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Psychometric Properties of Amharic Version of Becks depression inventory II among adult cancer patients in TASH,2021

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MASTER OF SCIENCE RESEARCH PROJECT

Psychometric Properties of Amharic Version of Becks depression inventory II among adult cancer patients in TASH,2021

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APPROVAL SHEET

This thesis by SOSINA WORKINEH thesis is accepted in its present form by the board of examiners as satisfying thesis requirement for the degree of masters in oncology nursing.

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STATEMENT OF THE AUTHOR

I would like to declare that this thesis work is my own work. All the sources of information I have been used in this thesis has been cited in the reference section fully. And this project work was not submitted to another institution or journal for purpose of any award.

BIOGRAPHICAL SKETCH

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ABBREVIATIONS AND ACRONYMS

BAI	Beck Anxiety Inventory
BASIS-24	Behavior and Symptom Identification Scale 24 items
BDI	Beck Depression Inventory
BDI -II	Beck Depression Inventory the Third Version
Dr.	Doctor
CES-D	Center for Epidemiologic Studies Depression Scale
CFA	Confirmatory Factor Analysis
CMDI	Chicago Multiscale Depression Inventory
CVD	Cardiovascular Disorder
DASS21	Depression Anxiety Stress Scales 21-item
DM	Diabetes Miletus
DSI4	Type D Personality Scale
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders
EFA	Exploratory Factor Analysis
HAD	Hospital Anxiety and Depression Scale
ITCC	Item total Corrected Correlation
LOT-R	Life Orientation Test-Revised version (LOT-R)
MDD	Major Depression Disorder
MSPSS	Multidimensional Scale of Perceived Social Support
NCCPE	National Cancer Control Plan of Ethiopia
NCDs	Non-communicable Diseases
OPD	Obstructive Pulmonary Disease
PCA	Principal Components Analysis

SF-20 Short Form of Survey

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ABSTRACT

Background: -Major depression disorder (MDD) or depression is a severe mental illness that relieved to be 8% among cancer patients. Even though the ambiguity of the development of depressive disorders among those patients continues, in Ethiopia, depression prevalence among cancer patients is 79.1%. Among the types of instruments to measure depression prevalence, BDI-II is the main and specific one. Even if there is a lack of studies indicating its validity and reliability among general cancer patients, this gap could lead studies about the prevalence of depression among cancer patients more complex and biased.

This study aims to examine the Psychometric properties of the BDI-II Amharic version among cancer patients.

Methodology: -The study implied a cross-sectional study design, and a total of 342 sample sizes were enrolled and data collected by interviewer-administered questionnaire. EFA was used to determine the factor structure used in the context of Ethiopia. Principal Axis Factoring with oblique rotation used to assess the BDI-II Amharic version's factor structure among cancer patients. Cronbach's alpha(α) was determined to decide the internal consistency of the tool and CFA was used to determine whether the model fit in the Ethiopia. And correlation coefficient was used to determine construct validity of the tool

Result: - This study evaluated the psychometric properties and factor structure of BDI-II among cancer patients. Principal Axis Factoring with oblique rotation indicated the presence of three factors among those populations. The cognitive, somatic and affective domain explains 46.3% of the variance. The study also demonstrated that the Amharic version BDI-II yields reliable and valid data among the population under study.

Conclusion: -This study concludes that Amharic version BDI-II can be used among cancer patients to measure depression and recommends researchers to use it.

Keywords: -BDI-II, Psychometric Properties

1.INTRODUCTION

1.1. Background

The four main non-communicable diseases (NCDs) that cause over 80% of deaths are cardiovascular disorder (CVD), cancer, diabetes Miletus (DM), and obstructive pulmonary disease (OPD) (1). Cancer is recently becoming the main problem in the world (2).

In history, there was a time when a meaningful attempt was not done to define cancer(3). The first written National Cancer Control Plan of Ethiopia (NCCPE), described it as a general term used to explain a condition in which the body's cell begins to grow and reproduce uncontrollably. This abnormal multiplication of cells arises from abnormal changes in the cells' genetic material, regulating average cell growth (1).

It has estimated that over 18.1 million new cases and 9.6 million deaths occurred due to cancer in 2018 around the world (4).In Africa, 715,000 new cases and 542,000 total deaths were reported and projection was made to be 1.28million new cases and 970,000 deaths per year by 2030 (5).

In Ethiopia total cases of 67,573(breast cancer, cervix cancer, and colorectum cancer constitute 22.2%,9.3%, and 7% respectively) and 47,954 deaths have been recorded due to cancer in 2018 (6).Of most cancer cases in Ethiopia, 68% were among females (7).Very few cancer specialists made the situation worst and access to treatments difficult for a great majority of the population (1).

Major depression disorder (MDD) or depression is a severe mental illness that interferes with the daily life and routine activity. Moreover, it reduces the quality of life and has several signs and symptoms (8). The ambiguity of depressive disorders among cancer patients is continued (8,9).

Among many cancer patients, depression prevalence was relieved to be 8% (10). In Turkey, 35.2% of the patients with cancer were depressed (11). Also, there was much-observed prevalence in Central Africa(124.56%), western sub-Saharan

Africa(124.42%),and Oceania(107.19%)(12). In Ethiopia, 9.1% documented depression prevalence (13).And among cancer patients, it was revealed to be 79.1% (14)which indicates a high number.

Among tools to measure the prevalence of depression in cancer patients, BDI(Beck Depression Inventory) (15,16), CES-D(Center for Epidemiologic Studies Depression Scale) (17), and Zung Self-Rating Depression Scale (18) are known to be specific. And HAD(Hospital Anxiety and Depression Scale) (19) is for the general one. Those tools may vary depending on the sample (patient status, type of cancer, location or stage of treatment) and selection bias of the researcher (9).

BDI, the so-called becks depression inventory was created by Aaron T Beck with 21 multiple questions in 1961. It was the tool that changed depression assessment from a psychodynamic perspective to self-thought and it has three versions. The first version was the one which was created in 1961, also the second version which is known as BDI-IA was invented in 1970 by Beck himself. This version was claimed for addressing six out of the nine DSM-III criteria of depression, even if it is for the past two weeks. The third version (BDI-II) was created in 1991 and had three subscales (affective subscales, cognitive subscales, and somatic subscales) (20).

