.

Cross-cultural validation of the Patient Health Questionnaire (PHQ-9) in Bahasa Indonesia to measure depression among people affected by leprosy in Central Java, Indonesia

Thesis for the master of Medicine, VUmc

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1 Abstract

Introduction
Although leprosy is curable since 1981, people affected by leprosy still experience stigmatisation and discrimination. The stigma towards people affected by leprosy may lead to a decreased quality of life. Few studies have focused on major depressive disorder as a comorbidity of leprosy. There is no simple and widely validated instrument that has been validated to diagnose depression among people affected by leprosy. For this study, the PHQ-9 was cross-culturally validated in Bahasa Indonesia. The PHQ-9 has been validated in other countries in Asia, however not in Indonesia or for people affected by leprosy.

Objective
The purpose of this study is to (A) perform a cultural validation of the PHQ-9 in Bahasa Indonesia and (B) to measure the depression status of people affected by leprosy with the validated PHQ-9.

Methods
This study took place in Central Java. The PHQ-9 was translated and back-translated and after that, 15 semi-structured interviews and one focus group were conducted for assessing the conceptual, operational, item and semantic equivalence. After analysing the interviews, a refined version of the PHQ-9 was made. For the quantitative part, 114 people affected by leprosy and 54 control group were included to assess the measurement equivalence. Forty-nine people repeated the questionnaire one week later. The following psychometric properties were calculated using SPSS: internal consistency, construct validity, reliability, floor and ceiling effects, interpretability, cut-off score and the prevalence of depression.

Results
Two questions were adapted and after that all questions were considered relevant, comfortable and clear. The internal consistency was defined with Cronbach's alpha and 0.718. Floor and ceiling effects were not found. The reliability was measured with the repeated interviews. The intra-class coefficient was 0.713 (p<0.001). For the construct validity, the Spearman correlation showed that there was a positive correlation between the total score of the PHQ-9 and the total score of the BDI-II. The means and standard deviations of the people affected by leprosy group and the control group showed that the PHQ-9 was able to distinguish between groups defined by gender, leprosy-related physical problems and visible signs of leprosy. A cut-off point of 10 was adopted on the basis of the original validation of the PHQ-9. The results showed a higher prevalence of depression in the people affected by leprosy group, but this was not significant.

Conclusion
The PHQ-9 is suitable to be used as a screening instrument of depression for people affected by leprosy and in Indonesia. The item, semantic and measurement equivalence are good.

2 Background

2.1 Leprosy

Leprosy is also known as Hansen's disease and belongs to the group of neglected tropical diseases (NTDs). It is a chronic infectious disease caused by *Mycobacterium leprae*. After the incubation period, the bacillus mainly affects the skin, the peripheral nerves, mucosa of the upper respiratory tract and the eyes. (1) Neuropathy of the nerves that lie close to the surface results in loss of feeling, loss of pain sensation and loss of autonomic function, especially in the palms and soles. Because of the loss, there is a dysfunction of the protective reflexes which can result in burns and other wounds that infect easily. (2)

Since 1981 it is possible to cure leprosy with multidrug therapy (MDT). Treatment stops the progression of the disease and kill the bacteria. After treatment has started the patient cannot infect other people anymore. Reversing the impairments with the MDT is impossible. (3) According to the World Health Organization, 210,671 new cases were detected worldwide in 2017. Most of them are found in India, Brazil and Indonesia. In total there are between one and two million persons with leprosy-related disabilities worldwide. (4)

2.2 Stigma

People affected by leprosy experience stigmatisation and discrimination because of several reasons. Sermrittirong and van Brakel (5) found that stigma related to leprosy is caused by a range of factors including the visible impairments in people affected by leprosy, the beliefs regarding the cause of leprosy, the fear for transmission of leprosy, the perception that people affected by leprosy are inferior and the public health measures regarding the treatment for leprosy which are perceived to be different than for other diseases. (5,6) Weiss defines stigma: 'A social process, experienced or devaluation that results from experience, perception or reasonable anticipation of an adverse social judgment about a person or group.' (7) The stigma towards people affected by leprosy has many negative consequences, for example, social exclusion, delay in health seeking and a decreased quality of life. (6) Despite the fact that leprosy is curable and that patients are not contagious anymore after treatment has started, other challenges remain: persisting discrimination and stigmatisation against people with leprosy, which may cause delay in detecting new patients and stopping the transmission of leprosy. (8)

2.3 Major depressive disorder

A major depressive disorder, simply known as 'depression', is a common, but neglected complication of stigmatisation. (9) Depression is a severe mood disorder. Symptoms affect how you feel, think and handle daily activities, for example sleeping, eating and working. People lose interest in activities, often have low self-esteem and may experience physical complaints that cannot be explained. To diagnose someone with depression, the symptoms must be present for at least two weeks. (9) Up to now, few studies have focused on the psychiatric comorbidity of leprosy. For example, in 2015, Attama (10) found that 49% of the subjects affected by leprosy in Nigeria suffered a depression. The high rate of depression among people affected by leprosy was in agreement with the results of Olivier (11) in India. They found that 30.8% of the subjects affected by leprosy were diagnosed with a current depression and 32.5% were diagnosed with a depression in the past. (11) In Bangladesh, Tsutsumi (12) concluded that leprosy-related stigmatisation is associated with decreased general mental health. Of the subjects interviewed, 87.9% had felt isolated from their family and 68.5% from the society. An experience of

being hurt by the attitude of their family against leprosy happened to 85% of the subjects. A study performed in New York using the PHQ-9 concluded that depressive symptoms are common in patients with wounds, especially when the wound duration was longer than 90 days. (13) This study also mentioned that depression has a negative effect on wound healing. (13,14)

2.4 Patient Health Questionnaire 9 (PHQ-9)

The Patient Health Questionnaire (see appendix 7.1 for the English version) is based on the DSM-IV criteria for a major depressive disorder and can be used for screening, diagnosing, monitoring and measuring the severity of depression. (15) The PHQ-9 has nine questions that can be answered with: not at all (0), several days (1), more than half the days (2) and nearly every day (3). For example the question: *'Over the last two weeks, how often have you been bothered by little interest or pleasure in doing things?*' The sum of the points given for each question is the depression severity score. (15) To use the questionnaire for a provisional diagnose for major depressive disorder, at least five out of the nine questions need to be answered with more than half the days and question one or two needs to be one of them. The last question, about hurting yourself or commit suicide, counts whenever it is present. The original validation of the PHQ-9 shows that the optimal cut-off score is 10 with a sensitivity of 88% and a specificity of 88% for major depressive disorder. (16) A comparison study showed that the algorithm method has a lower sensitivity for detecting depression than the cut-off point of 10. (17) When a person has major depressive disorder as provisional diagnose, the height of the score can say something about the depression severity. In Table 1 the PHQ-9 scores, provisional depression severity and proposed treatment actions for the English version are shown. The PHQ-9 can be completed in a few minutes, is easy to score by the clinician and non-specialist and can be used as screening, diagnosing and monitoring instrument. Therefore we chose for this instrument for the current study. As far as we know, the PHQ-9 had not yet been cross-culturally translated and validated in Bahasa Indonesia.

Table 1 Scores of the PHQ-9 and their provisional depression severity and proposed treatment actions for the English version.

PHQ-9 Score	Depression severity	Proposed Treatment Actions
0 – 4	None to minimal	None
5 – 9	Mild	Watchful waiting and repeating the questionnaire at follow-up
10 – 14	Moderate	Treatment plan, considering counselling, follow-up and/or pharmacotherapy
15 – 19	Moderately severe	Active treatment with pharmacotherapy and/or psychotherapy
20 – 27	Severe	Immediate initiation of pharmacotherapy and if severe impairment or poor response to therapy, expedited referral to a mental health specialist for psychotherapy and/or collaborative management

2.5 Beck Depression Inventory-II

In this research, the Beck Depression Inventory-II is used as an additional tool (see appendix 7.3). The Beck Depression Inventory-II consists of 21 questions and was recently validated for the general Indonesian population by Ginting (18) in 2013. Beck's Depression Inventory has 21 items. Every item consists of four statements. The respondent has to choose the statement that fits the best to his or her situation. For example, in item one of the questionnaire the following answer possibilities are: 'I

do not feel sad', 'I feel sad', 'I am sad all the time and can't snap out of it' and 'I am so sad and unhappy that I can't stand it'. The first option scores 0 points, the second 1 point, the third 2 points and the last 3 points. The study showed that the BDI-II is a reliable and valid instrument to assess depression in the general population with a cut-off score of 17 points . (18) For this study, we chose for the PHQ-9 instead of the BDI-II because the there was expected that the PHQ-9 is shorter and faster in use.

2.6 Sociographic data of the research area

Indonesia is located in south-east Asia and is one of the most populated countries. The total population was 266,794,980 on the first of July 2018. (19) Indonesia is an archipelago of more than 17,000 islands with a total of 1,904,569 square kilometres and lies between the north-Pacific Ocean and the Indian Ocean. Bahasa Indonesia is the official language, but there are more than 700 languages used. In 2010, 87.2% of the total population was Muslim, 7% Protestant, 2.9% Roman Catholic and 1.3% others or not specified. (20) Jakarta is the capital city, located on the island Java. The gross domestic product was 3.603 US Dollar in 2016. Indonesia is a middle-income country and has made a lot of improvement in reducing poverty the last twenty years. The life expectancy was 67 years for males and 71 years for males in 2016. (21)

Semarang, the city from where the research will be performed, is located on the north coast as the capital city of Central Java. At the end of 2017, the population of Semarang consisted of 1,658,552 people (823,173 male and 835,379 female), which makes Semarang the fifth populous city of Indonesia.

Figure 1 Map of Indonesia. (20)

2.6.1 Major depressive disorder in Indonesia

According to the WHO (2017), there are approximately 9.1 million cases of depressive disorder (3.7% of the total population) in Indonesia. However, several studies found a higher prevalence of depression among the Indonesian population. For example, Ferrari (22) found a prevalence of 12.1%. Peltzer (23) concluded that 21.8% of the national Indonesian population suffered a depression and 21.1% of the Javanese people. It is important to keep in mind that there can be a cultural variation in the presentation of depression. Brandt and Boucher (24) suggested that there can be different expressions and terms for depression. Few studies have investigated the expression of depression among the Indonesian population. Brintnell (25) concluded that the presentation of a depression in Indonesia has

a lot in common with the western representation, but will be influenced by cultural differences. For example, the Javanese people are considered the most '*halus'*. This means that they will keep their emotions to themselves, which makes it harder to recognize depression among Javanese people. They also concluded that it is important to include the aspects of religion and spiritual interconnectedness, because these are used as coping mechanisms. (25) Widiana (26) found that Javanese people use the term '*bingung'* (feel confused) to describe how they feel when they feel depressed. Peltzer (23) did research on risk factors for depression among the Indonesian population. They concluded that younger age, stressors (childhood adversity and disaster experience), lack of social support, health risk and behaviour variables are risk factors for developing depression in the Indonesian population. (23)

3 Objectives and research questions

3.1 Objective

The purpose of this study is to (A) perform a cultural validation of the PHQ-9 in Bahasa Indonesia, and (B) to measure the depression status of people affected by leprosy with the validated PHQ-9.
Until now, there is no simple and widely accepted instrument to diagnose depression as a comorbidity of leprosy or other diseases that cause skin lesions or disabilities. For this research, we will focus on people affected by leprosy. Most tools have been designed for use in high-income countries and have not been validated in other countries. Therefore, there is a need to cross-culturally validate an existing instrument to assess depression in countries where leprosy is endemic.

3.2 Specific research questions

1. Does the cross-culturally translated PHQ-9 have adequate conceptual, item, semantic, operational and measurement equivalence to diagnose depression among people affected by leprosy in Central Java, Indonesia?
2. What is the prevalence and severity level of depression among persons affected by leprosy in Central Java, Indonesia?

According to the statistics published by the WHO, the overall depression rate in Indonesia was 3.7%. (27) The hypothesis is that this figure will be significantly higher among people affected by leprosy because of the stigmatisation and discrimination that many persons affected are experiencing.

