ACCEPTED MANUSCRIPT

TITLE: Impact of Level of Effort on the Effects of Compliance with the 3-Hour Rule

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3   Impact of Level of Effort on the Effects of Compliance with the 3-Hour Rule
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6   **ABSTRACT**

7   Objective: To determine if patients' level of effort (LOE) in therapy sessions during traumatic

8   brain injury (TBI) rehabilitation modifies the effect of compliance with the 3-Hour Rule of the

9   Centers for Medicare & Medicaid Services.

10   Design: Propensity score methodology applied to the TBI-Practice-Based Evidence (TBI-PBE)

11   database, consisting of multi-site, prospective, longitudinal observational data.

12   Setting: Acute inpatient rehabilitation facilities (IRF).

13   Participants: Patients (n=1820) who received their first IRF admission for TBI in the US and

14   were enrolled for 3 and 9 month follow-up.

15   Main Outcome Measures: Participation Assessment with Recombined Tools-Objective-17,

16   FIM^{TM} Motor and Cognitive scores, Satisfaction with Life Scale, and Patient Health

17   Questionnaire-9.

18   Results: When the full cohort was examined, no strong main effect of compliance with the 3-

19   Hour Rule was identified and LOE did not modify the effect of compliance with the 3-Hour

20   Rule. In contrast, LOE had a strong positive main effect on all outcomes, except depression.

21   When the sample was stratified by level of disability, LOE modified the effect of compliance,

22   particularly on the outcomes of participants with less severe disability. For these patients,

23   providing 3 hours of therapy for 50%+ of therapy days in the context of low effort resulted in

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24   poorer performance on select outcome measures at discharge and up to 9 months post discharge

25   compared to patients with <50% of 3-hr therapy days.

26   Conclusions: LOE is an active ingredient in inpatient TBI rehabilitation, while compliance with

27   the 3-Hour Rule was not found to have a substantive impact on the outcomes. The results

28   support matching time in therapy during acute TBI rehabilitation to patients' LOE in order to

29   optimize long-term benefits on outcomes.

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34 **Key Words: B**rain injuries, traumatic; Health services research; Occupational therapy; Physical

35 therapy; Speech therapy; Recreation therapy; Rehabilitation; Therapeutics

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36 **List of Abbreviations**

37 ASD   Absolute standardized difference

38 CMS   Centers for Medicare & Medicaid Services

39 CSI   Comprehensive Severity Index

40 FIM^{TM} Functional Independence Measure^{TM}

41 GPS   Generalized propensity score

42 IRF   Inpatient rehabilitation facility

43 LOE   Level of effort

44 LOS   Length of stay

45 OT   Occupational therapy

46 PBE   Practice-based evidence

47 PART-O   Participation Assessment with Recombined Tools-Objective

48 PHQ-9   Patient Health Questionnaire-9

49 POC   Point of Care

50 PT   Physical therapy

51 RITS   Rehabilitation Intensity of Therapy Scale

52 ST   Speech therapy

53 SWLS   Satisfaction with Life Scale

54 TBI   Traumatic brain injury

55 US   United States

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58 Impact of Level of Effort on the Effects of Compliance with the 3-Hour Rule

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61 In 1982, the Centers for Medicare & Medicaid Services (CMS) imposed a regulatory

62 requirement on inpatient rehabilitation facilities (IRF) to provide 3 hours of therapy per day.[1]

63 The "3-Hour Rule" mandates that to qualify for Medicare-paid IRF-level reimbursement of

64 rehabilitation costs, IRFs must provide a minimum of 3 hours per day of either occupational

65 therapy (OT) or physical therapy (PT) and one additional therapy, usually speech therapy (ST)

66 for 5 of 7 days or 15 hours per week.[1] The rule is mandatory for CMS-affiliated payers, but it is

67 not uncommon for other payers to establish similar expectations for quantity of time in therapies.

68 Understanding whether the level of therapeutic intensity, as measured by time, is associated with

69 the best acute inpatient rehabilitation outcomes is critical to both consumers of rehabilitation and

70 to providers.[2,3]

71

72 The 3-Hour Rule was imposed before securing substantive evidence indicating time in therapy

73 alone affects outcomes. An early study conducted in 1986 suggested the rule may increase costs

74 without appreciable improvements in outcomes.[2] A Cochrane systematic review of

75 interdisciplinary rehabilitation for stroke and traumatic brain injury (TBI) concluded there is

76 strong evidence that more intensive treatment leads to earlier functional gains, and moderate

77 evidence for it shortening length of stay (LOS)[3] . However, the impact on longer-term outcomes

78 (e.g. 6-12 months post-injury) was not significant or was insufficiently studied. Also, the review

79 was based on 4 randomized controlled trials conducted in the 1990s, in countries whose systems

80 of care differ substantially from current rehabilitation in the United States (US), using varying

81 definitions of treatment intensity across the studies. A more recent meta-analysis calculated a

82 medium effect size for intensity of rehabililitation.[4] However, the analysis included 2 of the

83 studies from the previous systematic review and the remaining 3 were not conducted in an IRF

84 setting or did not involve multidisciplinary rehabilitation. Two studies conducted with patients

85 receiving stroke rehabilitation found $\geq$ 3 hours of therapy per day was associated with greater

86 functional gain at discharge[5] and shorter LOS.[6] Studies varied in either collection or analysis of

87 potential confounding variables such as age, severity, and time post-event. Despite substantial

88 changes in rehabilitation care and payment systems, no controlled studies in the past 18 years

89 include patients with TBI treated in US IRFs.

90

91 Recent research focuses on defining therapy intensity as a function of the complexity of

92 therapeutic activity rather than as treatment time per se, and on identifying factors that may

93 impact a patient's ability to participate in therapy sessions. Horn et al. found greater effort

94 extended by TBI patients within therapy sessions and more time spent in complex therapy

95 activities were associated with better outcomes at IRF discharge and similar, less pervasive

96 associations at 9 months post discharge.[7] Recent research suggests the amount of effort patients

97 are able to expend, and the content of therapy, may be the important active ingredients of

98 rehabilitation.[8][9] For individuals with TBI, the severity of the presenting disability is an

99 important factor influencing the ability to participate effortfully in treatment, as well as

100 responsiveness to different therapeutic approaches.[10]

101

102 The present study is one of a series utilizing propensity score methodology to control measured

103 confounders while evaluating rehabilitation approaches and methods of delivery. We

104 hypothesized that patients' level of effort (LOE) during therapy sessions modifies the impact of

105 compliance with the 3-Hour Rule. Given that the severity of the presenting disability has been

106 found to influence effort in treatment, we planned a priori to evaluate effect modification in

107 groups stratified by severity in addition to the full cohort. The study provides a preliminary

108 examination of possible causal relationships between compliance with the 3-Hour Rule, how

109 compliance may be modified by LOE, and outcomes up to 9 months post-discharge from

110 inpatient rehabilitation.

