
16	**የሰገራ ድርቀት ነበረብዎ?**	1	2	3	4
	ባለፈው ሳምንት ውስጥ፡-	**በጭራሽ**	**በትንሹ**	**በመጠኑ**	**በጣም በብዛት**
17	**ተቅማጥ ነበረብዎ?**	1	2	3	4
18	**የድካም ስሜት ነበረዎ?**	1	2	3	4
19	**ህመሙ የዕለት ተዕለት እንቅስቃሴዎትን ያውክብዎ ነበር?**	1	2	3	4

20	**አንዳንድ ነገሮችን ትኩረት ሰጥተው ለመስራት ያዉክዎት ነበር? (ለምሳሌ፤ ጋዜጣ ለማንበብ፤ ራዲዮ ለማዳመጥ)**	1	2	3	4
21	**የውጥረት ስሜት ነበረብዎ?**	1	2	3	4
22	**የመጨነቅ ስሜት ነበረብዎ?**	1	2	3	4
23	**የመነጫነጭ ስሜት ነበረብዎ?**	1	2	3	4
24	**የመደበር ስሜት ነበረብዎ?**	1	2	3	4
25	**ነገሮችን የማስታወስ ችግር ነበረብዎ?**	1	2	3	4
26	**አካላዊ ሁኔታዎ ወይም የሚከታተሉት ህክምና <u>በቤተሰባዊ</u> ሕይወትዎ ላይ ያሳደረው ተፅዕኖ ነበር?**	1	2	3	4
27	**የጤናዎ ሁኔታ ወይም የሚከታተሉት ህክምና <u>በማህበራዊ</u> ሕይወትዎ፤ በሚያደርጉት እንቅስቃሴዎ ላይ ያሳደረው ተፅእኖ ነበር?**	1	2	3	4
28	**የጤናዎ ሁኔታ ወይም የሚከታተሉት ህክምና ገንዘብ እንዲያጥርዎ /እንዲቸገርዎ/ አድርጓል?**	1	2	3	4

ለሚከተሉትን ጥያቄዎች ከ 1-7 ካሉት ቁጥሮች ውስጥ እርስዎን በደንብ የሚገልጽዎን አንዱን ቁጥር ያክብቡ

29 **በአጠቃላይ ባለፈዉ ሳምንት የነበረዎን <u>የጤንነት</u> ሁኔታ እንዴት ይመዝኑታል?**

1 2 3 4 5 6 7

በጣም መጥፎ **እጅግ በጣም ጥሩ**

30 **በአጠቃላይ ባለፈዉ ሳምንት የነበረዎን <u>የኑሮ ሁኔታ ጥራት</u> ዕንዴት ይመዝኑታል?**

1 2 3 4 5 6 7

በጣም መጥፎ እጅግ በጣም ጥሩ

3.1. EORTCQLQC-30(እትም -3)-Interviewer administered version

እርስዎንና ጤንነትዎን በተመለከተ የተወሰኑ ነገሮችን ለማወቅ እንፈልጋለን። እባክዎትን የሚከተሉትን ጥያቄዎች በሙሉ ሳነብልዎ እርስዎ ትክክለኛ ነው ብለው ያመኑበትን መልስ ይንገሩኝ። «ትክክለኛ» መልስ ወይም « የተሳሳተ» መልስ የሚባል የለም። የሚሰጡት መረጃ ሁሉ ምስጢራዊነቱ በደንብ የተጠበቀ ይሆናል።

ቀን፡___/___/_____ **መለያ ቁጥር/ካርድ**

		በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
1	**እንደ ከባድ ዘንቢል ወይም ሻንጣ ለመሸከም የመሳሰሉ ጉልበት የሚጠይቁ እንቅስቃሴዎችን ለማድረግ ችግር አለብዎት?**	1	2	3	4
2	**<u>ረዥም</u> የእግር ጉዞ ለማድረግ ችግር አለብዎ**	1	2	3	4
3	**ከቤትዎ ውጭ <u>አጭር</u> የእግር ጉዞ ለማድረግ ችግር አለብዎ?**	1	2	3	4
4	**በህመምዎ የተነሳ በቀን አልጋ ላይ ወይም ወንበር ላይ ሆነው ረዘም ላለ ሰዓት ያሳልፍሉ?**	1	2	3	4
5	**ሲመገቡ፣ ሲለብሱ፣ ሲታጠቡ፣ ወይም ሽንት ቤት ሲጠቀሙ እገዛ ያስፈልገዎታል?**	1	2	3	4
ባለፈው ሳምንት ውስጥ፡-		**በጭራሽ**	**በትንሹ**	**በመጠኑ**	**በጣም በብዛት**

