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## Psychometric evaluation of an interview-administered version of the Kessler 10-item questionnaire (K10) for measuring psychological distress in rural Bangladesh

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-022967
Article Type:	Research
Date Submitted by the Author:	15-Mar-2018
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Keywords:	Psychological Distress, Rasch Analysis, Validation, Kessler Psychological Distress Scale, Rural Bangladesh, Item Response Theory

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3 **1 Title: Psychometric evaluation of an interview-administered version of the Kessler 10-item**  
4 **2 questionnaire (K10) for measuring psychological distress in rural Bangladesh**  
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3 33 **Title: Psychometric evaluation of an interview-administered version of the Kessler 10-item**  
4 34 **questionnaire (K10) for measuring psychological distress in rural Bangladesh**  
5 35

6 36 **ABSTRACT**

7  
8 37 **Objective** The aim of this study was to translate, adapt and validate the Kessler 10-item  
9 38 questionnaire (K10) for measuring psychological distress in rural Bangladesh.

10  
11 39 **Design** Cohort study.

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13 40 **Setting** Narail district, Bangladesh.

14  
15 41 **Participants** A random sample of 2425 adults of age 18–90 years were recruited.

16  
17 42 **Outcome measure** Validation of the K10 was the major outcome. Socio-demographic factors  
18 43 were measured to assess if the K10 needed adjustment for factors such as age or gender. The  
19 44 Rasch measurement model was used for the validation, and RUMM2030 and SPSS24 software  
20 45 were used for analyses.  
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24 46  
25 47 **Results** Initial inspection of the total sample showed poor overall fit. A sample size of 300,  
26 48 which is more satiated for Rasch analysis, also showed poor overall fit, as indicated by a  
27 49 significant item-trait interaction ( $\chi^2 = 262.27$ ,  $df = 40$ ,  $p < 0.001$ ) and item fit residual values  
30 50 (mean =  $-0.25$ ,  $SD = 2.49$ ). Of 10 items, five items were disordered thresholds, and seven items  
31 51 showed misfit, suggesting problems with the response format and items. After removing three  
32 52 items (“feel tired”, “depressed” and “worthless”) and changing the Likert scale categories from  
33 53 five to four categories, the remaining seven items showed ordered threshold. A revised seven-  
34 54 item scale has shown adequate internal consistency, with no evidence of multidimensionality, no  
35 55 differential item functioning (DIF) on age and gender, and no signs of local dependency.  
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43 57 **Conclusions** Analysis of the psychometric validity of K10 using the Rasch model showed that  
44 58 10 items are not appropriate for measuring psychological distress in rural Bangladesh. A  
45 59 modified version of seven items (K7) with four-response category would provide a  
46 60 psychometrically more robust scale than the original K10. The study findings suggest repeating  
47 61 the K7 version in other remote areas for further validation can substantiate an efficient screening  
48 62 tool for measuring psychological distress among the general Bangladeshi population.  
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### 65 **Strengths and limitations of the study**

- 66 ➤ This study provides the first reliable data on the K10 questionnaire from a general  
67 population of a typical rural district in Bangladesh.
- 68 ➤ This study used numerous primary data on K10 and associated covariates.
- 69 ➤ The data were collected through face-to-face interviews of people from a typical rural  
70 district that generally represents Bangladesh.
- 71 ➤ The sophisticated Rasch analysis technique was applied to validate as well as identify a  
72 suitable unidimensional structure of the K10. The study provides a unique opportunity to  
73 assess psychological distress in a rural population of Bangladesh.
- 74 ➤ The potential drawback of this study is that it is based on a single-occasion collection of  
75 data from a rural district in Bangladesh. While we have attempted to capture the situation  
76 in the Narail district, the study needs to be repeated in a random sample of other rural  
77 districts to be truly representative of the national population.

### 80 **Introduction**

81  
82 A high prevalence of physiological distress is recognised worldwide.<sup>1</sup> Psychological distress is  
83 associated with chronic diseases and other health related problems,<sup>2</sup> and early diagnosis is seen  
84 as an important measure to ensure effective and targeted intervention.<sup>3</sup> In recent years,  
85 epidemiological studies have attempted to employ short dimensional scales to effectively  
86 measure and monitor the extent of psychological distress in the general community for the  
87 purposes of early diagnosis.<sup>4</sup> The Kessler 10-item questionnaire (K10) is one such scale among  
88 similar tools such as the Beck Depression Inventory (BDI),<sup>5</sup> the Hospital Anxiety and  
89 Depression Scale (HADS)<sup>6</sup> and the Depression Anxiety Stress Scales (DASS)<sup>7</sup> which are  
90 designed to assess non-specific psychological distress and screen for common psychiatric  
91 disorders.<sup>8-11</sup>

92  
93 The K10 was developed in 1992 by Professor Kessler and Mroczek<sup>12</sup> to be used in the United  
94 States National Health Interview Survey as a brief measure of non-specific psychological distress  
95 along the anxiety-depression spectrum. The K10 comprises ten questions (rated on five-point  
96 Likert-type scales, where 1 = none of the time to 5 = all of the time) about psychological distress.

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2  
3 97 Although K10 is not a diagnostic tool, it does indicate psychological distress and is used to  
4 98 identify people in need of further assessment for anxiety and depression. The K10 measurement  
5 99 of a client's psychological distress levels can also be used as an outcome measure and assist  
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7  
8 100 treatment planning and monitoring.<sup>13</sup> In the context of the general population, there is often a  
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10 101 shortage of space for the inclusion of more items in the scale. The BDI (21 items),<sup>5</sup> HADS (14  
11 102 items)<sup>6</sup> and the DASS (42 items)<sup>7</sup> are limited as screening tools because of their long list of  
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13 103 items. Moreover, studies confirm that well-constructed short scales can be as strong predictors as  
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15 104 the more lengthy instruments or interviews.<sup>12 14</sup> Because of its small number of items, the K10  
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17 105 has, since its development, been widely used in many countries, including the USA, Canada and  
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19 106 Australia. The tool has also been adopted in the World Health Organization's World Mental  
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21 107 Health Survey.<sup>8-11 15</sup> Moreover, another advantage of the K10 is that it was developed using  
22 108 methods associated with the item response theory.<sup>15</sup>  
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26 110 Although the K10 was originally developed to identify levels of non-specific psychological  
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28 111 distress in the general population, the tool has also demonstrated a strong relationship with  
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30 112 severe mental illnesses as defined by structured diagnostic interviews.<sup>16</sup> As such, clinicians have  
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32 113 been encouraged to use the K10 to screen for psychiatric illness.<sup>17 18</sup> Further, the K10 has been  
33  
34 114 used as a routine outcome measure in specialist public mental health services in multiple  
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36 115 Australian states and territories.<sup>4</sup> A recent review of the literature suggests that the K10 is an  
37  
38 116 effective and reliable assessment tool applicable to a variety of settings and cultures for detecting  
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40 117 the risk of clinical psychological disorders.<sup>19 20</sup> However, a major limitation of the K10 is the  
41  
42 118 lack of consistency across studies about its factor structure. Although it was initially designed to  
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44 119 yield a single score indicating the level of psychological distress,<sup>15</sup> one study demonstrated a  
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46 120 four-factor model with acceptable fit in large community samples;<sup>21</sup> another study proposed a  
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48 121 two-factor solution, one factor for depression and another for anxiety;<sup>4</sup> while another study did  
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50 122 not find an adequate fit.<sup>22</sup>  
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54 124 Bangladesh is a country of 163 million people<sup>23</sup> where mental health complaints are a major  
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56 125 public health concern, especially in rural areas.<sup>24-26</sup> The prevalence of mental disorders in such  
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58 126 areas varies between 6.5% and 31%, possibly due to the use of different protocols and definitions  
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60 127 of mental disorders.<sup>27</sup> A culturally validated tool is needed for quick screening of psychological

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3 128 distress in Bangladesh, as well as in other countries with similar socio-economic conditions. Due  
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5 129 to lack of published research on the K10 in rural settings, and uncertainties surrounding the scale  
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7 130 noted above, we need to develop a valid measurement scale of psychological distress in  
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9 131 Bangladesh.

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12 133 The present study pursues an update of Rasch analysis technique to evaluate the suitability of the  
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14 134 K10 for measuring psychological distress in rural Bangladesh, and to provide guidance on  
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16 135 suitable modification to the instrument to improve its performance. Accuracy and precision of  
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18 136 K10 scores can lead to a more efficient allocation of health care resources as well as more  
19  
20 137 efficient screening of psychological distress among the rural population.

21 138

## 22 139 **Materials and Methods**

### 23 24 140 **Study Population**

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26 141 Participants were recruited from the Narail district, located approximately 200 km south-west of  
27  
28 142 Dhaka, the capital city of Bangladesh. We recruited a total of 2425 adults aged 18–90 years,  
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30 143 from May to July 2017. The study protocol, including its geographic location and population  
31  
32 144 density, is described in detail elsewhere.<sup>28</sup>

33 145

### 34 146 **Sample Size and Statistical Power**

35  
36 147 A sample of approximately 300 is more suitable for a Rasch analysis, because large sample sizes  
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38 148 can result in type 1 errors that falsely reject an item for not fitting in the Rasch model.<sup>29</sup> A  
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40 149 sample size of 300 is considered large enough for 99% confidence that the estimated item  
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42 150 difficulty would be within  $\pm\frac{1}{2}$  logit of its stable value.<sup>30</sup> We did the analysis five times with five  
43  
44 151 different random sample sizes of 300 each, from the total sample of 2425, to check the  
45  
46 152 robustness of the models using different subsamples. For the initial test of the model, we also  
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48 153 used the total sample.

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### 50 155 **Sampling Frame**

51  
52 156 A multilevel cluster random sampling technique was used for this cohort study. Three unions  
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54 157 (smallest rural administrative unit) out of 13 and 1 Pourashava (smallest urban administrative  
55  
56 158 unit) of Narail Upazilla (the third largest type of administrative division in Bangladesh) were

1  
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3 159 randomly selected at level 1. Two to three villages (a smallest territorial and social unit for  
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5 160 administrative and representative purposes), from each selected union and two wards (an  
6  
7 161 electoral district, for administrative and representative purposes) were randomly chosen from  
8  
9 162 selected Pourashava at the second level. In total, 150 adults (18–59 year old) and 120 older  
10  
11 163 adults (60–90 year old) from each of the villages/wards were interviewed. Recruitment strategy  
12 164 and quality assurance in data collection are described previously.<sup>28</sup>  
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### 15 166 **Kessler Psychological Distress Scale**

16  
17 167 The K10 measures how often participants have experienced symptoms of anxiety and depressive  
18  
19 168 disorders in the previous four weeks prior to screening.<sup>12</sup> Respondents were asked, ‘During the  
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21 169 past four weeks, how often did you feel: 1) tired out for no good reason; 2) nervous; 3) so  
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23 170 nervous that nothing could calm you down; 4) hopeless; 5) restless or fidgety; 6) so restless you  
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25 171 could not sit still; 7) sad or depressed; 8) so depressed that nothing could cheer you up; 9)  
26  
27 172 everything was an effort; 10) worthless.’ Items are rated on a five-point ordinal scale: all of the  
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29 173 time (score 5), most of the time (score 4), some of the time (score 3), a little of the time (score 2)  
30  
31 174 and none of the time (score 1). Questions 3 and 6 are not asked if the preceding question was  
32  
33 175 answered ‘none of the time’, in which case questions 3 and 6 would automatically receive a  
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35 176 score of one. Scores for the ten questions are summed: the maximum score is 50, indicating  
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37 177 severe distress; the minimum score is ten indicating no distress. Low scores indicate low levels  
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39 178 of psychological distress and high scores indicate higher levels of psychological distress.<sup>12</sup>  
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41 179

### 42 180 **Outcome Variables**

43 181 The main outcome measure was the validation of the K10.  
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45 182

### 46 183 **Factor Variables of Differential Item Functioning (DIF)**

47 184 Participants were categorised as either adults (18 to 59 year old) or older adults (60 to 90 year  
48  
49 185 old), and by gender (male or female).  
50  
51 186

52 187 **Scale Validation:** Item response theory (IRT) and Classical Test Theory (CTT)  
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54 188



## 189 **Item Response Theory (IRT)**

190 IRT is a paradigm for the design, analysis and scoring of tests, questionnaires and similar  
191 instruments measuring abilities, attitudes or other variables.<sup>31</sup> It is based on the relationship  
192 between individuals' performances on a test item and their personal performance on an overall  
193 measure of the ability that the item seeks to quantify.<sup>32</sup> All IRT models attempt to explain  
194 observed (actual) item performance as a function of an underlying ability (unobserved) or latent  
195 trait.