111

112 **METHODS**

113 This study analyzes data from the multi-site longitudinal TBI Practice-Based Evidence study that

114 enrolled consecutive IRF admissions from 2008 to 2011 at 9 US sites and 1 in Canada.[11] The

115 TBI-PBE Database incorporates data abstracted from medical records, Point-Of-Care (POC)

116 documentation of IRF treatments, and follow-up interviews. During each therapy session, trained

117 therapists using standardized POC forms recorded time in each therapeutic activity and LOE

118 expended by the patient.

119

120 *Participants.* The portion of the TBI-PBE Database used in the current analysis included 1820

121 participants who were: aged 14 or older, received their first IRF admission for TBI rehabilitation

122 at a US facility, consented to follow-up, received therapy after the first 3 days of the admission,

123 and had valid LOE ratings (i.e. were not missing LOE or were not in a minimally conscious state

124 throughout the admission). See the Participant Flow Diagram in SDC. An additional 8

125 participants were excluded because they did not receive weights in the propensity score model

126 due to missing values on key variables.

127

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128   *Setting.* The IRFs that participated in the TBI-PBE study are described by Seel et al.[12]

129   The 9 US facilities were CMS-compliant with the 3-hour rule, typically delivering 3 hours across

130   the 5 weekdays or delivering 15 hours across a 7-day week by exception. The mean session

131   length was 38.6 minutes ($\pm$8.7) for PT, 37.7 ($\pm$7.7) for OT, and 32.5 ($\pm$6.1) for ST. Patients

132   received the majority of their therapy during the week, with a median of 0.3 hours of PT and OT

133   and 0.2 hours of ST provided on the weekend.

134

135   *Severity Stratification*. To evaluate heterogeneity of treatment effects, the sample was stratified

136   into two groups based on severity of disability at admission. The Severe group consisted of

137   patients who required maximal assistance with all self-care, mobility, and cognitive needs

138   (FIM^{TM} Cognitive scores at admission $\leq$ 15 and FIM^{TM} Motor scores < 28.75, n=805). The Less

139   Severe group comprised the remaining patients (n=1015).

140

141   *LOE.* Effort during each session was rated by the rehabilitation therapists with the Rehabilitation

142   Intensity of Therapy Scale (RITS[8]), a single-item, behaviorally anchored, 7-point scale. Higher

143   scores indicate more patient engagement and effort, with effort being operationally defined as

144   being attentive and engaged in goal-directed activity, including initiating activity, incorporating

145   therapist feedback, and persevering when therapies become challenging. [10] A number of steps

146   were taken to minimize rater variability, bias and missing data. Therapists were trained in

147   making RITS LOE ratings and tested twice during the study for accuracy. High accuracy rates

148   (% correct responses) were observed at the initial testing for ST (98%), PT (97%), and OT

149   (89%); they remained high at the 9-month follow-up test for ST (91%), PT (91%), and OT

150   (81%).[10] The level of effort ratings across ST, PT, and OT individual therapy sessions closely

151   conformed to a normative distribution with minimal skewness (-.02 to -.11) and kurtosis (-.08 to

152   -.12). Test-retest stability for the single-item level of effort ratings were excellent for all three

153   disciplines during both morning and afternoon sessions, with intraclass correlation coefficients

154   ranging from .76 to .80.[10] For the current study, LOE was averaged across disciplines and days

155   of the rehabilitation stay.

156

157   *Compliance with 3-Hour Rule.* Hours of therapy per day were calculated from the minutes

158   recorded on the POC forms, and used to determine the percentage of rehabilitation days in

159   compliance with the 3-Hour Rule. (Calculation details are provided in SDC, Methodology

160   Details). The distribution of percentage of days in compliance with the 3-Hour Rule

161   distinguished three groups of participants: a) 3 hours or more of therapy on 50% or more of days

162   (50%+ Compliant), b) 3 hours or more on 20-50% of days (20-50% Compliant) and c) 3 hours or

163   more on 0-20% of days (0-20% Compliant). Percentage of therapy time in group treatment and

164   total number of therapy hours over the entire rehabilitation stay were calculated and used in

165   sensitivity analyses.

166

167   *Outcomes.* Outcome data were collected at discharge (FIM[TM] [13] only), and 3 and 9 months post-

168   discharge. The primary outcome was community participation, as measured by the Participation

169   Assessment with Recombined Tools-Objective-17 (PART-O-17).[14,15] This study used the 3

170   domain scores (Out and About, Social Relations, and Productivity), the Total score derived from

171   the 3 domain scores, and a Rasch-adjusted Total score that measures participation on a ratio

172   scale.[16] Secondary outcomes included the FIM[TM] Rasch-adjusted Motor and Cognitive scores,[17]

173   Patient Health Questionnaire-9 (PHQ-9)[18] dichotomized into likely major depression versus no

174   major depression[19], and the Satisfaction with Life Scale (SWLS).[20] All of the measures have

175   established psychometrics.[21-23]

176

177   *Potential confounders.* To ensure characteristics considered potential confounders were not

178   impacted by the rehabilitation treatment, only variables measured at rehabilitation admission

179   (first 3 days) or earlier were included in the propensity score adjustment model. The full list of

180   potential confounders can be found in supplemental table S1, Balance Diagnostics.

181

182   *Analysis.* Data were analyzed using SAS v9.3[a] and STATA version 14.0.[b] Inverse probability

183   weighting (IPW) with generalized propensity scores (GPS) estimated by multinomial logistic

184   regression was used to control for measured confounders across the 3 Compliance groups. An

185   iterative process was used to develop models that achieved the optimal balance of potential

186   confounders, including trials of interaction terms. Balance across the three Compliance groups

187   was assessed using the absolute standardized difference (ASD) between all possible pairs of

188   groups[25] prior to and after weighting by the stabilized IPW. If, after IPW, the ASD for a potential

189   confounder exceeded a conservative 0.10, the potential confounder was included as a covariate

190   in the outcome analysis model.[25] The GPS model was estimated for the full cohort, and

191   separately for the Severe and Less Severe subgroups.

