

Detecting Response Shift in Health-related Quality of Life Measurement among Patients with Hypertension Using Structural Equation Modeling.

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Research

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1 **Detecting Response Shift in Health-related Quality of**
2 **Life Measurement among Patients with Hypertension**
3 **Using Structural Equation Modeling.**

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6 **Abstract**

7 **Background:** Outcomes derived from longitudinal self-reported health-related quality of life measures
8 can be confounded by response shift. This study was aimed to detect response shift phenomena among
9 patients with hypertension attending a community-based disease management program.

10 **Methods:** 240 consecutive consulting or followed up patients with diagnosed hypertension were
11 recruited. The SF-36 instruments were self-administered at 12 community health service stations and
12 four weeks after attending the program. RS was assessed by the 4-step structural equation modeling
13 approach.

14 **Results:** Data from 203 (84.6%) patients were eligible for analyses (mean age 65.9±10.8 years, 46,3%
15 female). The results showed uniform recalibration of social functioning ($\chi^2_{SBdiff}(1)=22.98$, $P<0.001$),
16 and non-uniform recalibration of role limitations due to physical problems ($\chi^2_{SBdiff}(1)=8.84$, $P=0.003$),
17 and bodily pain ($\chi^2_{SBdiff}(1)=17.41$, $P<0.001$). The effects of response shift were calculated as “small”,
18 but the influence on the measurement results was noticeable. After accounting for the response shift
19 effect, the general physical health of participants was improved (+0.234, $P<0.001$), while a
20 deterioration of general mental health (-0.165, $P=0.025$) was also found.

21 **Conclusions:** Recalibration existed among patients with hypertension attending the disease
22 management program. The adaptation to chronic illness might act as a catalyst that induced the
23 response shift. We concluded that response shift should be considered in hypertension researches with
24 longitudinal health-related quality of life data, and linking with measurement of the appraisal process
25 was recommended.

26 **Key words:** Health-related quality of life, Response shift, Structural equation modeling, Hypertension,
27 SF-36

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28 **Background**

29 Health-related quality of life (HRQOL), representing people's subjective assessment
30 of their sense of health-specific well-being, has been frequently used as a health
31 indicator in medical interventions or health surveys. However, the measurement of
32 change in HRQOL may be affected by the fact that individuals' frame of reference (or
33 standard) or the concept and meaning of HRQOL can differ over time, known as
34 Response Shift (RS) [1-2]. A theoretical model of RS have been proposed by
35 Sprangers and Schwartz who postulated a dynamic feedback loop, where "catalyst",
36 "antecedents", "mechanisms" and "RS" interacted and eventually maintained or led to
37 changes in HRQOL [1], among which, RS was defined as three different types: (a)
38 recalibration: a change in the respondent's internal standards of measurement; (b)
39 reprioritization: a change in the respondent's values; and (c) reconceptualization: a
40 redefinition of the target construct. With existence of RS, individual experience of
41 improvement or deterioration over time will be modified. In other word, substantial
42 change of HRQOL can be over- or under-estimated without adjusting for RS [3-5].
43 Therefore, it is important to consider RS effect when measuring changes in HRQOL
44 [6].

45 A variety of methodological methods are available to detect and adjust RS [2]. Based
46 on the latent variable measurement modeling, Oort and colleagues [7-8] have
47 proposed a 4-step RS detecting procedure for longitudinal measurement occasions,
48 named the Oort's structural equation modeling (SEM) approach. The invariance of the

49 patterns or magnitude of the corresponding parameters across occasions were
50 associated with the interpretation of all three types of RS. Due to its versatility, the
51 Oort's SEM approach has become the most widely used statistical method in RS
52 detection [9].

53 Hypertension is a common chronic disease and a major risk factor for cardiovascular
54 chronic diseases [10]. A copious number of studies have confirmed that hypertension
55 has been an influencing factor for deterioration of HRQOL [11-14]. Previous
56 researches have provided evidences that recalibration type of RS existed among
57 hypertensive male subjects [15] and hypertensive patients with coronary artery
58 disease (CAD). Whereas there is still dearth of records that address RS phenomena
59 against general hypertensive patients.