## 197 **Classical Test Theory (CTT)**

198 Classical test theory is a quantitative approach to testing the reliability and validity of a scale  
199 based on its items. CTT is a simple linear model which links the observable score (X) to the sum  
200 of two unobservable (often called latent) variables, true score (T) and error score (E); i.e.,  $X = T$   
201  $+ E$ . Because of, each examinee there are two unknowns, without simplified assumption the  
202 equation will not be solved. The assumptions in the classical test model are that (a) true scores  
203 and error scores are uncorrelated, (b) the average error score in the population of examinees is  
204 zero, and (c) error scores on parallel tests are uncorrelated.<sup>33</sup> The true score (T) is defined as the  
205 expected value of the observed score over an infinite number of repeat administrations of the  
206 same instrument.<sup>33 34</sup>

## 208 **Rationale for using the Rasch analysis instead of the CTT**

209 Similar to the IRT, the CTT is another fundamental measurement theory that researchers employ  
210 to construct measures of latent traits. Both IRT and CTT can be used to construct measures of  
211 latent traits, but the two measurement systems are entirely dissimilar. A more in-depth  
212 explanation of the literature on CTT<sup>35-37</sup> and IRT.<sup>38-41</sup> So far, the K10 was validated mostly using  
213 CTT in which the items and the latent trait being measured are considered separately and,  
214 therefore, cannot be meaningfully and systematically compared.<sup>42 43</sup> These limitations can be  
215 solved rationally using Rasch modelling.<sup>38 39 44-46</sup>

## 217 **The Rasch Model**

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2  
3 218 The Rasch model was named after the Danish mathematician Georg Rasch.<sup>47</sup> The model shows  
4  
5 219 what should be expected of responses to items if measurement (at the metric level) is to be  
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7 220 achieved. Two versions of the Rasch model are available:

8  
9 221 dichotomous,  $P\{X_{ni} = x\} = \frac{e^{x(\beta_n - \delta_i)}}{1 + e^{x(\beta_n - \delta_i)}}$ ,<sup>47</sup>

10  
11  
12 222 and polytomous,  $P\{X_{ni} = x\} = \frac{e^{-\tau_{1i} - \tau_{2i} \dots - \tau_{xi} + x(\beta_n - \delta_i)}}{\sum_{x'=0}^{m_i} e^{-\tau_{1i} - \tau_{2i} \dots - \tau_{xi} + x'(\beta_n - \delta_i)}}$ ;<sup>48</sup>

13  
14 223 where  $\beta_n$  is the location of person n and  $\delta_i$  is the location of item i.  $\tau_{xi}$ ,  $x = 1, 2, \dots, m_i$  are  
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16 224 thresholds which partitioned the latent continuum of item i into  $m_i + 1$  ordered categories. X is  
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18 225 the response value that qualifies the expression by  $\beta_n - \delta_i$ .

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20 226  
21 227 The Rasch analysis in this study was conducted using the RUMM 2030 package.<sup>49</sup> In the  
22  
23 228 assessment of K10, respondents were presented with the ten-item questionnaire regarding  
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25 229 psychological distress. The purpose of the Rasch analysis was to maximise the homogeneity of  
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27 230 the trait and to allow more significant reduction of redundancy without sacrificing the  
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29 231 measurement of information by decreasing items and scoring levels to yield a more valid and  
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31 232 straightforward measure. The Rasch model requires some assumptions that need to be evaluated  
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33 233 to ensure that an instrument has Rasch properties. The Rasch assumptions most commonly  
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35 234 assessed are a) unidimensionality, b) local independence and c) invariability.

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37 235  
38 236 Chi-square item-trait interaction statistics define the overall fit of the model for the scale.<sup>50</sup> A  
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40 237 non-significant chi-square probability value indicated that the hierarchical ordering of the items  
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42 238 is consistent across all levels of the underlying trait. A Bonferroni adjustment<sup>51</sup> is typical of the  
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44 239 alpha value used to assess statistical significance, by dividing the alpha value of 0.05 by the  
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46 240 number of items in the scale. Item-person interaction statistics distributed as z-statistic with a  
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48 241 mean of zero and SD of 1 (indicating perfect fit with the model). Values of SD above 1.5 for  
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50 242 either items or person suggest a problem. Individual item fit statistics are presented as residuals  
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52 243 (acceptable within the range  $\pm 2.5$ ) and chi-square statistic (require a non-significant chi-square  
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54 244 value).

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57 246 The Rasch model can be extended to analyse items with more than two response categories,  
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59 247 which involves a 'threshold' parameter, represented by the two response categories where either

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3 248 response is probable. Common sources of item misfit occur with ‘disorder thresholds’ failure of  
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5 249 the respondents to use the response category in a manner consistent with the level of the trait  
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7 250 being measured.

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10 252 Unidimensionality occurs when a set of items measures just one thing in common.<sup>52</sup> To establish  
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12 253 this, the first step is to run a Principal Component Analysis (PCA) on the residuals to identify  
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14 254 two subsets of the items having the most difference. Second, the items loading on the first factor  
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16 255 are extracted, items having positive and negative loadings are defined, and estimates for these  
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18 256 two sets are derived. Applying an independent t-test to both sets, which conduct t-tests for each  
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20 257 person in the sample comparing their score on the Set 1 items and Set 2 items. If less than 5% of  
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22 258 the estimates are outside the range of  $\pm 1.96$ , the scale is considered unidimensional.

23 259  
24 260 In case of local independence,<sup>53</sup> the items in a test are expected to be unrelated to each other; i.e.  
25  
26 261 the response on each item should not be associated with that of another items. To test for local  
27  
28 262 independence, we need to check the residuals correlation matrix, and any correlation coefficient  
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30 263 value greater than 0.3 suggests the two items are locally dependent. In a situation where the  
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32 264 correlation value is greater than 0.3, the two items need to be merged into one, called subtest  
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34 265 analysis, to achieve a significant improvement on PSI value. If so, it is a sign of local  
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36 266 dependency and a violation of one of the Rasch assumptions.

37 267  
38 268 Invariability indicates that ‘items are not dependent on the distribution of persons’ abilities and  
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40 269 the persons’ abilities are not dependent on the test items.<sup>54</sup> In Rasch measurement theory, the  
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42 270 scale should work in the same way, irrespective of which group (e.g., gender or age) is being  
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44 271 assessed. If for some reason one gender does not display equal likelihood of confirming the item,  
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46 272 then the items would display DIF and would violate the requirement of unidimensionality.<sup>55</sup> DIF  
47  
48 273 is an analysis of variance of the person-item deviation residuals with the person’s factors (e.g.,  
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50 274 age, gender).

51 275  
52 276 The reliability and internal consistency of the model are defined by the Person Separation Index  
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54 277 (PSI).<sup>56</sup> In addition to item fit, examination of person fit is essential. A few responses with  
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56 278 unusual response pattern (identified by high positive residuals) may seriously affect the fit at the

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3 279 item level. Such aberrant response patterns occur due to unrecorded co-morbidity or respondents  
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5 280 with cognitive defects. Therefore, if some response pattern showed high positive fit residuals,  
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7 281 removal from the analysis may make a significant difference to the scale internal construct  
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9 282 validity.

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## 14 287 **Results**

### 15 288 *Overview of the respondents*

16 289 Table 1 shows the summary statistics of both the validation and the total data sets by gender  
17 290 (male and female). The mean (SD, range) age of the total participant sample was 52.0 years (17,  
18 291 18–90). Of the total sample, 48.5% were men, 27.6% had no formal education, 4% had at least a  
19 292 bachelor's degree level of education.

20 293

### 21 294 *Primary analysis of the original set of ten items and five response categories*

22 295 K10 scores ranged from 10 to 50 with a mean of 16.7 (SD = 11.3). Initial inspection of the scale  
23 296 with the total 2425 participants showed poor overall fit with the Rasch model, as indicated by a  
24 297 significant item-trait interaction ( $\chi^2 = 1729.89$ ,  $df = 40$ ,  $p < 0.001$ ) and item fit residual values  
25 298 (mean =  $-0.25$ ,  $SD = 6.75$ ) outside the acceptable range. Eight items were found to be misfit  
26 299 based on the overall fit residual values outside the range of  $\pm 2.5$ . Five items were found to have  
27 300 disordered thresholds, signifying problems with the 5-point response format used for the scale. A  
28 301 check found multidimensionality: the model fit statistics for the five separate random subsamples  
29 302 of 300 each from the total participant sample produced almost identical results, indicating the  
30 303 results and sample selections were robust (Table 2).

31 304

32 305 Initial inspection of scores in the random sample of 300 participants showed poor overall fit to  
33 306 the Rasch model ( $\chi^2 = 262.27$ ,  $df = 40$ ,  $p < 0.001$ ) and items fit residual values (mean =  $-0.25$ ,  
34 307  $SD = 2.49$ ). However, the person fit residuals (mean =  $0.18$ ,  $SD = 1.24$ ) were within the  
35 308 acceptable range (Table 2, sample 1). Five items were found to have disordered thresholds, and  
36 309 seven of the individuals' item fit statistics showed misfit, suggesting problems with the 5-point

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3 310 response format used for the questionnaire. The value of the PSI (analogous to Cronbach's  
4 311 alpha) for the original set of ten items with five response categories was 0.84, indicating that the  
5 312 scale worked well to separate persons. The frequency distribution of the items showed (data not  
6 313 shown) mistargeting. Across all five items, the distribution was skewed towards the lower  
7 314 values, indicating low psychological distress among the respondents in the sample. Seven items  
8 315 (items 1, 2, 3, 4, 7, 8 and 9) showed misfit (Table 3: initial solution) while five items showed  
9 316 disorder thresholds (1, 4, 7, 8, 9) (Figure 1: initial solution). A visual examination of the  
10 317 threshold map shows that the estimates of the thresholds defining the categories in item 1 (tired)  
11 318 (Figure 2: category probability curve), item 4 (feel hopeless), item 7 (depressed), item 8 (an  
12 319 effort) and item 9 (so sad) do not form distinctive regions of the continuum. We have examined  
13 320 the category probability curve of each disorder threshold item, and found response 1 and 2  
14 321 adjacent category were not the same (Figure 2, category probability curve).  
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25 322  
26 323 To address the issue of disordered categories, Rasch analysis was conducted on only the  
27 324 disordered items, by merging the two middle categories ('a little of the time' and 'some of the  
28 325 time'). This reduced the scoring to a 4-point format from 01234 to 01123, and made the overall  
29 326 score range 0 to 40. Following this, eight misfit items were identified with significant chi-square  
30 327 probability values, or high positive or high negative residual values ( $\pm 2.5$ ), and found only item  
31 328 5 to be disordered. (Table 3: only disorder items were rescored as 01123). Then we carried out  
32 329 all items Likert scale categories from five to four categories and found all items were ordered  
33 330 thresholds. (Figure 1: rescore all items to 01123). However, five items were still misfit in the  
34 331 model (Table 3: rescore all items to 01123).  
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### 43 333 ***Proposed final analysis of the seven items and four response categories***

44 334 Misfit items were removed one at a time iteratively, based on positive or negative residual values  
45 335 as well as the degree of the significant chi-square probability values. The total model fit and  
46 336 individual item fit statistics were checked after each iteration, until the remaining items were  
47 337 shown to fit Rasch model's expectations. The three removed items were items 1, 7 and 10.  
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53 339 The final solution, retaining seven items, showed overall fit with the model (Table 4). The PSI  
54 340 was found to be high (PSI = 0.84), making the model suitable for individual use. The items of the  
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3 341 K7 scale were assessed for DIF across gender (male/female) and age (adults: 18–59 year old)  
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5 342 and older adults (60–90 year old) (Table 5). A significant DIF was found on item 9 (feel so sad);  
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7 343 however, using a Bonferroni-adjusted alpha value ( $.05/7=.007$ ), the value became non-  
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9 344 significant. In the final model, seven items with four response categories showed all items to  
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11 345 have ordered thresholds (Figure 3). There was no indication of item or person misfit (Table 4:  
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13 346 Individuals' items fit statistics of final K7). Unidimensionality of the K7 scale was tested using  
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15 347 PCA (3.34%, 95% CI 0.9% to 5.8%), and from a binomial distribution was found non-  
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17 348 significant, which supports unidimensionality of the K7 (Table 4, final solution of K10 and  
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19 349 Figure 4, final solution of K7).

## 20 350 **Discussion**

21 351 The purpose of the paper was to evaluate the suitability of the Kessler 10-item questionnaire for  
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23 352 measuring psychological distress in rural Bangladesh. This article examines the potential  
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25 353 contribution of Rasch analysis in exploring several issues concerning the K10. This includes an  
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27 354 assessment of the appropriateness of using all K10 items to represent the underlying dimension  
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29 355 of psychological distress. In addition, the article includes an evaluation of the validity of the  
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31 356 category scoring system, the fit of individual items and an assessment of the potential bias of  
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33 357 items by gender and age, from the perspective of the Rasch model. The initial descriptive  
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35 358 analysis of the frequency distributions indicated that the 10-item scale with five response  
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37 359 categories mistargeted the current sample of the rural Bangladeshi population. Non-responses or  
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39 360 very few responses in the categories may manifested to the mistargeting. Two items ('tired' and  
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41 361 'depressed') showed misfit, and two items ('so nervous' and 'so restless') showed redundancy  
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43 362 (i.e., little impact on the scale). Moreover, items with disordered thresholds indicating problems  
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45 363 with the categorisation of the items and scale showed evidence of multidimensionality. Since the  
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47 364 K10 scale has not previously undergone a rigorous psychometric analysis in rural Bangladesh  
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49 365 and even in neighbouring countries, the detection of problems was not surprising, even though  
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51 366 attention had been paid to targeting when the scale was constructed. In these circumstances, the  
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53 367 analysis elaborated on taking advantage of the Rasch model.

