

# Psychometric evaluation of a newly developed Elderly-Constipation Impact Scale

Patimah Abdul Wahab<sup>Corresp., 1, 2</sup>, Azidah Abdul Kadir<sup>3</sup>, Siti Hawa Ali<sup>4</sup>, Yeong Yeh Lee<sup>5</sup>, Yee Cheng Kueh<sup>6</sup>, Dariah Mohd Yusoff<sup>2</sup>

<sup>1</sup> Department of Medical-Surgical Nursing, Kulliyah of Nursing, International Islamic University Malaysia, Kuantan, Pahang, Malaysia

<sup>2</sup> Programme of Nursing, School of Health Sciences, Universiti Sains Malaysia, Kota Bharu, Kelantan, Malaysia

<sup>3</sup> Department of Family Medicine, School of Medical Sciences, Universiti Sains Malaysia, Kota Bharu, Kelantan, Malaysia

<sup>4</sup> Unit of Interdisciplinary Health Sciences, School of Health Sciences, Universiti Sains Malaysia, Kota Bharu, Kelantan, Malaysia

<sup>5</sup> Department of Medical, School of Medical Sciences, Universiti Sains Malaysia, Kota Bharu, Kelantan, Malaysia

<sup>6</sup> Unit of Biostatistics and Research Methodology, School of Medical Sciences, Universiti Sains Malaysia, Kota Bharu, Kelantan, Malaysia

Corresponding Author: Patimah Abdul Wahab  
Email address: patimah@iium.edu.my

**Background.** Chronic constipation is a common symptom among the elderly and it may affect their quality of life (QoL). A lack of available research focused on the elderly means that this effect is not well understood. This study aimed to develop and validate a new scale (Elderly-Constipation Impact Scale [E-CIS]) to measure the impact of chronic constipation on QoL among the elderly. **Methods.** A pool of items was generated from a qualitative study, literature reviews, and expert reviews. Exploratory factor analysis (EFA) was performed on the original 40 items of the E-CIS and followed by 27 items for confirmatory factor analysis (CFA). A total of 470 elderly people with chronic constipation were involved. **Results.** The mean age of the participants was  $68.64 \pm 6.57$ . Finally, only 22 items were indicated as appropriately representing the E-CIS, which were grouped into seven subscales: 'daily activities', 'treatment satisfaction', 'lack of control of bodily function', 'diet restriction', 'symptom intensity', 'anxiety' and 'preventive actions'. The scale was confirmed as valid (root mean square error of approximation [RMSEA] = 0.04, comparative fit index [CFI] = 0.961, Tucker-Lewis index [TLI] = 0.952 and chi-square/degree of freedom [chiSq/df] = 1.44) and reliable (Cronbach's alpha: 0.66 - 0.85, composite reliability [CR] = 0.699 - 0.851) to assess the impact of chronic constipation on the elderly's QoL. **Conclusions.** The E-CIS is useful to measure the impact of chronic constipation on the elderly's QoL. A further test is needed to determine the validity and reliability of this scale in other elderly population.

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<sup>1</sup> Department of Medical-Surgical Nursing, Kulliyyah of Nursing, International Islamic University Malaysia, Kuantan, Pahang, Malaysia

<sup>2</sup> Programme of Nursing, School of Health Sciences, Universiti Sains Malaysia, Kota Bharu, Kelantan, Malaysia

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<sup>4</sup> Unit of Interdisciplinary Health Sciences, School of Health Sciences, Universiti Sains Malaysia, Kota Bharu, Kelantan, Malaysia

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Corresponding Author:

Patimah Abdul Wahab<sup>1,2</sup>

Email address: [patimah@iium.edu.my](mailto:patimah@iium.edu.my)

## 35 Abstract

36 **Background.** Chronic constipation is a common symptom among the elderly and it may affect  
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38 effect is not well understood. This study aimed to develop and validate a new scale (Elderly-  
39 Constipation Impact Scale [E-CIS]) to measure the impact of chronic constipation on QoL  
40 among the elderly.

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52 impact of chronic constipation on the elderly's QoL.

53 **Conclusions.** The E-CIS is useful to measure the impact of chronic constipation on the elderly's  
54 QoL. A further test is needed to determine the validity and reliability of this scale in other elderly  
55 population.

## 56 Introduction

57 Constipation occurs frequently among the elderly and its prevalence may be as high as 20% of  
58 community-dwelling elderly people and 74% of nursing home residents (Bouras & Tangalos,  
59 2009). It is a symptom-based disorder of the gastrointestinal system which refers to a condition  
60 of having difficulties in bowel opening or infrequent passage of stool, hard stool, or a feeling of  
61 incomplete evacuation (Bharucha, Pemberton & Locke, 2013). Previous studies showed that  
62 constipation may cause a considerable impact on quality of life (QoL) and functional status, as  
63 well as being a significant driver of healthcare costs (Dennison et al., 2005; Nellesen et al., 2013;  
64 Pinto Sanchez & Bercik, 2011; Shalmani et al., 2011; Sun et al., 2011). The impact of  
65 constipation on QoL is usually predominated by mental health, and the magnitude of the impact  
66 is comparable to other diseases (Belsey et al., 2010). This impact is more obvious among the  
67 elderly with persistent or chronic conditions and the presence of abdominal pain or discomfort  
68 (Johanson & Kralstein, 2007; Jun et al., 2006; Koloski et al., 2013).

