Turkish adaptation and validation of the EMpowerment of PArents in THe Intensive Care (EMPATHIC-30) questionnaire to measure parent satisfaction in Neonatal Intensive Care Units

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20 Conflict of interest statement

- 21 The authors declare that the research was conducted in the absence of any commercial or
- 22 financial relationships that could be construed as a potential conflict of interest
- 23

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24 Author contribution statement

- 25 OT contributed to the design of the study, contributed to data collection, data analysis and
- 26 interpretation, drafted the first manuscript. HZ contributed to data collection, data analysis
- and interpretation, provided revisions to early drafts. NC contributed to data collection, data
- analysis and interpretation, provided revisions to early drafts. MU contributed to data
- 29 collection, data analysis and interpretation, provided revisions to early drafts. JML
- 30 contributed to the design of the study, drafted the first manuscript. All authors contributed,
- 31 read and approved the final manuscript.

ABSTRACT 32

33 Aim: The aim of this study was to translate and validate the shortened version of the 'EMpowerment of PArents in THe Intensive Care' (EMPATHIC-30) questionnaire into 34 Turkish to measure parent satisfaction in the Neonatal Intensive Care Units (NICU) 35

Method: The study used a cross-sectional design. The data of the study were collected from 36

parents with infants staying in the NICU of a training and research hospital in Sakarya, Turkey, 37

38 between July 2018-2019 after obtaining ethical approval. Totally, 238 parents (234 mothers, 4 39

fathers) agreed to participate in the study and completed the questionnaire. Of these, 35 mothers were recruited two weeks later for the test-retest reliability analysis. The questionnaire was 40

41 translated using back and forward translation. Reliability and validity test were performed to

measure the psychometric properties of the Turkish EMPATHIC-30. 42

Results: The mean age of the parents was 28.27 (SD 5.93), and 48.3% of them were primary 43 school graduates. The infants: 55.9% were male, the mean gestational age was 36.89 (SD 3.25) 44

- weeks, and mean length of hospital stay was 9.36 (SD 10.17) days. The mean scores of each 45
- item with a six-point scale of the EMPATHIC-30 questionnaire ranged between 4.01 and 4.87. 46
- The Cronbach's alpha of the total questionnaire was 0.95. Cronbach's alpha of the five domains 47
- 48 (Information, Care and Treatment, Organization, Parent Participation and Professional
- Attitude) ranged between 0.80 and 0.92. Pearson correlation coefficient between the domains 49
- and total questionnaire was r=0.988. The Intraclass Correlation Coefficient was 0.998 in the 50
- 51 test-retest evaluation. Confirmatory factor analysis was performed for construct validity and
- was moderate; Comparative Fit Index=0.792, Tucker-Lewis Index=0.770, Standardized Root 52 Mean Square Residual= 0.0811, and Root Mean Square Error of Approximation=0.107. 53

54 Conclusion: The Turkish version of EMPHATIC-30 has adequate psychometric properties.

- The EMPATHIC-30-Turkish questionnaire is an easy and appropriate instrument which can be 55
- used to measure satisfaction of Turkish parents with infants staying in the NICU. 56 57

Keywords: EMPATHIC-30; Parents; Infants; Satisfaction; Neonatal Intensive Care Unit; 58 Reliability; Validity. 59

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Contribution to the field 61

Family-centered care practices not only increase parental satisfaction but also improve the 62 quality of care. A search of the literature revealed that there are no questionnaires available to 63 measure parent satisfaction among Turkey parents in the NICU. The EMPATHIC-30 64 questionnaire is widely used in many countries to measure family satisfaction. Our findings are 65 in line with previous investigations of the adaptation of EMPATHIC-30 in other languages. It 66 67 seems that the EMPATHIC-30 instrument can be applied to measure parental satisfaction and

can be adapted in different cultural and linguistic backgrounds. 68

69 INTRODUCTION

The hospitalization of an infant in a neonatal intensive care unit (NICU) is a stressful situation for both parents and the infant (1). This may affect the family's daily routines and may lead to changes in their roles and responsibilities in the family environment (2). Besides these changes in the family environment, not knowing the NICU environment, encountering medical devices, and changing duties in the care of their infant can cause anxiety and fear among parents and