6	**ስራዎትን ወይም የዕለት ተለት እንቅስቃሴዎን ለማከናወን ተገድበው ነበር?**	1	2	3	4
7	**በትርፍ ጊዜ የሚከናወኑ ስራዎችን ወይንም ሌሎች የመዝናኛ ጊዜዎችን ለማሳለፍ ገድቦዎት ነበር?**	1	2	3	4
8	**ሲተነፍሱ የትንፋሽ ማጠር አጋጥሞት ነበር?**	1	2	3	4
9	**የህመም ስሜት ነበረብዎ?**	1	2	3	4
10	**ከወትሮው የተለየ ዕረፍት አስፈልጎዎት ነበር?**	1	2	3	4
11	**የእንቅልፍ ችግር ነበረብዎ?**	1	2	3	4
12	**አቅም ያንስዎት ነበር?**	1	2	3	4
13	**የምግብ ፍላጎትዎ ቀንሷል?**	1	2	3	4
14	**የማቅለሽለሽ ስሜት ነበረብዎ?**	1	2	3	4
15	**አስመልሶዎት ነበር?**	1	2	3	4
16	**የሰገራ ድርቀት ነበረብዎ?**	1	2	3	4
	ባለፈው ሳምንት ውስጥ፡-	**በጭራሽ**	**በትንሹ**	**በመጠኑ**	**በጣም በብዛት**
17	**ተቅማጥ ነበረብዎ?**	1	2	3	4
18	**የድካም ስሜት ነበረዎ?**	1	2	3	4
19	**ህመሙ የዕለት ተዕለት እንቅስቃሴዎትን ያውክብዎ ነበር?**	1	2	3	4

20	**አንዳንድ ነገሮችን ትኩረት ሰጥተው ለመስራት ያዉክዎት ነበር? (ለምሳሌ፤ ጋዜጣ ለማንበብ፤ ራዲዮ ለማዳመጥ)**	1	2	3	4
21	**የውጥረት ስሜት ነበረብዎ?**	1	2	3	4
22	**የመጨነቅ ስሜት ነበረብዎ?**	1	2	3	4
23	**የመነጫነጭ ስሜት ነበረብዎ?**	1	2	3	4
24	**የመደበር ስሜት ነበረብዎ?**	1	2	3	4
25	**ነገሮችን የማስታወስ ችግር ነበረብዎ?**	1	2	3	4
26	**አካላዊ ሁኔታዎ ወይም የሚከታተሉት ህክምና <u>በቤተሰባዊ</u> ሕይወትዎ ላይ ያሳደረው ተፅዕኖ ነበር?**	1	2	3	4
27	**የጤናዎ ሁኔታ ወይም የሚከታተሉት ህክምና <u>በማህበራዊ</u> ሕይወትዎ፤ በሚያደርጉት እንቅስቃሴዎ ላይ ያሳደረው ተፅእኖ ነበር?**	1	2	3	4
28	**የጤናዎ ሁኔታ ወይም የሚከታተሉት ህክምና ገንዘብ እንዲያጥርዎ /እንዲቸገርዎ/ አድርጓል?**	1	2	3	4

ለሚከተሉትን ጥያቄዎች ከ 1-7 ካሉት ቁጥሮች ውስጥ እርስዎን በደንብ የሚገልጽዎን አንዱን ቁጥር ያክብቡ

29	**በአጠቃላይ ባለፈዉ ሳምንት የነበረዎን <u>የጤንነት</u> ሁኔታ እንዴት ይመዝኑታል**						
	1	2	3	4	5	6	7
	በጣም መጥፎ						**እጅግ በጣም ጥሩ**