192

193   The hypothesis that LOE would modify the effect of compliance with the 3-Hour Rule was

194   evaluated through marginal regression models weighted by the standardized IPW, with robust

195   sandwich standard error estimates. The potential modification by LOE of Compliance's effect on

196   outcomes was tested first by the interaction term between LOE and Compliance (including

197 effects of the lower order terms), without including any covariates that were not balanced by

198 IPW. In the second step, models were adjusted for any unbalanced covariates. Primary inference

199 is based on and reported for the second step, because the first step was assumed to be biased by

200 confounders. If effect modification was not significant at the p<.05 level, the interaction term

201 was dropped and the main effects of Compliance and of LOE were estimated.

202

203 Sensitivity analysis evaluated the proportion of time in group therapy and total therapy hours

204 delivered over the LOS due to concerns that these factors might influence the effects of

205 Compliance. Multiple imputation (40 iterations) for all missing outcome measures was used to

206 examine if findings were substantially more efficient (i.e. reduced variance) in the full sample.

207 Heterogeneity of treatment effects in the Severe and Less Severe subgroups was evaluated by

208 conducting analyses separately for these groups. When effects were observed in a subgroup, we

209 compared confidence intervals of effect sizes to determine if the size of the effects differed based

210 on severity of disability. See SDC for additional details regarding statistical methods.

211 **RESULTS**

212 *Full cohort.* The extent to which confounders were balanced across Compliance groups was

213 evaluated by examining the ASDs for pairwise comparisons (Table 1 and supplemental table S1).

214 Prior to weighting, mean ASD was 0.13, with a maximum of 0.84. Forty-seven percent of the

215 confounders or levels of a confounder (for categorical variables) had ASDs greater than 0.10.

216 The estimated stabilized IPW had an average value of 0.99 (minimum: 0.30, maximum: 17.1).

217 After weighting, the mean ASD was reduced to 0.06 (maximum=0.13) with 4% (n=3) of the

218 variables had ASDs exceeding the 0.10 threshold. The three unbalanced confounders

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219   (Comprehensive Severity Index-Non-Brain Injury, premorbid alcohol misuse, private insurance)

220   were included in the outcome analyses.

221

222   The hypothesis regarding the effect modification of LOE on compliance was tested first.

223   Adjusting for the 3 unbalanced covariates, there was no significant effect modification between

224   LOE and Compliance with the 3-Hour Rule for any outcome. Given that the a priori hypothesis

225   was not supported, the interaction term was dropped and the main effects were estimated.

226   Compliance was associated with a significantly lower PART-O Social Relations score at 3

227   months for those with 20-50% Compliance versus those with 50%+ Compliance (adjusted

228   average difference: 0-20% Compliance vs. 50%+: -.08, 95% CI=-.29, .12; 20-50% Compliance

229   vs. 50%+ Compliance: -.18, 95% CI=-.31, -.04). However, after controlling for LOE,

230   Compliance was not strongly associated with any outcome (Table 2). LOE had a strong positive

231   association (main effect) with all outcomes, except PHQ-9 (Table 2). These findings did not

232   change substantially when total number of therapy hours and percentage of treatment in group

233   therapy were added to the model, with the exception of a weaker association with SWLS at 3

234   months. Following multiple imputation, SWLS at 3 months was again strongly associated with

235   LOE.

236

237   *Stratification by disability severity.* For the Severe subgroup, prior to weighting the mean ASD

238   was 0.14 with a maximum of 0.75; 56% of variables had ASDs greater than 0.10. After

239   weighting, the mean ASD was 0.10 (maximum=.0.26) with 46% of variables (36/79) had ASD

240   exceeding 0.10. After adjustment for unbalanced covariates, significant modification of the effect

241   of Compliance by LOE was noted for: FIM[TM] Cognitive at 3 months and PART-O Rasch Total

242 at 9 months (Table 3 and Figures 1 and 2). Post-hoc analysis of the difference in outcomes

243 between the Compliance groups for each rating of LOE were significant for FIM Cognitive, but

244 not for PART-O Rasch Total. Findings did not change substantially when total therapy hours and

245 percentage of group therapy were added to the models. For those outcomes for which a

246 significant effect modification was not found, the main effect of Compliance, adjusted for LOE,

247 was examined. No significant main effects of Compliance were identified.

248

249 For the Less Severe subgroup, before weighting the mean ASD was 0.12 with a maximum of

250 0.86; 42% of the variables had ASDs > 0.10. After weighting, the mean ASD was 0.08

251 (maximum= 0.19) with 29% of the variables with ASDs greater than 0.10. These 23 variables

252 were included in the adjusted outcome analysis. LOE was found to significantly modify the

253 effect of Compliance on: PART-O Total, Total Rasch, and Social Relations at 9 months, Out and

254 About at 3 and 9 months, Productivity at 3 months, SWLS at 3 and 9 months, and FIM^{TM}

255 Cognitive at discharge, after adjustment for unbalanced covariates (Table 3, Figures 3-5 and

256 supplemental Figures S1-S5). Adding percent of group therapy and total therapy minutes to the

257 models, the Compliance effect modification by LOE was no longer significant at the $p<.05$ level

258 for PART-O Total Rasch at 9 months, Out and About at 3 months, and Productivity at 3 months.

259 While effect modification of LOE remained significant for SWLS at both 3 and 9 months

260 (Supplemental figures S4 and S5), the post-hoc comparisons at the different ratings of LOE were

261 not significant. For those outcomes for which a significant effect modification was not found,

262 the main effect of Compliance was examined. Adjusting for LOE, no significant main effects of

263 Compliance were identified (Supplemental Table S2).

264

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265   For both severity groups, the moderating influence of LOE on Compliance's effects was similar

266   across the FIM^{TM} Cognitive and PART-O outcomes, and generally in the same direction for all

267   significant post-hoc analysis. As illustrated in Figures 1-5 (additional Figures in supplemental

268   material), LOE had a stronger positive influence on FIM^{TM} Cognitive and PART-O outcomes for

269   those with 50% or more of therapy days in compliance, as compared to its influence for those in

270   the 0-20% Compliance group. In particular for PART-O outcomes, as effort increased in those

271   with 50% or more therapy days in compliance, outcomes improved. For those with few therapy

272   days in compliance (0-20%) we did not see an impact on outcomes if LOE varied. The effects of

273   LOE on the 20-50% Compliance group often fell in between the other two groups. Table 3

274   describes the average difference in scores, relative to 50%+ compliance, for outcomes across

275   LOE. To determine if the size of the effects differed based on initial level of disability, we

276   evaluated the overlap of confidence intervals for the effects. The confidence intervals of the

277   effects overlapped substantially, suggesting that the effects of compliance and LOE on outcomes

278   were not different between the severity groups.