1.2. Statement of the problem

Depression in cancer patients exceeds depression that appears in average population without cancer and also affects cancer patients' outcomes (21)(22).Despite the diagnosis, depression should be treated appropriately as it impacts the cancer process (8).

Diagnosing depression is complex as illness, the treatments and even side effects from the treatments mimic sign and symptom of depression i.e., fatigue, weight loss and hopelessness in cancer patients. So, those patients are reluctant to report symptom of depression in early process which leads to loss of adherence to chemotherapy and low improvement in quality of life. Moreover, healthcare providers become less motivated to help those patients (19). Identifying burden of depression among cancer patients will help in preventing upcoming disaster.

Despite the recommendation of screening depression among cancer patients, more emphasis has given to the cancer (23). As depression remains prevalent and lets a remarkable impact on the quality of life of the patients, and the treatment outcome of the disease, there should be systematic screening of depression by standardized tool (24).

Two measures strictly tied to interpreting outcomes are validity and reliability (25).Researchers should use valid and reliable tools (26) to get consistent and related data among participants. Medical research questionaries are judgmental and subjective especially for those self-report type (24).Stated that there is lack of testing whether a tool is valid and reliable in developing countries especially in social and health science's useful tools (27).

Research done with strong and justifiable methods fails to show validity of questionaries with respect to the outcome (28,29).This limitation observed at a high percentage in health education and behavior scholarly validity (ranging from 40% to 93%) and reliability (ranging from 35% to 80%) statistics'(25) which leads researchers to come up with vast and complex conclusion with unasserted recommendation (30).

Of 967 analyzed articles ,only 298(31%) purported measurement of validity of the instrument (25) which shows significant limitation of researchers'. Among those authors

who measured the fact of the devices used for data collection, only 25% of authors use constructs validity and 21% use correlation coefficient to determine truth. And also, of the 967 articles, only 472 (48.8%) actually provided reliability statistics, even though, frequently reported types of reliability were internal consistency (74.2%).

BDI-II has shown excellent consistency in several different countries with different versions and well used by both clinicians and researchers (31).Since depression has different symptom and entities across different race, validity and reliability of BDI by language of one cannot guarantee another (32). BDI-II has several advantages as both clinician and researcher can apply to assess construction of depression among victims. It is also easier to administer in different settings with low risk of harming even though it needs expert interpretation (31).

BDI-II is written self-report way of assessing depression so it needs reliability and validity to help identify depression in patients with comorbid illness (19). The validity and reliability of BDI-II have been done in a number of cases among different population with different version. Coronary heart disease, HIV-positive, multiple sclerosis, primary medical care patients, adult clinical inpatient, clinically non-depressed substance abusers (33–38) are some of the cases.

In conclusion, BDI-II is has not validated in any corner of the world among general cancer patients. The absence of the validated BDI-II among cancer patient arose the need for this study. This study is going to validate BDI-II among cancer patients in the Amharic Version. Amharic version is selected as it is Federal language and most spoken language of the country. This dominancy of Amharic language will provide large sample to participate for the validation of the tool.

1.3. Significancy of the study

No indicated study that determines psychometric properties of BDI-II among general cancer patients. So, for the first time, the Amharic version and cancer patients involved.

This study will contribute several benefits to those who will be ready to use it. As validation of BDI II for measuring depression disorder among cancer patients is the first study, it will provide validated tool following the country context. So upcoming researchers can measure prevalence of depression and associated factors among general cancer patients by using this country-level validated tool which needs great attention because of its significant impacts on the victims.

2.LITERATURE REVIEW

2.1. Depression definition

Trask defined depression, which was cited as ’common cold’ of psychiatry by Seligman (39), through DSM-IV as the presence of depressed mood or loss of interest or pleasure in nearly all activities for at least two weeks (19,40).For measuring depression, several assessments are identified (structured and unstructured clinical interview ,self-report measurement);however those approaches are limited by their use of previously identified clinical diagnosis (19).

Diagnosing depression among cancer patients is difficult because of sharing symptoms among the two (fatigue(common symptom of cancer and depression) (41). ,sleep difficulties, loss of appetite) (42,43) .Those mentioned above was the case for which ,mental health team was recommended being team of oncology (19,44,45).The coexistence of depression and cancer was factor for increased death among patients (46).Depression has different theories, among these, one theory is thought to be related to cancer.

Cognitive Approach:-Relates depression with the thinking process(47) in which depressed people are prone to biased thinking than ordinary people. So, in the cognitive approach several theories have been raised,

Beck's (1967) Theory: -relates depression with negative thinking of events among the victims (48).Additional studies confirm Beck's theory, by relating cognitive style with depression (49).

Learned Helplessness:-States that depression occurs among victims when a person knew that attempt to get rid of difficult situation does not make difference (50).As a consequence, loss of helplessness prone victims to stop trying ,this leads to depression. However ,critics came up with idea that, helplessness is symptom of depression, not a cause of depression (51).

2.2. Introduction to Psychometric Properties

Accuracy and consistency of questionaries will be the main concern of a researcher, which is called validity and reliability,(key indicators of quality of measurement (24))(52). Those different words, were frequently misunderstood (53).Validity is more prominent than reliability because without fact we can't rely on an instruments (25).

As health science researchers rely on self-report of participants (depression, level of pain, patient satisfaction) and involve quantifying theoretical constructs. It cannot be measured directly (severity of disease, drug efficacy, drug safety, burden of illness, patient satisfaction, health literacy, quality of life, quality of provider–patient communication, and adherence to medical regimens),operationalization of these construct in definable variables is a core of measurement (24).

Validity

Validity is how an instrument measures what it is intended to measure and it is not property of the instrument rather a property of scores and their interpretation (25,27,52,54). The instrument will display the underlying construct more accurately /less accurately ,but never perfectly (55).Validity can never be proven. Validation is not a time process; rather it is a overtime process (54)which needs variety of population and setting.