- 75 family members (3).
- 76

77 Family-Centered Care (FCC) interventions have been developed and implemented to minimize 78 stress and anxiety experienced by parents and accelerate the healing process of infants (4, 5). An important element in maintaining the FCC approach is effective communication. 79 Furthermore, developing mutual trust, reducing conflict, minimizing stress levels of parents 80 and improving parental satisfaction are components of FCC (6,7,8). It is known that parents 81 whose have experienced an admission of their infant in the NICU need information on many 82 issues during admission, at discharge and when at home after hospital discharge. These 83 information needs can be clustered in five themes: communication, parental role clarity, 84 85 emotional support, information resources and financial resources (9). Studies exploring problems of parents with premature infants in the NICU identified that parents experienced 86 difficulties in bonding with their infant, breastfeeding, being worried when separated from their 87 88 infant and difficulties with information and communication with healthcare professionals (10, 89 11).

90

91 Implementing the principles of FCC can reduce hospital length of stay, improve the bonding 92 between parents and infants, and increase parent satisfaction (8, 12). Parental satisfaction is 93 used as an indicator to measure quality of care and the use of satisfaction surveys is an effective 94 method for evaluating health services (13). Currently, there are no validated parent satisfaction 95 in the service of the s

instruments available for parents in Turkish NICUs. Although the 65-item EMPATHIC-N has
been developed and tested specifically for parents in the NICU, there is no short version of this
questionnaire (14). To reduce the burden of parents we preferred a shorter version and therefore
opted for the short version of the EMPATHIC questionnaire, the EMPATHIC-30 (14,15).

99 Therefore, the aim of this study was to translate, culturally adapt, and validate the EMPATHIC 30 questionnaire to measure parent satisfaction in Turkish NICUs.

101

102 MATERIALS AND METHODS

103 Design

The study used a cross-sectional descriptive design. Ethical approval was obtained from the hospital research ethics committee (02/04/2018-72) and written consent was obtained from the parents who participated in the study. Data collection was performed between July 2018 and July 2019.

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109 Setting

The study setting was at the NICU of the Sakarya Training and Research Hospital in the west of Turkey. The tertiary NICU serves the province of Sakarya. The NICU has a capacity of 29 beds: one level III unit with 18 beds, one level II unit with nine beds, and one level I unit with six beds. The level III unit admits infants with a birth weight <1500 grams, the level II unit admits infants with a birth weight between 1500-2500 grams and the level I unit has infants

- 115 >2500 grams. Parents can visit the NICU once a day between 15.00-16.00. Before the infant's
- discharge, mothers are invited to stay 24 hours during the final two to three days of admission
- 117 while being accommodated in the parent guesthouse of the hospital. During these days, parents
- 118 receive specific training and involvement of care before going home with the infant.

120 Participants

Annual admission rate of the NICU is around 900 infants. Parents were selected with simple 121 random sampling selection according to the inclusion criteria. Inclusion criteria were: mothers 122 or fathers whose infants stayed in the NICU for at least two days and speak and understand 123 Turkish. During the study period, 260 parents were invited. Of these, 22 parents declined the 124 invitation. The final study sample consisted of 238 parents (234 mothers, 4 fathers) who agreed 125 to participate in the study, provided written consent and competed the questionnaire. Of these 126 study participants, 35 mothers agreed to be contacted for the test-retest of the Turkish 127 EMPATHIC-30 questionnaire. 128

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130 EMPATHIC-30 questionnaire