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57 369 One response category was warped, which resulted in four instead of five response categories for  
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59 370 each item. Moreover, those items showing misfit were removed from the model gradually after  
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371 going through all possible steps to improve the model. Item 1 ('how often did you feel tired out



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3 372 for no good reason') was removed because it showed high fit residuals value and DIF for age  
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5 373 (adults and older adults). Although techniques exist for solving uniform DIF by allowing the  
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7 374 item difficulty to vary by group, we believe that option is inappropriate because it is not useful as  
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9 375 an everyday screening environment. Therefore, we decided to delete the biased item, which also  
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11 376 had a large chi-square value. On the other hand, the item may not play the concepts of  
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13 377 psychological distress in Bangladesh. This could be one reason why the item works differently  
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15 378 according to age (adults and older adults). The removal of this item from the scale improved the  
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17 379 overall fit of the model, supporting this decision. Moreover, the item removed was one of the  
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19 380 four items that Kessler<sup>15</sup> had earlier used to reduce 10 to 6 items. Item 7 ('how often did you feel  
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21 381 depressed') was also removed from the scale due to misfit with the model. The large positive  
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23 382 residual value indicates misfit in that it contributed little or no information additional to other  
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25 383 items, as well as having a large chi-square value. However, the item showed no DIF on age and  
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27 384 gender. Removal of the item from the model significantly improved the fit of remaining items.  
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29 385 Moreover, the item removed was one of the four-item that Kessler<sup>15</sup> earlier used to reduce 10 to  
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31 386 six items. Item 10 ('how often did you feel worthless') has been removed from the scale due to  
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33 387 high chi-square value and significant chi-square probability, as well as high positive residuals  
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35 388 which contribute to an overall model misfit. The high chi-square value indicates that it adds  
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37 389 nothing to the information gained by other items, and this item is the only one, which increased  
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39 390 the overall chi-square value and made the overall model misfit. The study results support the  
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40 391 retention of item 10.  
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40 393 Removal of items from the scale would eliminate at least some redundancy.<sup>57-59</sup> However, our  
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42 394 analysis identified that Cronbach's alpha for the K7 (0.88) was equivalent to the original K10  
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44 395 Cronbach's alpha (0.87); in addition, the PSI of K7 (0.84) was the same as that of the original  
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46 396 K10's PSI (0.84). A study reported by Fassaert et al,<sup>19</sup> showed that some redundancy happens in  
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48 397 Cronbach's alpha, when comparing K10 (0.93) and K6 (0.89). However, our model showed  
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50 398 superior value of Cronbach's alpha K7 (0.88) compared to the original K10 (0.87) model, and  
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52 399 confirms adequate fit of the model in the rural settings in Bangladesh. Although we have  
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54 400 proposed seven validated items (K7), a previous study proposed six (K6) items<sup>17</sup> was more  
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56 401 robust than the K10. Of K7, five items were common in K6. We only tested K6 items using  
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58 402 Rasch analysis and found a poor overall fit. In particular, the presence of the item "feel

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3 403 worthless” showed a large positive fit residual and significantly large chi-square value, which  
4 404 influenced the overall model misfit under Rasch assumptions. Therefore, the current study found  
5 405 that the K7 model is more robust in our sample compared to K6.<sup>17 20</sup>  
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10 407 Gender differences in psychology are ubiquitous,<sup>60</sup> so it is essential to verify whether the model  
11 408 is affected by gender or not. Our revised seven-item model showed no DIF on gender, i.e., there  
12 409 is no gender bias in the revised K7 scale. The K7 scale is equally valid for men and women,  
13 410 which supports the previous findings reported in Australia.<sup>61</sup> Another important factor is age, and  
14 411 there is inconsistency in the literature on the relationship between age and psychological  
15 412 distress.<sup>62</sup> The study conducted by Kessler et al. documented a good deal of inequality in the  
16 413 relationship between age and screening scales of depressive symptoms.<sup>63</sup> However, other studies  
17 414 showed a stable nonlinear association between age and psychological distress in several cross-  
18 415 sectional epidemiologic surveys.<sup>62 64 65</sup> Our revised model of K7 confirmed that there is no age  
19 416 bias (adults and older adults), and the model is equally applicable to any one between the age of  
20 417 18–90 years.  
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31 419 Application of the Rasch measurement model in this study has supported the viability of a seven-  
32 420 item version of the K10 scale for measuring psychological distress in rural Bangladesh. The  
33 421 scale shows high reliability, with no disordering of thresholds and no evidence of DIF. The  
34 422 model also showed high PSI (0.84) and reliability (0.87), which indicated the power of the test of  
35 423 fit. Furthermore, there is good evidence from this sample that a single total score of  
36 424 psychological distress is viable. Thus, the seven-item scale appears robust when tested against  
37 425 the strict assumptions of the Rasch measurement model.  
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45 427 This paper shows how the Rasch model can be used for rigorous examination and development  
46 428 of measurement instruments such as the K10 psychological distress scale. The Rasch model  
47 429 simplifies measurement problems such as lack of invariance, which was overlooked in traditional  
48 430 analysis.<sup>66</sup> The Rasch analysis of the K10 scale indicates that the psychometric properties of the  
49 431 original scale most likely would have been much better if scale developmental had been guided  
50 432 by IRT (Rasch analyses). In future, importance should be given to improving the targeting of  
51 433 person and items. Reducing the number of response categories as well as the number of items  
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3 434 might also improve the properties of the scale.<sup>67</sup> Therefore, data on the general rural population  
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5 435 regarding psychological distress based on the revised seven-item scale from the K10, with four-  
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7 436 response category, is superior to the original scale.

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10 438 This study provides the first reliable data on levels of psychological distress among the general  
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12 439 population of rural Bangladesh. The analysis was based on a large data set of adults and older  
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14 440 adults across a wide range of age, from whom data were collected directly in a face-to-face  
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16 441 interview. The Rasch analysis in this study guided a detailed examination of the structure of the  
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18 442 scale. The response category orderings (threshold ordering) were not examined earlier, and  
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20 443 evidence from the current study does not support the response format or the validity of the  
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22 444 original 10-item scale.

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24 446 The potential drawback of this study is that it is based on single-occasion collection of data from  
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26 447 people in a rural district of Bangladesh. While we have attempted to capture the situation in the  
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28 448 Narail district, the study would obviously need to be repeated in a random sample of other rural  
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30 449 districts for the results to be truly representative of a national population.

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### 32 451 **Conclusion**

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34 452 Overall, the authors favours the use of K10 in rural Bangladesh, as has been used elsewhere.  
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36 453 However, this study acknowledges that due to cultural variations and strict adherence to Rasch  
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38 454 properties, modification is needed to measure psychological distress in rural Bangladesh. The  
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40 455 results of this study suggest that a revised seven-item version of the K10, with four-response  
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42 456 category, would provide a more robust psychometric scale than the original K10. The modified  
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44 457 seven-item scale fulfils all the assumptions of the Rasch model, and the model has shown no  
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46 458 differential item functioning (DIF) on age and sex as well as no local dependency. The study  
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48 459 findings can be repeated using a random sample of other remote areas in Bangladesh to further  
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50 460 validate the revised scale, as well as to better establish the level of psychological distress  
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52 461 nationwide. The tool can be applied in clinical settings at the national level, where psychological  
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54 462 distress has yet to be diagnosed.

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### 54 464 **List of abbreviations**

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3 465 CTT, Classical Test Theory; IRT, Item Response Theory; DIF, Differential Item Functioning;  
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5 466 PSI; Person Separation Index, K10, Kessler Psychological Distress Scale  
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8 468 **Ethical aspects:** Human Ethics Approval was received from the Swinburne University of  
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10 469 Technology Human Ethics Committee (SHR Project 2015/065) in accordance with the tenets of  
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12 470 the Declaration of Helsinki. Study participants provided written informed consent.  
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15 472 **Authors' contributions:** MNU and FMAI jointly designed the study. MNU analysed the data  
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17 473 and drafted the manuscript. FMAI contributed to writing the manuscript. FMAI supervised the  
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19 474 overall analyses and preparation of the manuscript. AAM reviewed the manuscript. All authors  
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21 475 contributed to the development of the manuscript and read and approved its final version.  
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24 477 **Acknowledgements:** We particularly acknowledge the contribution of Md Rafiqul Islam, Md  
25  
26 478 Sajibul Islam, Saburan Nesa and Arzan Hosen for their hard work in door-to-door data  
27  
28 479 collection. Finally, we would like to express our gratitude to the study participants for their  
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30 480 voluntary participation.  
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32 482 **Competing interests:** None declared  
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36 484 **Funding:** The Faculty of Health, Arts and Design of the Swinburne University Technology  
37  
38 485 under the Research Development Grant Scheme, funded data collection for this research project.  
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40 486 The funder had no role in the design of the study, data collection or analysis, interpretation of  
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42 487 data or writing of the manuscript.  
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44 489 **Data sharing statement:** Data will be available upon request.  
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**Table 1. Characteristics of participants who were included and who were not in the current study, by gender**

Characteristic	Total N=2425			In validation N=300		
	Total (2425)	Male (1176)	Female (1249)	Total (300)	Male (143)	Female (153)
<b>Age groups (in years)</b>						
18–59	1278 (52.7)	603 (51.3)	675 (54.0)	172 (57.3)	73 (51.0)	99 (63.1)
60–90	1147 (47.3)	573 (48.7)	574 (46.0)	128 (42.7)	70 (49.0)	58 (36.9)
<b>Education</b>						
No education	671 (27.7)	289 (24.6)	382 (30.6)	76 (25.3)	37 (25.9)	39 (24.8)
Primary (1–5)	946 (39.0)	447 (38.0)	499 (40.0)	124 (41.3)	58 (40.6)	66 (42.0)
Secondary (6–9)	327 (13.5)	146 (12.4)	181 (14.5)	38 (12.7)	13 (9.1)	25 (15.9)
SSC or HSC Pass (10–12)	385 (15.9)	224 (19.0)	161 (12.9)	50 (16.7)	26 (18.2)	24 (15.3)
Degree or equivalent (13–16)	96 (4.0)	70 (6.0)	26 (2.1)	12 (4.0)	9 (6.3)	3 (1.9)

SSC – Secondary School Certificate, HSC- Higher Secondary Certificate

**Table 2. Model Fit Statistics for total sample and five random samples of 300 with all 10 items**

Initial solution	Total sample N=2425	Sample 1 n=300	Sample 2 n=300	Sample 3 n=300	Sample 4 n=300	Sample 5 n=300
Overall model fit, Chi-square value	1727.89	262.27	212.30	204.07	194.37	282.14
Degree of freedom (DF)	40	40	40	40	40	40
P	0.00000	0.0000	0.0000	0.0000	0.0000	0.0000
Item fit residuals (mean (SD))	–0.25 (6.75)	0.13 (2.49)	0.05 (2.40)	–0.23 (2.12)	0.11 (2.38)	–0.16 (2.64)
Person fit residuals (mean (SD))	–0.29 (1.32)	–0.18 (1.24)	–0.28 (1.33)	–0.34 (1.32)	–0.30 (1.37)	–0.27 (1.32)
Person separation index (PSI)	0.84	0.84	0.83	0.85	0.82	0.83
Coefficient alpha	0.86	0.87	0.86	0.87	0.86	0.87
Unidimensionality test (% that goes beyond 95% CI)	10.3 (9.6–11.2)	9.3 (6.9–11.8)	11.7 (9.2–14.1)	8.3 (5.9–10.8)	9.0 (6.5–11.5)	10.33 (7.9–12.8)

**Table 3. Fit statistics (location, residuals and P values) of the 10 items for the first random sample of 300**

Items	Initial solution			Rescore only disordered items to 01123*			Rescore all items to 01123		
	Location	Residuals	P value	Location	Residuals	P value	Location	Residual	P value
Feel tired (1)	-0.42	4.28	0.000* <sup>^</sup>	0.00	1.35	0.005	-0.51	1.22	0.000 <sup>^</sup>
Feel nervous (2)	-0.11	-0.85	0.001 <sup>^</sup>	-0.56	-1.19	0.004 <sup>^</sup>	-0.12	-3.26	0.020
Feel so nervous (3)	0.13	-3.16	0.000 <sup>^</sup>	-0.32	-3.65	0.002 <sup>^</sup>	0.05	-4.13	0.002 <sup>^</sup>
Feel hopeless (4)	-0.06	-0.62	0.008*	0.34	-1.54	0.001 <sup>^</sup>	-0.03	-1.77	0.104
Feel restless or fidgety (5)	-0.22	0.46	0.002 <sup>^</sup>	-0.69	0.11	0.001* <sup>^</sup>	-0.26	-1.93	0.302
Feel so restless (6)	0.08	-3.11	0.000* <sup>^</sup>	-0.38	-3.39	0.007	0.04	-3.73	0.003 <sup>^</sup>
Feel depressed (7)	0.26	3.87	0.000* <sup>^</sup>	0.74	3.00	0.000 <sup>^</sup>	0.35	3.18	0.000 <sup>^</sup>
Everything was an effort (8)	-0.15	-0.33	0.125*	0.28	-1.90	0.000 <sup>^</sup>	-0.16	-2.36	0.301
Feel so sad (9)	0.16	-0.48	0.058	0.65	-2.32	0.001 <sup>^</sup>	0.25	-2.64	0.003 <sup>^</sup>
Feel worthless (10)	0.34	1.33	0.001 <sup>^</sup>	-0.06	2.41	0.003 <sup>^</sup>	0.39	0.60	0.247

\*Disordered items; <sup>^</sup> P values depend on chi-square values (Bonferroni correction (p value/number of items)) = .05/10 = .005