69 The impact of constipation on the elderly's QoL is usually measured using constipation-  
70 specific or generic instruments. The use of generic instruments is limited in terms of comparing  
71 the impact on QoL of those with and without constipation, but the constipation-specific  
72 instrument allows the detection of the specific impact of constipation on QoL. So far, there is one

73 main constipation QoL scale (Patient Assessment of Constipation Quality of Life [PAC-QoL])  
74 with psychometric validity and reliability available for the elderly population (Frank, Flynn &  
75 Rothman, 2001; Marquis et al., 2005). However, its usage is not suitable for the elderly because  
76 the impact is measured based on five items under the satisfaction domain, and the scale was  
77 validated only on the feasibility of the interview format among 24 nursing home residents with  
78 chronic constipation.

79 The existing constipation QoL scales also differ in terms of the domains measured. For  
80 example, Szeinbach et al. (2009), focused only on patients' satisfaction with the treatment  
81 because of its closed relationship with the other domains like daily life activity and psychosocial  
82 domains. In contrast to this, Wang et al. (2009), argued that the satisfaction domain is more  
83 likely to measure symptom severity, while the physical domain is not measuring the impact of  
84 chronic constipation on daily life activity. Based on the revised Wilson and Cleary model of  
85 health-related quality of life (HRQoL), an individual's constipation-QoL is influenced by the  
86 individual's characteristics, environment, biological function, symptoms, functional status,  
87 general health perceptions and overall QoL (Ferrans et al., 2005; Bakas et al., 2012).

88 Patimah and colleagues (2017) emphasized that the existing constipation-QoL scales  
89 were developed in Western countries and, thus, they have lack of cultural sensitivity and  
90 reference to issues of age. Most of the domains and items measured such as work/leisure,  
91 psychosocial or social impairment, and treatment satisfaction refer to Western cultures and  
92 lifestyles which are unsuitable for other populations, particularly elderly residents of Asian  
93 countries. A good scale should be developed based on the importance of the domains measured  
94 to the study population and the impact of symptoms as defined by the patient (Byrne et al., 2002;  
95 Damon, Dumas & Mion, 2004; Nilsson, Parker & Kabir, 2004). Thus, this study aimed to  
96 develop and validate a culturally sensitive scale - the Elderly Constipation Impact Scale (E-CIS)  
97 - with the purpose of assessing the impact of chronic constipation on QoL among elderly people,  
98 regardless of treatments they received or practised. In this study, we used the World Health  
99 Organization definition "a state of complete physical, mental, and social well-being not merely  
100 the absence of disease or infirmity" (International Health Conference, 2002) to define the impact  
101 of chronic constipation on health related QoL.  
102

## 103 **Materials & Methods**

### 104 **Sample**

105 The sample of this study was elderly with chronic constipation living in community settings of  
106 states of Terengganu and Kelantan. They were defined based on Malaysia's National Policy for  
107 Older Persons, which is an individual age 60 years old and above (Ministry of Women Family  
108 and Community Development, 2011). The criteria for inclusion were that participants must be  
109 men or women, who had lived in the community for at least 12 months and were able to  
110 understand Malay language (spoken in the local dialect). The criteria for exclusion were  
111 cognitive impairment - as determined by the elderly cognitive assessment questionnaire (ECAQ)

112 (Kue & Ko, 1992, 1995), hospitalization, significant hearing impairment, stoma, and  
113 gastrointestinal cancers. These eligibility criteria were applied to participants for all phases.

114 For diagnosis of chronic constipation, the elderly participants were asked the following  
115 question: ‘Do you have constipation for the past three months?’, and, if they answered ‘Yes’,  
116 they were asked to rate the level of severity based on a 5-point Likert scale (1 = not severe to 5 =  
117 very severe). Respondents with constipation for the past three months, with a severity level of at  
118 least ‘slightly severe’, were invited to participate in the study. The aim was to involve a  
119 heterogeneous population that allowed for the detection of differences in scores across the new  
120 scale (Marquis et al., 2005; Szeinbach et al., 2009). General health status was measured by  
121 asking the participants to rate their current perception on health status using a 5-point Likert  
122 scale between poor and very good.

123 The participants were recruited from two community settings: Terengganu in Phase 2 and  
124 Kelantan in Phase 3 of the study. A random cluster sampling to eight districts of Terengganu  
125 resulted in the elderly living in community setting in the district of Marang were selected. In  
126 Kelantan, purposive sampling was used to recruit the participants by using the homogenous  
127 sampling method (Etikan, Musa & Alkassim, 2016). They were among those who attended a  
128 family medicine specialist clinic in a teaching hospital situated in Kelantan.

