Validation of the GAD-7 (Malay version) among women attending a primary care clinic in Malaysia

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ABSTRACT

INTRODUCTION: Anxiety is a common mental health disorder in primary care, with a higher prevalence among women compared to men.

AIM: This is the first study to validate the Generalised Anxiety Disorder-7 questionnaire (GAD-7) as a case-finding instrument for anxiety in a primary care setting in Malaysia. The objective was to determine the diagnostic accuracy of the Malay version of the GAD-7 in detecting anxiety among women.

METHODS: This cross-sectional study was conducted in a government-funded primary care clinic in Malaysia. Consecutive women participants attending the clinic during data collection were given self-administered questionnaires including the GAD-7 (Malay version). Participants then were selected using systematic weighted random sampling for Composite International Diagnostic Interviews (CIDI). The GAD-7 was validated against the CIDI reference standard.

RESULTS: The response rate was 87.5% for the questionnaire completion (895/1023), and 96.8% for diagnostic interviews (151/156). The prevalence of anxiety was 7.8%. The GAD-7 had a sensitivity of 76% (95% CI 61%–87%), a specificity of 94% (88%–97%), positive LR 13.7 (6.2–30.5) and negative LR 0.25 (0.14–0.45).

DISCUSSION: The Malay version of the GAD-7 was found to be valid and reliable in case-finding for anxiety in this study. Due to its brevity, it is a suitable case-finding instrument for detecting anxiety in primary care settings in Malaysia.

KEYWORDS: Validation; anxiety; primary care; women; Malaysia

Introduction

Increasingly, anxiety is being recognised as a common mental disorder in primary care settings,[1] with generalised anxiety disorder (GAD) being the most prevalent disorder.[2] A World Health Organization (WHO) cross-cultural study conducted in primary care clinics in 14 developed and developing countries found that anxiety disorders were common in nearly all countries.[3] Studies have found consistently that the prevalence is two to three times higher among women compared to men.[2–4] GAD is found to be associated with depression, somatic symptom burden, functional impairment and high use of health care services.[1,5,6]

In Malaysia, mental disorders were ranked fourth as the leading cause of burden of disease, based on the 2000 Malaysian National Census.[7] The per capita burden of disease for mental disorders in women was due predominantly to unipolar major depression, followed by anxiety disorders. The second and third Malaysian national health and morbidity surveys NHMS II (1987–1996)[8] and NHMS III (1997–2006)[9] found that psychiatric morbidity was more common among women

compared to men. The prevalence of psychiatric morbidity detected by the General Health Questionnaire was found to be 11.1% and 12.1% among women, respectively.[8,9] Based on these findings, Malaysia began prioritising early detection and treatment of mental health problems in primary care settings in its Ninth Malaysia Plan (2006–2010). High risk groups identified for these programmes were women, adolescents, children and the elderly.[10]

The seven-item Generalised Anxiety Disorder scale (GAD-7) has been developed recently for use in primary care.[1,5] It is a self-reported questionnaire with demonstrated good reliability with a sensitivity for diagnosing anxiety (cut point ≥8) of 92% and specificity of 76%.[1] The GAD-7 has been found to be a good case-finding instrument for GAD, panic disorder, social anxiety disorder and post-traumatic stress disorder (PTSD), and is the most appropriate for use in primary care settings.[5]

This paper is part of a larger study funded under the Ninth Malaysia Plan (2006–2010).[10] The objectives of the study were to determine (1) the prevalence of depression and anxiety among women, and their associated factors, and (2) the validity of the Malay versions of depression and anxiety questionnaires in a primary care clinic in Malaysia, namely the Patient Health Questionnaire-9 (PHQ-9), the GAD-7, the two questions with help question (TQWHQ) and a single anxiety question with help question.