60 The adaptation of patients to their chronic illness could induce RS, because the
61 process where patients coping with their chronic condition may alter their perceptions
62 of quality of life [17]. For example, patients with multiple chronic diseases changed
63 perspective of their health status after attending self-management courses [18].

64 The community disease management program is a component of the national essential
65 public health services in China, providing disease screening, drug therapy, long-term
66 follow up, and health education services to improve hypertension care [19].

67 Theoretically, individuals undergo the program will experience RS as they changed
68 the way understanding or coping with the disease. The objective of this study was to
69 detect effects of RS on HRQOL changes in patients with hypertension involved in the
70 community disease management program.

71 **Methods**

72 **Study design and samples**

73 The study cohort recruited 240 patients with hypertension in the community disease
74 management program from a community health service center in Hangzhou, China.
75 On given week chosen by the study, all visiting or followed up patients in the
76 belonged 12 community health service stations were invited to self-administer a
77 health status survey before consultation until the quota for each station (n=20) was
78 met. Four weeks later, the participants were asked to complete the survey once again.
79 Patients who had cognitive or visual problems, or were unable to complete the
80 questionnaires independently, were not included. The protocol was approved by the
81 Ethics Committee of Zhejiang University School of Medicine and all participants
82 provided written informed consent. Two hundred and eleven (87.9%) patients
83 completed the questionnaire twice, while eight patients with missing data were
84 excluded, resulting in a data set of 203 (84.6%) patients used for analyses.

85 **Measures**

86 We used a validated Chinese (mainland) version of the Short-Form Health Survey
87 (SF-36) to evaluate HRQOL of patients with hypertension in this study [20]. The
88 SF-36 instrument consists of 36 items which measure eight scales: physical
89 functioning (PF), role limitations due to physical problems (RP), bodily pain (BP),
90 general health (GH), vitality (VT), social functioning (SF), role limitations due to

91 emotional problems (RE), and mental health (MH). All original scales were linearly
92 transformed to a scale from 0 to 100, with a higher score indicating better HRQOL
93 [21]. The demographic and disease information, including age, gender, marital status,
94 employment status, educational attainment, health insurance, self-reported severe
95 illness experience, duration of disease, blood pressure, high risk level, and medicine
96 taken were also collected.

97 **Analyses**

98 *Structural Equation Modeling*

99 The Oort's SEM approach was applied to detect RS in a 4-step procedure [7-8]: (1)
100 establishing a decent measurement model; (2) forming a no RS model; (3) detecting
101 RS; (4) evaluating adjusted change.

102 Step 1: in the first step, we established a longitudinal measurement model (Model 1)
103 based on the result of exploratory factor analyses (EFA) for baseline data and the
104 theoretical considerations. In this model, all parameters could be estimated freely
105 across occasions, except for the common factors means and variances that were
106 constrained at zero and one respectively as the scales and origins for the unobserved
107 variables. Only when the model 1 shows good fit, could further analyses be
108 conducted.

109 Step 2: the invariance constrains on all RS parameters (residual variances, intercepts,
110 factor loadings) across occasions were placed, forming the no RS model (Model 2).
111 By using the χ^2 difference test, overall existence of RS could be detected. If the

112 model fit of the model 2 was significantly worse than the model 1, we could conclude
113 that RS existed.

114 Step 3: in the third step, the invariance constrains that had been proved untenable by
115 the χ^2 difference test were released individually, leading to a model (Model 3) where
116 no modification index of RS parameters indicated a significantly better fitting (i.e. all
117 RS was taken into account). Different types of RS were operationalized by the
118 following parameters that varied across occasions: reconceptualization (factor
119 patterns); reprioritization (factor loadings); uniform recalibration (intercepts);
120 ununiform recalibration (residual variances). Given the backward approach could
121 result in over identification of RS, a Bonferroni-adjusted critical value of 0.05/8 was
122 used to control type I error [16,22-23].

123 Step 4: as the final step, the tenable constrains of means, variances and correlations of
124 common factors were placed to the final model (Model 4). In this model, the adjusted
125 change was assessed by testing the invariant hypothesis of common factor means
126 across occasions after account for all RS. The estimated parameters in the model 4
127 were used to calculate the effect-sizes of RS and the adjusted change.