129 The total sample size of this study was 470 participants. In Phase 2, the sample size of  
130 200 was derived based on a five participants per item ratio (Anthoine et al., 2014). Another  
131 group of elderly people were then recruited in Phase 3 with the sample size of 270, which was  
132 calculated based on the ratio of 10 participants to one item (Fabrigar & Wegener, 2012;  
133 Nunnally, 1978).

## 134 **Data assessment**

135 The E-CIS was developed and validated in three phases: a) items generation (Phase 1); b) items  
136 reduction and establishment of factor structure (Phase 2), and; c) confirmation of the factor  
137 structure and items (Phase 3). Meanwhile, its reliability was examined in the last two phases  
138 (*Fig. 1*). Findings of Phase 1 was used to generate initial items for the new scale. Following this,  
139 two cross-sectional studies were carried out among the elderly of a community setting in  
140 Terengganu and Kelantan from October 2015 to July 2016 to evaluate its psychometric property.  
141 A set of questionnaires consisting of socio-demographic data and items of the new scale were  
142 completed. In Phase 2, a face-to-face interview from door-to-door was conducted by an  
143 investigator and a research assistant (PAW & NFR) to prevent incomplete data. A similar  
144 approach of data collection was applied by the similar researcher in Phase 3 to avoid bias. The  
145 study involving human participants has obtained ethical approval from the Research Ethics  
146 Committee (Human), Universiti Sains Malaysia (USM/JEPeM/272.3. [1.7]). Permission to  
147 conduct the study was granted by the headmen and hospital director. Prior to data collection,  
148 verbal and written consents were obtained from the participants.

149

## 150 **Items Generation**

151 An initial pool of items was generated based on inputs from three sources that consisted of data  
152 from semi-structured interviews, comprehensive literature reviews, and opinions from an  
153 interdisciplinary group of experts. Data of semi-structured interviews were derived from a  
154 previously published study by the same group of investigators (Patimah et al., 2017). Initially,  
155 relevant codes from interviews were rereviewed to form items using layman descriptors in the  
156 standard Malay language. Crosschecking of these codes with literature reviews produced 74  
157 items (Marquis et al., 2005; Bowling & Stenner, 2011).

158 To ensure content validity, all 74 items were reviewed by an expert panel that consisted  
159 of two nurses, two medical doctors, two lecturers, and one researcher (DMY, AFI, LYY, AAK,  
160 SHA, MSBY, & IIH). In addition, decisions to delete or to retain items were guided by the  
161 content validity index (CVI), an index based on the aggregated ratings of a panel of experts  
162 (Polit & Beck, 2006). The recommended minimum CVI for scale (S-CVI) is 0.80 and for  
163 individual items (I-CVI) is 0.78 (Polit & Beck, 2006, 2012). For E-CIS, the S-CVI was 0.77 and  
164 I-CVI ranged 0.40 to 1.00. Subsequently, items with low I-CVI were either removed or revised  
165 and, at the end of this process, 43 of 74 items remained. Next, the remaining 43 items and their  
166 responses (visual analogue scale and Likert scale) were checked for wording, content,  
167 appropriateness and convenience by two elderly people with chronic constipation (IM & RY).

168 The 43-item questionnaire was then pre-tested on another 20 elderly people with chronic  
169 constipation recruited via a face-to-face approach in an informal educational center. A debriefing  
170 interview was conducted, where they were asked to complete the questionnaire and they were  
171 then asked to explain their understanding of the items using their own words. They were also  
172 asked to comment and provide suggestions on the instructions and contents of the questionnaire.  
173 After this process, three items were removed, and 40 items were further examined for their factor  
174 structure.

175 To summarize, the first version of E-CIS has 40 items of 5-point Likert scale. Responses  
176 on impact are measured based on frequency of experience, where 1 = never or very rare and 5 =  
177 always. In these items, a higher score indicates a greater impact of chronic constipation on QoL  
178 of the elderly person. On the other hand, four items are rated based on the level of agreement to  
179 their treatment satisfaction, with values ranging from 1 = strongly disagree to 5 = strongly agree.  
180 These are reversed coded items. The total score is determined as a percentage by summing the  
181 scores per the total score and multiplying by 100.

182

### 183 **Item reduction and establishment of factor structure**

184 Phase 2 was an exploratory factor analysis (EFA) to further reduce irrelevant items and to  
185 establish a factor structure. Principal axis factoring with promax rotation extraction was applied  
186 to explore the structure within the data as a basis for removal of redundancy or unnecessary  
187 items. The number of factors was determined based on the scree plot, eigenvalues greater than  
188 1.0, and that they met the variance criterion of higher than 60% (Hair et al., 2010). The items  
189 were retained for further analysis if they obtained the ideal communality value of 0.3 and higher  
190 and had factor loadings of 0.3 and higher on one factor without extensive cross-loadings on other

191 factors (Hair et al., 2010; Child, 2006). A low communality value and low factor loadings  
192 indicate the failure of items to represent its factor satisfactorily (Hair et al., 2010; Fabrigar &  
193 Wegener, 2012).