The EMPATHIC-30 questionnaire consists of three parts (16). The first part includes 131 demographic questions such as parent's age, education level, income level, number of children 132 in the family, and working status. Furthermore, mother's type of birth, number of pregnancies, 133 birth / postpartum problem status and characteristics of the infants such as infant's gender, 134 135 gestational week, days of NICU stay, and feeding type have been added. The second part of the EMPATHIC-30 questionnaire included the 30 items divided in five domains. The short 136 version of the EMPATHIC-30 questionnaire was developed from the EMPATHIC initial 137 version (15). This version was developed in eight Pediatric Intensive Care Units (PICU) in the 138 Netherlands (15). Further statistical redundancy testing with 3354 parents resulted in the short 139 version of the EMAPTHIC-30 questionnaire (16). The EMPATHIC-30 consists of five 140 141 domains: Information (5 items), Care & Treatment (8 items), Organization (5 items), Parent Participation (6 items) and Professional Attitude (6 items). The answer option scale is a 6-point 142 Likert type (1=certainly no; 6=certainly yes) and each item has an additional "Not Applicable" 143 option. The reliability estimates (Cronbach's α) of the domains were adequate and ranged from 144 0.73 to 0.93. Approval to use the EMPATHIC-30 was granted by the developer (J.M. Latour) 145 and was part of the research team. 146

147

148 Translation and Cultural Adaptation

149 The translation and cultural adaptation process followed the Principles of Good Practice for the Translation and Cultural Adaptation of Patient Penerted Outcomes Measures described by

- 150 the Translation and Cultural Adaptation of Patient-Reported Outcomes Measures described by 151 the task force of the International Society for Pharmacoeconomics and Outcomes Research
- 152 (17). This 10-step process included:
- 153 Step 1: Preparation: Permission was granted by the developer to use EMPATHIC-30 154 questionnaire. The EMAPTHIC-30 was revised before translation; PICU or ICU was reworded
- 155 to NICU.
- 156 Step 2: Forward translation: The translation was performed in Turkish language by two
- translators independently. With approval of the developer, the EMATHIC-30-UK was used forthe translation.
- Step 3: Reconciliation: The translated version was reviewed on meaning and spelling of theitems by PICU and research experts.
- 161 Step 4: Back translation: The Turkish EMPATHIC-30 was translated back to English by one 162 translator.
- 163 Step 5: Back translation review: The translation was found to be sufficiently translated to the 164 original questionnaire.
- 165 Step 6-Harmonization: The questionnaire was reviewed by the research team and the developer
- and was found to be suitable for the Turkish population.
- 167 Step 7: Cognitive debriefing: The Turkish EMPATHIC-30 was reviewed by nine experts in
- 168 Child Health and Diseases Nursing Department, Department of Child Health and Diseases,

- 169 Department of Child Psychiatry, and Internal Medicine Nursing Department. The experts were
- asked to assess the suitability and clarity of each item. They were asked to rate each statement
- between 1 and 4 points (1 point: not appropriate, 2 points: slightly appropriate, 3 points:appropriate, 4 points: completely appropriate), and write their opinions and suggestions for
- 172 appropriate173 each item.
- 174 Step 8: Review of cognitive debriefing results and finalization: In line with the opinions of the
- experts, the items were reviewed, and necessary changes were made. As a result of the
- evaluation of experts, all items were corrected in terms of language and expression with the suggestions and contributions of experts.
- 178 Step 9-Proofreading: The Turkish EMPATHIC-30 questions were reviewed. After applying 179 the final version of the scale to 10 parents, it was decided that there were no unclear 180 expressions.
- 181 Step 10-Final Report: This paper presents the final report and further validity testing.

183 Data Collection

- The data of the study were collected from parents when their infants were discharged from the NICU. Parents visiting the newborn outpatient clinic two weeks after discharge received the questionnaire and the consent form. Data collection was in line with the original EMPATHIC studies where data was collected two to three weeks after discharge (14-16). The questionnaires, in paper version, were completed during the outpatient clinic visit and completion time was between 10-15 minutes.
- We planned to use a minimum of 10% of the total sample for the test-retest (18). In order to assess the test-retest reliability of the questionnaire two weeks later, parents (n=35) who
- 192 previously agreed to be contacted were asked by phone to meet at the outpatient clinic at their
- 193 preferred day and time to complete the second questionnaire.
- 194