Results from assessing knowledge of symptom or health care provider cannot straight forward as that of measuring blood pressure or temperature. Instead ,they try to assess an underlying construct which has been based on specific attitudes and principles (56).This means the validity of the assessing instrument will be meaningful in the context of the construct not from the instrument itself.

Validity is classified into two major broad components namely; Internal validity (explain how result from a measurement accurately measures what it is designed to measure) and external validity (how accurately the result from the sample population accurately describes the population from which study sample was drawn) (57).There are four types of validity (27,52,54)with different properties and ways of processing.

Face validity: -It is a non-empirical judgment of an instrument if it actually fits the area of investigation. The weakest type of validation and does not encouraged (52,55).However, it is the most form of validity being in use in developing countries (27).

Content validity: -usually applied to a newly created instrument to determine its validity and requires external literature review and follow up by experts with different panels. (52,58).As a limitation, different geographical location of experts has been aroused ,but this can be diminished by sending the questionnaires to the experts ,to where they located (52).In some cases, to increase ability of validation, researchers may use face validity and content validity at once (59).

Criterion validity: -Measure how much the measure is related to outcome. It predicts performance in other situations(past, present or future) (52).

Construct validity:-It is how well you relate the construct with the behavior or how well the construct is operationalized or applied in reality (25,52,57).The most valuable and challenging types of validity (57).And it has two components; convergent and discriminant validity (52).

The evaluation of construct validity requires examining of the relationship of measure evaluated with variable theoretically related to the construct measured by the instruments (60).If correlation fits expected patterns it contributes to construct validity (27,52,54).By referring to Messick, cook and Beckman identifies five sources of evidence to support construct validity. The one called an umbrella (25,55)content ,response process, internal structure ,relation to other variable and consequences.

Reliability

Reliability concerns how far tests provide stable and consistent results in a repeatable ways (52,55,57).Lack of reliability in a tool may contribute to divergence between observers or the questionnaires' so-called measurement or instability of the one being measured (61). Even if it is not sufficient, reliability is necessary part of validity (30,55).

In contrast to validity, reliability only constitutes one source of evidence .But like that of validity, reliability is one property of instrument, not instrument by itself (55,57). There are three aspects of reliability, namely:

Test-retest reliability (stability): -Suppose a questionnaire keeps on providing the same result among the same respondents over different times (57).It is the most common aspect of reliability (27). Reliability coefficients range from 0.00 to 1.00, with higher coefficients indicating higher levels of reliability (54)**.**

Alternate form reliability (equivalence): -Two differently worded instrument and measure the same concepts would keep providing the same result if the administered at the same time (27).

Internal consistency reliability: -It focuses on correlation of the items (25,30).It asks if the instrument measures the same construct and use different measures. Cronbach's alpha(α) which is based on the assumption that items measuring the same construct should correlate (54), is a generalized form that is in use mostly. It assumes all items are equivalent and measure a single construct (55).According to this measure :excellent reliability (0.90 and above), high reliability(0.70-0.90), moderate reliability(0.50-0.70)and low reliability(0.50 and below) (52).

This study will look into the internal validity and consistency of BDI-II in the Amharic version among cancer patients in TASH, 2021.Construct validity is chosen because this study wants to study if BDI-II is applicable in the real world. Internal consistency will be looked into as there is time gap and lack investigators to see other dimensions of reliability.

2.3. Beck's depression inventory-II(BDI-II)

BDI-II was intended to address severity of depression by using Diagnostic and Statistical Manual of Mental Disorders(DSM-IV) (40).Since DSM-IV uses diagnostic conceptualization of two weeks rather than one week as time frame. BDI-II measure severity of depression by rating the 21 items (ranging 0-63) (62) and only the 4-point rating scale was retained expect for modification of some words of the item. It is responsibility of the psychologist to ensure that if the instrument shows sound psychometric properties (32).

2.3.1. Psychometric properties of BDI-II in chronic cases

BDI-II showed good internal consistency among patients with coronary heart disease(CHD)(α=0.87)(33)which is very near to HIV-positive(34) and multiple sclerosis (35)patients for which internal consistency were equal (α=0.89).Moreover ,there was excellent internal consistency (α=0.94) and item total correlation (0.54-0.74) was found among primary medical patients (36).Among adult clinical inpatients and substance abusers BDI-II got equal internal consistency(α=0.93) (37,38).

Among adult clinical inpatients item total correlations ranged from (r=0.37to r=0.74) (37)and it went (r=0.33 to r=0.76) for that of substance abusers (38).And for multiple sclerosis patients all item-total corrected correlation (ITCC) between individual items and BDI-II total score were ≥0.30 expect for item number 18 concerning with change in appetite item (35).

In a very resent year, the Bangla Version of BDI-II among Bangla population was done and internal consistency was (α=0.926).And by Pearson's correlation it was highly correlated with (Depression Anxiety Stress Scales 21-item)DASS21(63) (r=0.920).

Among CHD patients, BDI-II was significantly correlated ($p<0.01$) with Type D Personality Scale(DSI4) (64)(r=0.34) and Beck Anxiety Inventory(BAI) (65)(r=0.40) showing its convergent validity. In contrast, it was significantly less($p<0.01$) correlated with Multidimensional Scale of Perceived Social Support(MSPSS) (66)(r=-0.33) and Life Orientation Test-Revised version(LOT-R)(67)(-0.39)showing its discriminant validity (33).

For patients with chronic pain, BDI-II were significantly correlated ($p<0.001$) with CES-D (r=0.66 to r=0.72) which shows convergent validity of the tool among these population by Pearson correlation coefficient (68).By the same correlation coefficient correlations, BDI-II was indicated that it strongly correlated with CED-D(r=0.74) (34) showing its good convergent validity. Regarding discriminant validity, it was less correlated with social provision scale(r=-0.42) indicating acceptable degree of discriminating ability. Among those populations 55% of BDI-II measures depression and even by removing

somatic component still the BDI-I found to have good convergent validity(r=0.72) and acceptable discriminant validity (-0.39).