128

129 *Statistical analyses*

130 Mplus (version 7.4) was used for the SEM analyses. Given our data deviated from
131 multivariate normality, the Robust Maximum Likelihood Estimator (MLR) was
132 employed as the estimator [24]. When conducting the χ^2 difference tests in Mplus
133 with the MLR estimator, it was essential to adjust the χ^2 using the Satorra-Bentler
134 scaling correction [25]. A variety of alternative fit indexes were used to assess the

135 appropriateness of model fit. Those include the comparative fit index (CFI), the
136 Tucker-Lewis index (TLI), the standardized root mean square residual (SRMR) and
137 the root mean square error of approximation (RMSEA). With CFI, TLI>0.9,
138 SRMR<0.1, and RMSEA<0.08 indicate acceptable model fit [26-27].

139 **Results**

140 **Participants' characteristics and health information**

141 The initial cohort included 240 patients. 203(84.6%) patients with eligible data were
142 used for analyses, among which 94 were female (46,3%), and the mean age was 65.9
143 years (range 35-86, SD 10.8). About one fifth (19.2%) participants had college or
144 above education. Four fifth (75.4%) participants were unemployed or retired. More
145 than four fifths (83.7%) participants had an annual household income no more than
146 60,000 RMB. Seven (3.3%) participants did not have any health insurance (Table 1).

147 About one third participants reported own or family member serious diseases
148 experience. Sixteen (7.8%) participants had hypertension no more than six months.
149 More than half (54.2%) of participants had average blood pressure lower than
150 140/90mmHg. About three fourths (74.4%) participants had low or medium level of
151 health risks. Sixteen (7.9%) participants did not take any medicine (Table 2).

152 Table 1: Demographic characteristics of study participants

Variable	N	n (%)
Gender	203	
Female		94(46.3)
Male		109(53.7)
Marital status	201	
Married/co-habiting		181(89.2)

Other		20(9.6)
Education attainment	201	
No School		6(3.0)
Elementary School		55(27.1)
Middle School		60(29.6)
High School or vocational training		41(20.2)
College or above		39(19.2)
Employment status	191	
Employed		30(14.8)
Not employed/Retired		153(75.4)
Housework		8(3.9)
Annual household income (\$1US = 6.8Yuan)	203	
< 60,000 RMB		170(83.7)
≥ 60,000 RMB		27(13.3)
Health insurance	209	
Urban Employee Basic Medical Insurance		80(39.4)
Urban Resident Basic Medical Insurance		107(52.7)
Other insurances ^a		9(4.3)
No insurance		7(3.3)

153 ^a other insurances include new cooperative medical scheme, commercial medical
154 insurance, free medical service, etc.

155

156 Table 2: Health information of study participants

Variable	N	n (%)
Experienced severe illness	202	71(35.0)
Family members experienced severe illness	201	68(33.5)
Duration of hypertension	202	
< 6 months		16(7.8)
≥6 months		186(92.2)
Last month blood pressure	200	
< 140/90mmHg		110(54.2)
≥140/90mmHg		90(45.8)
Health risk level ^a	186	
Low		51(25.1)
Medium		100(49.3)
High		26(12.8)
Very high		9(4.4)
Anti-hypertensive medications	202	
0		16(7.9)
1		134(66.0)
2		44(21.7)

157 ^a health risk was assessed based on blood pressure, risk factors, and target organ
158 damage/diabetes mellitus, and multi-morbidities [19].

159

160 **Structural Equation Modeling**

161 *Measurement Model*

162 According to the guideline [7], we developed a measurement model based on the
163 result of EFA and the theoretical consideration (Figure 1). The ovals worded as
164 GenPHYS (General physical health) and GenMENT (General mental health)
165 represented two latent variables. The GenPHYS were measured by PF, RP, BP, RE,
166 while the GenMENT were measured by GH, SF, VT, MH. The eight scales were
167 represented by the rectangles. The circles below represented residual terms. We found
168 out the residual factors for RP and RE should be correlated, as both scales have close
169 questions and wording expression about social roles, which were agreed by several
170 corresponding RS studies with the SF-36 [8,16,28].

171

172

173 Fig 1 The measurement model used in RS detection.

174 Numbers are estimated parameters in Model 4, which are common factor correlations,
175 common factor loadings, intercepts, residual variances, and a residual correlation
176 successively. Parameters divided by a slash represent separate the first and second
177 occasion estimates.