3.3 Aim

In Indonesia, one of the countries with a high number of people affected by leprosy, there is no validated tool to screen for depression and very little is known about depression as comorbidity of leprosy. This study intends to validate a screening tool that can be widely used for people with leprosy, other NTDs and other disabilities. Furthermore, it is hoped that this research will contribute to a deeper understanding of depression as a comorbidity of leprosy. A deeper understanding is necessary for better mental health care and support and funding for this care.

4 Methods

4.1 Conceptual framework

4.1.1 Herdman/Stevelink Framework

For this validation, the Herdman framework was used. This framework was developed for the translation and adaption of health-related quality of life instruments to a different culture and language and shows the extent to which the instrument is equivalent to the original in measuring what the instrument is supposed to measure. The framework consists of six types of equivalences. The first four types of equivalence are conceptual equivalence, item equivalence, semantic equivalence and operational equivalence. These types are tested by qualitative research. The fifth equivalence is measurement equivalence. This type is tested by quantitative research. According to the Herdman framework the sixth equivalence is the functional equivalence. This type of equivalence can be defined as: 'The extent to which an instrument does what it is supposed to do equally well in two or more cultures.' (28) Stevelink and Van Brakel argued that the functional equivalence is not a separate category of equivalence, but an umbrella concept that combines the first five types. They suggested using the term 'cultural equivalence' instead of functional equivalence to describe this concept. (29) Table 1 explains the types of equivalences according to Herdman. (28)

Table 2 Types of equivalence of the Herdman/Stevelink Framework.

Equivalence	Explanation
Conceptual equivalence	If the questionnaire has the same relationship to the underlying concept in both cultures.
Item equivalence	If items are equally relevant and acceptable in both cultures.
Semantic equivalence	If the meaning is the same in both languages and has a similar effect on the respondents in different languages.
Operational equivalence	If it is possible to use a similar questionnaire format, instructions, mode of administration and measurement methods.
Measurement equivalence	If the psychometric properties (reliability, responsiveness and construct validity) are acceptable in the translated version.
Cultural equivalence	The extent to which an instrument is equally suitable for use in two or more cultures.

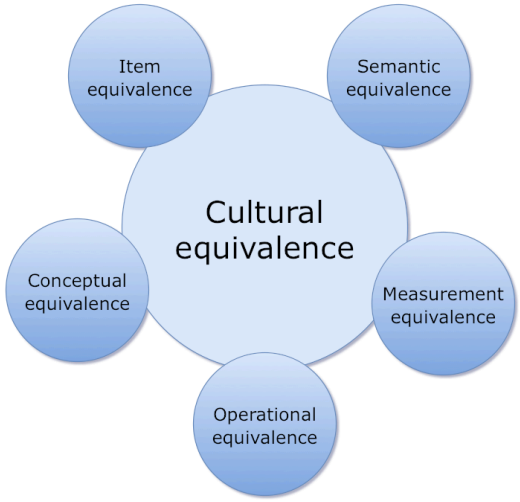

Figure 2 Model of equivalence for cultural translation and adaptation (Stevelink, 2013).

4.1.2 *Psychometric properties*

The measurement equivalence can be examined by analysing the psychometric properties. Herdman (28) only used the reliability, responsiveness and construct validity as psychometric properties. Terwee (30) provided a more extended description of the quality criteria for the measurement equivalence. Besides reliability, responsiveness and construct validity, they added content validity, internal consistency, criterion validity, reproducibility agreement, floor and ceiling effects and interpretability. Table 2 shows an overview of the definition and quality criteria of these psychometric properties. (30)

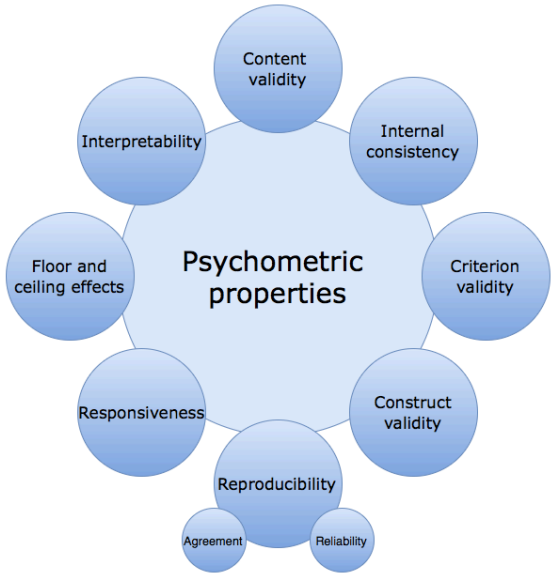

Figure 3 Oversight of the psychometric properties (Terwee, 2007).

Table 3 Definition and quality criteria of the psychometric properties (Terwee, 2007).

Psychometric property	**Definition**	**Quality criteria**
Content Validity	*'The extent to which the domain of interest is comprehensively sampled by the items in the questionnaire.'*	A clear description of: - The aim of the measurement - The target population - The outcome measures - Item selection and reduction Besides that, the questionnaire needs to be short and simple. The target population and the experts in the field need to be involved in the item selection and reduction.
Internal consistency	*'The extent to which in a (sub)scale are intercorrelated, thus measuring the same construct.'*	First, if necessary, a factor analysis needs to be done and after that, the Cronbach's alpha coefficient needs to be calculated per scale or sub-scale. A coefficient of 0.7 or higher is acceptable.

Psychometric property	Definition	Quality criteria
Criterion validity	*'The extent to which scores on a particular questionnaire relate to a gold standard.'*	The arguments have to be convincing that a standard is 'gold' and the correlation with the gold standard needs to be higher than 0.7.
Construct validity	*'The extent to which scores on a particular questionnaire relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured.'*	The specific hypotheses need to be formulated before the start of the data collection. At least 75% of the results need to be in accordance with the specific hypotheses.
Reproducibility	*'The degree to which repeated measurements in stable persons (test-retest) provide similar answers.'*	
Agreement	*'The extent to which the scores on repeated measures are close to each order (absolute measurement error).'*	The minimal important change (MIC) needs to be lower than the smallest detectable change (SDC_{group}) or there need to be given convincing arguments that the agreement is acceptable.
Reliability	*'The extent to which patients can be distinguished from each other, despite measurement errors (relative measurement error).'*	The intra-class correlation (ICC) coefficient needs to be calculated. A coefficient between 0.5 and 0.75 indicate moderate reliability, between 0.75 and 0.90 good reliability and a coefficient higher than 0.90 is excellent reliability.
Responsiveness	*'The ability of a questionnaire to detect clinically important changes over time.'*	To measure the responsiveness the area under the receiver operating characteristics (ROC) curve (AUC) is measured. An AUC of 0.70 or higher is adequate.
Floor and ceiling effects	*'The number of respondents who achieved the lowest or highest possible score.'*	Less than 15% of the respondents achieved the highest or lowest possible scores.
Interpretability	*'The degree to which one can assign qualitative meaning to quantitative scores.'*	The interpretability of the scores will be evaluated with the mean and 95% confidence interval with at least four relevant subgroups of the patients.

For this research, it was not possible to measure the criterion validity, because there no golden standard measure was available. The responsiveness can only be measured in a longitudinal study, therefore the responsiveness could not be measured in this study. The MIC cannot be reliably calculated, since no criteria for 'important change' are available, so just calculating the SDC was considered sufficient.

For the construct validity, the following hypotheses were formed:

1. There is a significant positive correlation between the total score of the PHQ-9 and the total score of the BDI-II
2. The mean score of the PHQ-9 is significantly lower in the control group than in the group of people affected by leprosy.

4.1.3 Process of translation and adaptation of instrument

To cross-culturally translate the PHQ-9 the 'process of translation and adaptation of instruments' according to the WHO was used. (31) The first step of this process is the forward translation. This must be done by one translator, preferably someone who is experienced in the field of leprosy and speaks fluently English and Bahasa Indonesia. It is important that the translator translates the questionnaire more conceptually than literally. This step had already been performed. On the official website of the PHQ-screeners, there is an Indonesian version available.[ref or footnote] Although the translation was already done, the tool had not been validated. The native Indonesian translators and supervisors checked the questionnaire and agreed on the translated version of the official website. When the first step is performed, an expert should reflect the translated questionnaire. Engaging a panel of psychiatrists, as is done in some studies, was outside the scope of this study. Any inadequate expressions or concepts and sensitive subjects were discussed with the translators and the staff at the Faculty of Psychology of Diponegoro University. The third step of the process is the back-translation by someone who speaks English and Bahasa Indonesia and does not have any knowledge about the subject. This was performed by a student of the English Faculty of Diponegoro University. After the back-translation and comparison with the original English version, the questionnaire was ready to be pre-tested.

4.2 Study design

This study used a cross-sectional validation design including a qualitative and quantitative approach.

4.3 Study population and study sample

The data was collected from the beginning of July 2018 to the end of September 2018 in cooperation with Diponegoro University (Semarang), Difabel Slawi Mandiri (Tegal), Donorojo Hospital (Jepara), the Community Health Office of Semarang and the Provincial Health Office of Central Java. Several 'Puskesmas' (community health centres) helped us with locating participants and informing them about the research. The study population for the quantitative part consisted of adults affected by leprosy in Semarang. For the quantitative part, the study population consisted of people from Central Java affected by leprosy and the control group consisted of people not affected by leprosy or another disability. Most of the participants of the control group were family members of the leprosy patients.

4.3.1 Inclusion criteria

- People affected by leprosy
- People with the age of sixteen years or older
- People who gave informed consent
- People who can communicate in Bahasa Indonesia

4.3.2 Exclusion criteria

- People diagnosed with a mental disorder
- People who cannot give the answers independently

4.4 Sample size and sampling method

4.4.1 Qualitative part

For the qualitative part of this study, we aimed to conduct in-depth semi-structured interviews with people affected by leprosy. (31) Besides one-to-one semi-structured interviews, we aimed to conduct a focus group discussion with people affected by leprosy. For both interviews, a convenience sample was used. In the focus group, we planned to discussed the knowledge of the participants about depression and the factors they think are important to be happy or which factors make one sad.

4.4.2 Quantitative part

The quantitative part consisted of interviews with people affected by leprosy and a control group of people not affected by leprosy. The control group had the same inclusion and exclusion criteria, except that they are not affected by leprosy. According to Terwee (30) the sample size had to have a minimum size of 90. Both groups represented both males and females. For the quantitative part, a random sample was needed for assessing the prevalence of depression, which can also be used for assessing the measurement properties. In association with the Faculty of Public Health of the Diponegoro University and the District Health Office of Semarang we wanted to draw an imagine of how many people affected by leprosy are living in Jepara and Tegal. Unfortunately, there was no access to the data about leprosy patients and therefore it was not possible to get a random sample. For the control group, people who were not affected by leprosy were interviewed. For example, the neighbours of the leprosy patients.

4.5 Technical methods

4.5.1 Qualitative part

First of all, the purpose of the interview was explained to the respondent and the respondent was asked to give informed consent for the semi-structured interview. After this, the following sociodemographic variables were collected: age, gender, marital status, education level, employment status, income level, time since diagnose, whether they participated in a self-care or self-help group and whether they have received any psychological help or rehabilitation assistance. Once the sociodemographic variables were collected, an audio recorder was switched on and the PHQ-9 questions were read out loud one by one in Bahasa Indonesia by the translator and the respondent was asked to answer each question with: not at all, several days, more than half the days or nearly every day. For example: ‘Over the last 2 weeks, how many times have you been bothered by having little interest or pleasure in doing things.’ After each item of the PHQ-9, the translator asked questions about the specific item to test the item, semantic and operational equivalence. After completing the whole instrument, questions were asked about the whole interview and their experience with depression. After the interview, the respondents received compensation for their travel costs and a small incentive. In Appendix 7.1 an overview is given of the questions and structure of the interview. Table 5 gives an overview of the general questions that can be asked to collect data for the different

equivalences. Each equivalence was analysed and tested while collecting the data. After each interview the translator transcribed the information to English and the data was analysed critically and thoroughly. Adjustments were made to the questionnaire if the information was relevant and an improvement for the interview. It was important that more than one respondent mentioned the improvement or unclarity and gave a good explanation or example for it. For example, when someone says that certain items are not clear and the respondent comes up with a clearer question or word, the questionnaire can be adjusted and re-tested in the next interview. We kept a detailed log of changes and reasons why these changes were made. The changes were discussed with the translators and supervisors. With this information, we were able to describe the item, semantic and operational equivalence. The PHQ-9 was refined for several questions and after testing these changes, it proved ready to use for the quantitative part.

