

A new patient-reported outcome measure to assess novel personal factors for people Living with Cochlear Implants: the LivCI

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Introduction

The **Living with Cochlear Implants (LivCI)** is a new patient-reported outcome measure (PROM) of human factors associated with living with cochlear implant(s) (CI). It measures constructs of importance to recipients not addressed by existing CI-specific measures. Its conceptual framework was co-developed with CI candidates/recipients.¹ Cognitive interviews and an expert panel confirmed content validity.² Development and psychometric evaluation of the LivCI³ is described below.

Methods

- Design:** Multi-phase, cross-sectional study in Australia.
- Participants:** Two samples of adult CI candidates/recipients (Study 1: n = 279; Study 2: n = 145).
- Data collection:** Study 1: Remote, electronic completion of the 54-item LivCI; Study 2: remote, electronic completion of the 22-item Rasch-constructed LivCI and 6 comparator PROMs
- Data analysis:** Rasch analysis for item reduction, assessment of response categories, and scale construction (Study 1). Classical test theory approaches evaluated internal consistency, construct and criterion validity (Study 2).

Results

- Rasch analysis:** Baseline analysis showed disordered thresholds (Fig.1) and poor model fit. Response scales were collapsed from a 6- to 4-point scale. Iterative analyses constructed a 22-item LivCI comprising 4 unidimensional scales (stigma, participation, wellbeing, and device aesthetics and management) (Table 1), with reasonable scale-to-sample targeting (Fig. 2). LivCI-Total was found to be multi-dimensional, precluding calculation of a summed total score.
- Internal consistency reliability:** Cronbach's alpha values ranged from 0.64 to 0.94. Inter-item correlation values were within the accepted 0.3 to 0.7 range for 3/4 domains (range = 0.025 to 0.775).
- Criterion validity:** Results support 6/6 (100%) of hypotheses (Table 2).
- Construct validity:** Results support 15/28 (54%) of hypotheses (Table 2), showing moderate correlation values with most comparator PROMs.