**Table 4. Individuals' item fit statistics of original Kessler K10 and final seven-items model**

Items	Individuals' items fit statistics of original K10					Individuals' items fit statistics of Final K7				
	Location	SE	Residual	$\chi^2$	P value	Location	SE	Residual	$\chi^2$	P value
Feel tired (1)	-0.42	0.08	4.28	46.76	0.000					
Feel nervous (2)	-0.11	0.09	-0.85	19.94	0.001	-0.20	0.15	-1.40	3.99	0.41
Feel so nervous (3)	0.13	0.09	-3.16	30.36	0.000	0.10	0.15	-2.66	11.01	0.03
Feel hopeless (4)	-0.06	0.08	-0.62	13.66	0.008	0.03	0.15	0.62	3.35	0.50
Feel restless or fidgety (5)	-0.22	0.09	0.46	16.88	0.002	-0.28	0.16	-0.81	3.98	0.41
Feel so restless (6)	0.08	0.09	-3.11	30.53	0.000	0.09	0.15	-2.78	8.04	0.09
Feel depressed (7)	0.26	0.09	3.87	70.15	0.000					
Everything was an effort (8)	-0.15	0.08	-0.33	7.21	0.125	-0.09	0.15	-0.86	7.03	0.13
Feel so sad (9)	0.16	0.09	-0.48	9.11	0.058	0.34	0.16	-0.56	2.42	0.65
Feel worthless (10)	0.34	0.09	1.33	17.69	0.001					
	<b>Initial solution of K10</b>					<b>Final solution of K7</b>				
Overall model fit	262.27					39.82				
Degree of freedom (DF)	40					28				
P	0.000					0.068				
Item fit residuals (mean (SD))	0.13 (2.49)					-0.20 (1.20)				
Person fit residuals (mean (SD))	-0.18 (1.24)					-0.63 (1.40)				
Person separation index (PSI)	0.84					0.84				
Coefficient alpha	0.87					0.88				
Unidimensionality test (% that goes beyond 95% CI)	9.33% CI (6.9–11.8)					3.34% CI (0.9–5.8)				

**Table 5. DIF on age (adults and older adults) and gender (male and female)**

Items	DIF on Age				DIF on Gender			
	MS	F	DF	Prob	MS	F	DF	Prob
Feel nervous (2)	0.58	0.88	1	0.35	0.59	0.91	1	0.34
Feel so nervous (3)	1.00	1.86	1	0.17	0.06	0.11	1	0.74
Feel hopeless (4)	0.07	0.08	1	0.78	2.41	2.59	1	0.11
Feel restless or fidgety (5)	0.49	0.67	1	0.41	0.66	0.89	1	0.35
Feel so restless (6)	0.50	0.92	1	0.34	0.00	0.00	1	0.98
Everything was an effort (8)	0.12	0.17	1	0.68	0.26	0.36	1	0.55
Feel so sad (9)	5.29	6.86	1	0.01	0.80	1.04	1	0.31

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## Appendix

Table 1. Analysis history

	Analysis	Item fit residuals mean (SD)	Person fit residuals mean (SD)	PSI (CF)	Overall model fit $\chi^2$ (p value)	Status of disorder items	% Significant t-test CI
	1	0.14 (2.50)	-0.19 (1.24)	0.85 (0.87)	262.28 (0.0000)	Five items (1,4,7,8,9)	9.33% CI (6.9–11.8)
	2	-0.71 (2.34)	-0.30 (1.13)	0.84 (0.87)	202.53 (0.0000)	One item (5)	7.3% CI (4.9–9.8)
	3	-1.48 (2.38)	-0.55 (1.44)	0.83 (0.87)	166.67 (0.0000)	No items	4.7% CI (2.2–7.1)
	4	-0.15 (1.92)	-0.30 (1.04)	0.85 (0.83)	107.05 (0.0000)	One item (1)	6.3% CI (3.9–8.8)
	5	0.51 (1.90)	-0.21 (1.03)	0.59 (0.80)	98.51 (0.0000)	Three items (4, 7, 8)	3.0% CI (0.5–5.5)
	6	-1.07 (2.39)	-0.57 (1.55)	0.81 (0.87)	107.13 (0.0000)	No item	6.7% CI (4.2–9.1)
	7	-1.50 (1.97)	-0.67 (1.49)	0.85 (0.88)	96.61 (0.0000)	No item	10.3% CI (7.9–12.8)
	8	-1.58 (2.59)	-0.53 (1.40)	0.82 (0.86)	164.14 (0.0000)	No item	8.3% CI (5.9–10.8)
	9	-1.27 (1.66)	-0.73 (1.62)	0.83 (0.88)	58.73 (0.0027)	No item	16.0% CI (13.5–18.5)
	10	-1.20 (2.61)	-0.55 (1.48)	0.80 (0.86)	126.24 (0.0000)	No item	12.0% CI (9.5–14.5)
	11	-1.55 (1.90)	-0.64 (1.42)	0.85 (0.87)	76.64 (0.0000)	No item	9.3% CI (6.9–11.8)
	12	-1.34 (1.27)	-0.70 (1.53)	0.84 (0.88)	40.11 (0.0647)	No item	6.7% CI (4.2–9.2)
	13	-0.20 (1.20)	-0.06 (1.41)	0.84 (0.88)	39.83 (0.0685)	No item	3.3% CI (0.9–5.8)



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3 The history of statistical analysis of the K10 using Rasch analysis has been mentioned in Table 1  
4 (supplementary file). First, we ran the Rasch analysis with original ten items. Out of the ten  
5 items, five items had disordered thresholds, and overall chi-square values as well as item fit  
6 residuals that were high and significant. We rescored only the disordered items by following the  
7 pattern of categorical probability curve, which suggested the combination of the middle two  
8 response categories into one, but one item still had a disordered threshold. Next, we rescored all  
9 items to 0,1,1,2, 3 from 0, 1, 2, 3, 4. The problem of disordered items was solved, but overall chi-  
10 square values and item fit residuals SD were high. Then, we tried to use the PCA technique to  
11 check whether the scale was more than one dimension. To achieve this, we used PCA technique  
12 to separate positively and negatively worded items. We found that items 1, 2, 3, 5 and 6 were  
13 positively worded items, and 4, 7, 8, 9 and 10 were negatively worded items. We applied Rasch  
14 analysis technique to positively and negatively worded items and found one disordered item  
15 among the positively worded items and three among the negatively worded items, and overall  
16 model fits were poor for both models. We confirmed that the K10 was not a two-factor solution.  
17 Then we revisited the model where we rescored all items to 01123.  
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21 We checked the individual items fit chi-square value, which might influence the overall chi-  
22 square value. We found that item 1 (feel tired) had a high chi-square value followed by item 7  
23 (feel depressed) and item 10 (worthless). First, we removed the item 'feel tired' from the model  
24 and then 'depressed' and finally 'worthless.' Removing one item at a time in the following  
25 sequential order, 'tired', 'depressed' and 'worthless' resulted in chi-square values (SD) of 107.13  
26 (SD = 2.34), 96.61 (SD=1.97) and 164.14 (2.59), respectively, indicating the models were poorly  
27 fit. Removing two items at a time in the following sequential order, 'tired and depressed',  
28 'depressed and worthless', and 'worthless and tired' did not improve the model significantly.  
29 Going through different iteration process in removing items, removing three items together  
30 produced the desired model except the individual's person fit statistics SD (1.53). Further  
31 investigation showed that one person was misfit. Removing the misfit person, Rasch analysis  
32 produced a perfect fit model with seven items, with four categories for each item (Appendix  
33 Table 1). All the assumptions of the Rasch analysis have been met in our model.  
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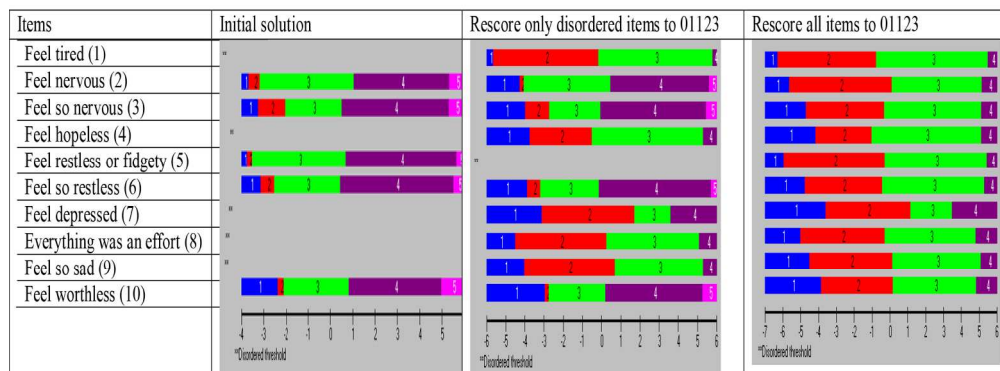
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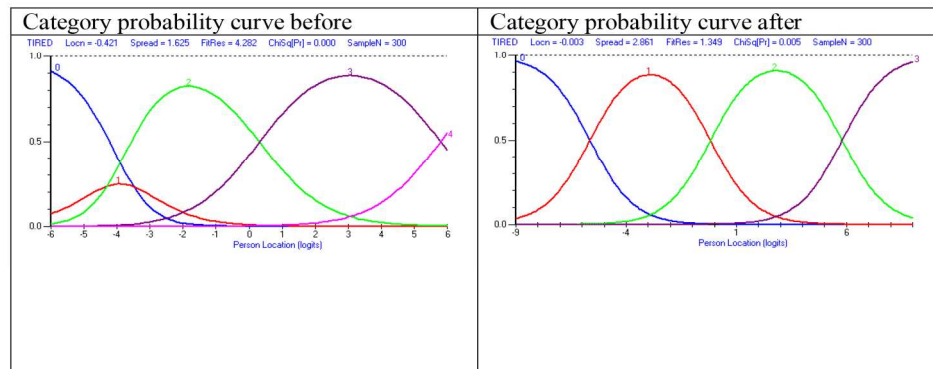
Figure 1. Threshold maps of the original Kessler K10 items



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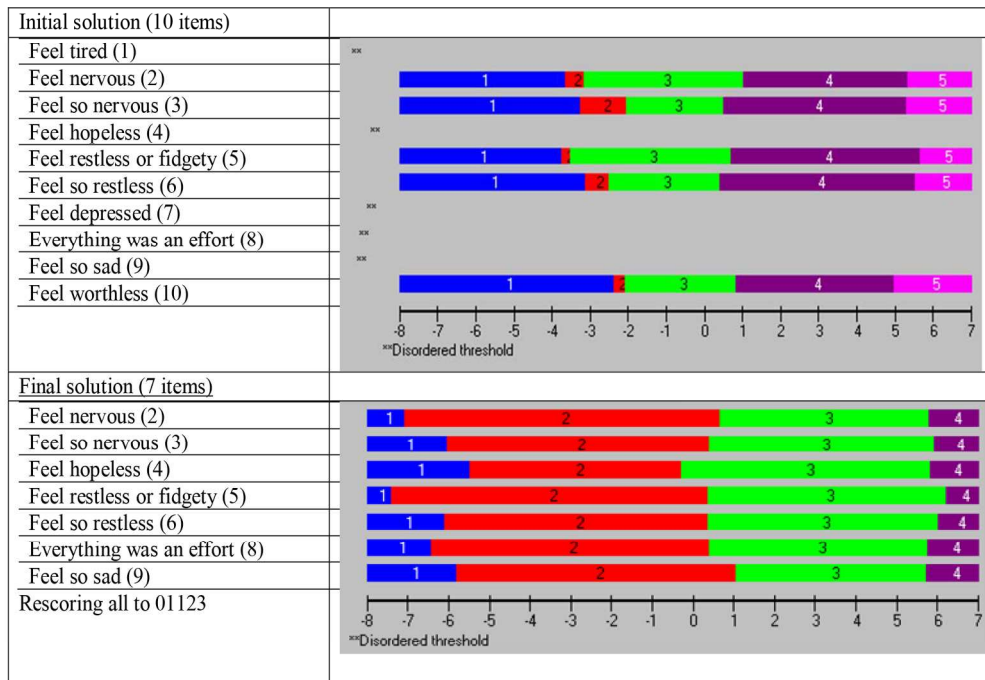
**Figure 2. Category probability curve of item ‘feel tired’ before and after rescoring**



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**Figure 3. Threshold maps of the original 10-items (Kessler 10) vs. the final 7-items model**



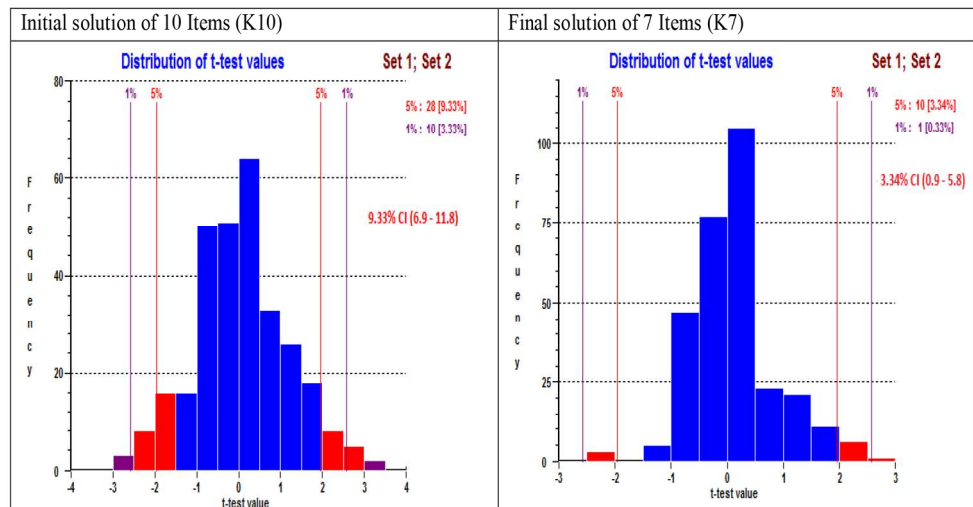
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Figure 4. Dimensionality testing original 10-items (Kessler 10) vs the final 7-items model



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Review only

**STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies***

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Pages 1 and 2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 3
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	Page 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5 (in protocol paper)(ref 28)
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 5 (in protocol paper)(ref 28)
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 6
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	Page 5 (in protocol paper)(ref 28)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Pages 7-9
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(d) If applicable, explain how loss to follow-up was addressed	In protocol paper (ref 28)
		(e) Describe any sensitivity analyses	

<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	Page 5
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	Table 1 on page 17
Outcome data	15*	Report numbers of outcome events or summary measures over time	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Appendix pages 21-22
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	Page 12
<b>Limitations</b>			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Pages 12-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 16

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

# BMJ Open

## Psychometric evaluation of an interview-administered version of the Kessler 10-item questionnaire (K10) for measuring psychological distress in rural Bangladesh

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-022967.R1
Article Type:	Research
Date Submitted by the Author:	29-Apr-2018
Complete List of Authors:	Uddin, Mohammed ; Swinburne University of Technology, Department of Statistics, Data science and Epidemiology Islam, Fakir; Swinburne University of Technology, Statistics, Data Science and Epidemiology Al-Mahmud , Abdullah ; Swinburne University of Technology, 3. School of Design; Faculty of Health, Arts and Design
<b>Primary Subject Heading</b>:	Health services research
Secondary Subject Heading:	Mental health
Keywords:	Psychological Distress, Rasch Analysis, Validation, Kessler Psychological Distress Scale, Rural Bangladesh, Item Response Theory

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4 **2 questionnaire (K10) for measuring psychological distress in rural Bangladesh**  
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7 **ABSTRACT**

8 **Objective** The aim of this study was to translate, adapt and validate the Kessler 10-item  
9 questionnaire (K10) for measuring psychological distress in rural Bangladesh.