Primary care clinics in Malaysia are busy and over-crowded with patients, with time constraint being a major problem. Brief case-finding instruments for anxiety and depression are required in the Malaysian language, Malay. Our aim is to determine the validity and diagnostic accuracy of the GAD-7 (Malay version) in a primary care setting. The results on the prevalence of anxiety and validation results for the TQWHQ are published elsewhere.[11,12]

Methods

We designed and analysed this study according to the STARD (STAndards for the Reporting of Diagnostic accuracy studies) statement.[13] We used a cross-sectional study design and data were col-

lected over a duration of eight weeks from 10 December 2009 to 30 January 2010. We validated the GAD-7 in the Malay language against the Composite International Diagnostic Interview (CIDI) anxiety module.

Instruments

GAD-7 (Malay version)

After we obtained permission from the copyright holder, the GAD-7 was translated following the guidelines for cross-cultural adaptation of self-report measures.[14] The process included two independent forward translations of the original GAD-7 into Malay, consensus between translators on the forward translation, back-translation by bilingual English teachers, and a review of the back-translation by an expert committee (content validity). We pre-tested the questionnaire in a location not included in the study. See the appendix in the web version of this paper for the GAD-7 (Malay version).

We used the GAD-7 to determine the presence or absence of anxiety at a recommended cut-off point of 8 and above.[5] The GAD-7 consists of seven items measuring GAD, panic disorder, social anxiety and PTSD. These items refer to symptoms experienced during the two weeks prior to answering the questionnaire. Each item has four answers ("not at all", "several days", "more than half the days" and "nearly every day") scored from 0 (not at all) to 3 (nearly every day). Scores of GAD-7 range from 0 to 21.

General Health Questionnaire (GHQ-12)

The GHQ-12 is one of the most evaluated instruments in community primary care clinics and has been found to be a reliable and valid instrument in different languages.[15,16] The GHQ-12 is widely used to assess psychiatric morbidity in Malaysia; including in hospital, primary care and community settings in both Malay and English languages.[8,17-21] While it does not specifically detect anxiety or depression, it gives an overall estimate of the prevalence of psychiatric morbidity in the population tested. We compared the GAD-7 scores obtained in this study to the GHQ-12 scores to determine the construct validity of the GAD-7.

*Composite International
Diagnostic Interview (CIDI)*

The CIDI is an instrument developed by the WHO to help coordinate the efforts of psychiatric epidemiologists around the world in conducting community surveys in which results can be directly compared by using the same instrument.[22] The CIDI was chosen as the reference standard for the GAD-7 in this study due to its extensive and in-depth development. It has been evaluated for test–retest reliability and compared with schedules for clinical assessment in neuropsychiatry,[23,24] and has excellent test characteristics in primary care, with moderate to excellent concordance (k=0.58–0.97) with diagnoses in the international classification of disease, 10th revision (ICD-10).[25] Studies conducted on its validation and use as a psychiatric diagnostic generating instrument found that the CIDI is a reliable and practical instrument to be used cross-culturally.[24,26–28]

Study population and setting

We carried out this study in a government primary care clinic in an urban district in Malaysia. We chose an urban location because the national surveys found that mental health problems are more prevalent in urban compared to rural settings.[8,9] We selected a clinic via simple random sampling from a list of government primary care clinics headed by a family medicine specialist (FMS)/family physician. This was a pre-determined criteria for the study due to safety issues. Participants diagnosed with anxiety and/or depression from the study were referred to the FMS for further consultation. The clinic provided outpatient, and maternal and child health care services by doctors, medical assistants and nurses.

Consecutive patients attending the clinic who fulfilled our selection criteria were approached by research assistants (RAs). Our inclusion criteria were all women patients who were Malaysian citizens aged 18 years old and above. Exclusion criteria were patients who were acutely ill and needed immediate medical attention, and those with communication problems. The RAs obtained written consent from each participant.

WHAT GAP THIS FILLS

What we already know: Anxiety is a common mental disorder in primary care settings, and the prevalence is higher among women compared to men. There is a need to develop brief case-finding instruments for anxiety worldwide, including Malaysia.

What this study adds: The Malay version of the GAD-7 was found to be a valid and reliable case-finding instrument for anxiety in this study. Together with its brevity, it is a suitable instrument to be used in primary care settings.