194

#### 195 **Confirmation of the factor structure and items**

196 Confirmatory factor analysis (CFA) was carried out in the last phase of this study. The CFA was  
197 performed using the analysis of moment structure (AMOS) software version 21 (SPSS Inc.,  
198 Chicago, US) to assess the fitness of the factor structure. Four types of fitness indexes were used  
199 to assess the goodness of fit: root mean square error of approximation (RMSEA) of  $< 0.08$ ,  
200 comparative fit index (CFI) and Tucker-Lewis fit index (TLI) of  $> 0.90$ , and chi-square/degrees  
201 of freedom (chisq/df) of  $< 3.0$  (Zainudin, 2014, 2015). The factor structure of E-CIS was fit, and  
202 the construct validity was achieved, if the model met the fitness indexes' required levels. The  
203 modification index (MI) was used to guide model modification because the emphasis on content  
204 of the construct above model fit adjustments was necessary, especially when our main research  
205 objective was scale development (Hair et al., 2010; DeVellis, 2012).

206

#### 207 **Data and statistical analysis**

208 Frequency or mean was used for descriptive data where appropriate. The construct validity of the  
209 new scale was examined firstly by EFA, followed by CFA - as described in above sections.  
210 Pairwise deletion for correlations, the listwise exclusion for the EFA, and full estimation  
211 maximum likelihood estimation in the CFA were used to handle the missing data. In addition,  
212 convergent validity and reliability were also assessed, as described below.

213         Convergent validity was assessed by computing the value of average variance extracted  
214 (AVE) for every construct. The validity was achieved when all of the AVE values exceeded 0.50  
215 (Zainudin, 2014, 2015). Having less than that would indicate more errors have remained in the  
216 items than the variance explained by the latent factor structure (Hair et al., 2010). The AVE  
217 value was also used to assess the discriminant validity of the new scale. The validity of  
218 respective construct was achieved if the square root of its AVE exceeded its correlation value  
219 with other constructs in the model (Zainudin, 2014, 2015).

220         The new scale's reliability was evaluated using internal consistency and composite  
221 reliability (CR), both performed after EFA and CFA. Cronbach's alpha value of 0.70 to 0.90  
222 indicates a satisfactory level of internal consistency (Zainudin, 2014, 2015) but, for exploratory  
223 research such as ours, 0.60 was preferable (Hair et al., 2010; Kline, 2010). In the EFA, the  
224 internal consistency of each factor was examined to improve the total score reliability. An item  
225 was to be eliminated if removal of that item would improve item-to-total correlation. A similar  
226 method was utilized to assess internal consistency in CFA to ensure a good fit model was  
227 obtained. The CR was used to indicate the reliability and internal consistency of a latent  
228 construct. The minimum threshold value for CR was 0.6, a higher value indicates better  
229 reliability (Zainudin, 2014, 2015; Fornell & Larcker, 1981).

230

## 231 Results

232 A total of 470 elderly with chronic constipation from various community settings in Kelantan  
233 and Terengganu participated in the study. Out of these, 200 of the participants were from Phase 2  
234 of the study and 270 from Phase 3. The age was between 60 and 100 years old, with a mean age  
235 of  $68.64 \pm 6.57$ . All participants were Muslims with more women than men (53.6 vs. 46.4%).

236 *Table 1* shows the background of the participants of this study.

237

### 238 Validity

239 From EFA, the initial 40 items were extracted into eight factors and this accounted for 61.0% of  
240 the cumulative variance. Subsequently, 27 items were maintained, and 13 items were removed.  
241 The Cronbach's alpha for the 27 items was 0.80. The removed items were redundant items that  
242 were highly intercorrelated, possess a communality value of less than 0.3, not identifiable with  
243 primarily one factor, and the deleted item improved internal consistency reliability (Child, 2006;  
244 Hair et al., 2010). *Table 2* shows the remaining items after EFA and the values of its factor  
245 loadings, communality, item-total correlation, Cronbach's alpha if an item was deleted, and the  
246 Cronbach's alpha of each.

247 Application of CFA to establish the fitness of the measurement model obtained from the  
248 EFA implied that the first version of E-CIS has a poor fit. This was illustrated by indexes  
249  $RMSEA = 0.076$ ,  $CFI = 0.799$ ,  $TLI = 0.761$ , and  $chisq/df = 2.566$ . Subsequent modifications to  
250 the EFA model resulted in seven factors and 22 items (*Fig. 2*). Five items were removed due to  
251 low factor loadings (0.17 and below). Factors of dietary fiber and fluid intake were justified as a  
252 single factor and named as "preventive actions". The revised CFA version was a good model fit,  
253 as shown by indexes  $RMSEA = 0.04$ ,  $CFI = 0.961$ ,  $TLI = 0.952$ , and  $chisq/df = 1.44$ .