Among primary care medical patients BDI-II was strongly correlated with mental health subscales of Short-Form General Health Survey(SF-20) (69) (r=-.65) showing good convergent validity and regarding divergent validity, it correlated less strongly with physical pain(r=-0.24) subscales and physical functioning(r=-0.19) subscales of the short form of survey(SF-20) (36).Among adult clinical inpatients BDI-II strongly correlated with depression/functioning subscales of behavior and Symptom identification Scale 24 items(BASIS-24)(70) (r=0.79.p<0.001) indicating convergent validity and with substance abuse subscales of BASIS-24 it was less strongly correlated (r=0.24,p<0.001) showing no discriminant validity (37).Good convergent and divergent validity with respect to Chicago multiscale depression inventory (CMDI) as the gold standard was observed among multiple sclerosis (35).

CFA has indicated three model factor structure of BDI-II among CHD patients (33) and patients with chronic pain (68) to be used for measuring depression among these populations. And also, a Principal Components Analysis(PCA) using oblique rotation has revealed dimensions of the BDI- II, which is cognitive, affective and somatic symptoms of depression respectively (34) even if somatic dimension can be removed. Expletory factor analysis(EFA)among primary medical patients reveals two factor model :somatic-affective(-0.37) and cognitive (-0.32) (36).CFA was able to identify that the three factor solution BDI-II was best fit substance abusers population (r=0.80,p<0.001) (38).The principal component analysis revealed a two factor-structure assessing cognitive-affective and somatic depressive symptoms respectively among patients with multiple sclerosis in the Italian Version (35).

2.3.2. Factor structure of BDI-II

The first authors were able to name those factors or index of BDI-II somatic ,affective and cognitive, even if they fail to organize elements of items which get under one structure (71).

The first model of two-factor structure was confirmed by (72) (somatic-affective (12 items) and cognitive (9 items) among 353 general populations. Then development of second model of two-factor structure fellow, which was developed by (73) and contains cognitive factor (8 items) and a factor that was labeled noncognitive (13 items) at the time of the discovery. The third model of two-factor structure (cognitive-affective (10 items) and a somatic-vegetative (11 items)) was introduced (74) by using exploratory factor analysis (EFA) among 611 sample of students.

A fourth alternative two-factor model was formulated by using principal components analysis (PCA) among 340 primary care medical settings and it was able to provide (somatic-affective factor, 12 items, and a cognitive factor, 8 items). This model contains one item (Item 8: self-criticalness) with high loadings on both factors, (36) which implies that the model is not unidimensional (71).

The fifth alternative two-factor model was developed (75) by using EFA among 127 primary care patients and was able to provide somatic-affective (10 items) and a cognitive factor (9 items). In this model, two items (Item 21: loss of interest in sex; Item 13: indecisiveness) load on both factors, and one item (Item 18: changes in appetite) does not have adequate loadings on any of the factors, according to the study.

Three factor model has four structures (76). The first of these structures was formulated through CFA(confirmatory factor analysis) and fit with 230 students (77). The factors of this model were negative attitude (10 items), performance difficulty (7 items), and somatic elements (5 items).

The second of these three-factor BDI-II models was formulated among two groups (clinical (226) and non- clinical (505))by applying simultaneous component analysis with ProMax rotation and the authors were able to obtain a model with cognitive (7 items), somatic (9 items), and affective (5 items) factors(78) that were judged to be theoretically plausible (71).

A third model with a three-factor structure was tested with CFA on clinical data (n = 416) and recognize cognitive (9 items), somatic (8 items), and affective (4 items) factors (79).

A fourth three-factor model was formulated by State (80).This model assumes a general (G) factor underlying the BDI-II, as well as a cognitive (8 items) and a somatic factor (5 items) that are all orthogonal

3.OBJECTIVE OF THE STUDY

3.1. General objective of the study

Psychometric Properties of Beck's Depression Inventory-II translated in the Amharic language among adult cancer patients.

3.2. Specific objectives of the study

- To assess reliability (internal consistency) of BDI-II (Amharic version)
- To assess the internal construct validity of BDI-II (Amharic version)

Question of the study: -Is BDI-II can measure depression among cancer patient in Amharic Version?

4.METHODS AND MATERIAL

4.1. Study Area and the Study Period

The study conducted at the oncology unit of Tikur Anbessa Specialized Hospital (TASH). TASH, the only hospital with a cancer center in Ethiopia with 700 beds. It is also a training Centre for undergraduate and postgraduate medical students, dentists, nurses, midwives, pharmacists, medical laboratory technologists, radiology technologists, and others who solve the community health problems and the country at large(81).

The oncology unit of TASH is the national sole cancer referral center since 1997, established by the Ethiopian Government in collaboration with an International Atomic Energy Agency. It has an outpatient unit that gives service to new and follow-up patients and an in-patient unit (with 19 beds) which for those who need to stay in the hospital for their treatment(14).

This study was conducted in one month and undertaken from February 08 to March 08 2021.

4.2. Study Design

The study used a cross-sectional study design.

4.3. Source population

Source population was all cancer patients admitted to the TASH oncology center during data collection period.

4.3.1 Study population

And the study population was randomly selected cancer patients who were admitted to the oncology unit of TASH and on follow up in the time of study period and fulfilled inclusion criteria.

4.3.2 Inclusion and exclusion criteria

4.3.2.1. Inclusion Criteria

- Cancer patients who were not previously diagnosed with depression.
- Cancer patients whose age were 18 or older

4.3.2.1 *Exclusion criteria*

- Critically ill patients and not able to communicate

4.4. Sampling method

4.4.1. Sample size

Sample size is recognized as key parameter for the planning of research studies, especially in clinical research. As it eases the research process and makes the researcher more focused. The sample size determination for studying psychometric properties are rarely justified (82)indicating low scientific-based recommendations. Whether performing EFA or CFA there is a major limitation in expressing issue of sample size (83–85).

It is widely understood that the use of large sample in application of factor analysis tends to provide results. For example, sample factor loading are more precise estimate of population loading, more stable /less variable across repeated samples (86).Sample size determination when conducting CFA was recommended to be ranging from 150-1000 (87–89).