195 Data Analysis

- Number and percentage (n, %) were used to define categorical variables in order to identify the 196 characteristics of the data of 238 participants; mean and standard deviation was used to define 197 numerical variables. Test-retest reliability analysis was performed using the correlation 198 coefficient (r) and intraclass correlation coefficient (ICC). Confirmatory factor analysis (CFA) 199 is tailored to unraveling the empirical structure of the interrelationship of the 30 statements. 200 The final model was based on both theoretical and statistical plausibility. The measures applied 201 in this study were v2 test of model fit, and the ratio of v2 df \3 represents a good model fit. 202 Other tests used for the model fit were: comparative fit index (preferably CFI C 0.95), Tucker-203 Lewis index (preferably TLI C 0.95), root mean square error of approximation (preferably 204 205 RMSEA \0.08), and the weighted root mean square residual (preferably WRMR\0.90) (19). Data were evaluated with the statistical software program IBM SPSS Statistics 22 and type 1 206 207 error (α) was set at 0.05.
- 208

209 **RESULTS**

- Of the 238 parents who returned the questionnaire, 98.3% were mothers with a mean age 28.27 (SD 5.93). Furthermore, 48.3% were primary school graduates, 21% were employed, and 44.5% had moderate income. According to pregnancy histories, 38.1% mother had their first baby, 78.1% had pregnancy planned, 95.8% had spontaneous pregnancy, 42.9% had normal birth, 42.9% had at least one child. 55.9% of the infants were male with a mean gestational age of 36.89 (SD 3.25) weeks and the mean birth weight was 2863.82 (SD 238.03) grams. Hospital length of stay was 9.36 (SD 10.17) days. During the hospital stay, 56.7% of the infants received
- only breast milk, 42.4% received both breast milk and formula (Table 1).
- 218

- The Cronbach's alpha of the domains of the EMPATHIC-30 questionnaire ranged from 0.804 to 0.922 (Table 2). The mean scores and standard deviations are presented in Table 2. The mean score, standard deviation, and total Cronbach's alpha coefficient of each item are presented in Table 3. The lowest mean score was the item 'We received understandable information about the effects of the medication' (mean 4,01, SD 1,40). The highest rated item was "The team respected the privacy of our child's and of us" (mean 4,81, SD 0,89).
- 225

The Pearson correlation coefficient (r) with the total score of each domain ranged from 0.806 226 to 0.900 (Table 4). One month after the test, 35 parents completed the retest questionnaire and 227 the Pearson correlation coefficient between the two evaluations was r=0.988; Intraclass 228 correlation coefficient was ICC=0.998. Confirmatory factor analysis for the construct validity 229 confirmed a moderate model fit with the preferred values of Comparative Fit Index and the 230 Tucker-Lewis Index slightly below the preferred ≥0.95. The Root Mean Square Error of 231 Approximation (preferably <0.08) was 0.107 while the Standardized Root Mean Square 232 Residual RMSEA was adequate performed with 0.081, preferably <0.90 (Table 5). 233

234

235 **DISCUSSION**

Family-centered care practices not only increase parental satisfaction but also improve the quality of care (20). A search of the literature revealed that there are no questionnaires available to measure parent satisfaction among Turkey parents in the NICU. The EMPATHIC-30 questionnaire is widely used in many countries to measure family satisfaction (21-23). Our findings are in line with previous investigations of the adaptation of EMPATHIC-30 in other languages. It seems that the EMPATHIC-30 instrument can be applied to measure parental satisfaction and can be adapted in different cultural and linguistic backgrounds.

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244 As a result of the analysis, the Cronbach's alpha values in our study of the five domains (between 0.804-0.922) showed that the reliability levels of the questionnaire are high. In the 245 original study of the shortened EMPATHIC-30 study, the Cronbach's alpha values ranged 246 between 0.73 and 0.81 (16). Other studies translating and validating the EMAPTHIC-30 in 247 Italy, Spain and Brazil reported similar internal consistency figure compared to the original 248 study (16, 22-24). Surprisingly, a study in South Africa reported much lower Cronbach's alpha 249 on domain levels; between 0.25-0.59 (21). The authors addressed these differences because of 250 a limitation of their small study sample of 100 parents influencing the scores (21). 251