Study design

Participants completed a self-administered questionnaire which included the Malay versions of the GAD-7 and PHQ-9 (the nine-item Patient Health Questionnaire), as well as the GHQ-12. The questionnaires were returned to the RAs who proceeded to score the PHQ-9 and GAD-7. Participants were then divided into two main groups: (1) Normal scores (PHQ-9 <10 and GAD-7 <5), and (2) High scores (PHQ-9 ≥10 and/or GAD-7 ≥5). This study tested the validity of the Malay versions of both PHQ-9 and GAD-7, but the subject of this paper is validation of the GAD-7.

Systematic weighted random sampling was conducted to select participants from both groups for validation of the instruments. One in 10 participants with normal scores and one in two participants with high scores were selected for interview with the CIDI. The purpose of the weighted sample was to create a higher prevalence of patients with anxiety and/or depression for the validation exercise using the diagnostic interview with the CIDI. This weighted sample enabled the sensitivity and specificity from the validation results to have a similar range of confidence intervals.

We used the CIDI anxiety module as the reference standard to validate the GAD-7 (concurrent validity). The primary investigator (SMS), who is an FMS, was blinded to the participants' scores. SMS administered the CIDI as a diagnostic interview to all selected participants in a consultation room which provided adequate privacy for the participants to disclose personal information if necessary. She asked questions from the CIDI-Auto software and keyed participants' answers into the software. The software then generated the diagnosis of the participant, based on the

DSM-IV criteria. Each interview varied from 10 minutes to 90 minutes, based on the participants' diagnosis. Refer Figure 1 for the flowchart of the study design.

Data analysis

Data were entered into the Statistical Package for the Social Sciences programme (SPSS 16.0), carefully verified and checked again. To ensure that the final analysed data did not include participants who were attending the clinic for pre-determined mental health reasons which could affect the results of the study, we excluded data from participants with known psychiatric illness and those who were on psychoactive drugs. Because it was not possible to exclude these participants during the data collection process, we excluded them during data analysis.

Reliability and validity of the GAD-7

We measured internal consistency reliability of the GAD-7 using the Cronbach's alpha coefficient. A Cronbach's alpha value of ≥0.7 reflects that the questionnaire is reliable.[29] We determined content, construct and concurrent validity of the GAD-7 (Malay version). For concurrent validity, we calculated the sensitivity, specificity and likelihood ratios (LRs) according to the calculator on the University of Toronto website (www.cebm.utoronto.ca) for participants who were not currently taking psychoactive drugs.[30] We used Pearson's correlation coefficient to establish the relationship between the GAD-7 and GHQ-12 scores.

Ethics approval

We obtained ethics approval from the Malaysian Ministry of Health, the Clinical Research Centre of Malaysia, the Ethics Committee of the Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, and the FMS-in-charge of the clinic.

Results

Participants

One thousand and twenty-three (n=1023) consecutive women patients fulfilling the selection criteria were approached to take part in the study. Of these, 895 agreed to participate, giving a response rate of 87.5%. The participants were aged between 18 and 81 years old (mean age 30.9±10.4), and the majority of them were married (62.1%, 525/845). Based on the PHQ-9 and GAD-7 scores, 730 (82%) participants had normal scores in both questionnaires, while 165 (18%) participants had high scores in either one or both questionnaires. The participants did not receive any help in completing the questionnaires. Seventy-five participants were selected from the group with normal scores and 81 from the group with high scores.

For data analysis, 50 questionnaires were excluded from the initially recruited patients due to missing data (n=30) and known psychiatric illness (n=20). This left 845 overall participants and 146 with CIDI data.

Using a cut-off point of ≥8 on the GAD-7, 7.8% (66/845) of the participants were classified as having anxiety disorders. Based on the CIDI (anxiety module), 38 out of the 146 participants interviewed were diagnosed as having anxiety, where all these cases were diagnosed as GAD.

Reliability of the GAD-7 (Malay version)

The Malay version of the GAD-7 was found to have good internal reliability (Cronbach's alpha = 0.74).