178 *Detection of RS and adjusted change*

179 Details for model fit are given in Table 3.

180 Step 1: all fit indexes for the model 1 were in an acceptable range, indicating an
181 appropriate unconstrained measurement model was established.

182 Step 2: in the model 2, all RS parameters were constrained to be invariant across

183 occasions. Fit of the model 2 was still acceptable, but was significantly worse than the
 184 model 1 ($\chi^2_{\text{SBdiff}}(20)=69.53, P<0.001$), indicating overall existence of RS.

185 Step 3: after controlling for Type I error (Bonferroni-adjusted critical value=0.006),
 186 constrains of the residual variances of RP ($\chi^2_{\text{SBdiff}}(1)=8.84, P=0.003$) and BP
 187 ($\chi^2_{\text{SBdiff}}(1)=17.41, P<0.001$), the intercept of SF ($\chi^2_{\text{SBdiff}}(1)=22.98, P<0.001$) were
 188 removed, indicating non-uniform recalibration of RP and BP, uniform recalibration of
 189 SF.

190 Step 4: all the tenable constrains were placed on common factor means, variances and
 191 correlations, forming the model 4. Difference of means of both common factors were
 192 significant, indicating significant adjusted change in both common factors. The
 193 GenPHYS improved (+0.234, $P<0.001$), whereas the GenMENT deteriorated (-0.165,
 194 $P=0.025$), with effect-sizes all considered “small” (effect-sizes=0.37, -0.21
 195 respectively). Estimated parameters of the model 4 are presented in Table 4.

196 Table 5 shows significant test of RS, and the effect-sizes of observed change, RS and
 197 adjusted change. RS in the SF, RP, and BP scale were all significant. The effect was
 198 calculated as “small” for uniform recalibration of SF (effect-size=0.35). The
 199 effect-sizes of RP and BP were zero at the group level, since the non-uniform
 200 recalibration indicated changes of individual internal standard in different directions.
 201 After accounting for the RS effect, all scales except for the PF scale were stable. The
 202 PF scale of the participants improved slightly (effect-size=0.21).

203 Table 3: Goodness of fit of models in the 4-step detection procedure

Model	Df	CHISQ	CFI	TLI	RMSEA (90%CI)	SRMR
Model 1	88	151.6	0.951	0.934	0.060 (0.043,0.075)	0.050
Model 2	108	222.6	0.912	0.903	0.072 (0.059,0.086)	0.067
Model 3	105	178.5	0.944	0.936	0.059 (0.044,0.073)	0.059
Model 4	106	179.7	0.944	0.936	0.059 (0.043,0.073)	0.060

204

205 Table 4: Parameters estimated in the model 4

	Pre-test				Post-test			
	GenPHYS ₁		Gen-MENT ₁		GenPHYS ₂		Gen-MENT ₂	
Factor loadings								
PF	17.557				17.557			
RP	29.074				29.074			
BP	13.761				13.761			
RE	18.159				18.159			
GH	14.339				14.339			
SF	12.508				12.508			
VT	12.664				12.664			
MH	13.713				13.713			
Intercepts								
	PF	RP	BP	RE	GH	SF	VT	MH
Pre-test	74.214	72.804	78.853	83.962	54.656	80.049	55.038	69.664
Post-test	74.214	72.804	78.853	83.962	54.656	87.290	55.038	69.664
Residual variance								
	ResPF	ResRP	ResBP	ResRE	ResGH	ResSF	ResVT	ResMH
Pre-test	236.00	777.51	255.96	670.02	141.12	243.06	169.46	282.52
Post-test	236.00	492.01	125.94	670.02	141.12	243.06	169.46	282.52
Common factor variances								
	Pre-test				Post-test			
	GenPHYS ₁		Gen-MENT ₁		GenPHYS ₂		Gen-MENT ₂	
	1.00		1.00		1.136		0.781	
Common factor correlations								
Pre-test								
GenPHYS ₁	1							
Gen-MENT ₁	0.840	1						
Post-test								
GenPHYS ₂	0.871	0.685		1				
Gen-MENT ₂	0.561	0.583		0.840	1			
Common factor means								
	Pre-test				Post-test			
	GenPHYS		Gen-MENT		GenPHYS		Gen-MENT	
	0.00		0.00		0.234	P<0.001	-0.165	P=0.025

206 Parameters of factor loadings are unstandardized; Results indicating
 207 across-measurement variance are printed in bold.