Table 4 Quality criteria of the different types if equivalences (Stevelink, 2007).

Equivalence	**Quality criteria**	**Example questions to test the equivalence**
Conceptual equivalence	"At least a mention of one of the following: 1) an assessment of the local population's conceptualization of the construct, or 2) an assessment of the appropriateness of the measure in the target setting, or 3) theoretical arguments questioning or accepting conceptual equivalence."	- Do you know what depression is? - Do you feel comfortable talking about your feelings?
Item equivalence	"Description of the assessment of either 1) the relevance or acceptability of individual items to the target population, or 2) item discussed in the light of any quantitative or quality analyses results, or 3) discussion of adaptations made based on findings regarding individual items."	- Can you repeat the question in your own words? - Is this question relevant to you? - Did you feel uncomfortable?
Semantic equivalence	"Description of at least two of the key issues related to semantic equivalence: 1) contact with developers, or 2) reference to the translation guidelines used, or user manual including translation instructions, or 3) details provided on the translation procedure, or 4) meaning of keywords and phrases, or 5) a description of any problems or difficulties encountered during the translation."	- Can you repeat the question in your own words? - Can you explain your answer? - Are there any words unclear to you?

Operational equivalence	"A description of at least one or two of the key issues listed under operational equivalence: 1) an assessment of missing data 2) discussion on administration format 3) pre-testing of the instrument"	- What did you think of this questionnaire? - Were the answer options clear to you? - Do you have any remarks/comments on this interview?

4.5.2 Quantitative part

The sociodemographic variables were collected and informed consent was singed. After that, the PHQ-9 was read out loud in Bahasa Indonesia by the translator and the respondent was asked to answer each question with: 'not at all (0)', 'several days (1)', 'more than half the days (2)' or 'nearly every day (3)'. After completing the PHQ-9, the BDI-II was read out loud and the respondent was asked to give an answer to each question. This procedure was the same for the study group as for the control group. After the interview all the respondents received a small appreciation for their participation.

In order to measure the repeatability of the questionnaire 49 interviews of the quantitative part were repeated six to ten days later. (30) At that time, the interview was repeated in exactly the same way as the first time.

4.6 Outcome measures

The outcome measures for research question 1 are conceptual, item, semantic, operational and measurement equivalence.
The outcome measure for research question 2 is the severity level of depression symptoms measured as the mean PHQ-9 sum score and BDI-II sum score for people affected by leprosy compared to the control group.

4.7 Data management and analysis

IBM SPSS Statistics 24 was used to analyse the data.

Internal consistency: To analyse the reliability of the questionnaire, we will divine the Cronbach's alpha coefficient. A coefficient of 0.7 or higher is acceptable. (32) Besides the Cronbach's alpha, the corrected item-total correlation was reported. This is the correlation between the score of the item and the overall score. An average between 0.2 and 0.4 represents an optimal level of correlation. (33)
Cut-off score: To find the optimal cut-off score for the PHQ-9, the 95th percentile of the control group was used.
Reliability: To analyse the reliability of the questionnaire the intra-class correlation coefficients will be calculated. A coefficient between 0.5 and 0.75 indicate a moderate reliability, between 0.75 and 0.90 a good reliability and a coefficient higher than 0.90 is an excellent reliability. (30)
Interpretability: The interpretability of the scores was evaluated with the mean and 95% confidence interval. (30)
Floor and ceiling effects: This is the number of participants who have the lowest or highest score. This should be under 15%. (30)

4.8 Ethical consideration

Ethical approval was obtained from the medical ethics committee of the Diponegoro University Semarang.

Every respondent in the quantitative and the qualitative part of the study was asked to give written informed consent. The respondents were informed about the aim of the study, which was to validate the PHQ-9 and test the outcomes of the questionnaire and that all data will be used anonymously. The participants were not obligated to answer all the questions when they had given informed consent. We informed the respondents that if they appeared to need and wanted further help because of depressive symptoms according to the PHQ-9, we would refer them to their nearest health facility. All the collected data was saved without personal identifying information.

5 Results

In this section, we will discuss the results of the qualitative part and the quantitative part of the research.

5.1 Results qualitative part of the research

First, the characteristics of the respondents will be described who participated in the semi-structured interviews and the focus group. After that, the findings of the conceptual, item, semantic and operational equivalence will be discussed.

5.1.1 Characteristics of the participants

Participants were recruited from five different community health centres in Semarang. The sample size for the semi-structured interviews was 15 participants who were all diagnosed with leprosy. The focus group discussion was held with 7 participants affected by leprosy. For the focus group discussion 10 participants confirmed to attend the focus group. However, 3 patients did not show up. Table 5 shows the demographic information of the participants. The mean score of the PHQ-9 for the participants who participated in the semi-structured interviews was 4.67 (SD 4.75; range 0-16).

Table 5 Demographic information participants semi-structured interviews and focus group discussion

Sex *n (%)*	Male	9 (40.9%)
	Female	13 (59.1%)
Age in years	Mean (min – max)	51.0 (18 – 73)
Marital status *n (%)*	Married	16 (72.7%)
	Unmarried	4 (18.2%)
	Widowed	2 (9.1%)
Religion *n (%)*	Christian	2 (9%)
	Muslim	20 (90.9%)
Residence *n (%)*	Rural	1 (4.5%)
	Urban	21 (95.5%)
Education level *n (%)*	Illiterate	1 (4.5%)
	Read and write only	2 (9.1%)
	Primary school	8 (36.4%)
	Secondary school	11 50%)
Employment status *n (%)*	Unemployed	9 (40.9%)
	Employed	9 (40.9%)
	Volunteer	1 (4.5%)
	Student	1 (4.5%)
	Retired	2 (9.1%)
Income level per month *n (%)*	No income	10 (45.5%)
	Less than Rp 2,300,000	5 (22.7%)
	More than Rp 2,300,000	7 (31.8%)
Visible signs of leprosy *n (%)*	No	6 (27.3%)
	Yes	16 (72.7%)
Time since diagnose in years	Mean (min – max)	3.2 (0.25 – 13)

Participation in a self-care group *n (%)*	Yes	0 (0%)
	No	22 (100%)
Psychiatric care *n (%)*	Yes	0 (0%)
	No	22 (100%)

5.1.2 Conceptual equivalence

During the second part of the semi-structured interviews, open questions led the interview that led to conversations about the effects of having leprosy, feelings of shame, depression and sharing feelings with others.

Life change after diagnosis

The participants were asked if they thought their life changed after the diagnosis 'leprosy'. Eight people answered this question with no; two people said a little and five people said yes. The main thing that was mentioned was that they felt ashamed and afraid after the diagnosis, because of the physical change and the lack of knowledge about transmission. They felt sad for a time, but everyone said that after a while they were fine with the diagnosis and did not feel sad anymore. Two participants reported that they did not tell their neighbours or family about their disease because of shame. Four participants mentioned that they were afraid of avoidance from their neighbours or friends because of their leprosy.

> *S15: 'Like other normal people, when diagnosed with leprosy, I felt sad and afraid and confused. And the society was a little bit different.*
> ***What do you mean with different?*** *I became the centre of attention. They asked me many things, also suggested me to see a doctor. Even when I said, it's okay, it will heal itself. But they keep suggested me to see a doctor. Even though I actually already start the treatment.* ***Do you think that was a positive or negative experience?*** *For me that was a negative experience. A bitter history.'*
>
> *S5: 'About two days to a month after the diagnose I felt ashamed. But now not anymore. I don't care, it is normal.'*
>
> *S3. At first [hearing about having leprosy], I was shocked. I felt down. But with some reasons I did the activity just like any other days.*
> ***Why did you feel down?*** *Like, why did I get infected by leprosy. What did I do wrong? Is it genetic? Because I never hang out with any leprosy patients. Even though I have a neighbour (leprosy patient), but we are far and we never physically contacted nor even touched. He is my relative actually. So I thought is this genetic disease? So I felt down at first. But, couple of weeks later I went to the doctor and I felt normal again.*
>
> *S8: 'Uh, well if other people heard about the diagnosis, my condition, I felt a little ashamed. But if anyone asked me, I didn't tell them the disease, I didn't know, it's just dead feeling. Like dead skin.*
> ***So, only your closest family know?*** *No, not even my closest family. Actually, I do not know myself, because Bu Ita (the PIC for leprosy) didn't tell me anything.*

So, when did Bu Ita told you? *Never, I just predict it. And I browsed, the medication is similar, and Bu Ita didn't say it clearly, but I understand that I am diagnosed with leprosy.'*

S10. I felt afraid, I felt less confident [after the diagnose leprosy]. Other people talked many things.
Was there any person who was badmouthing you or your husband? *Yes, that is right, they avoided us. Even though they avoided us, they passed us by, but they ignored us. Like they refused the food from us, because they were afraid of being infected. Just like that.* ***They said it like that?*** *Yes. Even nowadays some people still do that to us. So, I think, my neighbours do not know that leprosy need months to infect someone. They do not know.*
So, even now some people are still doing that to you? *Yes. Well they are not avoiding me, it is normal to me. But my husband is less confident due to his disability. So he never comes to social activities. I come to some social activities. I am active, because I am the breadwinner since years ago, ten years already. Even though I am working as household assistant, but at least I make some money even though just a little.*

Depression and sharing feelings

Six people did not know what depression was. The others defined depression. The things that came up were: feelings stressed, feeling hopeless, no motivation to live, having too many things in mind, suicide, lack of confidence and having problems. If participants did not know what depression was, we asked them what came up to their mind when they heard the term '*putus asa*' (hopelessness). The following things were said about '*putus asa*': suicidal, the feeling of giving up, if you do not want anything and no motivation to take the medicine or live. Five participants said that they do not feel comfortable sharing their feelings with someone if they feel down, sad, depressed or hopeless. Ten people felt comfortable to share their feelings with relatives (see Table 6). The main reason to not share feelings was that they thought it was a private matter and it is not usual to share sad feelings.

S11: ***Have you ever felt sad?*** *Yes, I have, but I kept it for myself. I never say it to my wife.*

S8: Yes, I feel comfortable to share my feelings, because maybe they have solutions. Like sharing, who knows they have solutions. So it can reduce the depression.

S3: If it's talking to my parents, I still feel comfortable. But if it's talking to my close neighbour, no, I don't feel comfortable. I never share my feelings about leprosy.

S4: No never, never shared feelings, I feel shy, I can't stand the laugh with my close friends.

S13: If I felt sad, I kept it for myself. I won't let anyone else know.
Why? *I just don't want to.*

S6: Yes, I did it with my younger sister. I told her like this this this, and she was like, okay just don't be sad, don't think too much, or you will be stressed, if you're tired, get some rest, if you feel tired you will feel stressed.

Table 6 Oversight of the question to test conceptual equivalence.

Question	Answer	N
Did your life change after the diagnose leprosy?	No	8
	A little bit	2
	Yes	5
Do or did you have feelings of shame because of your condition?	No	7
	Yes	6
	Unclear answer	2
Do you think there is a difference between someone with leprosy and someone without leprosy?	No	5
	Yes, a physical difference	9
	Unclear answer	2
Do you know what a depression is?	No	6
	Yes	9
Do you feel comfortable to tell someone if you feel down/sad/depressed/hopeless?	No	5
	Yes, to:	10
	Husband/wife	6
	Husband/wife and children	1
	Husband/wife and close friends	2
	Brother/sister	1

Religion

Six participants mentioned religion in the semi-structured interviews. They prayed to God for a cure or for being accepted as a leprosy patient and thought that the disease was owned by God or a test from God. One participant mentioned that he did not felt comfortable to share his feelings with his family, but he did share his feelings with God.