11 **Design** Cohort study.

13 **Setting** Narail district, Bangladesh.

15 **Participants** A random sample of 2425 adults of age 18–90 years were recruited.

17 **Outcome measure** Validation of the K10 was the major outcome. Socio-demographic factors  
18 were measured to assess if the K10 needed adjustment for factors such as age or gender. The  
19 Rasch measurement model was used for the validation, and RUMM2030 and SPSS24 software  
20 were used for analyses.  
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25 **Results** Initial inspection of the total sample showed poor overall fit. A sample size of 300,  
26 which is more satiated for Rasch analysis, also showed poor overall fit, as indicated by a  
27 significant item-trait interaction ( $\chi^2 = 262.27$ ,  $df = 40$ ,  $p < 0.001$ ) and item fit residual values  
28 (mean =  $-0.25$ ,  $SD = 2.49$ ). Of 10 items, five items were disordered thresholds, and seven items  
29 showed misfit, suggesting problems with the response format and items. After removing three  
30 items (“feel tired”, “depressed” and “worthless”) and changing the Likert scale categories from  
31 five to four categories, the remaining seven items showed ordered threshold. A revised seven-  
32 item scale has shown adequate internal consistency, with no evidence of multidimensionality, no  
33 differential item functioning (DIF) on age and gender, and no signs of local dependency.  
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43 **Conclusions** Analysis of the psychometric validity of K10 using the Rasch model showed that  
44 10 items are not appropriate for measuring psychological distress in rural Bangladesh. A  
45 modified version of seven items (K7) with four-response category would provide a  
46 psychometrically more robust scale than the original K10. The study findings suggest repeating  
47 the K7 version in other remote areas for further validation can substantiate an efficient screening  
48 tool for measuring psychological distress among the general Bangladeshi population.  
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### 65 **Strengths and limitations of the study**

- 66 ➤ This study provides the first reliable data on the K10 questionnaire from a general  
67 population of a typical rural district in Bangladesh.
- 68 ➤ This study used numerous primary data on K10 and associated covariates.
- 69 ➤ The data were collected through face-to-face interviews of people from a typical rural  
70 district that generally represents Bangladesh.
- 71 ➤ The sophisticated Rasch analysis technique was applied to validate as well as identify a  
72 suitable unidimensional structure of the K10. The study provides a unique opportunity to  
73 assess psychological distress in a rural population of Bangladesh.
- 74 ➤ The potential drawback of this study is that it is based on a single-occasion collection of  
75 data from a rural district in Bangladesh. While we have attempted to capture the situation  
76 in the Narail district, the study needs to be repeated in a random sample of other rural  
77 districts to be truly representative of the national population.

### 80 **Introduction**

81  
82 A high prevalence of psychological distress is recognised worldwide.<sup>1</sup> Psychological distress is  
83 associated with chronic diseases and other health related problems,<sup>2</sup> and early diagnosis is seen  
84 as an important measure to ensure effective and targeted intervention.<sup>3</sup> In recent years,  
85 epidemiological studies have attempted to employ short dimensional scales to effectively  
86 measure and monitor the extent of psychological distress in the general community for the  
87 purposes of early diagnosis.<sup>4</sup> The Kessler 10-item questionnaire (K10) is one such scale among  
88 similar tools such as the Beck Depression Inventory (BDI),<sup>5</sup> the Hospital Anxiety and  
89 Depression Scale (HADS)<sup>6</sup> and the Depression Anxiety Stress Scales (DASS)<sup>7</sup> which are  
90 designed to assess non-specific psychological distress and screen for common psychiatric  
91 disorders.<sup>8-11</sup>

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93 The K10 was developed in 1992 by Professor Kessler and Mroczek<sup>12</sup> to be used in the United  
94 States National Health Interview Survey as a brief measure of non-specific psychological distress  
95 along the anxiety-depression spectrum. The K10 comprises ten questions (rated on five-point  
96 Likert-type scales, where 1 = none of the time to 5 = all of the time) about psychological distress.

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3 97 Although K10 is not a diagnostic tool, it does indicate psychological distress and is used to  
4 98 identify people in need of further assessment for anxiety and depression. The K10 measurement  
5 99 of a client's psychological distress levels can also be used as an outcome measure and assist  
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8 100 treatment planning and monitoring.<sup>13</sup> In the context of the general population, there is often a  
9  
10 101 shortage of space for the inclusion of more items in the scale. The BDI (21 items),<sup>5</sup> HADS (14  
11 102 items)<sup>6</sup> and the DASS (42 items)<sup>7</sup> are limited as screening tools because of their long list of  
12  
13 103 items. Moreover, studies confirm that well-constructed short scales can be as strong predictors as  
14  
15 104 the more lengthy instruments or interviews.<sup>12 14</sup> Because of its small number of items, the K10  
16  
17 105 has, since its development, been widely used in many countries, including the USA, Canada and  
18  
19 106 Australia. The tool has also been adopted in the World Health Organization's World Mental  
20  
21 107 Health Survey.<sup>8-11 15</sup> Moreover, another advantage of the K10 is that it was developed using  
22 108 methods associated with the item response theory.<sup>15</sup>  
23  
24 109

25  
26 110 Although the K10 was originally developed to identify levels of non-specific psychological  
27  
28 111 distress in the general population, the tool has also demonstrated a strong relationship with  
29  
30 112 severe mental illnesses as defined by structured diagnostic interviews.<sup>16</sup> As such, clinicians have  
31  
32 113 been encouraged to use the K10 to screen for psychiatric illness.<sup>17 18</sup> Further, the K10 has been  
33  
34 114 used as a routine outcome measure in specialist public mental health services in multiple  
35  
36 115 Australian states and territories.<sup>4</sup> A recent review of the literature suggests that the K10 is an  
37  
38 116 effective and reliable assessment tool applicable to a variety of settings and cultures for detecting  
39  
40 117 the risk of clinical psychological disorders.<sup>19 20</sup> However, a major limitation of the K10 is the  
41  
42 118 lack of consistency across studies about its factor structure. Although it was initially designed to  
43  
44 119 yield a single score indicating the level of psychological distress,<sup>15</sup> one study demonstrated a  
45  
46 120 four-factor model with acceptable fit in large community samples;<sup>21</sup> another study proposed a  
47  
48 121 two-factor solution, one factor for depression and another for anxiety;<sup>4</sup> while another study did  
49  
50 122 not find an adequate fit.<sup>22</sup>  
51  
52 123

53  
54 124 Bangladesh is a country of 163 million people<sup>23</sup> where mental health complaints are a major  
55  
56 125 public health concern, especially in rural areas.<sup>24-26</sup> The prevalence of mental disorders in such  
57  
58 126 areas varies between 6.5% and 31%, possibly due to the use of different protocols and definitions  
59  
60 127 of mental disorders.<sup>27</sup> A culturally validated tool is needed for quick screening of psychological



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2  
3 128 distress in Bangladesh, as well as in other countries with similar socio-economic conditions. Due  
4  
5 129 to lack of published research on the K10 in rural settings, and uncertainties surrounding the scale  
6  
7 130 noted above, we need to develop a valid measurement scale of psychological distress in  
8  
9 131 Bangladesh.

10 132  
11  
12 133 The present study pursues an update of Rasch analysis technique to evaluate the suitability of the  
13  
14 134 K10 for measuring psychological distress in rural Bangladesh, and to provide guidance on  
15  
16 135 suitable modification to the instrument to improve its performance. Accuracy and precision of  
17  
18 136 K10 scores can lead to a more efficient allocation of health care resources as well as more  
19  
20 137 efficient screening of psychological distress among the rural population.

21 138

## 22 139 **Materials and Methods**

### 23 140 **Study Population**

24  
25 141 Participants were recruited from the Narail district, located approximately 200 km south-west of  
26  
27 142 Dhaka, the capital city of Bangladesh. We recruited a total of 2425 adults aged 18–90 years,  
28  
29 143 from May to July 2017. The study protocol, including its geographic location and population  
30  
31 144 density, is described in detail elsewhere.<sup>28</sup>

32 145

### 33 146 **Sample Size and Statistical Power**

34  
35 147 A sample of approximately 300 is more suitable for a Rasch analysis, because large sample sizes  
36  
37 148 can result in type 1 errors that falsely reject an item for not fitting in the Rasch model.<sup>29</sup> A  
38  
39 149 sample size of 300 is considered large enough for 99% confidence that the estimated item  
40  
41 150 difficulty would be within  $\pm\frac{1}{2}$  logit of its stable value.<sup>30</sup> We did the analysis five times with five  
42  
43 151 different random sample sizes of 300 each, from the total sample of 2425, to check the  
44  
45 152 robustness of the models using different subsamples. For the initial test of the model, we also  
46  
47 153 used the total sample.

48 154

### 49 155 **Sampling Frame**

50  
51 156 A multilevel cluster random sampling technique was used for this cohort study. Three unions  
52  
53 157 (smallest rural administrative unit) out of 13 and 1 Pourashava (smallest urban administrative  
54  
55 158 unit) of Narail Upazilla (the third largest type of administrative division in Bangladesh) were

1  
2  
3 159 randomly selected at level 1. Two to three villages (a smallest territorial and social unit for  
4  
5 160 administrative and representative purposes), from each selected union and two wards (an  
6  
7 161 electoral district, for administrative and representative purposes) were randomly chosen from  
8  
9 162 selected Pourashava at the second level. In total, 150 adults (18–59 year old) and 120 older  
10  
11 163 adults (60–90 year old) from each of the villages/wards were interviewed. Recruitment strategy  
12  
13 164 and quality assurance in data collection are described previously.<sup>28</sup>  
14  
15 165

### 166 **Patient and public involvement**

167 Our study participants are the general people with or without any particular disease. There was a  
168 public involvement in conducting the research including informing the district commissioner,  
169 district police super, civil surgeon, and the public representatives such as the Chairman of the  
170 union parishad. We conducted a pilot survey and arranged a focus group discussion regarding  
171 the understanding of the questionnaire by the general people.  
172

173 Recruitment strategy was reported in the protocol paper.<sup>28</sup> To maintain an approximately equal  
174 number of male and female participants, one female was interviewed immediately after a male  
175 participant. Participants did not involve in the recruitment to and conduct of the study. Although  
176 the results are being published in peer-reviewed journals, the results will be disseminated via  
177 community briefs and presentations at national and international conferences. However, the  
178 participants those will be identified with severe psychological depressed, the Organisation for  
179 Rural Community Development (ORCD) intends to refer them to the psychologists for their  
180 treatment. This is also plan to use the modified version of the questionnaire for mass scale  
181 screening program for measuring psychological distress.  
182

### 183 **Kessler Psychological Distress Scale**

184 The K10 measures how often participants have experienced symptoms of anxiety and depressive  
185 disorders in the previous four weeks prior to screening.<sup>12</sup> Respondents were asked, ‘During the  
186 past four weeks, how often did you feel: 1) tired out for no good reason; 2) nervous; 3) so  
187 nervous that nothing could calm you down; 4) hopeless; 5) restless or fidgety; 6) so restless you  
188 could not sit still; 7) sad or depressed; 8) so depressed that nothing could cheer you up; 9)  
189 everything was an effort; 10) worthless.’ Items are rated on a five-point ordinal scale: all of the

1  
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3 190 time (score 5), most of the time (score 4), some of the time (score 3), a little of the time (score 2)  
4  
5 191 and none of the time (score 1). Questions 3 and 6 are not asked if the preceding question was  
6  
7 192 answered 'none of the time', in which case questions 3 and 6 would automatically receive a  
8  
9 193 score of one. Scores for the ten questions are summed: the maximum score is 50, indicating  
10  
11 194 severe distress; the minimum score is ten indicating no distress. Low scores indicate low levels  
12  
13 195 of psychological distress and high scores indicate higher levels of psychological distress.<sup>12</sup>  
14  
15 196

### 15 197 **Outcome Variables**

16  
17 198 The main outcome measure was the validation of the K10.  
18  
19 199

### 20 200 **Factor Variables of Differential Item Functioning (DIF)**

21  
22 201 Participants were categorised as either adults (18 to 59 year old) or older adults (60 to 90 year  
23  
24 202 old), and by gender (male or female).  
25  
26 203