279
280   **DISCUSSION**

281   Compliance with the 3-Hour Rule did not have a significant impact on outcomes in this sample

282   of IRF patients with TBI. However, LOE was significantly associated with the majority of the

283   outcomes up to 9 months post-discharge, including community participation, functional

284   independence, and life satisfaction, but not likelihood of depression. Our *a priori* hypothesis that

285   the effect of 3-Hour Rule Compliance on outcomes is moderated by the LOE that patients were

286   able to expend in treatment was not supported when the full cohort was used in the analysis.

287   However, when the sample was stratified by initial severity of disability, there was a significant

288   interaction between 3-Hour Rule Compliance and LOE with regard to outcomes for patients with

289 less severe disability, and minimally for those with more severe disability. LOE had a stronger

290 impact on the outcomes of those participants with 50% or more days in compliance than its

291 impact on those with 0-20% days in compliance. Participants with lower LOE did poorly when

292 provided with 3+ hours of therapy for more than half of their therapy days in comparison to

293 patients who received 3+ hours of therapy during a small proportion of their rehabilitation days.

294 Matching intensity of therapy, as measured by total time, to the patient's LOE appears to

295 produce optimum results.

296

297 The results of this study do not support the mandate of 3 hours of therapy for all patients at all

298 times during the inpatient stay. Rather, time in therapy needs to be tailored for each patient based

299 on LOE, in order to maximize response to rehabilitation. This patient-centered approach is a

300 smarter use of resources. Unfortunately, short of a reversal of a federal regulation that has been

301 in place for over 35 years, providers will need to focus on other solutions to adapt therapy time

302 to the patient's needs (e.g., brief frequent therapy dosing across the day, increased rest breaks,

303 etc.) with the goal of finding the "sweet spot" between time and effort that maximizes patients'

304 outcomes. Providers will also need to identify unique features within each individual (i.e.,

305 person-focused) to enhance LOE during therapy.

306

307 Some people might argue that persons who are only able to expend low levels of effort should be

308 denied admission to IRFs since they do not benefit from the mandated 3 hours of therapy. This

309 contention was not tested in our study, and we would argue against this interpretation. LOE as

310 measured in this study was collected following admission to IRF and within the context of each

311 therapy session. The findings speak more to the need to change the therapeutic environment to

312 match patients' needs than to denying access to IRF-level of care.

313

314 This study focused on identifying what has the greatest impact on patient hospital discharge

315 outcomes and longer-term life outcomes. While time in therapy is likely to continue to be

316 debated as a potential active ingredient in inpatient rehabilitation, the current finding of the

317 importance of LOE within sessions adds to the growing body of literature indicating that time is

318 not the only ingredient to positively affect outcomes. Other studies have found that, for instance,

319 function-focused activities in rehabilitation are more effective than impairment-focused

320 activities.[9] The accumulating evidence confirms that rehabilitation is a complex process and

321 cannot be defined simply as an aggregate of time.[26] Future research must continue to focus on

322 identifying ingredients that promote the greatest benefits for patients.

323

324 **Study limitations**

325 We were not able to capture the reasons patients did not receive 3 hours of therapy, which could

326 better inform the interpretation of results. The current study based causal inference on propensity

327 score analysis of observational data, rather than on the more widely accepted randomized

328 controlled trial. We cannot be certain that all confounders were measured. In addition, while we

329 achieved excellent balance of the confounders across different levels of exposure to the treatment

330 (Compliance) for the full cohort, we were not able to achieve our pre-set criterion for a large

331 number of confounders when we stratified the sample, particularly in the Severe subgroup.

332 Adjusting the models by the unbalanced covariates increases our confidence in the results, but

333   interpretation still should be made cautiously. Further, while we use a comprehensive model for

334   multiple imputation of missing outcomes, which included all covariates believed to potentially

335   be related to outcomes, expected interactions and observed outcomes to impute missing

336   outcomes over time, there is no test to ensure that our data was not missing due to some

337   unobserved variables.

338

339   The associations found between LOE and the outcomes should also be interpreted carefully

340   because the propensity score methods were used to balance the confounders on 3 Hour Rule

341   Compliance, not on LOE. Causal inferences can only be made relative to Compliance, not LOE.

342   The association between LOE and outcomes could be reflective of underlying factors, such as

343   tenaciousness, that can impact performance in both rehabilitation and in the community.

344   However, this possibility should not discount the need to adapt rehabilitation to the individual's

345   ability to expend effort, whether this is a reflection of a temporary state or an enduring trait.

346

347   **Conclusions**

348   Engagement in therapy was found to be more important than the amount of time in therapy for

349   optimizing outcomes, providing evidence for a need to reconsider the 3-Hour rule.

350   Individualizing the amount of treatment per day to be in line with the person's ability to engage

351   and fully participate in therapy will likely yield better outcomes.

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REFERENCES

1. Centers for Medicare and Medicaid (CMS) Medicare Learning Network. Inpatient rehabilitation facility (IRF) medical review changes. *MLN Matters Number SE17035*. 2017.

2. Johnston MV, Miller LS. Cost-effectiveness of the medicare three-hour regulation. *Arch Phys Med Rehabil*. 1986;67(9):581-585.

3. Turner-Stokes L, Pick A, Nair A, Disler PB, Wade DT. Multi-disciplinary rehabilitation for acquired brain injury in adults of working age. *Cochrane Database Syst Rev*. 2015;(12):CD004170. doi(12):CD004170.

4. Konigs M, Beurskens EA, Snoep L, Scherder EJ, Oosterlaan J. Effects of timing and intensity of neurorehabilitation on functional outcome after traumatic brain injury: A systematic review and meta-analysis. *Arch Phys Med Rehabil*. 2018;99(6):1149-1159.e1.

5. Wang H, Camicia M, Terdiman J, Mannava MK, Sidney S, Sandel ME. Daily treatment time and functional gains of stroke patients during inpatient rehabilitation. *PM R*. 2013;5(2):122-128.