> *S1: It did affect my feeling. At the beginning, the first days I knew I have leprosy, I was afraid if my friends knew that I have leprosy. I was afraid if they avoid me, so I was afraid if they knew. But, I always kept praying that they will be fine if they knew, and that everything will be fine. But I never got avoided by everyone else. It is just in my own fears.*

> *S5: ***Do your family give you support?*** Yes, like they motivate me to be cured, so I can work again.. Don't give up, disease is owned by God, not me.*

> *S6: I always pray to ask for being cured. So every day I always feel happy.*

> *S7: My feeling is, why is it like this? I think it is a test from God. Just like that. I have never felt sad.*

Family and neighbours

Most participants mentioned that they get motivation from their neighbours (if they know about the leprosy) and their family. The family motives the participants to take treatment and to go the doctor at the *'puskesmas'* (local health centre). Some participants stay motivated because they want to help their family.

> *S2: I want to live. I still want to live. If I do not want to live anymore, I will not take treatments. Right? I still want to stay healthy. I want to help my wife, my children, my grandchildren.*

S5: Even though I am sick, I have to keep motivated. No obstacles can stop me. Even though I have a disease, I keep motivated.
So you still feel motived? *Yes, I mean like I have a family, children, that is why I feel motivated. If I don't, then I don't want to work, just stay at home. In my opinion, feeling of strong, even though I am sick, I still feel motivated. I remember my wife and children.*
How was your family to you? *They motivate me to be cured, so I can work again.*
What kind of support? *Yes, if I go to work again. Don't give up, disease is owned by God, not me. One thing for sure is that, that was what I will always remember so I will keep motivated. If I don't get cured, I will be excommunicated by my neighbourhood. I want to be cured.*

S6: Sometimes I feel like this. Why my disease is not cured yet. I take the medicine for years. But I want to be cured so I have to stay motivated. My environment, my neighbours they motivate me. If I never go out of the house, they will ask me. Why are you always inside of the house? My legs are hurt, if you miss me just come to my house

S14: They [family] gave me advice. They motivate me. "Don't give up, take the medicine, whatever they give you, take it."

5.1.3 Interview key informant

To gain more knowledge about depression in Indonesia, we met with the lecturer Dr Annastasia Ediati from the Faculty of Psychology, Diponegoro University. She said that depression is associated with withdrawal from the social society (living in a dark room, not eating and not sleeping). Indonesian people see it as the end spectrum of depression and have no clue about the mild or moderate depression. In the daily language, Indonesian people will use the term '*stres'* to express depressed feelings. The term stress is used for the normal stress, depression, burn-out and other mental health problems. For example, when they see a schizophrenic person, they will call that person stressed. People won't recognize the term depression ('*depressi'* in the Indonesian language). The problem with treating depression is the health-seeking behaviour. In most cases, people do nothing and try to live with it until someone becomes aware of their problems and forces them to go to a psychiatrist. Depression is only recognized when it is moderate or severe. People want to cure themselves and keep trying that. An interesting development is that people are noticing that something is wrong through social media. When they have followers, their peers will notice that there is something different. For example, when they are not posting anything. Another problem with mental health in the small villages is '*pasung*'. '*Pasung*' is physical restraint and confinement of the mentally ill. (34) Dr Annastasia said that people will be put in '*pasung*' when someone is aggressive and the mental hospital is not reachable. In their opinion this is the only way to get a safe environment for their family.
Furthermore, she said that Indonesian people are always thinking of what other people would think of them. They don't want to cause shame for the family and keep their problems to themselves. At last, she said that Javanese people easily give 'yes' as an answer. They are culturally trained to make other people happy and to not disappoint them. The 'yes' they give is sometimes not a real yes. She said the following about interviewing the leprosy patients:

'*I think leprosy patients in leprosy communities will not trust you. They will never say it, but they will have an awkward feeling, and that will influence their answers.*'

She had no comments on the PHQ-9.

5.1.4 Focus group discussion

Unfortunately, the translation of the focus group discussion came after the quantitative part, so we were not able to adapt the PHQ-9 to the results of the focus group discussion. The participants discussed the definition of a depression, which factors influence how they feel, how they think you can notice that someone is depressed or feels sad and if they think leprosy is a risk factor for developing depression or feeling sad.
The participants gave the following answers as explanations for depression: stress, having a past trauma, mental pressure, easily getting mad, feeling offended by negative words and feeling insecure.

We asked about the factors that affect depression and the main factors that came up was economic problems and not being able to work. These two factors were most important according to the participants. After that, a bad relationship with neighbours or family was an important factor for the participants to feel down. Next, health problems were discussed and put after the bad relationship with neighbours or family. The participants did not come up with health problems as a risk factor for depression, but the translator suggested it. The translator asked if health problems can also affect your feeling. The group answered with: yes, if the health problems result in not being able to work. Furthermore, rivalry with colleagues or neighbours and complaints at work or from family were mentioned. The participants described someone who is depressed as always daydreaming, having a lot of things on their mind and not talking about it, not socialising/being alone and easily getting mad. None of the participants knew or had met someone diagnosed with depression and never thought that someone had depressive symptoms in their environment.

> *F1: 'Having many problems but always keep it buried inside their heart. Not letting it out to friends or family. If the problems are buried too deep, then they will be crazy.'*

The translator asked if they think leprosy could be a risk factor for developing depression. The conclusion of the conversation was that having leprosy does not make you feel depressed, but they could understand if you have a more severe form of leprosy, that you could feel sad or depressed.
Two participants said they feel just ordinary. One person felt sad in the beginning because he did not know it could be cured, but after that, he felt normal. Others felt they had to accept it and pray to God. One woman said that when she asks God for forgiveness, she feels better.

> *F3: 'Sometimes I feel sad, sometimes I feel a little bit burdened, but well, accept whatever it is, if God give me this trial so I have to accept it so I will be closer to God.'*

Finally, factors were discussed that make people happy. All the participants said that being cured makes them happy. After that, having money and being able to work (participating in the economy), supporting family and a good relation with friends and family.

5.1.5 Item and semantic equivalence

The PHQ-9 had already been translated by the phq.screeners.com. We discussed the translated version of the PHQ-9 with our two translators and the two supervisors from the Public Health Faculty of Diponegoro University. According to the translators and supervisors, the translation was done well, so we used the translation of phqscreeners.com. A student from the English Faculty of Diponegoro University did the back-translation. The back-translation showed only minor differences in the words

used and the meaning of the questions had not changed. The only thing that was noticeable was that 'Feeling bad about yourself' in question 6 was translated as 'Feeling unconfident'. This was discussed with the translator and supervisor, and the conclusion was that this had the same meaning in Bahasa Indonesia. Therefore, there was decided to leave the question as it was.

The table below illustrates what the participants thought about the relevance/suitability of the items, whether they felt comfortable with the items and whether the items were clear to them. Overall, no one felt totally uncomfortable with the questions. Some participants said they felt uncomfortable answering the questions about the items because they found it hard to explain their answer and talk about the question. In some cases, the participants said that a particular question was not relevant to their situation, because they did not experience it, for example, thoughts about hurting themselves. It was difficult for the respondents to repeat the questions in their own words. After the first interviews, this was discussed with the translator, and the conclusion was that the questions were concise and used an easy language, so the respondents could not think of an easier option. The respondents were asked to explain their answer and with this, it was possible to figure out if they understood the question. There were no difficulties with questions 3, 4 and 5. One respondent interpreted question 1 as being about having sex, but later the respondent explained that he also had interest in other activities, such as house chores. One respondent answered question 1 with 'never', but explained later that he experienced lack of interest every day. Most of the respondents explained their answer to question 2 by explaining that they feel motivated because they still take their medicine. Several respondents did not understand why we asked them about suicide and hurting yourself with question 9. The respondents explained their answer by telling that they still take their medicine:

> *'I want to live. I still want to live. I do not want to live anymore, I will not take treatments. Right? I still want to stay healthy. I want to help my wife, my children, my grandchildren.'*

For two respondents it was not clear or relevant that we asked question 9. One respondent said it is not normal to have a wish to be dead and one said that leprosy patients do not have to feel inferior.

> *'No it is not relevant. Why would I have a wish to be dead? No it is not normal.'*

> *'It is not clear, we have leprosy, but we do not need to feel like that. We have to stay motivated. We do not have to feel inferiority or what is that, unconfident.'*

For several respondents, question 6 and question 8 were too long. Table 7 shows the changes that have been made to make these questions more understandable. After these changes, there were no comments on the length of the questions anymore. Question 7 had two examples, which were not suitable for every person, so a third example has been added to make the question more clear. See the table in the appendix for the clarity, relevance, comfort and notes per question

Table 7 Adaptions that have been made on the PHQ-9.

Item	Original	New	Reason
Question 6	Feeling bad about yourself — or that you are a failure or have let yourself or your family down.	Feeling bad about yourself. For example that you feel a failure or that you have let yourself or your family down	Three respondents said that the question was too long. They understood the language. We put 'for example' before 'that you are a failure or have let yourself or your family down'. We did this to make it more clear that the last sentence are examples.
Question 7	Trouble concentrating on things, such as reading the newspaper or watching television	Trouble concentrating on things, such as reading the newspaper, watching television or cooking.	Three respondents said that they do not read the newspaper or watch television. When they said that, the translator used cooking as a different example. They understood this example and were able to answer the question, therefor we added this example to the question.
Question 8	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	8a. Moving or speaking so slowly that other people could have noticed 8b. Being so fidgety or restless that you have been moving around a lot more than usual	Four respondents said that this question was too long and one of the four said that the language was difficult. Question eight consists of two different things, so we decided to divide the question into option A and B. The last respondents had no difficulty answering 8a and 8b. For calculation of the total score of the PHQ-9 only the highest score of 8a or 8b will be included.

5.1.6 Operational equivalence

In general, people understood the meaning of the questions and no one reported difficulties about the questions at the end of the interview. After finishing the PHQ-9 the participants were asked whether they felt comfortable with the interview and whether they thought it was relevant/suitable to their situation. All the participants said that it was relevant and that they felt comfortable during the interview.

In the translated version of the PHQ-9 from the website phqscreeners.com 'more than half the days' was used as an answer option. After evaluating the questionnaire with the translators and supervisors, there was decided to change it into 'more than seven days' to make the answer option more concrete. All the respondents said that the answer options were clear to them. One respondent said that it was sometimes hard to remember the last two weeks, but the respondent did understand the concept. Two respondents suggested changing the last two weeks in the last week or 'have you ever experienced this in your life'. During the interview, many respondents answered 'sometimes' instead of 'several days' or 'more than half the days'. The interviewer had to make it clear that they needed to

choose one option. If the respondent found it hard to specify 'sometimes', the interviewer asked how many days they experienced it.

The average time for the semi-structured interviews was 32 minutes and the focus group discussion took 1 hour and 2 minutes.

5.2 Results quantitative part

5.2.1 Characteristics

After adapting the PHQ-9 on the basis of the findings of the qualitative validation study, the data for the quantitative part were collected in September 2018 in Tegal and Jepara. In total, we interviewed 114 people affected by leprosy and 55 people without leprosy or another disability. Most of the participants of the control group were related to the leprosy patients. One interview of the control group was not valid and was therefore excluded because the participant did not give the answers herself. In the group of people affected by leprosy, two participants came from East Java and were staying in Jepara for treatment. We decided to not exclude these interviews. Two people stopped with the interview after the PHQ-9 and did not want to proceed with the BDI-II. The last two participants of the qualitative part were included in the quantitative sample. Table 8 shows an overview of the characteristics of both groups.

Table 8 Characteristics of the group of people affected by leprosy and the control group.