A wide range of recommendations regarding sample size in factor analysis has been proposed. These guidelines typically are stated in terms of either minimum necessary sample size N or the minimum ratio of N to number of variables being analyzed p (86).

Different authors recommend different N for factor analysis studies; (90) recommends that N should be at least 100. Which was the same with (91).On the contrary (92) argued that N should be at least 200. A rough rating scale for adequate sample size in factor analysis has been offered in which 100=poor,200=fair,300=good ,500=very good and 1000 or above =excellent (93).

In this study a sample size of 300(good) (93) used to make the study carriable and to make it more stable . As the study was cross sectional with available resource: time and budget, 300 minimum sample size was covenant. On this sample size 20% response rate was added as recommended for tool validation study(93) and the final sample size was 360.

4.4.2 Sampling technique

Study participants were selected using a systematic random sampling technique. Initially, the oncology follows up regular patients, monthly flow data was obtained from the adult clinical oncology department. From the monthly incoming patient flow, daily patient flow was calculated. Then the sample size was divided by those calculated number of patients per day. The gained number was number of data that is going to be gathered each day to get 360 participants in a month. This sampling technique was selected as we don't have sampling frame to use simple random sampling.

4.5. Data collection process

The data was collected using an interview-administered questionnaire and secondary data from the patient's document. And also national comprehensive cancer network(NCCN) Clinical Practice Guidelines in Adult Oncology (NCCN Guidelines) was used for numeric scaling of pain (94).The questionnaire was first prepared in English language. At first BDI-II was translated by professional psychiatrist Dr.Dawit Mulegeta into Amharic Version and then it was back translated by a person who is fluent in both Amharic and English.

At first the data was pre-tested by picking 5% of the original sample. This pre-tested study was conducted to check the acceptability of the Amharic version of BDI-II and the required time to collect data. The pre-test was performed among cancer patients those who were admitted to TASH at the time of data collection process and going to be excluded from the analyzing process.

Eligible cancer patients were given information to help them understand the study and then consent received. Oncology nurses, those holders of masters from the oncology center

were participated in collection of the data. One supervisor was selected for supervising the data collection. The supervisor was qualified in BSc nurses.

4.5.1. Measurement

I. Beck's Depression Inventory -II(BDI-II)

BDI-II, to be validated instrument among cancer patients, was created in 1991 by Aoron Beck with 21 items (20) with three subscales (somatic, affective and cognitive). It uses DSM-IV (40)as diagnostic conceptualization of two weeks rather than one week as time frame to measure prevalence of depression. It rates the 21 items (ranging 0-63) (62) and only the 4-point rating scale will be used. The severity of depression will be increases as the ranging number increased. Previously the instrumented has been validated among different kind of patients; coronary heart disease, HIV-positive, multiple sclerosis, primary medical care patients, adult clinical inpatient, clinically non-depressed substance abusers showing good reliability and acceptable validity.

4.6. Data Quality Control

Eligible cancer patients were given information to help them understand the study and receive their consent. Pre-test was conducted among 5% of the original participants by the questionaries that is translated by the professional psychiatrists.

Supervision and review of collected data was done every other day by the principal investigator. Data quality was controlled by principal investigator during data entry and analysis.

4.7. Data Analysis

Before entry into software data was checked for completeness and if there is a missing paper. Epidata 4.1, the software that used for data entry.

SPPS 25.0 *statistical package* (SPSS Inc) the expletory factor analysis in order to determine factorial structure of the Amharic version BDI-II among cancer patients and Stata 14 did the CFA. Principal Axis Factoring with oblique rotation was used to determine factor structure of BDI-II Amharic version among cancer patients. For each of

the factors, Cronbach's alpha (54),values was computed to determine the internal consistency of each factors of the Amharic version of BDI-II.

4.8. Ethical consideration

Approval for the general confidential data gained from the Ethics Review Board of the school of Nursing and Midwifery; College of Health Sciences, Addis Ababa University; and from the Institutional Review Board (IRB) of college of health science. Written consent gained from each cancer patients, reminding them that the information they are going to give was confidential

4.9. Limitation of the study

A limitation of the current project is the use of Ethiopian cancer patients for which prevalent type cancer is different from that of the developed countries. So those population does not represent cancer patients in worldwide.

5.RESULT

Out of 342(5% excluded after pre-test) participants 331 was able to answer the questionnaire, in which case response rate was 96.8%.

5.1. Sociodemographic result

Table 1 summarized the sociodemographic data for the 331 cancer patients in this study. Mean age of the participants was 47.53 and SD was 14. 069 as there is outlier number of age of one participant. And for purpose of report the age has been categorized into four labels with interval of 10. In the categorized age participants with 52 years old or above have got the major frequency which is 39.3%. Female participants constitute 209(63.1) while men were 122(36.9) in number. Orthodox religion was the prevalent religion constitutes 62.5%. Majority of the participants were married (71.6%). Majority of the participants did not have school leaving certification (31.7%).

Table 1: Sociodemographic characteristics of the sample (percentage and numbers)**, TASH 2021.**

Variable	Frequency	Percent (%)
Age		
19-29	32	9.7%
30-40	88	26.6%
41-51	81	24.5%
≥52	130	39.3%
Sex		
Male	122	36.9
Female	209	63.1
Religion		
Orthodox	207	62.5
Muslim	73	22.1
Protestant	48	14.5
Catholic	3	0.9
Marital Status		
Single	46	13.9
Married	237	71.6
Widow/er	28	8.5
Divorced	20	6.0
Educational level		
No school leaving qualification	105	31.7
Primary (1-8)	83	25.1
Secondary(9-12)	83	25.1
Tertiary(≥ diploma)	60	18.1

5.2. Clinical characteristics result

Table 2 shows clinical characteristics of the participants. The prevalent cancer type was Breast cancer (33.2%) followed by Cervical cancer (13.0%). The majority of the patient have Eastern Cooperative Oncology Group (ECOG) II (50%) and ECOG III (37.5%) for performance status. Chemotherapy was the major treatment type that is being used (90%). Majority of the participants had severe pain (29.3%).