254 The factors and items in the final E-CIS were daily activities (four items), treatment  
255 satisfaction (four items), lack of control of bodily function (three items), diet restriction (two  
256 items), symptom intensity (two items), anxiety (four items), and preventive actions (three items)  
257 (*Table 3*). The AVE value for all items ranged from 0.53 to 0.61, which exceeded their minimum  
258 threshold values. The AVE analysis indicated that all items were statistically significant for the  
259 measurement model and were free from redundancy, therefore achieving convergent validity.  
260 The square root of AVE for each construct had exceeded its correlation value with the other  
261 constructs in the model, thus confirming discriminant validity.

262

### 263 Reliability

264 Cronbach's alpha of the final E-CIS was 0.78 and the value for all subscales ranged from 0.66 to  
265 0.85. Specifically, the Cronbach's alpha value for each subscale is as follows: daily activities  
266 (0.85), treatment satisfaction (0.82), lack of control of bodily function (0.78), diet restriction  
267 (0.66), symptom intensity (0.76), anxiety (0.81) and preventive actions (0.83). The CR values for  
268 all the constructs ranged from 0.70 to 0.85. These results indicated that the new scale was  
269 accurate and reliable.

270

## 271 Discussion

272 Seven factors were identified to have impacted QoL and were further simplified into a 22-item  
273 scale, taking into consideration the needs and values of elderly people and their families (Bakas  
274 et al., 2010). Based on factor analysis, these factors were ‘daily activities’, ‘treatment  
275 satisfaction’, ‘lack of control of bodily function’, ‘diet restriction’, ‘symptom intensity’,  
276 ‘anxiety’, and ‘preventive actions’. The factors identified in this study were also similar to the  
277 irritable bowel syndrome (IBS)-specific QoL. Included among them were illness experience,  
278 stressors, coping mechanisms and psychological state (Wong & Drossman, 2010).

279 In the context of a chronic and complex disorder such as constipation, improvement in  
280 health-related QoL is often considered a paramount treatment outcome for the elderly, and  
281 therefore it is pertinent to first understand the impact of this disorder (Pinto Sanchez & Bercik,  
282 2011; Belsey et al., 2010). The current study indicates that the newly developed E-CIS is a valid,  
283 reliable and specific tool for elderly people to evaluate the impact of chronic constipation on  
284 their QoL.

285 Although there are several QoL scales for chronic constipation, none fulfilled all the  
286 criteria needed to evaluate the impact of this disorder in elderly people (Marquis et al., 2005;  
287 Szeinbach et al., 2009; Wang et al., 2009). Firstly, these existing scales were not specifically  
288 developed or validated for the elderly population, and it is known that the elderly engage in very  
289 different behaviors from the younger population. Secondly, other local or cultural factors such as  
290 religion and dietary intake were not included in these scales, but these factors were found to be  
291 especially important for the elderly Malaysian population, as reported in a qualitative study  
292 (Patimah et al., 2017).

293 The factor of ‘preventive action’ in E-CIS was important to the elderly - especially the  
294 intake of water, fruits, and vegetables. This factor, in addition to factor of ‘diet restriction’ was a  
295 newly identified factor associated with the effect of constipation on QoL. However, previous  
296 studies have reported on these factors in other gastrointestinal disorders such as the  
297 ‘coping/behavior’ factor in Fecal Incontinence Quality of Life (FIQoL) (Hashimoto et al., 2010;  
298 Kunduru et al., 2015; Rockwood et al., 2000).

299 ‘Treatment satisfaction’, as factor or an item, is a common inclusion in many  
300 constipation-related scales (Li, Lee & Suen, 2014; Müller-lissner et al., 2010; Müller-lissner et  
301 al., 2013; Nour- Eldein et al., 2014). Earlier QoL scales had a ‘satisfaction’ subscale, but items  
302 were heterogeneous and based on frequency and regularity in bowel movements, activities,  
303 expectations, values, effectiveness and treatment satisfaction (Marquis et al., 2005; Szeinbach et  
304 al., 2009). In newly developed E-CIS, the ‘treatment satisfaction’ subscale focused on  
305 satisfaction with the utilization and effectiveness of an unspecified treatment.

306 In our study, there are three items reflecting fear in factor ‘anxiety’. Kalat (2014) had  
307 differentiated between fear and anxiety by asserting that fear is an individual’s response to an  
308 immediate danger, whereas anxiety is their vague sense that ‘something bad might happen’.  
309 Based on this understanding, we identified that the three items reflected the elderly’s fear  
310 emotion because the responses were focussed on a specific condition. However, we labelled

311 these items as ‘anxiety’ factor because of the response to different conditions due to an unknown  
312 or poorly defined threat.