	Options	People affected by leprosy		Control group	
Sex *n (%)*	Male	58	(50.9%)	27	(50.0%)
	Female	56	(49.1%)	27	(50.0%)
Age in years	Mean (min – max)	48.2 (20–79)		41.8 (19–70)	
Marital status *n (%)*	Unmarried	14	(12.3%)	5	(9.3%)
	Married	78	(68.4%)	47	(87.0%)
	Widowed	19	(6.7%)	2	(3.7%)
	Divorced	3	(2.6%)	0	(0.0%)
Religion *n (%)*	Christian	9	(7.9%)	10	(18.5%)
	Muslim	104	(91.2%)	44	(81.5%)
	Other	1	(0.9%)	0	(0.0%)
Residence *n (%)*	Rural	107	(93.9%)	53	(98.1%)
	Urban	7	(6.1%)	1	(1.9%)
Education level *n (%)*	Illiterate	9	(7.9%)	2	(3.7%)
	Read and write only	6	(5.3%)	1	(1.9%)
	Primary school	83	(72.8%)	34	(63.0%)
	Secondary school	16	(14.0%)	13	(24.1%)
	Higher education	0	(0.0%)	4	(7.4%)
Employment status *n (%)*	Unemployed (health reasons)	42	(36.8%)	0	(0.0%)
	Unemployed (other reasons)	11	(9.6%)	9	(16.7%)
	Employed	61	(53.5%)	43	(79.6%)
	Student	0	(0.0%)	2	(3.7%)

Income level per month *n (%)*	No income	53	(46.5%)	13	(24.1%)
	Less than Rp 2,00,000	61	(53.5%)	36	(66.7%)
	More than Rp 2,300,000	0	(0.0%)	5	(9.3%)
Leprosy-related physical problems	No	23	(20.2%)		
	Yes	91	(79.8%)		
Occurrence of visible signs of leprosy *n (%)*	No	18	(15.8%)		
	Yes	94	(82.5%)		
Time since diagnosis in years	Mean (min – max)	20.2 (0.2–84)			
Participation in a self-care group *N (%)*	No	30	(26.3%)	42	(96.3%)
	Yes	84	(73.7%)	2	(3.7%)
Psychiatric care	No	71	(62.3%)	50	(92.6%)
	Yes	43	(37.7%)	4	(7.4%)

In the group of people affected by leprosy the mean score of the PHQ-9 was 6.1 (standard deviation (SD) 4.53), range 0-21). The mean score of the BDI-II was 12.7 (SD 9.98; range 0-47). In the control group the mean score of the PHQ-9 was 4.93 (SD 4.11; range 0-16). The mean score of the BDI-II was 9.37 (SD 8.74; range 0-33). The average time for administering the PHQ-9 was 3.0 minutes.

5.2.2 Floor and ceiling effects

There were no floor and ceiling effects found for the PHQ-9 and the BDI-II in either group. In the group of people affected by leprosy, seven people (6.1%) scored zero points, and no one scored the highest score. In the control group, six people (11.1%) scored the lowest score, and no one scored the highest score.

5.2.3 Internal consistency

The PHQ-9 has been shown to be a unidimensional questionnaire, and therefore we did not perform a factor analysis. Cronbach's alpha for the whole scale was 0.718 for the group of people affected by leprosy. Cronbach's alpha was lower for every item deleted. The alpha for the control group was 0.730. If both groups were combined, Cronbach's alpha was 0.724. Table 9 gives an overview of the Cronbach's Alpha and the corrected item – total correlation.

Table 9 Overview of the Cronbach's Alpha per group and per item deleted and the corrected item – total correlation.

	People affected by leprosy		Control group		Both groups together	
Cronbach's alpha	0.718		0.730		0.724	
	Cronbach's Alpha if item deleted	Corrected item - total correlation	Cronbach's Alpha if item deleted	Corrected item - total correlation	Cronbach's Alpha if item deleted	Corrected item - total correlation
Q1	0.708	0.319	0.708	0.392	0.711	0.343
Q2	0.672	0.528	0.694	0.476	0.682	0.508
Q3	0.704	0.372	0.701	0.435	0.705	0.395
Q4	0.687	0.431	0.661	0.617	0.684	0.486
Q5	0.703	0.354	0.723	0.386	0.713	0.358
Q6	0.685	0.441	0.721	0.312	0.698	0.414
Q7	0.697	0.377	0.705	0.412	0.704	0.383
Q8	0.669	0.529	0.697	0.511	0.679	0.526
Q9	0.715	0.254	0.735	0.276	0.723	0.250

5.2.4 Interpretability

Interpretability of the quantitative score was investigated with the help of the control group and the group of people affected by leprosy. See table 10 for an overview of the means and the standard deviation of the total score of the PHQ-9 for the subgroups.

Table 10 Means and standard deviations of the PHQ-9 for subgroups.

		People affected by leprosy			*Control group*		
	Options	N	Mean	Standard deviation	N	Mean	Standard deviation
Diagnosed with leprosy	No	54	4.93	4.11			
	Yes	114	6.10	4.53			
Sex	Male	58	7.12	5.21	27	4.70	4.19
	Female	56	5.04	3.42	27	5.15	4.10
Age in years	≤ 45	47	5.62	4.04	32	4.75	4.13
	> 45	67	6.43	4.84	22	5.18	4.17
Marital status	Unmarried	36	6.17	4.78	7	5.57	3.99
	Married	78	6.06	4.44	47	4.83	4.16
Religion	Christian	9	6.67	4.38	10	3.70	4.32
	Muslim	104	6.10	6.25	44	5.20	2.91
Residence	Rural	107	6.71	5.79	53	5.02	4.09
	Urban	7	6.06	4.46	1	1.00	
Education level	No education	15	6.53	4.34	3	5.67	2.89
	Educated	99	6.03	4.57	51	4.88	4.19
Employment status	Unemployed (health reasons)	42	6.38	4.41			
	Unemployed (other reasons)	11	5.09	3.02	9	3.56	2.88
	Employed	61	6.08	4.86	43	5.26	4.38
Income level	No income	53	6.32	4.53	13	4.08	2.81
	Less than Rp 2,300,000	61	5.90	4.56	36	5.50	4.58
	More than Rp 2,300,000				5	3.00	2.65
Leprosy-related physical problems	No	23	4.96	4.84			
	Yes	91	6.38	4.43			
Visible signs of leprosy	No	18	4.72	4.80			
	Yes	94	6.45	4.45			
Participation in a self-care group	No	30	6.10	5.03			
	Yes	84	6.10	4.37			
Received psychological help	No	71	6.14	4.49	50	4.62	5.32
	Yes	43	6.02	4.64	4	8.75	3.91

5.2.5 Reliability

To measure the reliability of the PHQ-9 49 interviews were repeated six to ten days later under the same circumstances and with the same interviewer. We used a two-way mixed method and an absolute agreement definition. The intraclass correlation for the average measures was 0.713 with a significance of p=0.000.

5.2.6 Construct validity

As an additional tool, we used the BDI-II. The following hypothesis was formed:

> There is a significant positive correlation between the total score of the PHQ-9 and the total score of the BDI-II

A Spearman correlation was used to predict the correlation between the total score of the PHQ-9 and the BDI-II. There was a significance of $p<0.0001$ and a positive coefficient *rho* of 0.532.

The second hypothesis was:

> The mean score of the PHQ-9 is significantly lower in the control group than in the group of people affected by leprosy.

The significance for Levene's Test for equality of variances was 0.580, which means that the variability in both groups was about the same. The T-test showed a significance of 0.109, which is higher than 0.05. Therefore, while the difference is still likely to be real, this hypothesis is not confirmed.

5.2.7 Cut-off score

For the cut-off score, the 95th percentile of the control group was used. The 95th percentile of the control group has a weighted average of 13.25 points for the PHQ-9. This means that the cut-off score according to the control group should be 13. However, the frequency distribution of the control group was not normally distributed (see Figure 4).

5.3 Prevalence of depression

Table 7 shows the percentage of major depressive disorder as provisional diagnose for both groups and for different cut-off scores.

Table 7 Prevalence of depression for different cut-off points of the PHQ-9 and the BDI-II.

	Major depressive disorder as provisional diagnose	People affected by leprosy		Control group	
PHQ-9 cut-off score $\geq$ 10	Yes	25	(21.9%)	9	(16.7%)
	No	89	(78.1%)	45	(83.3%)
PHQ-9 cut-off score $\geq$ 13	Yes	13	(11.4%)	4	(7.4%)
	No	101	(88.6%)	50	(92.6%)
BDI-II	Yes	30	(26.5%)	10	(18.5%)
	No	83	(73.5%)	44	(81.5%)

6 Discussion

The purpose of this study was to test and validate the PHQ-9 in Bahasa Indonesia for people affected by leprosy in Central Java. This done by assessing the cultural equivalence between the original English version and the Bahasa Indonesia version. The first part of the cultural equivalence (conceptual, semantic, item and operational equivalence) has been assessed using a qualitative approach and the second part (measurement equivalence) with a quantitative approach. Not all the data of the qualitative part could be analysed before starting with the quantitative part of the research.

6.1 Conceptual equivalence

The conceptual equivalence was partly demonstrated. It was difficult to get a good and complete picture of the underlying concept of depression in Central Java. Some respondents had no idea of mental health or depression and found it hard to give their opinion. The main word for describing depression that came up was *'stres'.* Other things that were mentioned were feeling sad, having a trauma, easily getting mad, mental pressure, feeling insecure or lack of confidence, not socialising, committing suicide, no motivation to live or feeling hopeless. Surprisingly, the word '*bingung'* (feel confused) was not brought up, whereas Widiana (26) reported that this was a unique expression for Javanese people to describe depressive thoughts. In this study, the term *'putus asa'* (hopeless/desperate) was found to describe depressive thoughts or feeling. The concept mapping study of Brintnell (25) also found this term and put it under the cluster discouragement.

Only a few criteria of the DSM-V were mentioned when describing depression or a depressed person. The aspects like eating, energy level and sleeping behaviour were not named. This finding is contrary to a previous study about the depressive symptom profiles in Asian countries. In this study they found that insomnia was the most commonly reported symptom of depression in Indonesia. (35) Due to limited time, there was no separate discussion about each of the criteria of the DSM-V. We are therefore not sure whether the underlying concept of depression in this study includes all the criteria. No major other subjects were mentioned that did not agree with the DSM-V. Only self-isolation, which is not a criterion in the DSM-V, was mentioned often. Widiana (26) also reported this finding. They concluded that Javanese people express depression through unwillingness to be involved in their social environment. Brintnell (25) found self-isolation as an expression of depression in Central Java.

Some participants mentioned faith as support or motivation. Leprosy was mentioned by some participants as a test from or the will of God. In Indonesia, religion plays an important role in society. Purwono (36) showed religiosity is negatively associated with depressive symptoms for Muslim adolescents in Indonesia. Brintnell (25) suggested that screening tools for depression might benefit from including religion as a common coping mechanism. (25) Faith was mentioned in this study, but not in every interview. The tool might benefit from including faith as an example or adding, for example, the question: 'Reduced interest in religious activities'. It could also be possible that the instrument does not benefit from introducing faith, but that it works as a support factor or coping mechanism. Pramesona (37) concluded that religious-based interventions are effective to relieve depressive symptoms among Indonesian elderly in nursing homes. However, the semi-structured interviews did not involve a question about religion and therefore, we are not sure if this would improve the tool. Further research should focus on faith in the in-depth interviews.

One problem experienced during this study was that participants found it hard to talk about their feelings and some participants mentioned that they would never share their feelings with others. Some said they were afraid of being laughed at and others said that they just do not want to share it. A majority became nervous or self-conscious when they were asked about how they felt. They were not used to this question. In the semi-structured interviews it became clear that the knowledge about depression was not really good and in the quantitative part, most respondents did not appear to know what depression was either. Hartini (38) showed that there is a correlation between the level of knowledge about mental health and level of stigma towards people with mental health problems in Indonesia. This implies that it is essential to make people more aware of mental health problems to create a more open environment. For a better and deeper understanding of all aspects of the PHQ-9 and possible additions, we suggests that qualitative research is with more conversations per participant is needed to gain trust and a comfortable environment for sharing opinions and feelings.

6.2 Item and semantic equivalence

All the items were considered relevant and acceptable to answer. However, the last question about self-harm and suicide invoked some confusion and resistance. Most participants said they felt comfortable with the question, but some showed a different reaction. Some started to laugh nervously, and others said they did not understand why this question was asked. Even the translators in the quantitative part of the study found it hard initially to ask about suicide and started apologising for asking the question. Most of the participants were Muslim, and in the Islamic culture, it is a sin to commit suicide. The Quran forbids suicide and stresses that God is merciful (Quran:29). As shown in the semi-structured interviews and experienced by the researcher during the quantitative part, most of the participants were very religious and living by the rules of the Islam. Widiana (26) decided after qualitative analysis not to include suicidal thoughts for the Indonesian Depression Checklist because clinical psychologists were ambivalent if this item should be asked to people with depression for ethical reasons. Therefore, despite the fact that participants still said that the question was acceptable, we doubt the acceptability of the question.