6. Nagai S SS. Relationship between the intensity of stroke rehabilitation and outcome: A survey conducted by the kaifukuki rehabilitation ward association in japan (second report). *Jpn J Compr Rehabil Sci*. 2011;2:77-81.

7. Horn SD, Corrigan JD, Beaulieu CL, et al. Traumatic brain injury patient, injury, therapy, and ancillary treatments associated with outcomes at discharge and 9 months postdischarge. *Arch Phys Med Rehabil*. 2015;96(8 Suppl):S304-29.

8. Pegg P, Auerbach S, Seel R, Buenaver L, Kiesler D, Plybon L. The impact of patient-center information on patients' treatment satisfaction and outcomes in traumatic brain injury rehabilitation. *Rehabil Psychol*. 2005;50(4):366-374.

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9. Bode RK, Heinemann AW, Semik P, Mallinson T. Relative importance of rehabilitation therapy characteristics on functional outcomes for persons with stroke. *Stroke*. 2004;35(11):2537-2542.

10. Seel RT, Corrigan JD, Dijkers MP, et al. Patient effort in traumatic brain injury inpatient rehabilitation: Course and associations with age, brain injury severity, and time postinjury. *Arch Phys Med Rehabil*. 2015;96(8 Suppl):S235-44.

11. Horn SD, Corrigan JD, Bogner J, et al. Traumatic brain injury-practice based evidence study: Design and patients, centers, treatments, and outcomes. *Arch Phys Med Rehabil*. 2015;96(8 Suppl):S178-96.e15.

12. Seel RT, Barrett RS, Beaulieu CL, et al. Institutional variation in traumatic brain injury acute rehabilitation practice. *Arch Phys Med Rehabil*. 2015;96(8 Suppl):S197-208.

13. Heinemann AW, Linacre JM, Wright BD, Hamilton BB, Granger C. Relationships between impairment and physical disability as measured by the functional independence measure. *Arch Phys Med Rehabil*. 1993;74(6):566-573.

14. Whiteneck GG, Dijkers MP, Heinemann AW, et al. Development of the participation assessment with recombined tools-objective for use after traumatic brain injury. *Arch Phys Med Rehabil*. 2011;92(4):542-551.

15. Bogner JA, Whiteneck GG, Corrigan JD, Lai JS, Dijkers MP, Heinemann AW. Comparison of scoring methods for the participation assessment with recombined tools-objective. *Arch Phys Med Rehabil*. 2011;92(4):552-563.

16. Malec JF, Whiteneck GG, Bogner JA. Another look at the PART-O using the traumatic brain injury model systems national database: Scoring to optimize psychometrics. *Arch Phys Med Rehabil*. 2016;97(2):211-217.

17. Linacre JM, Heinemann AW, Wright BD, Granger CV, Hamilton BB. The structure and stability of the functional independence measure. *Arch Phys Med Rehabil*. 1994;75(2):127-132.

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18. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med*. 2001;16(9):606-613.

19. Fann JR, Bombardier CH, Dikmen S, et al. Validity of the patient health questionnaire-9 in assessing depression following traumatic brain injury. *J Head Trauma Rehabil*. 2005;20(6):501-511.

20. Diener E, Emmons RA, Larsen RJ, Griffin S. The satisfaction with life scale. *J Pers Assess*. 1985;49(1):71-75.

21. Hamilton BB, Laughlin JA, Fiedler RC, Granger CV. Interrater reliability of the 7-level functional independence measure (FIM). *Scand J Rehabil Med*. 1994;26(3):115-119.

22. Pavot W, Diener E, Colvin CR, Sandvik E. Further validation of the satisfaction with life scale: Evidence for the cross-method convergence of well-being measures. *J Pers Assess*. 1991;57(1):149-161.

23. Williams RT, Heinemann AW, Neumann HD, et al. Evaluating the psychometric properties and responsiveness to change of 3 depression measures in a sample of persons with traumatic spinal cord injury and major depressive disorder. *Arch Phys Med Rehabil*. 2016.

25. Austin PC, Stuart EA. Moving towards best practice when using inverse probability of treatment weighting (IPTW) using the propensity score to estimate causal treatment effects in observational studies. *Stat Med*. 2015;34(28):3661-3679.

26. Whyte J, Hart T. It's more than a black box; it's a russian doll: Defining rehabilitation treatments. *Am J Phys Med Rehabil*. 2003;82(8):639-652.

Figures

Figure 1. Severe subgroup: Interaction plot for PART-O Total Rasch at 9 months (adjusted model).
Figure 2: Severe subgroup: Interaction plot for FIM Cognitive Rasch at 3 months (adjusted model).

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Figure 3. Less Severe subgroup: Interaction plot for PART-O Total Rasch at 9 months (adjusted model).
Figure 4. Less Severe subgroup: Interaction plot for PART-O Total at 9 months (adjusted model).
Figure 5. Less Severe subgroup: Interaction plot for FIM Cognitive (Rasch) at discharge (adjusted model).

Suppliers

[a]SAS v9.3 38 (SAS Institute, Inc., Cary, NC)

[b]STATA version 14.0 39 (StataCorp, College Station, TX).

Level of Effort Effects on 3-Hour Compliance

Level of Effort Effects on 3-Hour Compliance

Table 1: Demographic and clinical characteristics at admission, by Compliance with the 3-Hour Rule exposure groups, prior to and with IPW