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The means of all items in the EMPATHIC-30 in our study were all below 5. This is in contrast 253 254 with all other similar studies (16, 21-25). The study in South Africa is the only study reporting that all items had a mean score above 5 (21). This might indicate that parent satisfaction is 255 culturally dependent. However, another explanation could be the family-centered care practices 256 257 that may vary across countries. In our study and setting it can be argued that family-centered care is not yet fully implemented and therefore parents might have rated the satisfaction items 258 lower as reported in other countries. Further studies are needed to explore the relationship 259 between different family-centered care practices and parent satisfaction outcomes (26,27). 260

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In our NICU, parents whose infants are hospitalizing generally take the role of visitors while their babies are cared for and treated by nurses and doctors. However, when parents are accepted as members of the healthcare team and value their own knowledge and skills, they feel more adequate and safer in caring for their infants (28,29). In this case, it becomes easier to deal with changes in the family role. Although our study is important in terms of revealing that the satisfaction of parents in this regard is not at the desired level, we think that this questionnaire, which has been adapted in Turkish will increase the interest in the subject andcontribute to improving family-centered care practices in Turkish NICUs.

270

The highest rated domain of the Turkish EMPATHIC-30 questionnaire was the domain of 271 'Professional Attitude'. This was comparable with the EMPATHIC-30 AUS study in Australia, 272 while other similar studies from Italy, Brazil and Greek-Cyprus demonstrated the highest mean 273 values in the domain "Care and Treatment" (12,23,24,25). Variables such as functioning of the 274 international health system, the NICU conditions and the demographic characteristics of 275 parents and their expectations might affect their perceptions of health. The high level of trust 276 in nurses and doctors in our study increased the value of 'Professional Attitude'. However, and 277 overall, our findings indicate that a revisit of our family-centered care practices is needed. 278 Consequently, we have extended the visiting policies, provided visuals and information about 279 family-centered care for parents on boards in the NICU and waiting rooms, further brochures 280 for parents about family-centered care practices such as their involvement in care are in 281 progress and in-service family-centered care training for NICU staff will commence in the near 282 future. 283

284

Our study warrants some limitations. First, the number of fathers participating in the study was

low. This might be because in our culture, fathers are often working during the daytime and 286 have limited time to visit the NICU while also caring for siblings and other socio-economic 287 issues. Another limitation is the translation process. Although agreed by the developer, we did 288 not use the original Dutch version but instead the translated English version which has been 289 used in the UK. We acknowledge that our study included only parents from a NICU in one 290 hospital. Further multi-center testing would be needed and could enhance the acceptability of 291 the validated Turkish version of the EMPATHIC-30 instrument. Finally, most parents who 292 participated in the study were those whose infants were admitted to the level I and II units. 293 Further research is needed to assess parent satisfaction across all levels of care in a Neonatal 294 department. 295

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297 CONCLUSION

Based on the results of our study, the Turkish version of EMPATHIC-30 is a reliable and valid instrument that can be used to measure satisfaction of the parents in NICU settings. The EMPATHIC-30 Turkish can be considered as a benchmark tool to learn from parental reported outcomes of other NICUs. Finally, the instrument can be used among parents from Turkish origin in other countries.

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394	Table 1. Descriptive	Characteristics	of Parents a	and Infants
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Characteristics	N=238	%
Participant		
Mother	234	98.3
Father	4	1.7
Education		
Primary education	115	48.3
High school	79	33.2
License	49	16.8
Postgraduate	4	1.7
Working Condition		
Yes	50	21
No	188	79
Income Status (family's own statement)		
Good	55	23
Middle	106	44.5
Bad	77	32.5
Gender of Infant	, ,	52.5
Girl	105	44 1
Male	103	55 0
Number of Children	155	55.9
	102	12 8
1	102	42.0
~ 2	15	26.5
23 Descent Taken Information Delated to Information	03	20.3
Person Taken Information Related to Infant	205	96.1
Doctor	205	86.1
Nurse	24	10.1
Doctor and Nurse	5	2.1
Medical secretary	4	1.7
Total Pregnancy Number of Mother	22	2 0 7
	92	38.7
2	64	26.9
3	51	21.4
4	13	5.4
\geq 5	18	7.6
Birth Type		
Normal	102	42.9
Cesarean	136	57.1
Planned Pregnancy		
Yes	174	73.1
No	64	26.9
Infant Feeding Type		
Breast Milk Only	135	56.8
Breast Milk and Formula	101	42.4
Only Formula	2	0.8
Age Parents (mean, SD)	28.27 (5.93)	min-max: 15-48
Infant Gestational Age in weeks (mean, SD)	36.89 (3.25)	min-max: 26-41
Infant's birth weight (mean, SD)	2863.82 (238.03)	min-max: 630-5800
Length of stay NICU in days (mean, SD)	9.36 (10.17)	min-max: 2-78)