After refining the PHQ-9, all the items were considered clear and understandable. Question 8 was divided into two questions, with the highest scoring item counting towards the total. This means, that if a respondent gives 2 points for question 8a and 1 point for question 8b, the 1 point for 8b is left out in the total score. In theory, it is possible that for example, the answer for question 8 would be nearly every day, but for 8a more than half the days and for 8b more than half the days. This means that there is a loss of 1 point. The researcher decided to keep it this way because this is the easiest option to carry out. A validation study in the Afaan Oromo language divided the question as well, but they did not mention any problems with the scoring. (39)

Question 6 gives two examples, namely letting yourself or your family down. During the quantitative part, it became clear that the community and neighbours play a big role in the Indonesian society. We think that also letting your neighbours or the community down can make the participants feel like a failure and therefore we recommend to add the community as an example to question 6.

6.3 Operational equivalence

The operational equivalence can be considered good. The format, instructions and mode of administrations were practical and easy to understand. Knowledge about the concepts of the

questionnaire was an advantage, but even interviewers without any experience in the field were able to use the questionnaire easily and fast after a short explanation. The participants did not report important difficulties regarding the format of the questionnaire. To explain the two-week time frame, we added an example question at the beginning of the questionnaire. This turned out to be effective. We suggest implementing more examples for the questions as part of the instrument. There are no standardised examples with each question (with exception for question 6 and 8), also not in the English version. There were no problems in this study, and one example was added to question 8, but still we think it would be of benefit to provide an example guide for the interviewers, especially when they do not have a lot of knowledge about depression.

6.4 Measurement equivalence

The measurement equivalence was partly shown.

6.4.1 Internal consistency

The PHQ-9 is known to be a unidimensional scale, which is why no factor analysis was performed. The internal consistency of the scale can be rated positive because Cronbach's alpha was above the 0.7. (30) However, the internal consistency was well below the internal consistency of the original study. The original study showed a Cronbach's alpha of 0.89 in a primary care study in the United States. (16) A validation study performed in Malaysia showed a similar Cronbach's Alpha to this study. (40) Other validation studies of the PHQ-9 in Asia (Thailand, Singapore, Nepal and China) showed a higher Cronbach's alpha than found in this study. (35,41–43) The alpha of this study is acceptable, however, according to the criteria of Terwee et al.[ref] The corrected item-total correlation indicates whether items are correlating with the overall score of the scale. A correlation less than 0.30 indicates that the item may not belong in the scale. (44) All the items but the last item had a corrected item-total correlation of >0.30, which means that the first 8 items are contributing more to the total score of the scale than the last question about suicide and self-injury. The validation in Thailand showed a lower corrected-item total correlation for question 9 than for the other questions as well. However, the correlation was just above the 0.3. (41) This finding supports the thought that asking about suicide might not be relevant and acceptable in a Muslim culture.

6.4.2 Floor and ceiling effects

No floor and ceiling effects were found. This means that it is still possible to differentiate among people with low depression scores and among those with high depression scores. (30)

6.4.3 Interpretability

Men affected by leprosy scored 2.1 points higher than women affected, but this difference was not significant at the 5% level. While the finding in our study is not conclusive, it is consistent with Attama (10) and Tsutsumi (12), who found that being a male was associated with an increased risk of psychiatric morbidity. A possible explanation for the difference in the group of people affected by leprosy might be that men feel more responsibility to gain an income for their family. In the focus group discussion, the main subject that came up was income. People said that they do not want to let their family down and it would make them unhappy if they are not able to pay for food or their child's school. However, we could not find studies that support this theory.

As hypothesised, the participants with leprosy-related physical problems scored 1.42 points higher than participants that had no physical problems. This is in accordance with previous research that showed a positive correlation between mental health and disability in leprosy patients. (45,46) The participants with visible signs scored 1.73 points higher than participants without visible signs of leprosy. There are several possible explanations for this result. They can experience more stigma and/or disability, which can result in a lower income or no work at all, lower self-esteem or decreased quality of life. (6)

We expected that participation in self-care groups would lead to a different score than no participation . A lower score could be expected, because the people in a self-care group (in this study the self-care group was a rehabilitation village) live in an environment where leprosy is understood, common and accepted. On the other hand, a higher score might be expected, because the participants that live in the rehabilitation village generally have more severe consequences of leprosy. In this study, there was no difference in mean score for both groups.

6.4.4 Reliability

The intra-class correlation showed that the PHQ-9 used for in this study has only moderate reliability. (30) However, the ICC at group level was close to good reliability (0.71). The original validation of the PHQ-9 showed an excellent test-retest coefficient of 0.84. A weakness of the retesting in that study was that they repeated the second interview 48 hours later. (16) According to Terwee (30) the second interview should be done one to two weeks later. A possible explanation for the lower reliability in this study could be that some questions were too difficult for some respondents, who have answered without properly understanding the questions. The results of the semi-structured interviews did not show a lack of clarity. It could be argued that the positive results were due the difference in the sample of the qualitative part and the quantitative part. It is recommended for further studies on this topic to conduct the qualitative part in the same area as the quantitative part.

6.4.5 Construct validity

The first hypothesis was confirmed. There was a correlation between the BDI-score and the PHQ-9 score measured with Spearman correlation (*rho*=0.53). Although the correlations of this study did not reach the 0.8, it can still be described as a strong correlation. This is because studies using social science data require a less-strong correlation than 'core' scientific data. (47) The second hypothesis was not formally confirmed since the difference in PHQ-9 score between participants affected by leprosy and the control group was not statistically significant. However, the difference is still likely to be real, since the *p*-value was only 0.10. This is likely to be due to the similarities between the participants affected by leprosy and the control group: most of the people in the control group had a family member that was affected by leprosy. A systematic review of the economic impact of having leprosy concluded that the economic impact of leprosy is high. According to Van Heuvel (48), the family of a leprosy patient may also experience economic consequences in the form of unemployment and income loss because of the stigma associated with leprosy. In the focus group discussion, the participants gave the economic situation as most import reason for feeling sad or depressed. So, if the control group may have experienced the negative effects of having a leprosy patient in the family, it may have had an effect on their level of depression also.

6.4.6 Cut-off score

As indicated in the above paragraph, it is possible that the control group was not a good reference group. Based on the 95th centile of the control group, the cut-off score should be 13, which is very high compared to the cut-off point determined in other validation studies (14,16,17,41–43,49). Due to the uncertainty of the control group, it was decided to use the cut-off point of 10 determined by Kroenke. (16)

6.5 Prevalence of depression

This study found a high prevalence of depression under people affected by leprosy in Central Java when looking at the PHQ-9 with the cut-off point of 10 and the BDI-II. This finding is consistent with previous studies that investigated the relationship between mental health and leprosy. (10–12) Because of the non-random sample size that has been used for this study (see limitations), the results may be biased. It is not possible to be certain about the prevalence figure, and therefore we cannot give a definitive comment on the prevalence of depression.

6.6 Limitations

The present study had several limitations. Firstly, it was not always clear if the participants gave a real answer or the 'socially acceptable answer'. As mentioned by Dr Annastasia Ediati, Javanese people are eager to please other people. Especially the presence of the researcher made some participants feel honoured. Most participants in the semi-structured interviews answered the questions positively. For example, when was asked: 'Is the question clear to you?' they always said yes, but it was not always clear if they totally understood the question. At the end of the interview, the participants were asked about the comfortability, relevance and clarity of the question. All these questions were answered positively by the respondents. This means that the questionnaire was either comfortable, relevant and clear for all the respondents, or they did not feel free to say so if it was not clear.

Secondly, the data of the qualitative part was collected in Semarang. Semarang is a big city, and most respondents were still under treatment for leprosy. They had discovered leprosy in an early stage, and most of them had only a few lesions on their skin and or some loss of sensation in hands or feet or strength of their muscles. Most of the participants that were interviewed for the quantitative part lived in the rehabilitation village in Jepara or visited Donorojo Hospital. In their case, the consequences of leprosy were more severe, such as open wounds, amputated fingers, hands or legs. The education level and income level was higher in the qualitative study sample. The time since diagnosis was significantly lower in the qualitative sample than in the quantitative sample. Also, none of the participants of the semi-structured interviews had participated in self-care groups or received psychological help. It would have been preferable if both groups had the same socio-demographic characteristics and the same state of disease, but, due to the numbers of (former) patients available for inclusion in the study, this was not possible.

Thirdly, it was sometimes hard to ensure the privacy of the participants. During the quantitative interviews, the participants were visited in the hospital or at home. When the researcher and interviewer did the interview at home, the whole family was really excited and wanted to join the conversation. The translator always explained that the interview was about private information and that it would be better if the interview was done with only the participant, but sometimes the participant did not bother that the family was present. This might have caused a bias in information.

Finally, the lead researcher had no Indonesian background and did not speak the language. The collection and translation of the interview data were dependent on the translator. The translator was a staff member of the Public Health Faculty of Diponegoro University, who was very busy. It was therefore not always possible to translate interview data promptly. Sometimes, the next semi-structured interviews started without reflecting on the previous interviews, because there was no translation yet. The researchers kept in close contact with the translator and asked for comments and observations after each interview. During the quantitative part, other translators were hired that had time to come to Jepara and stay for two weeks at the Donorojo Hospital.

7 Conclusions

The first aim of this study was to validate the Patient Health Questionnaire-9 for leprosy patients in Central Java. The results of this study show that there is an adequate item, semantic and measurement equivalence, but the conceptual equivalence can be improved. Further research with different and bigger samples may show ways to improve the measurement properties and gain more knowledge about depression. However, the PHQ-9 shows potential to become a useful screening tool for depression in Indonesia and for people affected by leprosy.

The second aim of this study was to determine the prevalence of depression among people affected by leprosy in Central Java. Due to a sample that was not random, it was not possible to give a definitive answer to this research question. Although the current study is based on a non-random sample of participants, the findings suggest that the prevalence of depression is still likely to be high.

We hope that the findings of this study will encourage Diponegoro University, Donorojo hospital, Difabel Slawi Mandiri and the National Leprosy Control Programme in Indonesia will continue to take into account depression as a likely comorbidity of leprosy and other disabilities and that they take the necessary measures to create an open environment and provision of staff with adequate counselling training to talk about this with the persons affected.

7.1 Recommendations

Further research is needed to investigate the concept of depression on Java. Some concepts, such as religion and suicide, need to be studied in-depth to develop a full picture and to see if these concepts need to be added or omitted from to the questionnaire. Moreover, the PHQ-9 should be tested in other areas and with a representative control group of the general society. It is recommended to bear in mind that there is still a stigma towards depression and mental health and further research will benefit from more knowledge about how to overcome the stigma. Further studies need to be carried out to test the validity of the questionnaire for people with other NTDs or disabilities.

8 Acknowledgement

First of all, I would like to thank Dr. Wim H. van Brakel from NLR for all the helpful feedback, advice and support. I would also like to thank Dean Prof dr. Hanifa Maher Denny, Dr. Bagoes Widjarnako and Ibu Praba Ginandjar from the Faculty of Public Health of the Diponegoro University for supervising, helpful comments, arranging meetings and arranging authorisation for conducting research. In particular, I would like to thank my translator and interpreter, Ms. Novia Handayani, for all the efforts she put in the study and giving my insights into the Indonesian culture and customs. Finally, I would like to thank my supervisor from VUmc, Dr. Marianne van Elteren, for the motivational speeches and supervision.