Validity of the GAD-7 (Malay version)

Convergent validity

The Pearson's correlation coefficient between the GAD-7 and GHQ-12 was 0.62 ($p<0.001$). This indicated a positive association with moderate strength between the two instruments.

Concurrent validity

The sensitivity for the GAD-7 against the CIDI for anxiety was 76.3% (95% CI 60.8%–87.0%), specificity 94.4% (88.4%–97.4%), positive LR 13.7 (6.2–30.5) and negative LR 0.25 (0.14–0.45). Table 1 shows the raw data for the GAD-7 and Table 2 shows the sensitivity, specificity and LRs for the GAD-7, using the CIDI as the reference standard.
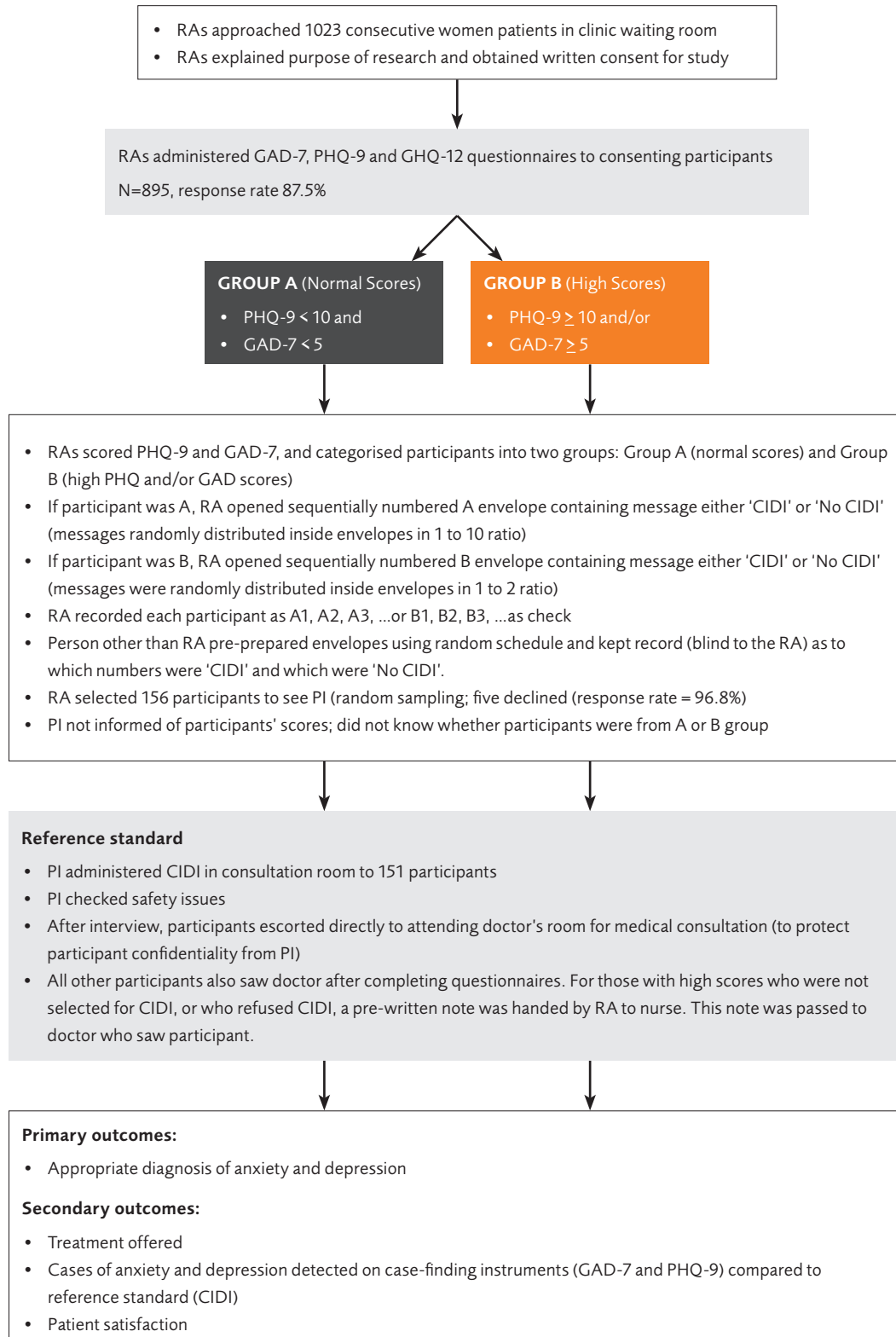
Figure 1. Flowchart of study design

