

Psychometric Evaluation of the mCEQ Applied to Cigarettes and Heat-not-Burn Products in the US and Japan

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Introduction

The modified Cigarette Evaluation Questionnaire (mCEQ; Cappelleri et al., 2007) is a measurement instrument that assesses the self-reported reinforcing effects of smoking cigarettes. Conceptually, the mCEQ consists of three multi-item and two single-item domains (Figure 1). The increasing availability of alternative products to cigarettes raises the question whether the mCEQ can also be used to assess the reinforcing effects of other tobacco or nicotine-containing products.

The study aimed at a psychometric evaluation of the mCEQ applied to cigarettes and a heat-not-burn tobacco product, the candidate Modified Risk Tobacco Product (MRTP) Tobacco Heating System (THS). Furthermore, the potential to integrate items from two other instruments was investigated: the Minnesota Withdrawal Scale-Revised (MNWS-R; Hughes and Hatsukami, 1986) and the Questionnaire on Smoking Urges – brief version (QSU-brief; West and Ussher, 2010).

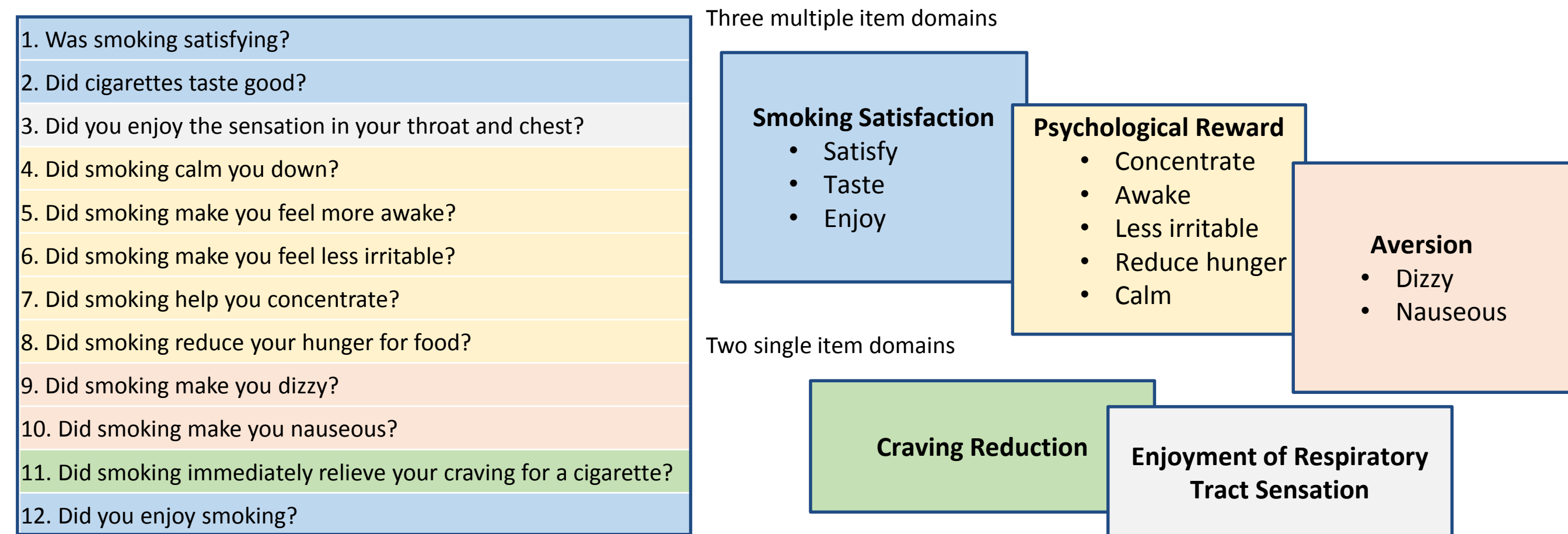


Figure 1: 12 Items and Five Domains of the mCEQ.

Methods

The mCEQ, QSU-brief and MNWS-R were administered in two 3-month reduced-exposure studies (Figure 2), one conducted in the US (ZRHM-REXA-08-US - NCT01989156) and one in Japan (ZRHM-REXA-07-JP - NCT01970995; Lüdicke et al., 2017a; Lüdicke et al., 2017b).