Variable	Frequency	Percent (%)
Site of the cancer		
Breast	110	33.2
Cervical	43	13
Colon	39	11.8
Lung	18	5.4
ECOG*		
I	33	10
II	167	50
III	124	37.5
IV	7	2.1
Treatment type		
Chemotherapy	298	90
Surgery	16	4.8
Radiotherapy	16	4.8
Hormonal therapy	1	0.3
Prescence of Pain		
Absent (0)	57	17.2
Mild (1-3)	92	27.8

Moderate (4-6)	85	25.7
Severe (7-10)	97	29.3

*East oncology Cooperation Group

Table 2 clinical characteristics of the participants (number and percentage (%))**, TASH 2021**

5.3 Exploratory Factor Analysis

In developing the first translation of the BDI-II, special attention was paid to retain the original construction of the English BDI-II. All the questions in BDI-II correlate reasonably well with all others and determinant value is 0.001which is greater than 0.00001 which lets us proceed to the next stage.

The Kaiser–Meyer–Olkin Measure (KMO) indicated good sampling adequacy is 0.856 which is well above the minimum criteria of 0.5 and falls into the range of marvelous. Bartlett's test of sphericity (**X^2=2221.110, df=210, P≤0.001**) indicating significant value (0.000).

Also, anti-image correlation matrix was used to determine value of KMO for each variable. For the individual variables there is no anti-image correlation matrix which is less than 0.5. So, at this stage there is no variables to be eliminated from the analysis. Still the sample size is adequate.

Principal axis factoring was used to extract the factors. By Kaiser's criterion 5 factors were extracted. The eigenvalues associated with each factor represent the variance explained by that particular factor and the output contains this information: the eigenvalue is translated into the percentage of variance explained (e.g., factor 1 explains 28.646% of total variance). The first few factors explained relatively large amounts of variance (especially factor 1) whereas subsequent factors explain only small amounts. All factors with eigenvalues greater than 1 were then extracted, leaving the data with five factors **(Table 3).**

Total Variance Explained

Factor	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings[a]
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total
1	6.016	28.646	28.646	5.467	26.034	26.034	4.050
2	2.259	10.759	39.405	1.756	8.364	34.398	2.760
3	1.448	6.897	46.302	.887	4.223	38.621	3.963
4	1.098	5.227	51.529	.559	2.664	41.285	.992
5	1.024	4.876	56.405	.429	2.043	43.328	2.057
6	.961	4.576	60.981				
7	.854	4.068	65.050				

Table 3 eigenvalues associated with each factor before rotation

The scree plot recommended three factors to be extracted. And additional information from Monte Carlo by using parallel analysis by comparing actual eigenvalue from total variance explained table of SPSS with average eigenvalue obtained from parallel analysis**.** If SPSS explained value is larger than the criterion value from parallel analysis, we retain this factor; if it is less, we reject it. The result of parallel analysis indicates to retain only two factors for further analysis **(Table 4)**.

Table 4 Comparison of eigenvalues from the first five factors and criterion values from parallel analysis

Component number	Actual eigenvalue	Criterion value from parallel analysis	Decision
1	6.016	1.472780	Accept
2	2.259	1.394315	Accept
3	1.448	1.332932	Reject
4	1.098	1.276460	Reject
5	1.024	1.225132	Reject

For rotation, oblique was selected as there is assumption that there is correlation between the items(95). Extraction was made for both scree plot indicated three factors and Monte Carlo indicated two factors, even though the three factors was accepted with some evidences.

Two factor which was recommended by parallel analysis accounted for 39.4% of the variances. For that of two factor, 14 items excluding 21st item significantly loaded on the first factor and 6 items were significantly loaded on the second factor excluding 21st item. The first factor of the two-factor solution contained cognitive domain in items (7,5,8,3,14,2, 6,19) and affective domain in items (4,1,10,11) with suicidal thought and indecisiveness' and second factor of the two-factor solution contained the somatic factor in items (15,20,18 and 16) and affective domain (12 and 17).

The three-factor solution which was recommended by scree plot was accounted for 46.3%. From table of pattern matrix **(Table 6)** item 19 does not load on any of the factors, but in structurematrix**(Table5),**(95), item 19 does load significantly on factor 1.
For that of three factors 9 items were significantly loaded the first factor,6 items were significantly loaded on the second factor and 6 items were significantly loaded on the third factor. The first factor contained cognitive domain representing items (14,7,5,8,3,6 and19)

with indecisiveness and suicidal thought. Thus, it is labeled as cognitive domain. The second factor contained somatic domain representing items (15,20,18,16and 21) with loss of interest. Thus, it is labeled as somatic domain. The third factor contained affective domain representing items (1,4,10,7 and 11) and pessimism. Thus, it is labeled as affective domain.

Table 5 Structure Matrix after oblique rotation

	cognitive	somatic	affective
Worthlessness	.685		
Self-Dislike	.681		-.350
Guilty Feelings	.644		-.376
Self-criticalness	.622		-.405
Past failure	.617		-.390
Punishement feelings	.596		
Indecisiveness	.522		-.436
Suicidal Thoughts or Wishes	.498		
Concentration Difficulty	.389		-.376
Loss of Energy		.755	-.320
Tiredness or Fatigue		.739	
appetiitte		.594	
sleeping		.530	
Loss of Interest		.489	-.341
Loss of Interest in Sex		.381	
Sadness	.407		-.727
Loss of pleasure	.433	.423	-.675
Crying	.365		-.588
Pessimism	.532		-.563
Irritability		.330	-.520
Agitation			-.481

Extraction Method: Principal Axis Factoring.

Rotation Method: Oblimin with Kaiser Normalization.