208

209 Table 5: Significance tests of RS, and the effect-sizes of observed change, RS, and
 210 adjusted change

Scale	RS	Significance test		Effect-sizes ^a		
		$\chi^2_{SBdiff}(df=1)$	Prob.	observed change	RS	adjusted change
PF				0.21		0.21
RP	Non-unif. recalibration	8.84	0.003	0.19	0.00	0.19
BP	Non-unif. recalibration	17.41	<0.001	0.16	0.00	0.16
RE				0.12		0.13
GH				-0.13		-0.13
SF	Uniform recalibration	22.98	<0.001	0.25	0.35	-0.10
VT				-0.12		-0.11
MH				-0.10		-0.10

211 ^a Effect-sizes were calculated as corresponding parameters difference in model 4
212 divided by the estimated standard deviation;
213 Values of 0.2, 0.5, 0.8 indicate “small”, “medium”, and “large” effect-sizes. Values
214 less than 0.2 are considered “negligible”;
215 Bonferroni-adjusted critical value=0.006.

216 Discussion

217 This study explored the occurrence of RS in patients with hypertension attending the
218 community disease management program by using the Oort’s SEM approach. In our
219 sample, we detect recalibration type of RS in the SF, RP, and BP scale. The effects of
220 RS in the SF scale were calculated as “small”, but the influence of RS on the
221 measurement results was noticeable, which, emphasized the importance of adjustment
222 of RS impact in longitudinal HRQOL studies against patients with hypertension.

223 Further, the RS could be recognized as an important effectiveness consequence in
224 clinical interventions.

225 After accounting for all RS effects, we also found slight improvement in the general
226 physical health (GenPHYS), and slight deterioration in the general mental health
227 (GenMENT) of participants. The physical functioning (PF) of patients was
228 significantly improved during the program. The community disease management

229 program in this study was more effective in physical dimensions than mental.

230 Four weeks after the program, the meaning of the response scale anchors of the SF

231 scale has changed. A possible explanation for this result could be that when obtained

232 more information about the illness, or compared themselves with other patients, the

233 participants felt actual limitations in their social functioning, or the gaps between their

234 current status and ideal criterion. Therefore, they recalibrated their internal standards

235 of the SF scale, so that their functioning improved less than would be expected on

236 account of the interventions.

237 Prior researches have explored the mechanisms where RS produced. Sprangers and

238 Schwartz [1] have proposed several such mechanisms, including social comparisons,

239 and coping strategies. Empirical evidences have provided that social comparison acted

240 as a mediator between life events and RS [29], and that patients who considered

241 themselves better off than others tend to be able to maintain their quality of life even

242 with a worsening functioning [30]. Oort inferred that learning how to cope with

243 illness could induced RS in patients' physical functioning [14]. By integrating

244 appraisal process into the theoretical model of RS, Rapkin and Schwartz proposed the

245 concepts and methods for direct measurements of individual psychological process

246 involved in rating a QOL item [31], which provided a deep sight into how and when

247 RS occurred.

248 The then-test method was used to detect RS for this cohort in our previous work [32].

249 The group level results were deviate in the PF scale, where the recalibration has been

250 found by the then-test. Then-test approach was susceptible to inaccurate recall [33],

251 especially among elderly participants (mean age=65.9) [34], while the SEM approach
252 was immune to recall issues. However, one thing should be noted, the RS interpreted
253 by the model-based methods including the SEM approach are not unambiguous [35].
254 The group level model-based methods identify RS in terms of the variances of model
255 patterns or parameters, but RS may not be the only reason that arises these differences.
256 This explains why the direct measurement of individual appraisal process is
257 necessary. As mentioned by Rapkin and Schwartz [35], linking these group-level
258 statistical methods to appraisal is central to the (RS research) field, which is the
259 direction for our future researches.