### 27 204 **Scale Validation:** Item response theory (IRT) and Classical Test Theory (CTT)

28  
29 205  
30  
31 206 **Item Response Theory (IRT)**  
32  
33 207 IRT is a paradigm for the design, analysis and scoring of tests, questionnaires and similar  
34  
35 208 instruments measuring abilities, attitudes or other variables.<sup>31</sup> It is based on the relationship  
36  
37 209 between individuals' performances on a test item and their personal performance on an overall  
38  
39 210 measure of the ability that the item seeks to quantify.<sup>32</sup> All IRT models attempt to explain  
40  
41 211 observed (actual) item performance as a function of an underlying ability (unobserved) or latent  
42  
43 212 trait.  
44  
45 213

### 46 214 **Classical Test Theory (CTT)**

47  
48 215 Classical test theory is a quantitative approach to testing the reliability and validity of a scale  
49  
50 216 based on its items. CTT is a simple linear model which links the observable score (X) to the sum  
51  
52 217 of two unobservable (often called latent) variables, true score (T) and error score (E); i.e.,  $X = T$   
53  
54 218 + E. Because of, each examinee there are two unknowns, without simplified assumption the  
55  
56 219 equation will not be solved. The assumptions in the classical test model are that (a) true scores  
57  
58 220 and error scores are uncorrelated, (b) the average error score in the population of examinees is

221 zero, and (c) error scores on parallel tests are uncorrelated.<sup>33</sup> The true score (T) is defined as the  
 222 expected value of the observed score over an infinite number of repeat administrations of the  
 223 same instrument.<sup>33 34</sup>

224

### 225 **Rationale for using the Rasch analysis instead of the CTT**

226 Similar to the IRT, the CTT is another fundamental measurement theory that researchers employ  
 227 to construct measures of latent traits. Both IRT and CTT can be used to construct measures of  
 228 latent traits, but the two measurement systems are entirely dissimilar. A more in-depth  
 229 explanation of the literature on CTT<sup>35-37</sup> and IRT.<sup>38-41</sup> So far, the K10 was validated mostly using  
 230 CTT in which the items and the latent trait being measured are considered separately and,  
 231 therefore, cannot be meaningfully and systematically compared.<sup>42 43</sup> These limitations can be  
 232 solved rationally using Rasch modelling.<sup>38 39 44-46</sup>

233

### 234 **The Rasch Model**

235 The Rasch model was named after the Danish mathematician Georg Rasch.<sup>47</sup> The model shows  
 236 what should be expected of responses to items if measurement (at the metric level) is to be  
 237 achieved. Two versions of the Rasch model are available:

238 dichotomous,  $P\{X_{ni} = x\} = \frac{e^{x(\beta_n - \delta_i)}}{1 + e^{x(\beta_n - \delta_i)}}$ ,<sup>47</sup>

239 and polytomous,  $P\{X_{ni} = x\} = \frac{e^{-\tau_{1i} - \tau_{2i} - \dots - \tau_{xi} + x(\beta_n - \delta_i)}}{\sum_{x'=0}^{m_i} e^{-\tau_{1i} - \tau_{2i} - \dots - \tau_{xi} + x'(\beta_n - \delta_i)}}$ ,<sup>48</sup>

240 where  $\beta_n$  is the location of person n and  $\delta_i$  is the location of item i.  $\tau_{xi}$ ,  $x = 1, 2, \dots, m_i$  are  
 241 thresholds which partitioned the latent continuum of item i into  $m_i + 1$  ordered categories. X is  
 242 the response value that qualifies the expression by  $\beta_n - \delta_i$ .

243

244 The Rasch analysis in this study was conducted using the RUMM 2030 package.<sup>49</sup> In the  
 245 assessment of K10, respondents were presented with the ten-item questionnaire regarding  
 246 psychological distress. The purpose of the Rasch analysis was to maximise the homogeneity of  
 247 the trait and to allow more significant reduction of redundancy without sacrificing the  
 248 measurement of information by decreasing items and scoring levels to yield a more valid and  
 249 straightforward measure. The Rasch model requires some assumptions that need to be evaluated

1  
2  
3 250 to ensure that an instrument has Rasch properties. The Rasch assumptions most commonly  
4  
5 251 assessed are a) unidimensionality, b) local independence and c) invariability.

6  
7 252  
8 253 Chi-square item-trait interaction statistics define the overall fit of the model for the scale.<sup>50</sup> A  
9  
10 254 non-significant chi-square probability value indicated that the hierarchical ordering of the items  
11  
12 255 is consistent across all levels of the underlying trait. A Bonferroni adjustment<sup>51</sup> is typical of the  
13  
14 256 alpha value used to assess statistical significance, by dividing the alpha value of 0.05 by the  
15  
16 257 number of items in the scale. Item-person interaction statistics distributed as z-statistic with a  
17  
18 258 mean of zero and SD of 1 (indicating perfect fit with the model). Values of SD above 1.5 for  
19  
20 259 either items or person suggest a problem. Individual item fit statistics are presented as residuals  
21  
22 260 (acceptable within the range  $\pm 2.5$ ) and chi-square statistic (require a non-significant chi-square  
23  
24 261 value).

25  
26 263 The Rasch model can be extended to analyse items with more than two response categories,  
27  
28 264 which involves a 'threshold' parameter, represented by the two response categories where either  
29  
30 265 response is probable. Common sources of item misfit occur with 'disorder thresholds' failure of  
31  
32 266 the respondents to use the response category in a manner consistent with the level of the trait  
33  
34 267 being measured.

35  
36 269 Unidimensionality occurs when a set of items measures just one thing in common.<sup>52</sup> To establish  
37  
38 270 this, the first step is to run a Principal Component Analysis (PCA) on the residuals to identify  
39  
40 271 two subsets of the items having the most difference. Second, the items loading on the first factor  
41  
42 272 are extracted, items having positive and negative loadings are defined, and estimates for these  
43  
44 273 two sets are derived. Applying an independent t-test to both sets, which conduct t-tests for each  
45  
46 274 person in the sample comparing their score on the Set 1 items and Set 2 items. If less than 5% of  
47  
48 275 the estimates are outside the range of  $\pm 1.96$ , the scale is considered unidimensional.

49  
50 277 In case of local independence,<sup>53</sup> the items in a test are expected to be unrelated to each other; i.e.  
51  
52 278 the response on each item should not be associated with that of another items. To test for local  
53  
54 279 independence, we need to check the residuals correlation matrix, and any correlation coefficient  
55  
56 280 value greater than 0.3 suggests the two items are locally dependent. In a situation where the

1  
2  
3 281 correlation value is greater than 0.3, the two items need to be merged into one, called subtest  
4  
5 282 analysis, to achieve a significant improvement on PSI value. If so, it is a sign of local  
6  
7 283 dependency and a violation of one of the Rasch assumptions.  
8  
9 284

10 285 Invariability indicates that ‘items are not dependent on the distribution of persons’ abilities and  
11  
12 286 the persons' abilities are not dependent on the test items.<sup>54</sup> In Rasch measurement theory, the  
13  
14 287 scale should work in the same way, irrespective of which group (e.g., gender or age) is being  
15  
16 288 assessed. If for some reason one gender does not display equal likelihood of confirming the item,  
17  
18 289 then the items would display DIF and would violate the requirement of unidimensionality.<sup>55</sup> DIF  
19 290 is an analysis of variance of the person-item deviation residuals with the person’s factors (e.g.,  
20  
21 291 age, gender).  
22  
23 292

24 293 The reliability and internal consistency of the model are defined by the Person Separation Index  
25  
26 294 (PSI).<sup>56</sup> In addition to item fit, examination of person fit is essential. A few responses with  
27  
28 295 unusual response pattern (identified by high positive residuals) may seriously affect the fit at the  
29  
30 296 item level. Such aberrant response patterns occur due to unrecorded co-morbidity or respondents  
31  
32 297 with cognitive defects. Therefore, if some response pattern showed high positive fit residuals,  
33  
34 298 removal from the analysis may make a significant difference to the scale internal construct  
35  
36 299 validity.  
37  
38 300

## 301 **Results**

### 302 *Overview of the respondents*

303 Table 1 shows the summary statistics of both the validation and the total data sets by gender  
304  
305 (male and female). The mean (SD, range) age of the total participant sample was 52.0 years (17,  
306  
307 18–90). Of the total sample, 48.5% were men, 27.6% had no formal education, 4% had at least a  
308  
309 bachelor’s degree level of education.

### 308 *Primary analysis of the original set of ten items and five response categories*

309 K10 scores ranged from 10 to 50 with a mean of 16.7 (SD = 11.3). Initial inspection of the scale  
310  
311 with the total 2425 participants showed poor overall fit with the Rasch model, as indicated by a  
312  
313 significant item-trait interaction ( $\chi^2 = 1729.89$ ,  $df = 40$ ,  $p < 0.001$ ) and item fit residual values

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2  
3 312 (mean = -0.25, SD = 6.75) outside the acceptable range. Eight items were found to be misfit  
4  
5 313 based on the overall fit residual values outside the range of  $\pm 2.5$ . Five items were found to have  
6  
7 314 disordered thresholds, signifying problems with the 5-point response format used for the scale. A  
8  
9 315 check found multidimensionality: the model fit statistics for the five separate random subsamples  
10  
11 316 of 300 each from the total participant sample produced almost identical results, indicating the  
12  
13 317 results and sample selections were robust (Table 2).

14 318  
15 319 Initial inspection of scores in the random sample of 300 participants showed poor overall fit to  
16  
17 320 the Rasch model ( $\chi^2 = 262.27$ ,  $df = 40$ ,  $p < 0.001$ ) and items fit residual values (mean = -0.25,  
18  
19 321 SD = 2.49). However, the person fit residuals (mean = 0.18, SD = 1.24) were within the  
20  
21 322 acceptable range (Table 2, sample 1). Five items were found to have disordered thresholds, and  
22  
23 323 seven of the individuals' item fit statistics showed misfit, suggesting problems with the 5-point  
24  
25 324 response format used for the questionnaire. The value of the PSI (analogous to Cronbach's  
26  
27 325 alpha) for the original set of ten items with five response categories was 0.84, indicating that the  
28  
29 326 scale worked well to separate persons. The frequency distribution of the items showed (data not  
30  
31 327 shown) mistargeting. Across all five items, the distribution was skewed towards the lower  
32  
33 328 values, indicating low psychological distress among the respondents in the sample. Seven items  
34  
35 329 (items 1, 2, 3, 4, 7, 8 and 9) showed misfit (Table 3: initial solution) while five items showed  
36  
37 330 disorder thresholds (1, 4, 7, 8, 9) (Figure 1: initial solution). A visual examination of the  
38  
39 331 threshold map shows that the estimates of the thresholds defining the categories in item 1 (tired)  
40  
41 332 (Figure 2: category probability curve), item 4 (feel hopeless), item 7 (depressed), item 8 (an  
42  
43 333 effort) and item 9 (so sad) do not form distinctive regions of the continuum. We have examined  
44  
45 334 the category probability curve of each disorder threshold item, and found response 1 and 2  
46  
47 335 adjacent category were not the same (Figure 2, category probability curve).

48 336  
49 337 To address the issue of disordered categories, Rasch analysis was conducted on only the  
50  
51 338 disordered items, by merging the two middle categories ('a little of the time' and 'some of the  
52  
53 339 time'). This reduced the scoring to a 4-point format from 01234 to 01123, and made the overall  
54  
55 340 score range 0 to 40. Following this, eight misfit items were identified with significant chi-square  
56  
57 341 probability values, or high positive or high negative residual values ( $\pm 2.5$ ), and found only item  
58  
59 342 5 to be disordered. (Table 3: only disorder items were rescored as 01123). Then we carried out



all items Likert scale categories from five to four categories and found all items were ordered thresholds. (Figure 1: rescore all items to 01123). However, five items were still misfit in the model (Table 3: rescore all items to 01123).

### ***Proposed final analysis of the seven items and four response categories***

Misfit items were removed one at a time iteratively, based on positive or negative residual values as well as the degree of the significant chi-square probability values. The total model fit and individual item fit statistics were checked after each iteration, until the remaining items were shown to fit Rasch model's expectations. The three removed items were items 1, 7 and 10.

The final solution, retaining seven items, showed overall fit with the model (Table 4). The PSI was found to be high (PSI = 0.84), making the model suitable for individual use. The items of the K7 scale were assessed for DIF across gender (male/female) and age (adults: 18–59 year old) and older adults (60–90 year old) (Table 5). A significant DIF was found on item 9 (feel so sad); however, using a Bonferroni-adjusted alpha value ( $.05/7=.007$ ), the value became non-significant. In the final model, seven items with four response categories showed all items to have ordered thresholds (Figure 3). There was no indication of item or person misfit (Table 4: Individuals' items fit statistics of final K7). Unidimensionality of the K7 scale was tested using PCA (3.34%, 95% CI 0.9% to 5.8%), and from a binomial distribution was found non-significant, which supports unidimensionality of the K7 (Table 4, final solution of K10 and Figure 4, final solution of K7). The details statistical analysis history of the K10 using Rasch analysis is shown in (Appendix).