Table 6 Pattern Matrix after oblique rotation,BDI-II Amharic Version

	Cognitive	Somatic	affective
Worthlessness	.712		
Self-Dislike	.675		
Punishement feelings	.654		
Guilty Feelings	.601		
Self-criticalness	.556		
Past failure	.553		
Suicidal Thoughts or Wishes	.509		
Indecisiveness	.402		
Concentration Difficulty			
Loss of Energy		.727	
Tiredness or Fatigue		.723	
appetiitte		.572	
sleeping		.503	
Loss of Interest in Sex		.433	
Loss of Interest		.410	
Sadness			-.680
Loss of pleasure			-.554
Crying			-.543
Irritability			-.463
Agitation			-.453
Pessimism	.336		-.392

Extraction Method: Principal Axis Factoring.

Rotation Method: Oblimin with Kaiser Normalization.

a. Rotation converged in 9 iterations.

Each factor of the three-factor solution is more homogenous than that of two factor solution. In addition, total variance of the three-factor solution explained 46.3% of the variances which was greater than two factor solution, which explained 39.4% of the variances **(Table 3).** Also, item 21 doesn't load in the two-factor solution. These explanations gave likely to use the three factors in those population. Also, internal consists of each factor was $\alpha \geq 0.74$, giving more strength to the use of the three-factor.

In this study the somatic domain had greater mean (M=8.9 SD=4.1)) than affective (M=4.70 SD=3.79) and cognitive (M=4.42 SD=5.02). Hence by assessing only somatic factor it is possible to measure degree of prevalence among cancer patients.

5.4. Confirmatory Factor Analysis

Stata 14 was used to analysis the CFA to decide whether the model fit the population. Value of root means square error of approximation (RMSEA), relative likelihood ration (RLP(x^2/d_f), comparative fit index (CFA), standardized root mean squared residual (SRMR) and p-value indices was determined for one-factor, two-factor model and three-factor model. As shown in the **Table 7** those indices were more in line with three-factor model. And this result led the three-factor model to be a good fit of Amharic version BDI-II among cancer patients.

Table 7 Model fit statistics for the confirmatory factor analysis of the three models

	One factor model	Two factor model	Three factor model
X^2	907.980	640	486
d_f	189	170	186
RLP	4.80	3.76	2.6
RMSEA	0.107	0.091	0.07
CFA	0.653	0.766	0.855
SRMR	0.088	0.132	0.062
P-value	0.000	0.000	0.000

The value of root means square error of approximation (RMSEA) = .070(90% confidence interval [CI]: .062, .077). These results indicated that the latent structure of the Amharic version BDI-II was the same across groups. The cut-off value of RSMEA is < .08 for adequate fit and < .06 for an excellent fit(96). CFI =0.855 of the three-factor model was the more near to the criteria for CFA=0.95 indicating good fit(96). SRMR values “less than .10 are generally considered favorable. For this study SRMR=0.062 indicating it is favorable. So, at overall the model cognitive, somatic, affective well fit the cancer

patient's population. Also, when loss of interest in sex deleted from the CFA those indices get more adjusted for good fit confirming validity of three factor model.

The three factors were moderately correlated with one another (r_{cs}=0.36 r_{sa}=0.53 rca=0.69) suggesting a single general depression factor may underlie the Amharic version BDI-II among cancer patients. Every item in a construct correlated significantly to the corresponding construct at ≥0.43 expect for loss of interest in sex which is less correlated with its corresponding construct. This explanation is showing construct validity of the Amharic version of BDI-II among those population.

To make the tool convergently and discriminantly valid there was a need to remove item 21(loss of interest in sex). But with the presence of item 21(loss of interest in sex) the tool was construct valid according to AMOS 23. In Ethiopia, sexual matters are not discussed openly and it is considered immodest to talk about it in public. However, as 'loss of interest in sex' is important indication of depression there is a need to keep it.

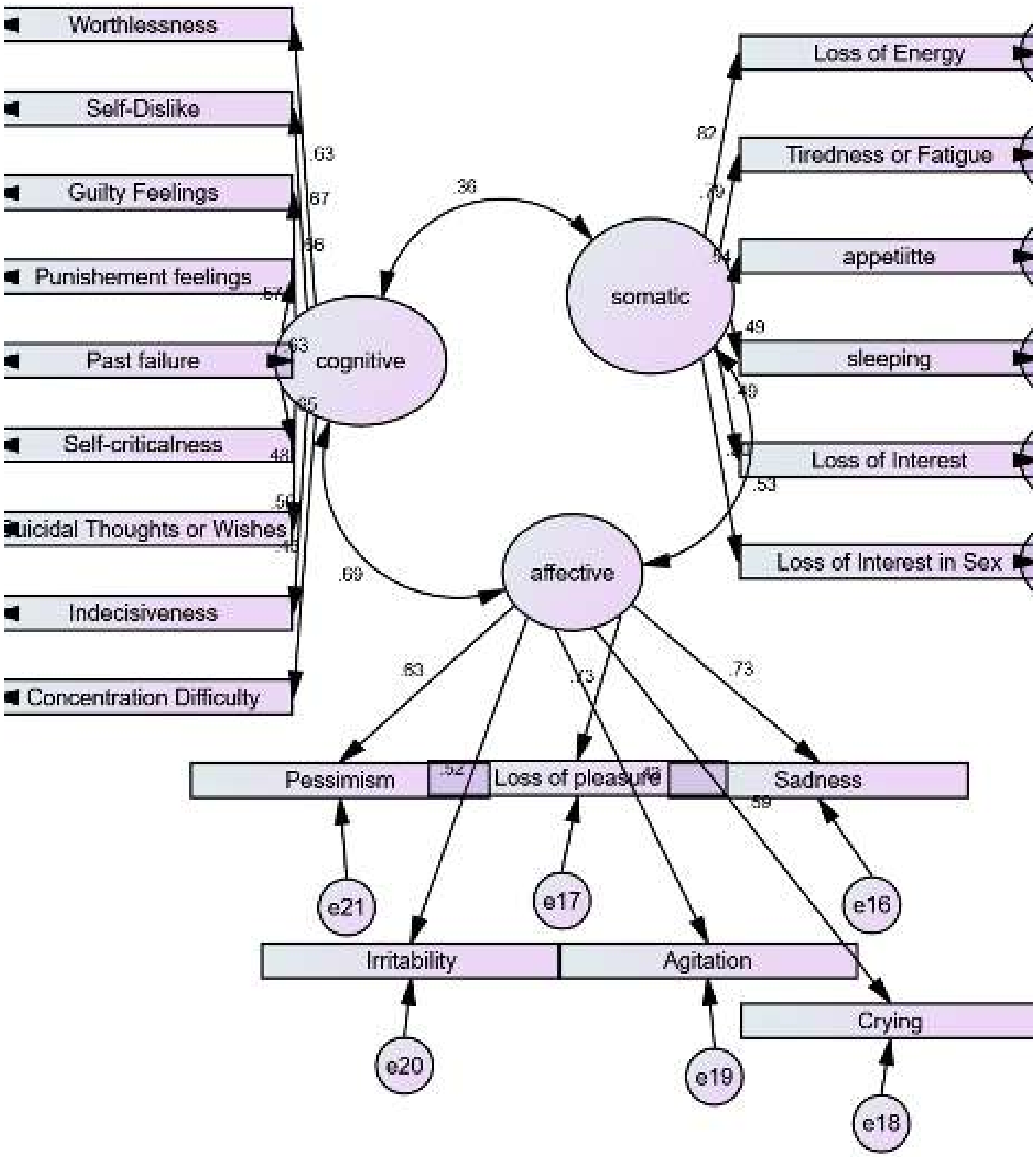
Worthlessness
Self-Dislike
Guilty Feelings
Punishement feelings
Past failure
Self-criticalness
uicidal Thoughts or Wishes
Indecisiveness
Concentration Difficulty
cognitive
somatic
affective
Loss of Energy
Tiredness or Fatigue
appetiitte
sleeping
Loss of Interest
Loss of Interest in Sex
Pessimism
Loss of pleasure
Sadness
Irritability
Agitation
Crying
e21
e17
e16
e20
e19
e18
.36
.69
.63
.67
.66
.57
.63
.65
.48
.59
.45
.82
.79
.54
.49
.49
.53
.83
.73
.73
.52
.59