| | Prior to IPW | | | With IPW | | | |
| | Compliance Group | | | Compliance Group | | | |
	0-20%	20-50%	50%+	0-20%	20-50%	50%+	ASD[*]
Demographics							
Age at admission							0.03
Mean(SD)	45.79 (20.1)	44.82 (22.0)	43.09 (21.74)	45 (21.26)	44.1 (21.58)	44.86 (21.17)	
Male gender n(%)							0.04
	396 (74.72)	486 (71.89)	427 (69.32)	394.64 (74.96)	493.65 (72.09)	432.08 (72.47)	
Race/Ethnicity n(%)							
White non-Hispanic	380 (71.7)	508 (75.15)	490 (79.55)	384.23 (72.99)	509.34 (74.38)	454.7 (76.26)	0.05
White Hispanic	38 (7.17)	47 (6.95)	29 (4.71)	31.19 (5.93)	40.69 (5.94)	28.94 (4.85)	0.03
Black	94 (17.74)	102 (15.09)	80 (12.99)	94.26 (17.91)	114.13 (16.67)	82.68 (13.87)	0.07
Other or Unknown race/ethnicity	18 (3.4)	19 (2.81)	17 (2.76)	16.74 (3.18)	20.59 (3.01)	29.92 (5.02)	0.07
At least High school education n(%)	389 (73.4)	487 (72.04)	441 (71.59)	362.91 (68.94)	503.21 (73.49)	440.73 (73.92)	0.07
Insurance n(%)							
Private/MCO/HMO	196 (36.98)	303 (44.82)	263 (42.69)	186.03 (35.34)	286.15 (41.79)	260.9 (43.76)	0.12
Medicare	115 (21.7)	152 (22.49)	122 (19.81)	122.12 (23.2)	146.46 (21.39)	124.48 (20.88)	0.04
Medicaid	118 (22.26)	87 (12.87)	110 (17.86)	101.8 (19.34)	122.59 (17.9)	87.91 (14.74)	0.08
Self-pay/other payer	76 (14.34)	91 (13.46)	76 (12.34)	79.11 (15.03)	91.4 (13.35)	73.54 (12.33)	0.05
Workers comp	25 (4.72)	43 (6.36)	45 (7.31)	37.36 (7.1)	38.14 (5.57)	49.39 (8.28)	0.07
Premorbid Conditions							
Alcohol Misuse n(%)	259 (48.87)	215 (31.8)	177 (28.73)	199.9 (37.97)	244.93 (35.77)	176.16 (29.55)	0.12
Other drug use n(%)	159 (30)	128 (18.93)	109 (17.69)	113.46 (21.55)	152.28 (22.24)	119.86 (20.1)	0.04
Injury and status at Admission to Rehabilitation							
Cause of Injury n(%)							
Fall	169 (31.89)	208 (30.77)	189 (30.68)	178.3 (33.87)	217.91 (31.82)	177.49 (29.77)	0.06
Sports	35 (6.6)	36 (5.33)	29 (4.71)	21.49 (4.08)	35.13 (5.13)	43.29 (7.26)	0.09
Motor vehicle	279 (52.64)	380 (56.21)	374 (60.71)	278.66 (52.93)	386.31 (56.42)	339.99 (57.02)	0.05
Violence	47 (8.87)	52 (7.69)	24 (3.9)	47.98 (9.11)	45.4 (6.63)	35.46 (5.95)	0.08

Site n(%)‡							
Site group 1	28 (5.28)	223 (32.99)	190 (30.84)	140.19 (26.63)	168.36 (24.59)	152.26 (25.54)	0.03
Site group 2	289 (54.53)	160 (23.67)	31 (5.03)	140.06 (26.61)	180.22 (26.32)	152.66 (25.61)	0.02
Site group 3	129 (24.34)	79 (11.69)	174 (28.25)	90.49 (17.19)	146.26 (21.36)	112.9 (18.94)	0.07
Site group 4	84 (15.85)	214 (31.66)	221 (35.88)	155.69 (29.57)	189.9 (27.73)	178.4 (29.92)	0.03
Time to Rehabilitation (days) Mean(SD)	24.35 (33.52)	26.2 (30.03)	28.81 (32.4)	31.15 (41.93)	27.15 (29.02)	26.17 (28.52)	0.09
FIM Motor at admission (Rasch) Mean(SD)	36.16 (16.62)	31.64 (16.76)	25.63 (17.28)	32.23 (16.11)	31.22 (17.63)	30.69 (16.22)	0.06
FIM Cognitive at admission (Rasch) Mean (SD)	39.85 (19.22)	37.89 (18.06)	30.68 (19.32)	36.55 (19.13)	35.6 (19.55)	36.42 (18.87)	0.03
Post traumatic amnesia cleared prior to rehab admission n(%)	243 (45.85)	246 (36.39)	163 (26.46)	180.29 (34.25)	245.97 (35.92)	189.52 (31.79)	0.06
CSI Brain Injury	39.11(21.12)	45.18(22.18)	53.92 (23.08)	45.35(22.28)	46.38(22.82)	46.80(22.36)	0.04
CSI Non-Brain Injury	16.34(14.76)	19.16(15.43)	17.13(14.25)	21.34(24.99)	17.43(14.55)	18.72(15.62)	0.13
Glasgow Coma Score n(%)							
Intubated/Missing	285 (53.77)	300 (44.38)	277 (44.97)	263.09 (49.98)	313.92 (45.84)	273.75 (45.91)	0.06
Mild	99 (18.68)	96 (14.2)	69 (11.2)	71.74 (13.63)	105.89 (15.46)	95.69 (16.05)	0.05
Moderate-Severe	146 (27.55)	280 (41.42)	270 (43.83)	191.6 (36.4)	264.94 (38.69)	226.79 (38.04)	0.03

* ASD of the three, two group comparisons.

‡Site group 1 consists of sites with less than 10% of participants receiving Medicare; Site group 2 consists of sites with 10-20% of participants receiving Medicare; Site group 3 consists of sites with 20-30% of participants receiving Medicare and Site group 4 consists of sites with >30% receiving Medicare

Table 2: Full cohort, adjusted main effects of LOE and Compliance with the 3-Hour Rule,
(*average adjusted effect, 95% confidence interval*)