313 In the new scale, the item associated with the effect of constipation on worship activities  
314 was identified under the subscale of ‘daily activities’. We have shown in our published  
315 qualitative study that prayer or worship, a daily practice for many elderly people, was often  
316 disturbed because of constipation (Patimah et al., 2017). Studies have shown that, in later life,  
317 religiosity is a well-documented coping strategy in terms of improvements to psychological well-  
318 being (Momtaz, Hamid & Yahaya, 2009; Momtaz et al., 2010).

319 The items of this new scale were developed and validated based on a qualitative study  
320 using the grounded theory approach (Patimah et al., 2017). Besides, the content and face validity  
321 of these items were supported by extensive literature reviews and experts’ opinions. All the  
322 measured items were well loaded to its constructs. This was evidenced by the ideal estimate for  
323 standardized loading of 0.7 that was shown for most items in the CFA results (Hair et al., 2010).  
324 Two items with factor loadings of 0.55 and 0.59 and two items with R-square of 0.3 and 0.34  
325 were retained. According to the rule of thumb, these values are accepted when the main research  
326 objective is scale development (DeVellis, 2012; Hair et al., 2010). Moreover, the model achieved  
327 the required level of the fitness indices and the new 22-item E-CIS has been shown to have good  
328 discriminant validity and convergent validity. These findings suggest that the items represent the  
329 effect of constipation on the QoL of the elderly satisfactorily.

330 Calculation of the E-CIS score could be in the form of the total mean score or the total  
331 mean subscale scores. Each subscale score provides additional information about individual  
332 factors that affect the impact of constipation, compared to a single score. The minimum total  
333 score is 20 (very low impact on QoL) and the maximum is 100 (very high impact on QoL). This  
334 baseline value is obtained by dividing the minimum and maximum total scores of 22 items by  
335 110, which is the maximum score of the scale. The values are then multiplied by 100 to find the  
336 percentage.

337 The new scale is reliable based on its internal reliability and CR of 0.7 and above  
338 (DeVellis, 2012). In many studies on scales validation, only a limited number of measures in the  
339 construct validity or reliability were reported (Szeinbach et al., 2009; Wang et al., 2009). In our  
340 study, we performed most - if not all - of the validity and reliability assessments, also including  
341 EFA and CFA. The reason was that we aimed to have a more comprehensive evaluation of the  
342 new scale, but also to have the highest minimum number of items which will suit elderly  
343 respondents in our culture better.

344 Several limitations to this study were identified. The E-CIS was specifically made for  
345 elderly people without cognitive impairment - which is a common condition among the elderly.  
346 The results on validity and reliability indicated by this scale were not tested with the existing  
347 validated and reliable scales, and its sensitivity is not tested by pre and post-treatment. Out of  
348 seven factors of the E-CIS, there are two factors, namely ‘diet restriction’ and ‘symptoms  
349 intensity’ that have only two items. It is generally accepted to have two items per factor or  
350 subscale, but the interpretation of results based on the subscale score should be performed

351 cautiously (Chan et al., 2010; Tabachnick & Fidell, 2007). Other than that, the scale is measured  
352 using a 5-point Likert scale to produce the mean score. According to Chua (2008), treating the  
353 Likert scale as an interval scale may lead to bias because the mean score tends to accumulate to  
354 the middle value. These limitations should be kept in mind when assessing the impact of chronic  
355 constipation on the elderly's QoL using this scale.

## 356 **Conclusions**

357 The E-CIS is a constipation-specific QoL scale, which in this study was written in the standard  
358 Malay language. This multidimensional scale consists of 22 items with seven subscales. It is  
359 proven to be valid and reliable in assessing the impact of chronic constipation on the elderly's  
360 QoL among the Malays in Kelantan, regardless of the type of treatment that they have practiced  
361 or received. However, further validation study is required in other elderly populations and other  
362 ethnic groups to confirm its robustness for multi-ethnic or multinational studies.