- RAs approached 1023 consecutive women patients in clinic waiting room
- RAs explained purpose of research and obtained written consent for study

RAs administered GAD-7, PHQ-9 and GHQ-12 questionnaires to consenting participants

N=895, response rate 87.5%

GROUP A (Normal Scores)
- PHQ-9 < 10 and
- GAD-7 < 5

GROUP B (High Scores)
- PHQ-9 $\geq$ 10 and/or
- GAD-7 $\geq$ 5

- RAs scored PHQ-9 and GAD-7, and categorised participants into two groups: Group A (normal scores) and Group B (high PHQ and/or GAD scores)
- If participant was A, RA opened sequentially numbered A envelope containing message either 'CIDI' or 'No CIDI' (messages randomly distributed inside envelopes in 1 to 10 ratio)
- If participant was B, RA opened sequentially numbered B envelope containing message either 'CIDI' or 'No CIDI' (messages were randomly distributed inside envelopes in 1 to 2 ratio)
- RA recorded each participant as A1, A2, A3, ...or B1, B2, B3, ...as check
- Person other than RA pre-prepared envelopes using random schedule and kept record (blind to the RA) as to which numbers were 'CIDI' and which were 'No CIDI'.
- RA selected 156 participants to see PI (random sampling; five declined (response rate = 96.8%)
- PI not informed of participants' scores; did not know whether participants were from A or B group

Reference standard
- PI administered CIDI in consultation room to 151 participants
- PI checked safety issues
- After interview, participants escorted directly to attending doctor's room for medical consultation (to protect participant confidentiality from PI)
- All other participants also saw doctor after completing questionnaires. For those with high scores who were not selected for CIDI, or who refused CIDI, a pre-written note was handed by RA to nurse. This note was passed to doctor who saw participant.

Primary outcomes:
- Appropriate diagnosis of anxiety and depression

Secondary outcomes:
- Treatment offered
- Cases of anxiety and depression detected on case-finding instruments (GAD-7 and PHQ-9) compared to reference standard (CIDI)
- Patient satisfaction

Table 1. Results for GAD-7 compared with the CIDI as the reference standard for anxiety

	Anxiety on CIDI	No anxiety on CIDI	Total
GAD-7 positive (≥8)	29	6	35
GAD-7 negative (<8)	9	102	111
Total	38	108	146

Discussion

Summary of main findings

The prevalence of anxiety in this study was 7.8% based on the GAD-7 scores of 8 and above. The Malay version of the GAD-7 had good sensitivity and excellent specificity compared to the CIDI as the reference standard. This established good concurrent validity of the GAD-7. Comparison of the GAD-7 scores to those of the GHQ-12 established convergent validity of the GAD-7.

Strengths and limitations of this study

This is the first study to validate the GAD-7 as a case-finding instrument on anxiety in a primary care setting in Malaysia. Due to its brevity as well as its reliability and validity, the Malay version of the GAD-7 will be a useful and important case-finding instrument in primary care clinics and community settings throughout Malaysia.

A limitation (necessitated by time and resource constraints) is that the study was conducted among women in one government-funded primary care clinic in an urban community setting, where the participants were mostly of lower to middle income socioeconomic status and therefore cannot be ensured to represent the Malaysian women population as a whole.

Comparison with existing literature

The GAD-7 (Malay version) has acceptable validity results compared to the findings of the original GAD-7.[1] This is taking into consideration that the validation of the GAD-7 in this study was conducted on a much smaller sample (n=146) compared to Spitzer et al.'s study (n=965). This could have resulted in the much lower prevalence of anxiety detected by the GAD-7 in this study compared to Spitzer et al.'s study (8% vs 29%), including a lower sensitivity (76% vs 92%), a higher specificity (94% vs 76%), and a higher positive LR (13.7 vs 3.8).