30	**በአጠቃላይ ባለፈዉ ሳምንት የነበረዎን <u>የኑሮ ሁኔታ ጥራት</u> ዕንዴት ይመዘኑታል**						
	1	2	3	4	5	6	7
	በጣም መጥፎ						እጅግ በጣም ጥሩ

4. Brief fatigue inventory (BFI-Am)- Self-administered version

እባክዎ እያንዳንዳቸውን መጠይቅ በጥንቃቄ ካነበቡ በኋላ በተጠቀሰው ሰዓት ወይም ቀናት ውስጥ በደንብ ይገልጸኛል ያሉትን ከመጠይቁ ቀጥሎ ካሉት ቁጥሮች አንድ ቁጥር ብቻ መርጠው ያክብቡ፡፡

ቀን፡___/___/_____ **መለያ ቁጥር/ካርድ ቁጥር፡**___

አብዛኞቻችን በህይወታችን ውስጥ ድካም ይሰማናል፡፡ እርሶ ባለፈው ሳምንት ውስጥ ያልተለመደ የድካም ስሜት ተሰምቶት ነበር? አዎ ------ አይ -----

1. **እባኮትን አሁን እየተሰማዎት ያለውን የድካም ስሜት ደረጃውን ቁጥሩን በማክበብ ይግለጹ**

0 1 2 3 4 5 6 7 8 9 10

ምንም ድካም የለኝም **በከፍተኛ ሁኔታ ይሰማኛል**

2. **እባኮትን ባለፉት 24 ሰዓታት ይሰማዎት የነበረው የተለመደ የድካም ስሜት ደረጃውን ቁጥሩን በማክበብ ይግለጹ**

0 1 2 3 4 5 6 7 8 9 10

ምንም ድካም የለኝም **በከፍተኛ ሁኔታ ይሰማኛል**

3. **እባክዎትን ባለፉት 24 ሰዓታት ይሰማዎት የነበረው አስከፊ የሆነ የድካም ስሜት ደረጃውን ቁጥሩን በማክበብ ይግለጹ**

0 1 2 3 4 5 6 7 8 9 10

ምንም ድካም የለኝም **በከፍተኛ ሁኔታ ይሰማኛል**

4. **እባክዎትን ባለፉት 24 ሰዓታት ይሰማዎት የነበረው የድካም ስሜት የነበረው ማወክ (ተጽእኖ)**

ሀ. በአጠቃላይ እንቅስቃሴዎት ላይ

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

ለ. በስሜትዎ ላይ

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

ሐ. በሚራመዱበት ጊዜ

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

መ. በመደበኛ ስራዎት (በቤትና በውጪ በሚያደርጉት የዘወትር የስራ እንቅስቃሴ)

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

ሠ. ከሰዎች ጋር ባሎት ግንኙነት

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

ረ. በኑሮዎት መደሰት ላይ

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

4.1. Brief fatigue inventory (BFI-Am) Amharic version- for Interviewer administered version

እባክዎ እያንዳንዳቸውን መጠይቅ ካነበብኩለዎት በኋላ በተጠቀሰው ሰዓት ወይም ቀናት ውስጥ በደንብ ይገልጸኛል ያሉትን ከመጠይቁ ቀጥሎ ካሉት ቁጥሮች አንድ ቁጥር ብቻ መርጠው ይንገሩኝ፡፡

ቀን፡___/___/_____ መለያ ቁጥር/ካርድ ቁጥር፡_____

አብዛኞቻችን በህይወታችን ውስጥ ድካም ይሰማናል፡፡ እርሶ ባለፈው ሳምንት ውስጥ ያልተለመደ የድካም ስሜት ተሰምቶት ነበር? አዎ ------ አይ -----