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10 Appendix

10.1 PHQ-9 in English

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

If you ticked any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

10.2 PHQ-9 in Bahasa Indonesia

KUESIONER KESEHATAN PASIEN-9 (PHQ-9)

Selama 2 minggu terakhir, seberapa sering Anda terganggu oleh masalah-masalah berikut? *(Gunakan "✔" untuk menandai jawaban Anda)*	**Tidak pernah**	**Beberapa hari**	**Lebih dari separuh waktu yang dimaksud**	**Hampir setiap hari**
1. Kurang tertarik atau bergairah dalam melakukan apapun	0	1	2	3
2. Merasa murung, muram, atau putus asa	0	1	2	3
3. Sulit tidur atau mudah terbangun, atau terlalu banyak tidur	0	1	2	3
4. Merasa lelah atau kurang bertenaga	0	1	2	3
5. Kurang nafsu makan atau terlalu banyak makan	0	1	2	3
6. Kurang percaya diri — atau merasa bahwa Anda adalah orang yang gagal atau telah mengecewakan diri sendiri atau keluarga	0	1	2	3
7. Sulit berkonsentrasi pada sesuatu, misalnya membaca koran atau menonton televisi	0	1	2	3
8. Bergerak atau berbicara sangat lambat sehingga orang lain memperhatikannya. Atau sebaliknya — merasa resah atau gelisah sehingga Anda lebih sering bergerak dari biasanya.	0	1	2	3
9. Merasa lebih baik mati atau ingin melukai diri sendiri dengan cara apapun.	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

Jika Anda mencentang salah satu masalah, seberapa besar kesulitan yang ditimbulkan karenanya dalam melakukan pekerjaan, mengurus pekerjaan rumah tangga, atau bergaul dengan orang lain?

Sangat tidak sulit	**Sedikit sulit**	**Sangat sulit**	**Luar biasa sulit**
☐	☐	☐	☐

10.3 Beck's Depression Inventory in English

Beck's Depression Inventory

This depression inventory can be self-scored. The scoring scale is at the end of the questionnaire.

1.
- 0 I do not feel sad.
- 1 I feel sad
- 2 I am sad all the time and I can't snap out of it.
- 3 I am so sad and unhappy that I can't stand it.

2.
- 0 I am not particularly discouraged about the future.
- 1 I feel discouraged about the future.
- 2 I feel I have nothing to look forward to.
- 3 I feel the future is hopeless and that things cannot improve.

3.
- 0 I do not feel like a failure.
- 1 I feel I have failed more than the average person.
- 2 As I look back on my life, all I can see is a lot of failures.
- 3 I feel I am a complete failure as a person.

4.
- 0 I get as much satisfaction out of things as I used to.
- 1 I don't enjoy things the way I used to.
- 2 I don't get real satisfaction out of anything anymore.
- 3 I am dissatisfied or bored with everything.

5.
- 0 I don't feel particularly guilty
- 1 I feel guilty a good part of the time.
- 2 I feel quite guilty most of the time.
- 3 I feel guilty all of the time.

6.
- 0 I don't feel I am being punished.
- 1 I feel I may be punished.
- 2 I expect to be punished.
- 3 I feel I am being punished.

7.
- 0 I don't feel disappointed in myself.
- 1 I am disappointed in myself.
- 2 I am disgusted with myself.
- 3 I hate myself.

8.
- 0 I don't feel I am any worse than anybody else.
- 1 I am critical of myself for my weaknesses or mistakes.
- 2 I blame myself all the time for my faults.
- 3 I blame myself for everything bad that happens.

9.
- 0 I don't have any thoughts of killing myself.
- 1 I have thoughts of killing myself, but I would not carry them out.
- 2 I would like to kill myself.
- 3 I would kill myself if I had the chance.

10.
- 0 I don't cry any more than usual.
- 1 I cry more now than I used to.
- 2 I cry all the time now.
- 3 I used to be able to cry, but now I can't cry even though I want to.

11.

0	I am no more irritated by things than I ever was.
1	I am slightly more irritated now than usual.
2	I am quite annoyed or irritated a good deal of the time.
3	I feel irritated all the time.

12.

0	I have not lost interest in other people.
1	I am less interested in other people than I used to be.
2	I have lost most of my interest in other people.
3	I have lost all of my interest in other people.

13.

0	I make decisions about as well as I ever could.
1	I put off making decisions more than I used to.
2	I have greater difficulty in making decisions more than I used to.
3	I can't make decisions at all anymore.

14.

0	I don't feel that I look any worse than I used to.
1	I am worried that I am looking old or unattractive.
2	I feel there are permanent changes in my appearance that make me look unattractive
3	I believe that I look ugly.

15.

0	I can work about as well as before.
1	It takes an extra effort to get started at doing something.
2	I have to push myself very hard to do anything.
3	I can't do any work at all.

16.

0	I can sleep as well as usual.
1	I don't sleep as well as I used to.
2	I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3	I wake up several hours earlier than I used to and cannot get back to sleep.

17.

0	I don't get more tired than usual.
1	I get tired more easily than I used to.
2	I get tired from doing almost anything.
3	I am too tired to do anything.

18.

0	My appetite is no worse than usual.
1	My appetite is not as good as it used to be.
2	My appetite is much worse now.
3	I have no appetite at all anymore.

19.

0	I haven't lost much weight, if any, lately.
1	I have lost more than five pounds.
2	I have lost more than ten pounds.
3	I have lost more than fifteen pounds.

20.

0	I am no more worried about my health than usual.
1	I am worried about physical problems like aches, pains, upset stomach, or constipation.
2	I am very worried about physical problems and it's hard to think of much else.
3	I am so worried about my physical problems that I cannot think of anything else.

21.

0	I have not noticed any recent change in my interest in sex.
1	I am less interested in sex than I used to be.
2	I have almost no interest in sex.
3	I have lost interest in sex completely.

INTERPRETING THE BECK DEPRESSION INVENTORY

Now that you have completed the questionnaire, add up the score for each of the twenty-one questions by counting the number to the right of each question you marked. The highest possible total for the whole test would be sixty-three. This would mean you circled number three on all twenty-one questions. Since the lowest possible score for each question is zero, the lowest possible score for the test would be zero. This would mean you circles zero on each question. You can evaluate your depression according to the Table below.

Total Score	Levels of Depression
1-10	These ups and downs are considered normal
11-16	Mild mood disturbance
17-20	Borderline clinical depression
21-30	Moderate depression
31-40	Severe depression
over 40	Extreme depression

10.4 Beck's Depression Inventory in Bahasa Indonesia

BDI – II

Nama :			Status Marital : (Menikah/Belum Menikah)*
Usia :	thn	Agama :	Jenis Kelamin : (Laki-laki/Perempuan) *
Pekerjaan :			Pendidikan :

*Coret yang tidak perlu

Petunjuk : Kuesioner berikut ini terdiri dari 21 kelompok pernyataan. Mohon setiap kelompok pernyataan dibaca dengan cermat, setelah itu pilih satu dari pernyataan di dalam setiap kelompok yang paling menggambarkan perasaan anda selama 2 minggu terakhir, termasuk hari ini. Lingkarilah angka di samping pernyataan yang anda pilih. Apabila di dalam satu kelompok terdapat beberapa pernyataan yang terasa sama, lingkarilah angka yang paling tinggi dari kelompok pernyataan yang terasa sama tersebut. Pastikan bahwa anda tidak memilih lebih dari satu pernyataan di dalam setiap kelompok, termasuk pernyataan 16 (Perubahan pola tidur) dan pernyataan 18 (Perubahan selera makan).

1. Kesedihan 0. Saya tidak merasa sedih. 1. Saya sering kali merasa sedih. 2. Saya merasa sedih sepanjang waktu. 3. Saya merasa sangat tidak bahagia atau sedih sampai tidak tertahankan.	**3. Kegagalan masa lalu** 0. Saya tidak merasa gagal. 1. Saya telah gagal lebih dari yang seharusnya. 2. Saya melakukan banyak kegagalan di masa lalu. 3. Saya merasa gagal sama sekali (betul-betul gagal).
2. Pesimis 0. Saya tidak meragukan masa depan saya. 1. Saya merasa lebih meragukan masa depan saya dibanding biasanya. 2. Saya merasa segala sesuatu tidak berjalan dengan baik bagi saya. 3. Saya merasa masa depan saya tidak ada harapan dan akan semakin buruk.	**4. Kehilangan gairah** 0. Saya mendapatkan kesenangan dari hal-hal yang saya lakukan. 1. Saya tidak menikmati sesuatu seperti biasanya. 2. Saya hanya mendapatkan sangat sedikit kesenangan dari hal-hal yang biasanya bisa saya nikmati. 3. Saya tidak mendapatkan kesenangan sama sekali dari hal-hal yang biasanya bisa saya nikmati.

5. Perasaan bersalah 0. Saya sama sekali tidak merasa bersalah. 1. Saya merasa bersalah atas banyak hal yang telah atau seharusnya saya lakukan. 2. Saya sering merasa bersalah. 3. Saya merasa bersalah setiap saat.	**8. Mengkritik diri sendiri** 0. Saya tidak mengkritik atau menyalahkan diri sendiri lebih dari biasanya. 1. Saya mengkritik diri sendiri lebih dari biasanya. 2. Saya mengkritik diri sendiri atas semua kesalahan yang saya lakukan. 3. Saya menyalahkan diri sendiri untuk semua hal-hal buruk yang terjadi.
6. Perasaan dihukum 0. Saya tidak merasa bahwa saya sedang dihukum. 1. Saya merasa bahwa mungkin saya akan dihukum. 2. Saya yakin bahwa saya akan dihukum. 3. Saya merasa bahwa saya sedang dihukum.	**9. Pikiran-pikiran atau keinginan bunuh diri** 0. Saya tidak berpikir untuk bunuh diri. 1. Saya berpikir untuk bunuh diri, tetapi hal itu tidak akan saya lakukan. 2. Saya ingin bunuh diri. 3. Saya akan bunuh diri seandainya ada kesempatan.
7. Tidak menyukai diri sendiri 0. Saya tidak merasa kecewa pada diri sendiri. 1. Saya kehilangan kepercayaan pada diri sendiri. 2. Saya merasa kecewa pada diri sendiri. 3. Saya benci pada diri sendiri.	**10. Menangis** 0. Saya tidak menangis lagi seperti biasanya. 1. Saya lebih sering menangis dibanding biasanya. 2. Saya menangis bahkan untuk masalah masalah kecil. 3. Rasanya saya ingin sekali menangis tetapi tidak bisa.

11. Gelisah 0. Saya tidak lagi merasa gelisah atau tertekan dibandingkan biasanya. 1. Saya merasa lebih mudah gelisah atau tertekan dibanding biasanya. 2. Saya sangat tertekan dan gelisah sampai sulit untuk berdiam diri. 3. Saya sangat gelisah sehingga harus senantiasa bergerak atau melakukan sesuatu.	**14. Merasa tidak layak** 0. Saya merasa layak. 1. Saya merasa tidak layak dan tidak berguna dibandingkan biasanya. 2. Saya merasa lebih tidak layak dibanding orang lain. 3. Saya merasa sama sekali tidak layak.
12. Kehilangan minat 0. Saya tidak kehilangan minat untuk berelasi dengan orang lain atau melakukan aktivitas. 1. Saya kurang berminat untuk berelasi dengan orang lain atau terhadap sesuatu dibandingkan biasanya. 2. Saya kehilangan hampir seluruh minat saya untuk berelasi dengan orang lain atau terhadap sesuatu. 3. Saya tidak berminat akan apapun.	**15. Kehilangan tenaga (semangat)** 0. Saya memiliki tenaga (semangat) seperti biasanya. 1. Saya memiliki tenaga lebih sedikit dibanding yang seharusnya saya miliki. 2. Saya tidak memiliki tenaga yang cukup untuk berbuat banyak. 3. Saya tidak memiliki tenaga yang cukup untuk melakukan apapun.
13. Sulit mengambil keputusan 0. Saya dapat mengambil keputusan sebagaimana yang biasanya saya lakukan. 1. Saya agak sulit mengambil keputusan dibanding biasanya. 2. Saya lebih banyak mengalami kesulitan dalam mengambil keputusan dibanding biasanya. 3. Saya sangat mengalami kesulitan setiap kali mengambil keputusan.	**16. Perubahan pola tidur** 0. Saya tidak mengalami perubahan apapun dalam pola tidur saya. 1a. Saya tidur lebih dari biasanya. 1b. Saya tidur kurang dari biasanya. 2a. Saya tidur jauh lebih lama dari biasanya. 2b. Saya tidur sangat kurang dari biasanya. 3a. Saya tidur hampir sepanjang hari. 3b. Saya bangun 1-2 jam lebih awal dan tidak dapat tidur kembali.