Fig 2. Person-item threshold map for the Psychosocial and Wellbeing scale

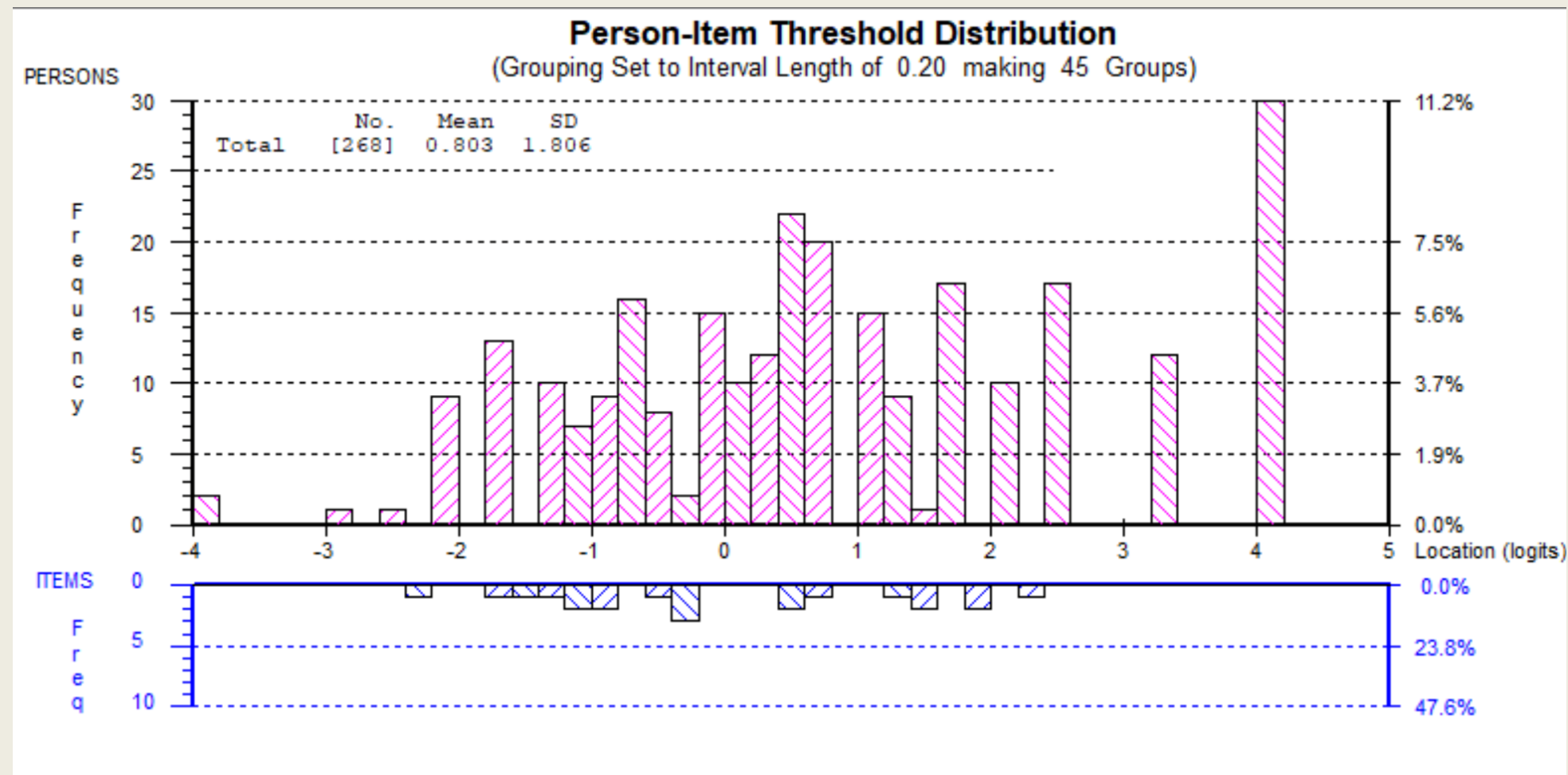


Table 1: Rasch analysis for the final 22-item LivCI scales

Analysis	No items	Valid n (no of extremes)	Item-Trait interaction (Overall fit)			Uni-dimensional t-test (%)	Reliability		Item-Residual		Person-Residual		LID	DIF	Item misfit (>±2.5) Item number
			X ²	df	p-value		PSI	A	M	SD	M	SD			
Function & Participation Stigma	4	268	16.64	16	0.41	2.6	0.71	n/a	0.15	1.26	-0.37	0.96	No	No	No
Psychosocial	4 testlets	268	18.72	16	0.28	0.8	0.63	0.95	0.39	0.8	-0.4	1.27	No	No	No
Device Aesthetics & Management	6	268	36.6	24	0.48	1.9	0.57	n/a	0.57	0.77	-0.27	1.07	1 pair	No	No

X² = Chi-square; df = degrees of freedom; PSI = person separation index; LID = local item dependence; A = common variance between subscales; M = mean; SD = standard deviation; DIF = differential item functioning

Table 2: Criterion and construct validity assessment showing *a priori* hypotheses and results (Pearson correlation coefficient values, green = results support hypothesis). Bright yellow cells indicate domains of comparator PROMs hypothesised to be similar conceptually to LivCI domains (criterion validity).

COMPARATIVE PROM (no. items)	GLOBAL/ DOMAIN	PARTICIPATION		PSYCHOSOCIAL AND WELLBEING		STIGMA		MANAGEMENT AND AESTHETICS	
		Hypothesis	r	Hypothesis	r	Hypotheses	r	Hypothesis	r
CIQoL35 Profile (35)	Communication	strong (>0.6)	0.751		0.698		0.397		0.406
	Social		0.663	strong (>0.6)	0.647		0.48		0.404
	Emotional		0.628	strong (>0.6)	0.687		0.562		0.537
	Entertainment		0.581		0.537		0.33		0.408
	Environment		0.634		0.585		0.358		0.38
	Listening Effort		0.677		0.603		0.447		0.411
CIQoL Global (10)	Global	strong (>0.6)	0.724	moderate (0.4-0.6)	0.703	low (<0.4)	0.516	low (<0.4)	0.487
SSQ-12 (12)	Speech	strong (>0.6)	0.615		0.556		0.352		0.351
	Spatial		0.451		0.391		0.25		0.329
	Quality		0.282		0.273		0.155		0.19
	Global	moderate (0.4-0.6)	0.576	low (<0.4)	0.519	low (<0.4)	0.329	low (<0.4)	0.36
SSCI-8 (8)	Stigma	low (<0.4)	-0.483	low (<0.4)	-0.548	strong (>0.6)	-0.615	low (<0.4)	-0.434
QUEST 2.0 (12)	Services	low (<0.4)	0.415	low (<0.4)	0.525	low (<0.4)	0.263	low (<0.4)	0.381
AQoL-4D (12)	Devices	low (<0.4)	0.578	low (<0.4)	0.654	low (<0.4)	0.388	strong (>0.6)	0.649
	Health-related QoL	low (<0.4)	-0.538	low (<0.4)	-0.533	low (<0.4)	-0.366	low (<0.4)	-0.311

Conclusions

- The **LivCI** is formed of four standalone, unidimensional scales measuring human factors associated with CI: **stigma, participation, wellbeing, and device aesthetics and management**.
- It is one of the few CI-specific PROMs developed according to COSMIN principles.⁴ Further validation to establish norms, test-retest reliability and responsiveness to change is required.
- The LivCI is suitable for use as a **research tool** and with **individual patients**. It measures constructs of importance to recipients not addressed by existing CI-specific measures.
- Contact livci@cochlear.com to access the LivCI free-of-charge.

1. Lo et al. *Health Expect.* 2024;27:e14060.
2. Laird et al. *Int J Audiol.* In Review.
3. Hughes et al. *BMC Health and Quality of Life Outcomes.* In Review.
4. Mokkink LB et al. *Qual Life Res.* 2010;19:539–49.