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# Figure 1

Development and validation of the scale

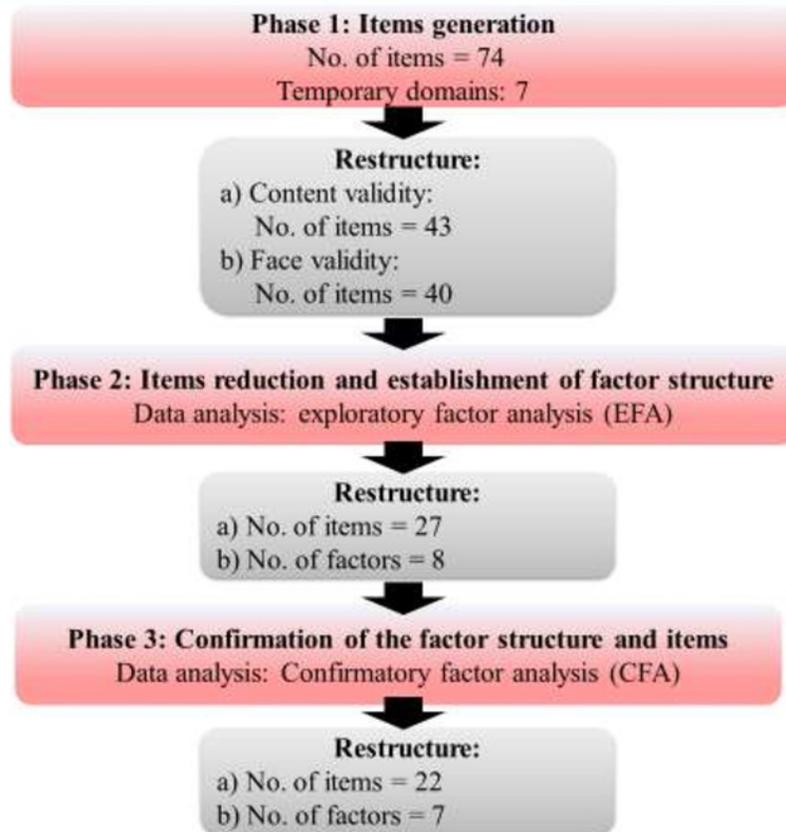


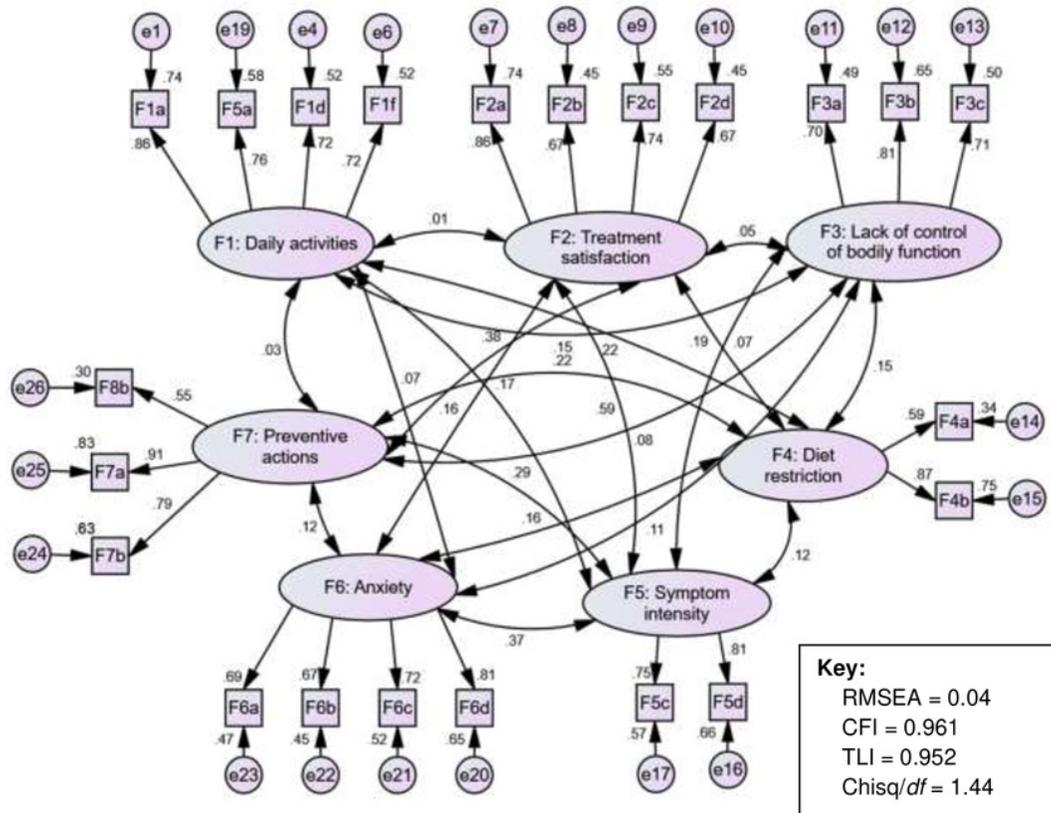
Figure 1 Development and validation of the scale

## Figure 2

The measurement model for pooled-CFA

RMSEA = 0.04, CFI = 0.961, TLI = 0.952,  $\text{chisq}/df = 1.44$

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Figure 2 The measurement model for pooled-CFA.

**Table 1** (on next page)

Characteristics participants of the study

*Notes:*  $N$  = number of participants;  $SD$  = standard deviation.