Implications for practice and policy

This is the first validation of the GAD-7 in the Malay language for a primary care population, and the GAD-7 has the potential to be an international anxiety inventory based on its validity, reliability and brevity. The use of the GAD-7 as the instrument of choice to detect anxiety in primary care settings is supported by other studies as well.[1,5,31] As the prevalence of anxiety detected in this study was 7.8%, it would be worthwhile to use the GAD-7 to detect anxiety among women in other primary care settings in Malaysia, even though anxiety has not been an area of concern in Malaysian primary care so far. Clinically in this setting, a positive test would have over a 50% chance of having anxiety and a negative test would have about a 2% chance of having anxiety.[32] Therefore, using the GAD-7 (Malay) would enhance accurate detection of anxiety among primary care patients, and aid in developing practical policies in managing anxiety in Malaysian primary care clinics.

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Table 2. Sensitivity, specificity and LR for GAD-7 with the CIDI as the reference standard for anxiety

	Sensitivity % (95% CI)	Specificity % (95% CI)	LR	
			Positive test (95% CI)	Negative test (95%CI)
GAD-7	76.3 (60.8 to 87.0)	94.4 (88.4 to 97.4)	13.74 (6.19 to 30.50)	0.25 (0.14 to 0.45)

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APPENDIX: Generalised Anxiety Disorder (GAD)-7 (Malay version)

dalam tempoh **2 minggu** lepas, berapa kerapkali anda terganggu oleh masalah berikut? /

Over the last **2 weeks**, how often have you been bothered by any of the following problems?

No.	Questions	Coding
Q1	Berasa resah, gelisah atau tegang. *Feeling nervous, anxious, or on edge.*	Tidak pernah sama sekali / *Not at all* **0** Beberapa hari / *Several days* **1** Lebih dari seminggu / *More than half the days* **2** Hampir setiap hari / *Nearly everyday* **3**
Q2	Tidak dapat menghentikan atau mengawal kebimbangan. *Not being able to stop or control worrying.*	Tidak pernah sama sekali / *Not at all* **0** Beberapa hari / *Several days* **1** Lebih dari seminggu / *More than half the days* **2** Hampir setiap hari / *Nearly everyday* **3**
Q3	Terlalu bimbang mengenai pelbagai perkara yang berlainan. *Worrying too much about different things.*	Tidak pernah sama sekali / *Not at all* **0** Beberapa hari / *Several days* **1** Lebih dari seminggu / *More than half the days* **2** Hampir setiap hari / *Nearly everyday* **3**
Q4	Mempunyai masalah untuk tenang. *Having trouble relaxing.*	Tidak pernah sama sekali / *Not at all* **0** Beberapa hari / *Several days* **1** Lebih dari seminggu / *More than half the days* **2** Hampir setiap hari / *Nearly everyday* **3**
Q5	Terlalu resah sehingga susah untuk berdiam diri. *Being so restless that it is hard to sit still.*	Tidak pernah sama sekali / *Not at all* **0** Beberapa hari / *Several days* **1** Lebih dari seminggu / *More than half the days* **2** Hampir setiap hari / *Nearly everyday* **3**
Q6	Mudah menjadi rimas dan menjengkelkan. *Being easily annoyed or irritable.*	Tidak pernah sama sekali / *Not at all* **0** Beberapa hari / *Several days* **1** Lebih dari seminggu / *More than half the days* **2** Hampir setiap hari / *Nearly everyday* **3**
Q7	Berasa takut bahawa sesuatu yang buruk akan terjadi. *Feeling afraid as if something awful might happen.*	Tidak pernah sama sekali / *Not at all* **0** Beberapa hari / *Several days* **1** Lebih dari seminggu / *More than half the days* **2** Hampir setiap hari / *Nearly everyday* **3**