## **Discussion**

The purpose of the paper was to evaluate the suitability of the Kessler 10-item questionnaire for measuring psychological distress in rural Bangladesh. This article examines the potential contribution of Rasch analysis in exploring several issues concerning the K10. This includes an assessment of the appropriateness of using all K10 items to represent the underlying dimension of psychological distress. In addition, the article includes an evaluation of the validity of the category scoring system, the fit of individual items and an assessment of the potential bias of items by gender and age, from the perspective of the Rasch model. The initial descriptive



1  
2  
3 374 analysis of the frequency distributions indicated that the 10-item scale with five response  
4 375 categories mistargeted the current sample of the rural Bangladeshi population. Non-responses or  
5 376 very few responses in the categories may manifested to the mistargeting. Two items ('tired' and  
6 377 'depressed') showed misfit, and two items ('so nervous' and 'so restless') showed redundancy  
7 378 (i.e., little impact on the scale). Moreover, items with disordered thresholds indicating problems  
8 379 with the categorisation of the items and scale showed evidence of multidimensionality. Since the  
9 380 K10 scale has not previously undergone a rigorous psychometric analysis in rural Bangladesh  
10 381 and even in neighbouring countries, the detection of problems was not surprising, even though  
11 382 attention had been paid to targeting when the scale was constructed. In these circumstances, the  
12 383 analysis elaborated on taking advantage of the Rasch model.  
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22 385 One response category was warped, which resulted in four instead of five response categories for  
23 386 each item. Moreover, those items showing misfit were removed from the model gradually after  
24 387 going through all possible steps to improve the model. Item 1 ('how often did you feel tired out  
25 388 for no good reason') was removed because it showed high fit residuals value and DIF for age  
26 389 (adults and older adults). Although techniques exist for solving uniform DIF by allowing the  
27 390 item difficulty to vary by group, we believe that option is inappropriate because it is not useful as  
28 391 an everyday screening environment. Therefore, we decided to delete the biased item, which also  
29 392 had a large chi-square value. On the other hand, the item may not play the concepts of  
30 393 psychological distress in Bangladesh. This could be one reason why the item works differently  
31 394 according to age (adults and older adults). The removal of this item from the scale improved the  
32 395 overall fit of the model, supporting this decision. Moreover, the item removed was one of the  
33 396 four items that Kessler<sup>15</sup> had earlier used to reduce 10 to 6 items. Item 7 ('how often did you feel  
34 397 depressed') was also removed from the scale due to misfit with the model. The large positive  
35 398 residual value indicates misfit in that it contributed little or no information additional to other  
36 399 items, as well as having a large chi-square value. However, the item showed no DIF on age and  
37 400 gender. Removal of the item from the model significantly improved the fit of remaining items.  
38 401 Moreover, the item removed was one of the four-item that Kessler<sup>15</sup> earlier used to reduce 10 to  
39 402 six items. Item 10 ('how often did you feel worthless') has been removed from the scale due to  
40 403 high chi-square value and significant chi-square probability, as well as high positive residuals  
41 404 which contribute to an overall model misfit. The high chi-square value indicates that it adds

nothing to the information gained by other items, and this item is the only one, which increased the overall chi-square value and made the overall model misfit. The study results support the retention of item 10.

Removal of items from the scale would eliminate at least some redundancy.<sup>57-59</sup> However, our analysis identified that Cronbach's alpha for the K7 (0.88) was equivalent to the original K10 Cronbach's alpha (0.87); in addition, the PSI of K7 (0.84) was the same as that of the original K10's PSI (0.84). A study reported by Fassaert et al,<sup>19</sup> showed that some redundancy happens in Cronbach's alpha, when comparing K10 (0.93) and K6 (0.89). However, our model showed superior value of Cronbach's alpha K7 (0.88) compared to the original K10 (0.87) model, and confirms adequate fit of the model in the rural settings in Bangladesh. Although we have proposed seven validated items (K7), a previous study proposed six (K6) items<sup>17</sup> was more robust than the K10. Of K7, five items were common in K6. We only tested K6 items using Rasch analysis and found a poor overall fit. In particular, the presence of the item "feel worthless" showed a large positive fit residual and significantly large chi-square value, which influenced the overall model misfit under Rasch assumptions. Therefore, the current study found that the K7 model is more robust in our sample compared to K6.<sup>17 20</sup>

Gender differences in psychology are ubiquitous,<sup>60</sup> so it is essential to verify whether the model is affected by gender or not. Our revised seven-item model showed no DIF on gender, i.e., there is no gender bias in the revised K7 scale. The K7 scale is equally valid for men and women, which supports the previous findings reported in Australia.<sup>61</sup> Another important factor is age, and there is inconsistency in the literature on the relationship between age and psychological distress.<sup>62</sup> The study conducted by Kessler et al. documented a good deal of inequality in the relationship between age and screening scales of depressive symptoms.<sup>63</sup> However, other studies showed a stable nonlinear association between age and psychological distress in several cross-sectional epidemiologic surveys.<sup>62 64 65</sup> Our revised model of K7 confirmed that there is no age bias (adults and older adults), and the model is equally applicable to any one between the age of 18–90 years.

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3 435 Application of the Rasch measurement model in this study has supported the viability of a seven-  
4  
5 436 item version of the K10 scale for measuring psychological distress in rural Bangladesh. The  
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7 437 scale shows high reliability, with no disordering of thresholds and no evidence of DIF. The  
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9 438 model also showed high PSI (0.84) and reliability (0.87), which indicated the power of the test of  
10  
11 439 fit. Furthermore, there is good evidence from this sample that a single total score of  
12  
13 440 psychological distress is viable. Thus, the seven-item scale appears robust when tested against  
14  
15 441 the strict assumptions of the Rasch measurement model.  
16

17 442  
18 443 This paper shows how the Rasch model can be used for rigorous examination and development  
19  
20 444 of measurement instruments such as the K10 psychological distress scale. The Rasch model  
21  
22 445 simplifies measurement problems such as lack of invariance, which was overlooked in traditional  
23  
24 446 analysis.<sup>66</sup> The Rasch analysis of the K10 scale indicates that the psychometric properties of the  
25  
26 447 original scale most likely would have been much better if scale developmental had been guided  
27  
28 448 by IRT (Rasch analyses). In future, importance should be given to improving the targeting of  
29  
30 449 person and items. Reducing the number of response categories as well as the number of items  
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32 450 might also improve the properties of the scale.<sup>67</sup> Therefore, data on the general rural population  
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34 451 regarding psychological distress based on the revised seven-item scale from the K10, with four-  
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36 452 response category, is superior to the original scale.  
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39 454 This study provides the first reliable data on levels of psychological distress among the general  
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41 455 population of rural Bangladesh. The analysis was based on a large data set of adults and older  
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43 456 adults across a wide range of age, from whom data were collected directly in a face-to-face  
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45 457 interview. The Rasch analysis in this study guided a detailed examination of the structure of the  
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47 458 scale. The response category orderings (threshold ordering) were not examined earlier, and  
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49 459 evidence from the current study does not support the response format or the validity of the  
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51 460 original 10-item scale.  
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54 462 The potential drawback of this study is that it is based on single-occasion collection of data from  
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56 463 people in a rural district of Bangladesh. While we have attempted to capture the situation in the  
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58 464 Narail district, the study would obviously need to be repeated in a random sample of other rural  
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60 465 districts for the results to be truly representative of a national population.

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5 467 **Conclusion**

6 468 Overall, the authors favours the use of K10 in rural Bangladesh, as has been used elsewhere.  
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8 469 However, this study acknowledges that due to cultural variations and strict adherence to Rasch  
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10 470 properties, modification is needed to measure psychological distress in rural Bangladesh. The  
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12 471 results of this study suggest that a revised seven-item version of the K10, with four-response  
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14 472 category, would provide a more robust psychometric scale than the original K10. The modified  
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16 473 seven-item scale fulfils all the assumptions of the Rasch model, and the model has shown no  
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18 474 differential item functioning (DIF) on age and sex as well as no local dependency. The study  
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20 475 findings can be repeated using a random sample of other remote areas in Bangladesh to further  
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22 476 validate the revised scale, as well as to better establish the level of psychological distress  
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24 477 nationwide. The tool can be applied in clinical settings at the national level, where psychological  
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26 478 distress has yet to be diagnosed.

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28 480 **List of abbreviations**

29 481 CTT, Classical Test Theory; IRT, Item Response Theory; DIF, Differential Item Functioning;  
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31 482 PSI; Person Separation Index, K10, Kessler Psychological Distress Scale

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34 484 **Ethical aspects:** Human Ethics Approval was received from the Swinburne University of  
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36 485 Technology Human Ethics Committee (SHR Project 2015/065) in accordance with the tenets of  
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38 486 the Declaration of Helsinki. Study participants provided written informed consent.

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41 488 **Authors' contributions:** MNU and FMAI jointly designed the study. MNU analysed the data  
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43 489 and drafted the manuscript. FMAI contributed to writing the manuscript. FMAI supervised the  
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45 490 overall analyses and preparation of the manuscript. AAM reviewed the manuscript. All authors  
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47 491 contributed to the development of the manuscript and read and approved its final version.

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50 493 **Acknowledgements:** We particularly acknowledge the contribution of Md Rafiqul Islam, Md  
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52 494 Sajibul Islam, Saburan Nesa and Arzan Hosen for their hard work in door-to-door data  
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54 495 collection. Finally, we would like to express our gratitude to the study participants for their  
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56 496 voluntary participation.

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5 498 **Competing interests:** None declared

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8 500 **Funding:** The Faculty of Health, Arts and Design of the Swinburne University Technology  
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10 501 under the Research Development Grant Scheme, funded data collection for this research project.  
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12 502 The funder had no role in the design of the study, data collection or analysis, interpretation of  
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14 503 data or writing of the manuscript.

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17 505 **Data sharing statement:** Data will be available upon request.

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**Table 1. Characteristics of participants who were included and who were not in the current study, by gender**

Characteristic	Total N=2425			In validation N=300		
	Total (2425)	Male (1176)	Female (1249)	Total (300)	Male (143)	Female (153)
Age groups (in years)						
18–59	1278 (52.7)	603 (51.3)	675 (54.0)	172 (57.3)	73 (51.0)	99 (63.1)
60–90	1147 (47.3)	573 (48.7)	574 (46.0)	128 (42.7)	70 (49.0)	58 (36.9)
Education						
No education	671 (27.7)	289 (24.6)	382 (30.6)	76 (25.3)	37 (25.9)	39 (24.8)
Primary (1–5)	946 (39.0)	447 (38.0)	499 (40.0)	124 (41.3)	58 (40.6)	66 (42.0)
Secondary (6–9)	327 (13.5)	146 (12.4)	181 (14.5)	38 (12.7)	13 (9.1)	25 (15.9)
SSC or HSC Pass (10–12)	385 (15.9)	224 (19.0)	161 (12.9)	50 (16.7)	26 (18.2)	24 (15.3)
Degree or equivalent (13–16)	96 (4.0)	70 (6.0)	26 (2.1)	12 (4.0)	9 (6.3)	3 (1.9)

SSC – Secondary School Certificate, HSC- Higher Secondary Certificate

**Table 2. Model Fit Statistics for total sample and five random samples of 300 with all 10 items**

Initial solution	Total sample N=2425	Sample 1 n=300	Sample 2 n=300	Sample 3 n=300	Sample 4 n=300	Sample 5 n=300
Overall model fit, Chi-square value	1727.89	262.27	212.30	204.07	194.37	282.14
Degree of freedom (DF)	40	40	40	40	40	40
P	0.00000	0.0000	0.0000	0.0000	0.0000	0.0000
Item fit residuals (mean (SD))	–0.25 (6.75)	0.13 (2.49)	0.05 (2.40)	–0.23 (2.12)	0.11 (2.38)	–0.16 (2.64)
Person fit residuals (mean (SD))	–0.29 (1.32)	–0.18 (1.24)	–0.28 (1.33)	–0.34 (1.32)	–0.30 (1.37)	–0.27 (1.32)
Person separation index (PSI)	0.84	0.84	0.83	0.85	0.82	0.83
Coefficient alpha	0.86	0.87	0.86	0.87	0.86	0.87
Unidimensionality test (% that goes beyond 95% CI)	10.3 (9.6–11.2)	9.3 (6.9–11.8)	11.7 (9.2–14.1)	8.3 (5.9–10.8)	9.0 (6.5–11.5)	10.33 (7.9–12.8)

**Table 3. Fit statistics (location, residuals and P values) of the 10 items for the first random sample of 300**

Items	Initial solution			Rescore only disordered items to 01123*			Rescore all items to 01123		
	Location	Residuals	P value	Location	Residuals	P value	Location	Residual	P value
Feel tired (1)	-0.42	4.28	0.000*^	0.00	1.35	0.005	-0.51	1.22	0.000^
Feel nervous (2)	-0.11	-0.85	0.001^	-0.56	-1.19	0.004^	-0.12	-3.26	0.020
Feel so nervous (3)	0.13	-3.16	0.000^	-0.32	-3.65	0.002^	0.05	-4.13	0.002^
Feel hopeless (4)	-0.06	-0.62	0.008*	0.34	-1.54	0.001^	-0.03	-1.77	0.104
Feel restless or fidgety (5)	-0.22	0.46	0.002^	-0.69	0.11	0.001*^	-0.26	-1.93	0.302
Feel so restless (6)	0.08	-3.11	0.000*^	-0.38	-3.39	0.007	0.04	-3.73	0.003^
Feel depressed (7)	0.26	3.87	0.000*^	0.74	3.00	0.000^	0.35	3.18	0.000^
Everything was an effort (8)	-0.15	-0.33	0.125*	0.28	-1.90	0.000^	-0.16	-2.36	0.301
Feel so sad (9)	0.16	-0.48	0.058	0.65	-2.32	0.001^	0.25	-2.64	0.003^
Feel worthless (10)	0.34	1.33	0.001^	-0.06	2.41	0.003^	0.39	0.60	0.247

\*Disordered items; ^ P values depend on chi-square values (Bonferroni correction (p value/number of items)) =.05/10=.005)