260 **Conclusions**

261 This study detected RS in HRQOL measurement among patients with hypertension
262 attending the community-based disease management program by using the 4-step
263 SEM approach. The existence of recalibration had been detected, and the influence on
264 the SF scale was noticeable. We deduced that by initiating the social comparisons and
265 learning a better coping strategy in the program, the participants recalibrated their
266 internal standards of social functioning, so that it improved less than would be
267 expected on account of the intervention effects. We concluded that response shift
268 should be considered in longitudinal health-related quality of life researches among
269 patients with hypertension, and could be recognized as an effectiveness consequence
270 in clinical interventions. We recommended direct measurement of the appraisal
271 process in the future researches to explore the nature of RS.

272 **Abbreviations**

273 RS: Response Shift; SEM: Structural Equation Modeling; HRQOL: Health-Related
274 Quality of Life; CAD: Coronary Artery Disease; SF-36: 36-item Short Form Health
275 Survey; PF: Physical Functioning; RP: Role limitations due to Physical problems; BP:
276 Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role
277 limitations due to Emotional problems; MH: Mental Health; SD: Standard Deviation;
278 EFA: Exploratory Factor Analysis; MLR: Robust Maximum Likelihood Estimator;
279 CFI: Comparative Fit Index; TLI: Tucker-Lewis Index; SRMR: Standardized Root
280 Mean Square Residual; RMSEA: Root Mean Square Error of Approximation;
281 GenPHYS: General Physical Health; GenMENT: General Mental Health

282 **Declarations**

283 **Ethics approval and consent to participate**

284 All patients provided written informed consent to participate in the study. The
285 protocol was approved by the Ethics Committee of Zhejiang University School of
286 Medicine.

287 **Consent for publication**

288 Not applicable.

289 **Availability of data and materials**

290 The datasets used and/or analyzed during the current study are available from the
291 corresponding author on reasonable request.

292 **Competing interests**

293 The authors declare that they have no competing interests.

294 **Authors' contributions**

295 HC performed statistical analysis, interpreted the data. HC and LZ wrote the first draft.
296 HW, PL, and HC designed the study. HW, RZ, XL, DLP, and TCE contributed to the
297 writing of the final version of manuscript. All authors have read and approved the
298 final version of the manuscript and its conclusions.

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Figures

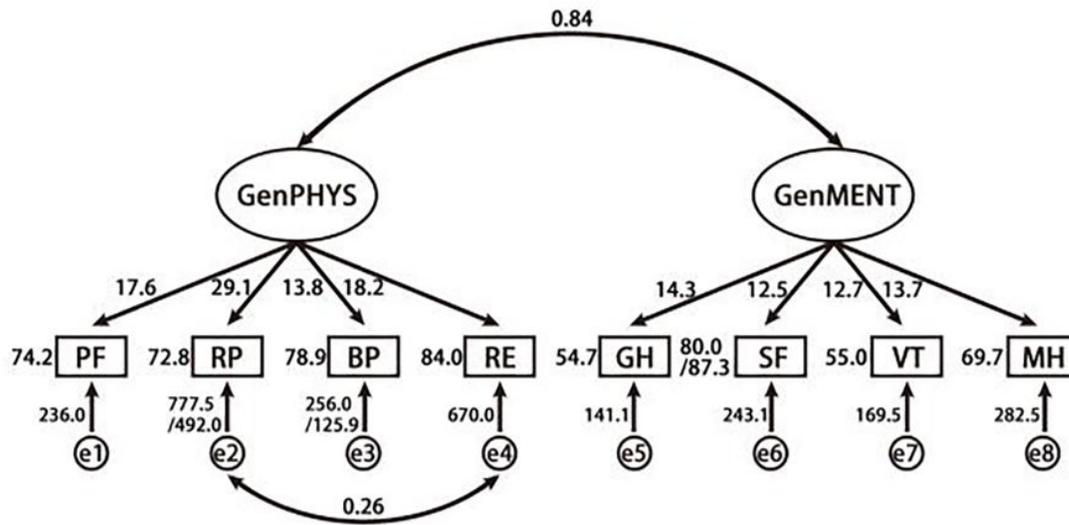


Figure 1

The measurement model used in RS detection. Numbers are estimated parameters in Model 4, which are common factor correlations, common factor loadings, intercepts, residual variances, and a residual correlation successively. Parameters divided by a slash represent separate the first and second occasion estimates.