Figure 1 Confirmatory Factor Analysis Model of BDI-II, Amharic Version among cancer patients

5.3. Reliability

Cronbach's Alpha coefficient was α=0.860. So, 86% of the BDI-II items among cancer patients are highly reliable or internally consistent. Inter item total correlation was r>0.36 expect for item number 21, loss of interest in sex, which loads 0.15.

Cronbach's Alpha coefficient was also calculated for each factor, hence; cognitive, somatic, domain and showed acceptable value of reliability. **Table 8.**

	Factor 1 (cognitive domain)	Factor 2 (somatic domain)	Factor 3 (affective domain)
Cronbach's Alpha (α)	0.81	0.74	0.77

Table 8 Cronbach's Alpha value (α) of the three factors separately.

6.DISCUSSION

This study evaluated the psychometric properties and factor structure of BDI-II among cancer patients in Black lion. The finding indicates that BDI-II yields acceptable psychometric properties and three factor structure among those population.

With regard to reliability, BDI-II demonstrates high reliability(52)among those population. And the outcome was very near to reliability obtained among CHD patients(33),HIV-positive patients(34) and patients with multiple Sclerosis(35).This data showed reliability less than those observed among primary medical patients(36),Adult clinical inpatients(37),substance abusers(38) and Bangla version of Bangla population(63) for which reliability was excellent(52).Still the Amharic version BDI-II was reliable among those population(52).

Inter-item total correlation was $r \geq 0.3$ expect for loss of interest in sex. This result was the same with ITCC which was found among patients with multiple sclerosis(35)even if the item which did not load effectively was 18 which deals with appetite. This difference appears because, in context of our country asking and talking about sex openly is culturally unacceptable. And this cultural impact has been affected the outcome of the item.

Principal axis factoring suggested that three factors (cognitive, somatic, affective) summarize the data parsimoniously. Although a few items loaded differently, the three extracted factors were the same factors found among CHD patients in Indonesia Version(33),patients with chronic pain(68),HIV-positive patients(34) and population those who are substance abusers(38) in Myanmar version of BDI-II. Therefore, it seems that the structure of depression in cancer patients similar to that of which found among CHD patients, patients with chronic pain, HIV-positive population and Bangla population.

As mentioned previously, a few items in this samples demonstrated different factor pattern from those population with the same factor structure. i.e. pessimism loads more on affective domain than cognitive domain which observed among patients with chronic pain(68).Also, indecisiveness and concentration difficulty load on cognitive domain, than affective unlike that of patients with chronic pain. And loss of interest loads more on somatic domain rather than affective domain which was observed among patients with chronic pain. These differences are in line with the hypothesis of (97) which states that affective domain related items may get loaded on different domain basing its rout on the back ground and diagnostic compression of the population under study.

In this study, the somatic domain had greater mean than the other domains, which was also the case among HIV-positive patients (34) even if the mean number was different. Being chronic disease and physical impact of those diseases, somatic domain can measure depression in both of those population.

To adequately discriminate between categories of symptoms as assessed by the Amharic version BDI-II, labeling which was proposed by first authors(71)were applied rather than labeling of letter researchers(77).

The CFA resulted supported a three-factor model (cognitive, affective and somatic) that is consistent with study of (34,38,68,71).This result of CFA was confirmed by comparing the recommended model in the study which has been adopted in researches(38,68).

In this study CFI was 0.855 which is less than value obtained in parallel study(68).This difference may be due to study population. But the CFI of cancer patients was the same as that of HIV-positive population(34).This similarity may be the type of the diseases and the impact they have on the victims.

7.CONCLUSION AND RECOMMENDATION

In conclusion, despite its limitation, this study has provided evidence that the Amharic version BDI-II has sound psycho- metric properties among cancer patients in low–middle-income countries.i.e., Ethiopia. So BDI-II in Amharic version can measure depression among cancer patients.

This study recommends further evaluation of psychometric properties of BDI-II among cancer patients from another countries. And also, more validation of the tool among large sample size do recommended by this study. If applicability of the tool among other groups (i.e. General population, Patients with active depression,) can be done, it will

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