1 Table 1. Characteristics participants of the study

2

Characteristics	<i>N</i> (%)	Mean ± <i>SD</i>
Age		68.64 ± 6.57
60-69	281 (59.8)	
70-79	157 (33.4)	
80 and above	32 (6.8)	
Sex		
Men	219 (46.4)	
Women	251 (53.6)	
Educational level		
Never to school	136 (28.9)	
Informal school	30 (6.4)	
Primary school	158 (33.6)	
Secondary school	134 (28.5)	
College/university	12 (2.6)	
Employment status		
Employed	133 (28.3)	
Pensioner	46 (9.8)	
Unemployed	291 (61.9)	
General health status		
Poor to very poor	65 (13.8)	
Moderate	187 (39.8)	
Good to very good	218 (46.4)	

3 *Notes.* *N* = number of participants; *SD* = standard deviation

**Table 2** (on next page)

Exploratory factor solution for 27 items

*Notes:* F1 = daily activities; F2 = treatment satisfaction; F3 = lack of control of bodily function; F4 = diet restriction; F5 = symptom intensity; F6 = anxiety; F7 = dietary fiber intake; F8 = fluid intake.

1 Table 2. Exploratory factor solution for 27 items

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Factor (F)	Items	Factor loading	Communality	Item-total correlation	Cronbach's alpha if item deleted	Cronbach's alpha
F1	F1a	0.66	0.47	0.57	0.77	0.80
	F1b	0.65	0.40	0.54	0.78	
	F1c	0.55	0.40	0.53	0.78	
	F1d	0.54	0.58	0.58	0.77	
	F1e	0.59	0.49	0.53	0.78	
	F1f	0.60	0.53	0.61	0.76	
F2	F2a	0.88	0.76	0.79	0.84	0.88
	F2b	0.82	0.69	0.76	0.85	
	F2c	0.94	0.84	0.83	0.82	
	F2d	0.49	0.59	0.63	0.90	
F3	F3a	0.59	0.51	0.55	0.79	0.79
	F3b	0.86	0.67	0.67	0.66	
	F3c	0.65	0.58	0.67	0.67	
F4	F4a	0.76	0.63	0.64	-	0.78
	F4b	0.77	0.66	0.64	-	
F5	F5a	0.45	0.39	0.43	0.59	0.66
	F5b	0.58	0.43	0.49	0.55	
	F5c	0.68	0.53	0.49	0.56	
	F5d	0.55	0.36	0.35	0.64	
F6	F6a	0.54	0.48	0.52	0.72	0.76
	F6b	0.53	0.34	0.45	0.75	
	F6c	0.58	0.57	0.56	0.69	
	F6d	0.63	0.74	0.69	0.61	
F7	F7a	0.96	0.87	0.73	-	0.84
	F7b	0.75	0.73	0.73	-	
F8	F8a	0.96	0.82	0.56	-	0.70
	F8b	0.48	0.45	0.56	-	

3 *Notes.* F1 = daily activities; F2 = treatment satisfaction; F3 = lack of control of bodily function;  
4 F4 = diet restriction; F5 = symptom intensity; F6 = anxiety; F7 = dietary fiber intake; F8 = fluid  
5 intake.

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**Table 3** (on next page)

The new version of the Elderly-Constipation Impact Scale (E-CIS)

*Notes:* F = factor; CR = composite reliability; AVE = average variance extracted

1 Table 3. The new version of the Elderly Constipation Impact Scale (E-CIS)

Factor/Items	Factor loading	Cronbach's alpha	CR	AVE
F1: Daily activities		0.85	0.851	0.590
F1a I feel tired after defecation	0.86			
F5a I feel depressed when I want to defecate	0.76			
F1d The constipation interrupt my daily activity	0.72			
F1f I feel interrupted to pray because of the constipation	0.72			
F2: Treatment satisfaction		0.82	0.828	0.548
F2a I am satisfied with the effectiveness of the treatment	0.86			
F2b I am satisfied with the methods used for the constipation treatment	0.67			
F2c I am satisfied that I get to defecate as I wish for after the treatment	0.74			
F2d I am confident that constipation will be easy to treat if it recurs	0.67			
F3: Lack of control of bodily function		0.78	0.783	0.546
F3a My body feels sick as if I were to have a fever	0.70			
F3b The effects of my constipation treatment is slow	0.81			
F3c I feel that I fail to control my constipation	0.71			
F4: Diet restriction		0.66	0.699	0.546
F4a Constipation makes me control the quantity of food taken	0.59			
F4b Constipation makes me choose the type of food taken	0.87			
F5: Symptom intensity		0.76	0.761	0.614
F5c I extract the feaces out	0.75			
F5d I strain strongly during defecation	0.81			
F6: Anxiety		0.81	0.815	0.525
F6a I think that my intestinal function has been damaged	0.69			
F6b I fear that there will be blood coming out from the anus when I want to defecate	0.67			
F6c I fear that the anus will come out if I strain	0.72			
F6d I fear that the anus will tear because of the big feaces	0.81			
F7: Preventive actions		0.83	0.804	0.587
F7a Constipation makes me take more vegetables in my diet	0.91			
F7b Constipation makes me take more fruits in my diet	0.79			
F8b Constipation makes me drink a lot of drinking	0.55			

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water

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2 *Notes.* F = factor; CR = composite reliability; AVE = average variance extracted.

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