**Table 4. Individuals' item fit statistics of original Kessler K10 and final seven-items model**

Items	Individuals' items fit statistics of original K10					Individuals' items fit statistics of Final K7				
	Location	SE	Residual	$\chi^2$	P value	Location	SE	Residual	$\chi^2$	P value
Feel tired (1)	-0.42	0.08	4.28	46.76	0.000					
Feel nervous (2)	-0.11	0.09	-0.85	19.94	0.001	-0.20	0.15	-1.40	3.99	0.41
Feel so nervous (3)	0.13	0.09	-3.16	30.36	0.000	0.10	0.15	-2.66	11.01	0.03
Feel hopeless (4)	-0.06	0.08	-0.62	13.66	0.008	0.03	0.15	0.62	3.35	0.50
Feel restless or fidgety (5)	-0.22	0.09	0.46	16.88	0.002	-0.28	0.16	-0.81	3.98	0.41
Feel so restless (6)	0.08	0.09	-3.11	30.53	0.000	0.09	0.15	-2.78	8.04	0.09
Feel depressed (7)	0.26	0.09	3.87	70.15	0.000					
Everything was an effort (8)	-0.15	0.08	-0.33	7.21	0.125	-0.09	0.15	-0.86	7.03	0.13
Feel so sad (9)	0.16	0.09	-0.48	9.11	0.058	0.34	0.16	-0.56	2.42	0.65
Feel worthless (10)	0.34	0.09	1.33	17.69	0.001					
	<b>Initial solution of K10</b>					<b>Final solution of K7</b>				
Overall model fit				262.27					39.82	
Degree of freedom (DF)				40					28	
P				0.000					0.068	
Item fit residuals (mean (SD))				0.13 (2.49)					-0.20 (1.20)	
Person fit residuals (mean (SD))				-0.18 (1.24)					-0.63 (1.40)	
Person separation index (PSI)				0.84					0.84	
Coefficient alpha				0.87					0.88	
Unidimensionality test (% that goes beyond 95% CI)				9.33% CI (6.9–11.8)					3.34% CI (0.9–5.8)	



**Table 5. DIF on age (adults and older adults) and gender (male and female)**

Items	DIF on Age				DIF on Gender			
	MS	F	DF	Prob	MS	F	DF	Prob
Feel nervous (2)	0.58	0.88	1	0.35	0.59	0.91	1	0.34
Feel so nervous (3)	1.00	1.86	1	0.17	0.06	0.11	1	0.74
Feel hopeless (4)	0.07	0.08	1	0.78	2.41	2.59	1	0.11
Feel restless or fidgety (5)	0.49	0.67	1	0.41	0.66	0.89	1	0.35
Feel so restless (6)	0.50	0.92	1	0.34	0.00	0.00	1	0.98
Everything was an effort (8)	0.12	0.17	1	0.68	0.26	0.36	1	0.55
Feel so sad (9)	5.29	6.86	1	0.01	0.80	1.04	1	0.31

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3 **Figure legends**  
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6 **Figure 1: Threshold maps of the original Kessler K10 items**  
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8 **Figure 2: Category probability curve of item ‘feel tired’ before and after rescoring**  
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10 **Figure 3: Threshold maps of the original 10-items (Kessler 10) vs. the final 7-items model**  
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12 **Figure 4: Dimensionality testing original 10-items (Kessler 10) vs the final 7-items model**  
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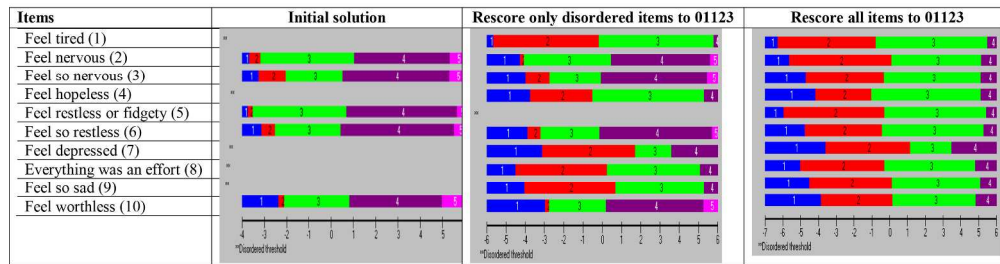


Figure 1: Threshold maps of the original Kessler K10 items

247x77mm (300 x 300 DPI)

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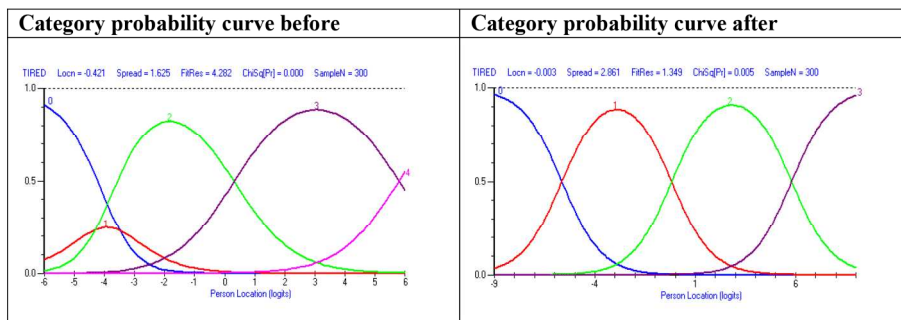


Figure 1: Category probability curve of item 'feel tired' before and after rescoring

176x78mm (300 x 300 DPI)

Peer review only



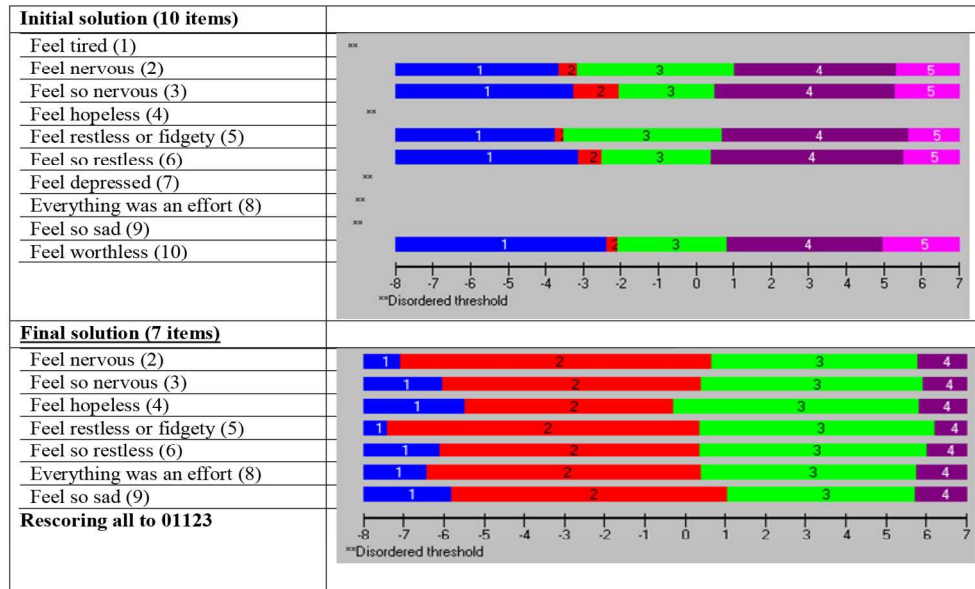


Figure 3: Threshold maps of the original 10-items (Kessler 10) vs. the final 7-items model

156x102mm (300 x 300 DPI)

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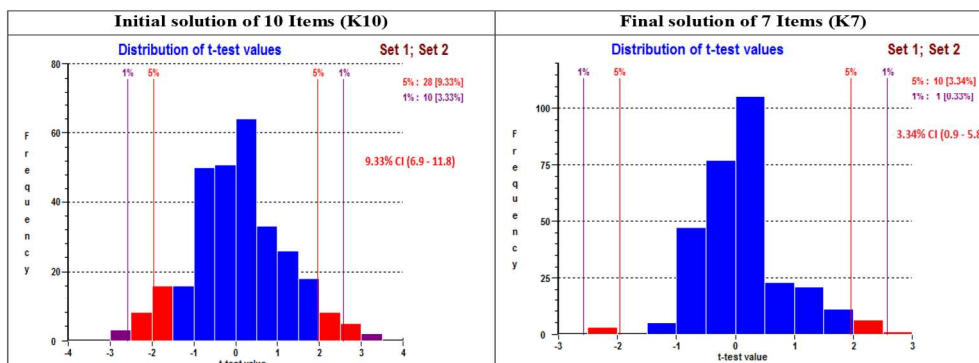


Figure 4: Dimensionality testing original 10-items (Kessler 10) vs the final 7-items model

163x67mm (300 x 300 DPI)

Peer review only

## Appendix

Table 1. Analysis history

	Analysis	Item fit residuals mean (SD)	Person fit residuals mean (SD)	PSI (CF)	Overall model fit $\chi^2$ (p value)	Status of disorder items	% Significant t-test CI
	1	0.14 (2.50)	-0.19 (1.24)	0.85 (0.87)	262.28 (0.0000)	Five items (1,4,7,8,9)	9.33% CI (6.9–11.8)
	2	-0.71 (2.34)	-0.30 (1.13)	0.84 (0.87)	202.53 (0.0000)	One item (5)	7.3% CI (4.9–9.8)
	3	-1.48 (2.38)	-0.55 (1.44)	0.83 (0.87)	166.67 (0.0000)	No items	4.7% CI (2.2–7.1)
	4	-0.15 (1.92)	-0.30 (1.04)	0.85 (0.83)	107.05 (0.0000)	One item (1)	6.3% CI (3.9–8.8)
	5	0.51 (1.90)	-0.21 (1.03)	0.59 (0.80)	98.51 (0.0000)	Three items (4, 7, 8)	3.0% CI (0.5–5.5)
	6	-1.07 (2.39)	-0.57 (1.55)	0.81 (0.87)	107.13 (0.0000)	No item	6.7% CI (4.2–9.1)
	7	-1.50 (1.97)	-0.67 (1.49)	0.85 (0.88)	96.61 (0.0000)	No item	10.3% CI (7.9–12.8)
	8	-1.58 (2.59)	-0.53 (1.40)	0.82 (0.86)	164.14 (0.0000)	No item	8.3% CI (5.9–10.8)
	9	-1.27 (1.66)	-0.73 (1.62)	0.83 (0.88)	58.73 (0.0027)	No item	16.0% CI (13.5–18.5)
	10	-1.20 (2.61)	-0.55 (1.48)	0.80 (0.86)	126.24 (0.0000)	No item	12.0% CI (9.5–14.5)
	11	-1.55 (1.90)	-0.64 (1.42)	0.85 (0.87)	76.64 (0.0000)	No item	9.3% CI (6.9–11.8)
	12	-1.34 (1.27)	-0.70 (1.53)	0.84 (0.88)	40.11 (0.0647)	No item	6.7% CI (4.2–9.2)
	13	-0.20 (1.20)	-0.06 (1.41)	0.84 (0.88)	39.83 (0.0685)	No item	3.3% CI (0.9–5.8)

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3 The history of statistical analysis of the K10 using Rasch analysis has been mentioned in Table  
4 1 (supplementary file). First, we ran the Rasch analysis with original ten items. Out of the ten  
5 items, five items had disordered thresholds, and overall chi-square values as well as item fit  
6 residuals that were high and significant. We rescored only the disordered items by following  
7 the pattern of categorical probability curve, which suggested the combination of the middle  
8 two response categories into one, but one item still had a disordered threshold. Next, we  
9 rescored all items to 0,1,1,2, 3 from 0, 1, 2, 3, 4. The problem of disordered items was solved,  
10 but overall chi-square values and item fit residuals SD were high. Then, we tried to use the  
11 PCA technique to check whether the scale was more than one dimension. To achieve this, we  
12 used PCA technique to separate positively and negatively worded items. We found that items  
13 1, 2, 3, 5 and 6 were positively worded items, and 4, 7, 8, 9 and 10 were negatively worded  
14 items. We applied Rasch analysis technique to positively and negatively worded items and  
15 found one disordered item among the positively worded items and three among the negatively  
16 worded items, and overall model fits were poor for both models. We confirmed that the K10  
17 was not a two-factor solution. Then we revisited the model where we rescored all items to  
18 01123.  
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22  
23 We checked the individual items fit chi-square value, which might influence the overall chi-  
24 square value. We found that item 1 (feel tired) had a high chi-square value followed by item 7  
25 (feel depressed) and item 10 (worthless). First, we removed the item 'feel tired' from the model  
26 and then 'depressed' and finally 'worthless.' Removing one item at a time in the following  
27 sequential order, 'tired', 'depressed' and 'worthless' resulted in chi-square values (SD) of  
28 107.13 (SD = 2.34), 96.61 (SD=1.97) and 164.14 (2.59), respectively, indicating the models  
29 were poorly fit. Removing two items at a time in the following sequential order, 'tired and  
30 depressed', 'depressed and worthless', and 'worthless and tired' did not improve the model  
31 significantly. Going through different iteration process in removing items, removing three  
32 items together produced the desired model except the individual's person fit statistics SD  
33 (1.53). Further investigation showed that one person was misfit. Removing the misfit person,  
34 Rasch analysis produced a perfect fit model with seven items, with four categories for each  
35 item (Appendix Table 1). All the assumptions of the Rasch analysis have been met in our  
36 model.  
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**STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies**

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	Pages 1 and 2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 3
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	Page 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5 (in protocol paper)(ref 28)
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 5 (in protocol paper)(ref 28)
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 6
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	Page 5 (in protocol paper)(ref 28)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Pages 7-9
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(d) If applicable, explain how loss to follow-up was addressed	In protocol paper (ref 28)
		(e) Describe any sensitivity analyses	

<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	Page 5
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	Table 1 on page 17
Outcome data	15*	Report numbers of outcome events or summary measures over time	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Appendix pages 21-22
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	Page 12
<b>Limitations</b>			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Pages 12-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 16

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).