2. **እባኮትን አሁን እየተሰማዎት ያለውን የድካም ስሜት ደረጃውን ቁጥሩን በማክበብ ይግለጹ**

0 1 2 3 4 5 6 7 8 9 10

ምንም ድካም የለኝም **በከፍተኛ ሁኔታ ይሰማኛል**

3. **እባኮትን ባለፉት 24 ሰዓታት ይሰማዎት የነበረው የተለመደ የድካም ስሜት ደረጃውን ቁጥሩን በማክበብ ይግለጹ**

0 1 2 3 4 5 6 7 8 9 10

ምንም ድካም የለኝም **በከፍተኛ ሁኔታ ይሰማኛል**

4. **እባክዎትን ባለፉት 24 ሰዓታት ይሰማዎት የነበረው አስከፊ የሆነ የድካም ስሜት ደረጃውን ቁጥሩን በማክበብ ይግለጹ**

0 1 2 3 4 5 6 7 8 9 10

ምንም ድካም የለኝም **በከፍተኛ ሁኔታ ይሰማኛል**

5. **እባክዎትን ባለፉት 24 ሰዓታት ይሰማዎት የነበረው የድካም ስሜት የነበረው ማወክ (ተጽእኖ)**

ሀ. በአጠቃላይ እንቅስቃሴዎት ላይ

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

ለ. በስሜትዎ ላይ

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

ሐ. በሚራመዱበት ጊዜ

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

መ. በመደበኛ ስራዎት (በቤትና በውጪ በሚያደርጉት የዘወትር የስራ እንቅስቃሴ)

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

ሠ. ከሰዎች ጋር ባሎት ግንኙነት

0 1 2 3 4 5 6 7 8 9 10

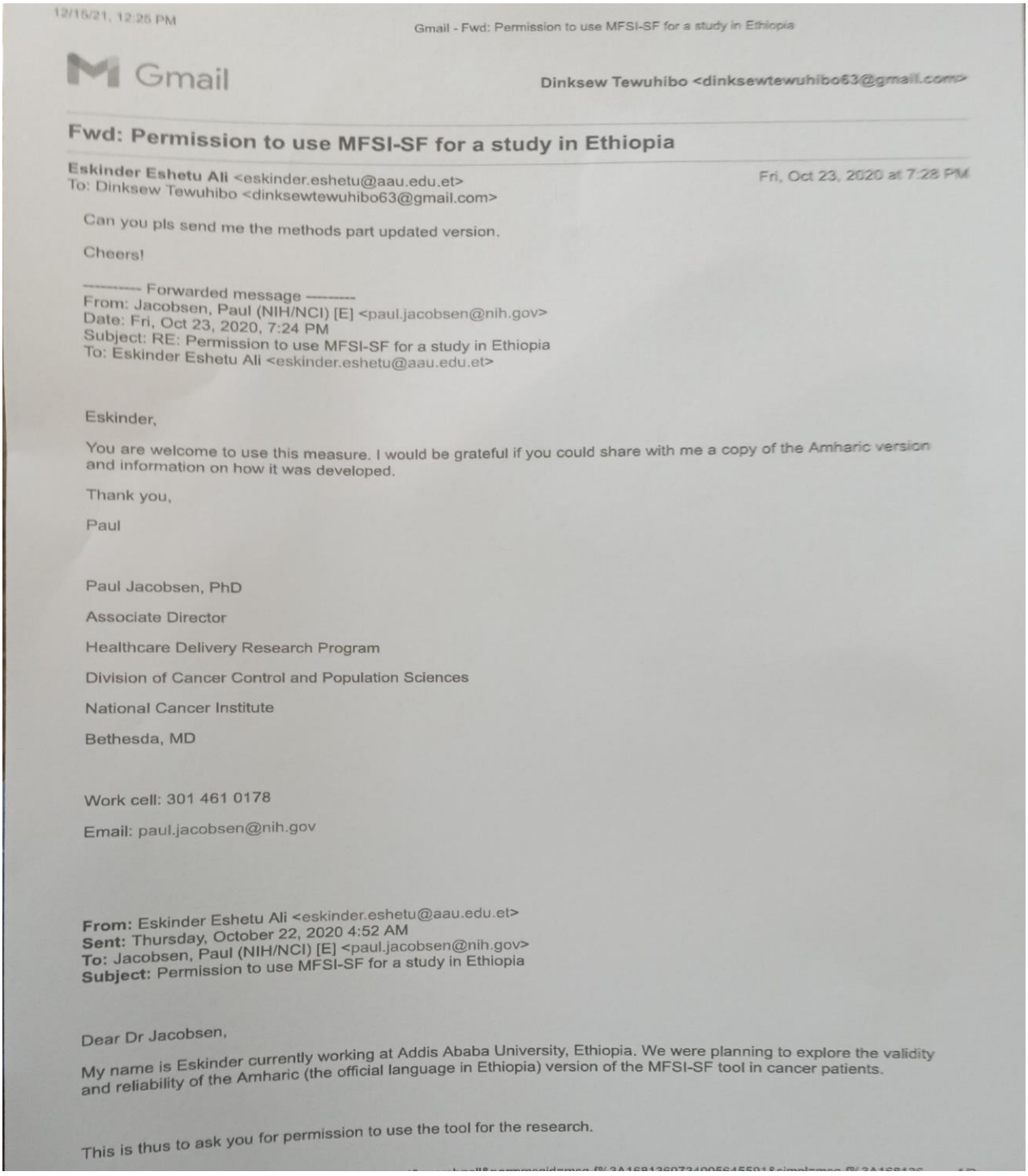
ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