Outcome	Time Point	LOE** (adjusted for Compliance)	Compliance Group	Compliance** (adjusted for LOE)
PART-O Total	3 months	0.25 (0.21, 0.30)‡	0-20% vs. >=50%	-0.2 (-0.12, 0.09)
			20-50% vx. >=50%	-0.02 (-0.11, 0.07)
	9 months	0.26 (0.20, 0.32)‡	0-20% vs. >=50%	-0.04 (-0.19, 0.10)
			20-50% vx. >=50%	-0.02 (-0.12, 0.09)
PART-O Rasch Total	3 months	4.31 (3.39, 5.23)‡	0-20% vs. >=50%	-0.82 (-2.29, 0.65)
			20-50% vx. >=50%	-0.94 (-2.37, 0.49)
	9 months	3.57 (2.58, 4.56)‡	0-20% vs. >=50%	0.08 (-1.86, 2.03)
			20-50% vx. >=50%	0.00 (-1.49, 1.49)
PART-O Social	3 months	0.24 (0.15, 0.32)‡	0-20% vs. >=50%	-0.03 (-0.22, 0.15)
			20-50% vx. >=50%	-0.15 (-0.28, -0.02)
	9 months	0.21 (0.13, 0.28)‡	0-20% vs. >=50%	-0.09 (-0.26, 0.09)
			20-50% vx. >=50%	-0.06 (-0.18, 0.06)
PART-O Productivity	3 months	0.29 (0.24, 0.34)‡	0-20% vs. >=50%	0.02 (-0.11, 0.15)
			20-50% vx. >=50%	0.09 (-0.03, 0.20)
	9 months	0.36 (0.30, 0.43)‡	0-20% vs. >=50%	0.01 (-0.18, 0.20)
			20-50% vx. >=50%	0.01 (-0.14, 0.17)
PART-O Out and About	3 months	0.23 (0.17, 0.29)‡	0-20% vs. >=50%	-0.04 (-0.19, 0.12)
			20-50% vx. >=50%	-0.01 (-0.13, 0.12)
	9 months	0.21 (0.14, 0.27)‡	0-20% vs. >=50%	-0.05 (-0.23, 0.14)
			20-50% vx. >=50%	0.02 (-0.11, 0.15)
FIM Rasch Cognitive	Discharge	11.42 (10.55, 12.30)‡	0-20% vs. >=50%	1.18 (-0.86, 3.22)
			20-50% vx. >=50%	0.38 (-1.29, 2.06)
	3 months	8.69 (6.87, 10.50)‡	0-20% vs. >=50%	0.88 (-2.66, 4.43)
			20-50% vx. >=50%	-0.94 (-4.06, 2.18)
	9 months	7.55 (5.56, 9.54)‡	0-20% vs. >=50%	1.08 (-2.69, 4.85)
			20-50% vx. >=50%	0.63 (-1.91, 3.16)

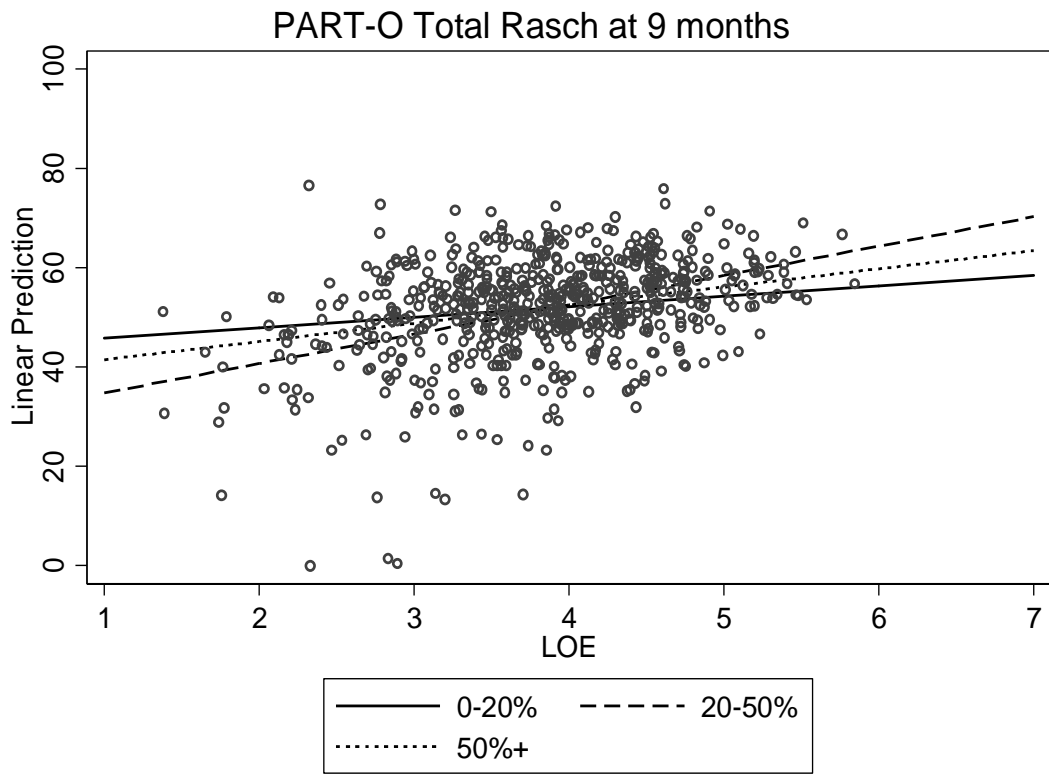|				
	Discharge	8.52 (7.40, 9.63)‡	0-20% vs. >=50%	0.81 (-1.05, 2.66)
			20-50% vx. >=50%	0.86 (-0.65, 2.37)
FIM Rasch Motor	3 months	11.02 (9.11, 12.93)‡	0-20% vs. >=50%	1.35 (-2.61, 5.31)
			20-50% vx. >=50%	1.85 (-1.01, 4.70)
	9 months	9.73 (7.34, 12.12)‡	0-20% vs. >=50%	0.14 (-4.34, 4.62)
			20-50% vx. >=50%	-0.35 (-3.23, 2.53)
	3 months	0.77 (0.09, 1.44)*	0-20% vs. >=50%	0.21 (-1.73, 2.14)
			20-50% vx. >=50%	-0.31 (-1.80, 1.18)
Satisfaction with Life	9 months	1.25 (0.48, 2.02)†	0-20% vs. >=50%	-0.42 (-2.63, 1.78)
			20-50% vx. >=50%	0.56 (-0.85, 1.97)
	3 months	1.13 (0.89, 1.43)	0-20% vs. >=50%	0.71 (0.38, 1.31)
			20-50% vx. >=50%	0.65 (0.40, 1.05)
PHQ-9	9 months	0.99 (0.80, 1.23)	0-20% vs. >=50%	1.16 (0.66, 2.05)
			20-50% vx. >=50%	0.68 (0.42, 1.08)

** Mean differences (95% Confidence Intervals) for all outcomes except PHQ-9, which is an Odds Ratio

* $p<.05$; † p<.01; ‡ p<.001

Table 3: Subgroup adjusted, significant (p<.05) effect modification (mean differences) of LOE on Compliance with the 3-Hour Rule, by LOE (*average adjusted effect (95% confidence interval)*