395 SD=Standard Deviation

					400
Domains	Mean	Standard Deviation	Min	Max	Cronbach Alpha
1. Information	21.87	4.54	8	30	0.831
2. Care & Treatment	35.98	6.36	20	48	0.848
3. Organization	22.54	4.22	9	30	0.804
4. Parent Participation	27.69	4.71	15	36	0.869
5. Professional Attitude	27.85	5.10	9	36	0.922
					405

Table 2. Mean (SD) and Cronbach's α of the domains of the Turkish EMPATHIC-30

EMPATHIC-30 items	Mean	Standard Deviation	Cronbach's Alpha if Item Deleted
1. We had daily talks about our child's care and treatment with the doctors	4.59	1.04	0.953
2. We had daily talks about our child's care and treatment with the nurses	4.44	1.14	0.953
3. The doctor clearly informed us about the consequences of our child's treatment	4.56	1.08	0.952
4. We received clear information about the examinations and tests	4.27	1.19	0.952
5. We received understandable information about the effects of the medication	4.01	1.40	0.954
6. The doctors and nurses worked closely together	4.74	0.91	0.952
7. We were well prepared for our child's discharge by the doctors	4.22	1.48	0.955
8. We were well prepared for our child's discharge by the nurses	4.31	1.40	0.955
9. The team was alert to the prevention and treatment of pain in our child	4.75	0.80	0.952
10. Our child's comfort was taken into account by the doctors	4.80	0.83	0.952
11. Our child's comfort was taken into account by the nurses	4.76	0.87	0.953
12. Every day we knew who was responsible for our child, regarding the doctors	4.12	1.32	0.952
13. Every day we knew who was responsible for our child, regarding the nurses	4.27	1.28	0.952
14. The team worked efficiently	4.64	1.01	0.952
15. The IC-unit could easily be reached by telephone	4.31	1.28	0.955
16. There was enough space around our child's bed	4.45	1.21	0.953
17. The IC-unit was clean	4.69	0.95	0.952
18. Noise in the IC-unit was muffled as good as possible	4.45	1.15	0.952
19. During our stay the staff regularly asked for our experiences	4.41	1.13	0.952
20. We were actively involved in decision-making on care and treatment of our child	4.47	1.09	0.951
21. We were encouraged to stay close to our child	4.72	0.93	0.952
22. We had confidence in the doctors	4.87	0.77	0.952
23. We had confidence in the nurses	4.87	0.79	0.952
24. Even during intensive procedures we could always stay close to our child	4.36	1.25	0.953
25. We received sympathy from the doctors	4.48	1.14	0.952
26. We received sympathy from the nurses	4.49	1.12	0.952
27. The team worked hygienically	4.72	0.92	0.952
28. The team respected the privacy of our child's and of us	4.81	0.89	0.952
29. The team showed respect for our child and for us	4.80	0.85	0.952
30. At admission we felt welcome	4.55	1.05	0.952

Table 3. Descriptive analysis EMPATHIC-30 items

Domains	Total
1.Information	0.80¢15
2.Care & Treatment	0.900
3.Organization	0.847
4.Parent Participation	0.874
5.Professional Attitude	0.861

Table 4. Correlations of Domains412and total EMPATHIC-30112

420	Table 5. Compliance Index	Values of Measurement Model
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421

EMPATHIC-30 items	Compliance Index Values
CFI	0.792 423
TLI	0.770
RMSEA	0.107 425
SRMR	0.081

427 CFI=Comparative Fit Index; TLI=Tucker-Lewis Index; SRMR=Standardized Root Mean

428 Square Residual; RMSEA=Root Mean Square Error of Approximation.