ረ. በኑሮዎት መደሰት ላይ

0 1 2 3 4 5 6 7 8 9 10

ምንም አላወከኝም **ሙሉ በሙሉ አውኮኛል**

5. Permission through e-mail confirmation from the University of South Florida and the H. Lee Moffitt Cancer Center & Research Institute to use MFSI-SF.



12/15/21, 12:25 PM Gmail - Fwd: Permission to use MFSI-SF for a study in Ethiopia

Gmail

Dinksew Tewuhibo <dinksewtewuhibo63@gmail.com>

Fwd: Permission to use MFSI-SF for a study in Ethiopia

Eskinder Eshetu Ali <eskinder.eshetu@aau.edu.et> Fri, Oct 23, 2020 at 7:28 PM
To: Dinksew Tewuhibo <dinksewtewuhibo63@gmail.com>

Can you pls send me the methods part updated version.

Cheers!

---------- Forwarded message ---------
From: Jacobsen, Paul (NIH/NCI) [E] <paul.jacobsen@nih.gov>
Date: Fri, Oct 23, 2020, 7:24 PM
Subject: RE: Permission to use MFSI-SF for a study in Ethiopia
To: Eskinder Eshetu Ali <eskinder.eshetu@aau.edu.et>

Eskinder,

You are welcome to use this measure. I would be grateful if you could share with me a copy of the Amharic version and information on how it was developed.