Outcome	Compliance group	LOE: 1[†]	LOE: 4	LOE: 7
Severe Cohort				
PART-O Total Rasch, 9 months				
	0-20% vs. 50% +	4.34 (-2.38, 11.06)	-0.33 (-3.02, 2.37)	-4.99 (-13.64, 3.66)
	20-50% vs. 50% +	-6.71 (-14.77, 1.35)	0.05 (-1.55, 1.65)	6.82 (-0.97, 14.61)
FIM Rasch Cognitive, 3 months				
	0-20% vs. 50% +	25.66 (10.63, 40.69)	-0.58 (-4.87, 3.71)	-26.82 (-44.17, -9.47)
	20-50% vs. 50% +	-1.65 (-17.32, 14.01)	0.72 (-2.72, 4.17)	3.1 (-14.42, 20.63)
Less Severe Cohort				
PART-O Total, 9 months				
	0-20% vs. 50% +	0.99 (0.37, 1.61)	0.24 (0.06, 0.42)	-0.51 (-0.92, -0.1)
	20-50% vs. 50% +	0.62 (-0.02, 1.27)	0.15 (-0.03, 0.33)	-0.32 (-0.72, 0.08)
PART-O Total Rasch, 9 months				
	0-20% vs. 50% +	11.71 (4.27, 19.15)	3.74 (1.66, 5.82)	-4.23 (-9.24, 0.78)
	20-50% vs. 50% +	7.07 (-0.95, 15.08)	2.62 (0.45, 4.79)	-1.83 (-7.1, 3.45)
PART-O Out and About, 3 months				
	0-20% vs. 50% +	1.06 (0.12, 2)	0.18 (-0.07, 0.44)	-0.7 (-1.27, -0.12)
	20-50% vs. 50% +	0.36 (-0.5, 1.23)	0.05 (-0.19, 0.28)	-0.27 (-0.81, 0.27)
PART-O Out and About, 9 months				
	0-20% vs. 50% +	1.12 (0.39, 1.86)	0.31 (0.1, 0.52)	-0.51 (-0.99, -0.02)
	20-50% vs. 50% +	0.9 (0.15, 1.65)	0.27 (0.06, 0.47)	-0.37 (-0.86, 0.13)
PART-O Productivity, 3 months				
	0-20% vs. 50% +	1.17 (0.28, 2.07)	0.27 (0.07, 0.48)	-0.63 (-1.28, 0.03)
	20-50% vs. 50% +	0.7 (-0.21, 1.61)	0.26 (0.06, 0.46)	-0.18 (-0.84, 0.48)
PART-O Social, 9 months				
	0-20% vs. 50% +	1.37 (0.57, 2.17)	0.28 (0.05, 0.51)	-0.81 (-1.32, -0.3)
	20-50% vs. 50% +	0.81 (-0.06, 1.69)	0.13 (-0.12, 0.38)	-0.56 (-1.08, -0.03)
FIM Rasch Cognitive, Discharge				
	0-20% vs. 50% +	12.56 (2.07, 23.05)	3.68 (1.06, 6.3)	-5.21 (-12.26, 1.85)
	20-50% vs. 50% +	-0.55 (-12.12, 11.01)	0.51 (-2.11, 3.12)	1.57 (-6.35, 9.48)
Satisfaction with Life, 9 months				
	0-20% vs. 50% +	8.66 (-2.64, 19.95)	1.98 (-1.23, 5.19)	-4.7 (-11.16, 1.77)
	20-50% vs. 50% +	-0.97 (-12.79, 10.84)	1.04 (-2.2, 4.27)	3.05 (-3.54, 9.63)
Satisfaction with Life, 3 months				
	0-20% vs. 50% +	7.06 (-1.53, 15.65)	1.27 (-1.43, 3.97)	-4.52 (-9.75, 0.7)
	20-50% vs. 50% +	-5.49 (-14.08, 3.1)	-1.41 (-4.1, 1.28)	2.68 (-2.04, 7.39)

[†] LOE=2,3,5,6 are excluded from table for readability, see figures for all values.

PART-O Total Rasch at 9 months

FIM Cognitive Rasch at 3 months

Legend:
- —— 0-20%
- – – – 20-50%
- ·········· 50%+
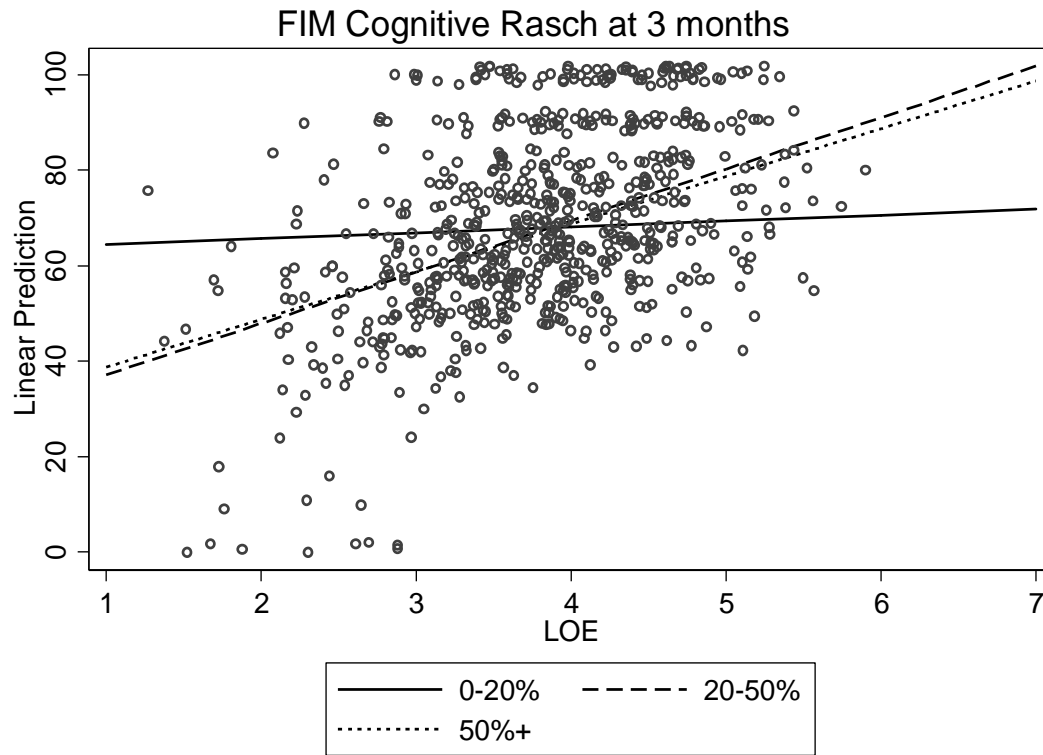
X-axis: LOE
Y-axis: Linear Prediction

Figure 3. Less Severe subgroup: Interaction plot for PART-O Total Rasch at 9 months (adjusted model).

PART-O Total at 9 months

FIM Cognitive (Rasch)