17. Mudah marah

0. Saya tidak lebih mudah marah seperti biasanya.
1. Saya lebih mudah marah dibanding biasanya.
2. Saya jauh lebih mudah marah dibanding biasanya.
3. Saya mudah marah sepanjang waktu.

18. Perubahan selera makan

0. Selera makan saya tidak berubah (tidak lebih buruk) dari biasanya.

1a. Selera makan saya kurang dari biasanya.

1b. Selera makan saya lebih dari biasanya.

2a. Selera makan saya sangat kurang dibanding biasanya.

2b. Selera makan saya sangat lebih dibanding biasanya.

3a. Saya tidak punya selera makan sama sekali.

3b. Saya ingin makan setiap waktu.

19. Sulit berkonsentrasi

0. Saya mampu berkonsentrasi seperti biasanya.
1. Saya tidak mampu berkonsentrasi seperti biasanya.
2. Saya sangat sulit untuk tetap memusatkan pikiran terhadap sesuatu dalam jangka waktu yang panjang.
3. Saya merasa saya tidak mampu berkonsentrasi dalam semua hal.

20. Capek atau Kelelahan

0. Saya tidak lebih capek atau lelah dibanding biasanya.
1. Saya lebih mudah capek atau lelah dari biasanya.
2. Saya merasa capek atau lelah untuk melakukan banyak hal yang biasanya saya lakukan.
3. Saya terlalu capek atau lelah untuk melakukan hampir semua hal yang biasanya saya lakukan.

21. Kehilangan gairah seksual

0. Saya tidak melihat adanya perubahan pada gairah seksual saya.
1. Gairah seksual saya berkurang, tidak seperti biasanya
2. Saya menjadi sangat kurang berminat pada aktivitas seksual saat ini.
3. Gairah seksual saya hilang sama sekali.

10.5 Guideline semi-structured interview

Introducing the research and translator (Anne)
Thank you very much for wanting to participate in this study! My name is Anne and together with Novi were are conducting the interview. Most of the speaking will be done by Novi, because she speaks Bahasa. Novi is working at the Faculty of Public Health at UNDIP and I am studying there.

Explaining the research and the aim of this interview (Ibu Novia)
The aim of this study is to test a questionnaire to screen for depression at people affected by leprosy in Central Java. In this part of the research we are pre-testing the questionnaire. For this interview we want to conduct the questionnaire and after that ask you questions about the questionnaire itself and about leprosy and depression.

Signing informed consent (Ibu Novia)
First, we need to sign informed consent. You have to know that all the data will be anonymously. If you feel uncomfortable or for any reason don't want to answer a question, you can stop anytime. See appendix 7.7 for the informed consent format.

Conducting sociodemographic questions (Ibu Novia)
Now were are going to ask you some general questions.

Assessing item, semantic and operational equivalence (Ibu Novia)
During this part research statements will be read out loud to you one by one. After each statement you answer how often that was for the last two weeks. The answer possibilities are not at all, several days, more than half the days and nearly every day. For example:

'How many days did you watch television for the last two weeks?'

- □ Not at all
- □ Several days
- □ More than half the days
- □ Nearly every day

After you asked the question, I will ask you some questions about the statement. Remember that there are no right or wrong answers.

1. What came to your mind when you heard this question?
2. Can you explain your answer (not at all, several days, more than half the days or nearly every day)?
3. Can you repeat this question in your own words?
4. Were any words in the question unclear to you?
    a. If yes, which word and why?
    b. Can you think of a different word that would make it more clear for you?
5. Was this question relevant to your situation?
    a. If yes, can you give an example?
    b. If no, why not?

6. Did you feel uncomfortable answering this question?
    a. If yes, why did you feel uncomfortable?
    b. Can you think of any change that would make you feel less uncomfortable?

We completed all the items of the questionnaire. Now I want to ask you some questions about the whole questionnaire.

1. What did you think of this questionnaire?
2. Were the answer options clear for you?
    a. If not, why not?
    b. Did you understand the two-week time framework?
    c. Can you think of any change that would make it more clear for you?
3. Was the questionnaire relevant to your situation?
4. Did you feel uncomfortable during this interview?
    a. If yes, which question(s) or words made you feel uncomfortable?
    b. Why did it make you feel uncomfortable?
    c. Can you think of any change that it wouldn't make you feel uncomfortable?
5. Do you have any remarks or comments about this interview?
6. Are there things we need to know we did not ask?
7. Do you have any questions?

<u>Assessing conceptual equivalence (Ibu Novia)</u>
These were the questions about the interview itself. Now I want to ask you some questions about depression.

1. I understand that you have (had) leprosy. What can you tell me about it?
    a. When did it start?
    b. Did/do you get treatment?
        i. If yes, why?
        ii. If no, why not?
2. Did your life change after the diagnose leprosy?
    a. If yes, how did it change?
3. Do you have feelings of shame because of your condition?
    a. If yes, why?
4. According to your experience, how do other people (family, neighbours, community members) think about your condition?
    a. Are these positive or negative experiences for you?
    b. Do you talk to other people about your condition?
        i. With whom can you talk about it?
    c. Do you receive support from other people?
        i. If yes, how?
        ii. If no, why not?

5. Do you think there is a difference between people with leprosy and without leprosy?
    a. If yes, what do you think the difference is?
6. Can you tell me something about how living with leprosy affects how you feel?
7. Do you know what depression is?
    a. If yes, can you explain it to me?
    b. If no, have you heard of the term 'putus asa'?
        i. If yes, can you explain it to me?
8. Do you talk with people in your direct environment about depression/mental health?
    a. If yes, what is said about it?
        i. Do you feel comfortable during this talks?
    b. If no, why not?
9. Do you feel comfortable to talk about how you feel?
    a. If yes, why?
    b. If no, why not?
10. Do you think that having leprosy affects how you feel?
    a. If yes, how does it effect it?
    b. If no, why not?

<u>Ending interview (Anne)</u>

The interview is now finished. Thank you very much for your time. I appreciate your willingness to participate in this study.

10.6 Guideline focus group discussion

Welcome

- Welcome everyone to the focus group discussion and thanking for participating in the focus group discussion.

Introduction

- Introduction of the researchers
- Introduction of the participants
- Ask the participants to make nameplates

Purpose of the focus group discussion

- The translator introduces the study and explains the aim of the focus group.
- The aim of the study is to develop a questionnaire. This questionnaire will be to screen for mental health among leprosy patients. The purpose of this focus group is to learn more about depression and discuss the factors that will have an influence on how you feel.
- The informed consent forms will be signed and the personal data collected.

Ground rules

- We would like to hear everyone.
- There are no right or wrong answers: we are not seeking for consensus.
- Confidential: what is said in this room, stays in this room.
- Stay with the group and please try to avoid to have side conversations.
- Put away your cell phones if possible.
- We will be tape recording the group. We want to capture everything you say, but will not identify anyone by name in the report.

Focus group discussion

Question 1: *Do you know what a depression is?*

Participants writing down their definition of depression. After this, the interviewer will read out loud all the answers and discuss the answers with the group.

Question 2: *What factors do you think have influence on getting a depression/feeling sad/'bingung'?*

Participants writing down factors that have influence on getting a depression. After this, the interviewer will read out loud all the answers and discuss the answers with the group. Besides that, the factors will be ranked from most important to less important.

Examples: younger age, stressors (childhood adversity and disaster experience), lack of social support, health risk and behaviour variables

Question 3: *How can you notice that someone has a depression/feels sad?*

Participants writing down symptoms of depression. After this, the interviewer will read out loud all the answers and discuss the answers with the group.

Question 4: *Do you think having leprosy is a risk factor for getting a depression/feeling sad? Why?*

Participants will discuss this question together.

Question 5: *Which things give you a happy feeling?*

Participants write down things that make them happy. After this, the interviewer will things that make the participants happy will be ranked. This will be done by marks.

0 marks = does not make you happy
1 mark = makes you a bit happy
2 marks = makes you really happy

Examples: family, friends, food, good health, money, etc.

Ending

- Are there any questions?
- Thanking the participants for the focus group discussion.

10.7 Informed consent form English version

Mode of administration: Verbal
Principle investigator: Anne van der Linden
Organization: Netherlands Leprosy Relief and Diponegoro University
Title of study: Cross-cultural validation of the Patient Health Questionnaire (PHQ-9) in Bahasa Indonesia to measure depression among people affected by leprosy in Central Java, Indonesia

Introduction

The aim of the study is to (A) perform a cultural validation of the PHQ-9 in Bahasa Indonesia, and (B) to measure the depression status of people affected by leprosy with the validated PHQ-9.

We want to translate the words and the sentences in the questionnaire so that everyone can understand. Therefore we want to ask you the questions and would like to know what you think about the questions. If you think that the questions are too personal, we can skip the question.

Your participation in this research is voluntary, which means that you can decide to stop at any time of the interview.

The interview will be recorded. To protect your privacy, we will not share your information with anyone outside the research team. The information will be stored in a safe place and all the collected data will be saved without personal identifying information.

Do you have any questions?

Consent of participants
I have understood the information, and the researcher has answered my questions. I have the opportunity to refuse to participate in this study. I am a voluntarily participant in this study.

Name participant: ……

Signature: ……..

Date: ...../...../..... (day/month/year)

Name researcher: ……..

Signature: ……

Date: ...../...../..... (day/month/year)

10.8 Overview of the answers about the clarity, relevance and comfort per question given in the semi-structed interviews

Table 11 Clarity, relevance and comfort per question.

Question	Subject	Yes	A little bit	No	Unclear answer	Notes
Q1	Clear	13	1	0	1	- One respondent asked what kind of things about the question. - One respondent was a little bit confused and therefore a little bit uncomfortable with the question.
	Relevant/suitable	14	0	0	1	
	Comfortable	14	1	0	0	
Q2	Clear	14	0	1	0	- One respondent said to understand the question, but the question needed to be explained - One respondent found the question not relevant because he did not feel hopeless. - One respondent felt a little bit uncomfortable, because the language was difficult for her.
	Relevant/suitable	13	0	1	1	
	Comfortable	14	1	0	0	
Q3	Clear	14	0	0	1	- One respondent said that the question was not relevant, but did not explain why. - One respondent said that she tried hard to feel comfortable.
	Relevant/suitable	12	0	1	1	
	Comfortable	14	1	0	0	
Q4	Clear	14	0	0	1	
	Relevant/suitable	15	0	0	0	
	Comfortable	15	0	0	0	
Q5	Clear	14	0	0	1	
	Relevant/suitable	14	0	0	1	
	Comfortable	15	0	0	0	
Q6 version 1	Clear	8	0	3	0	- Three respondents said the question was too long.
	Relevant/suitable	11	0	0	0	
	Comfortable	11	0	0	0	
Q6 refined version	Clear	4	0	0	0	
	Relevant/suitable	4	0	0	0	
	Comfortable	4	0	0	0	
Q7	Clear	14	0	1	0	- One respondent asked to repeat the question and said that she was confused and therefore a little bit uncomfortable with the question. She could not explain why the question was confusing. She said that the words were clear and that the question was not too long. - Three respondents said that they do not read the newspaper or watch television, with these respondents the example cooking was used.
	Relevant/suitable	13	0	0	2	
	Comfortable	14	1	0	0	

Q8 version 1	Clear	6	0	4	1	-	Four respondents said that the question was too long and one respondent said the language was difficult but understandable and suggested to simplify the language for other people. - One respondent said the question was almost relevant.
	Relevant/suitable	8	1	0	3		
	Comfortable	10	0	0	1		
Q8-A refined version	Clear	4	0	0	0		
	Relevant/suitable	4	0	0	0		
	Comfortable	4	0	0	0		
Q8-B refined version	Clear	4	0	0	0		
	Relevant/suitable	4	0	0	0		
	Comfortable	4	0	0	0		
Q9	Clear	14	0	1	0	-	One respondent said that the question was not clear, because he did not understand why we would ask this question to leprosy patients: 'we are not inferior'. - Two respondents said the question was not relevant, because they had no wish to be dead.