Thank you,

Paul

Paul Jacobsen, PhD

Associate Director

Healthcare Delivery Research Program

Division of Cancer Control and Population Sciences

National Cancer Institute

Bethesda, MD

Work cell: 301 461 0178

Email: paul.jacobsen@nih.gov

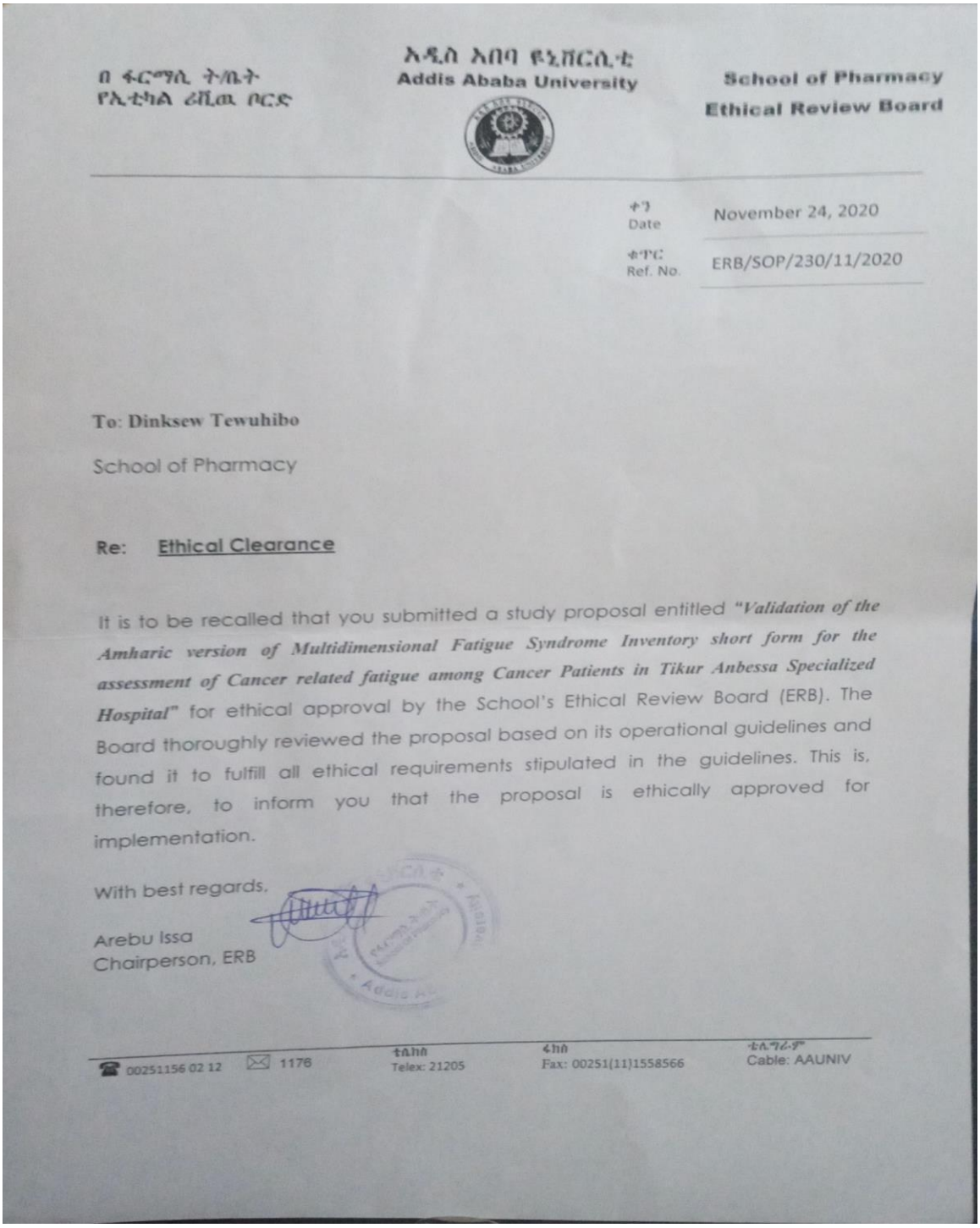
From: Eskinder Eshetu Ali <eskinder.eshetu@aau.edu.et>
Sent: Thursday, October 22, 2020 4:52 AM
To: Jacobsen, Paul (NIH/NCI) [E] <paul.jacobsen@nih.gov>
Subject: Permission to use MFSI-SF for a study in Ethiopia

Dear Dr Jacobsen,

My name is Eskinder currently working at Addis Ababa University, Ethiopia. We were planning to explore the validity and reliability of the Amharic (the official language in Ethiopia) version of the MFSI-SF tool in cancer patients.

This is thus to ask you for permission to use the tool for the research.

6. Ethical clearance obtained from Addis Ababa university, School of Pharmacy Ethical Review Committee.



በ ፋርማሲ ትምህርት
የኢቲካል ሪቪው ቦርድ

አዲስ አበባ ዩኒቨርሲቲ
Addis Ababa University

School of Pharmacy
Ethical Review Board

ቀን Date November 24, 2020

ቁጥር Ref. No. ERB/SOP/230/11/2020

To: Dinksew Tewuhibo

School of Pharmacy

Re: Ethical Clearance

It is to be recalled that you submitted a study proposal entitled *"Validation of the Amharic version of Multidimensional Fatigue Syndrome Inventory short form for the assessment of Cancer related fatigue among Cancer Patients in Tikur Anbessa Specialized Hospital"* for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the proposal based on its operational guidelines and found it to fulfill all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,

Arebu Issa
Chairperson, ERB

☎ 00251156 02 12 ✉ 1176 ቴሌክስ Telex: 21205 ፋክስ Fax: 00251(11)1558566 ቴሌግራም Cable: AAUNIV