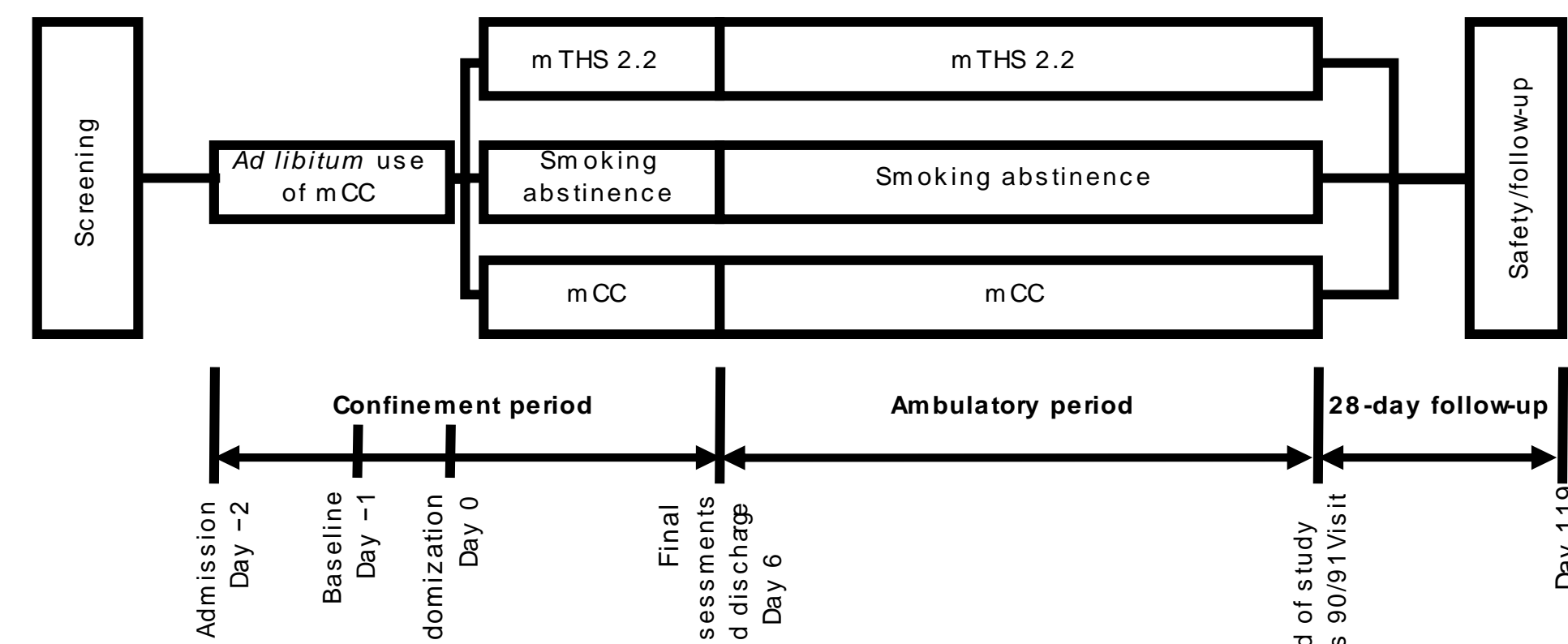


Figure 2: Study Design. mCC = menthol Conventional Cigarette; mTHS = Tobacco Heating System 2.2 Menthol.

The analysis was based on traditional Classical Test Theory (CTT) and Rasch Measurement Theory (RMT) (Table 1 and Figure 3).

Table 1: Overview of the Data Set.

Study Code	ZRHM-REXA-08-US	ZRHM-REXA-07-JP
Time-points	Day 0, 1, 2, 3, 4, 5, 30, 60, 90	
Outcome Measures	mCEQ, QSU-brief and MNWS-R	
mCC (CC)	n=310 responses (from 36 respondents)	n=371 responses (from 42 respondents)
mTHS 2.2 (THS)	n=661 responses (from 75 respondents)	n=683 responses (from 76 respondents)
Smoking abstinence	n=26 respondents (disregarded)	n=39 respondents (disregarded)
Total	Total n=2025 considered responses (from 229 respondents) n=2013 actually usable responses (excluding all-missing-response patterns)	

mCC: menthol Conventional Cigarette; mTHS: Tobacco Heating System 2.2 Menthol

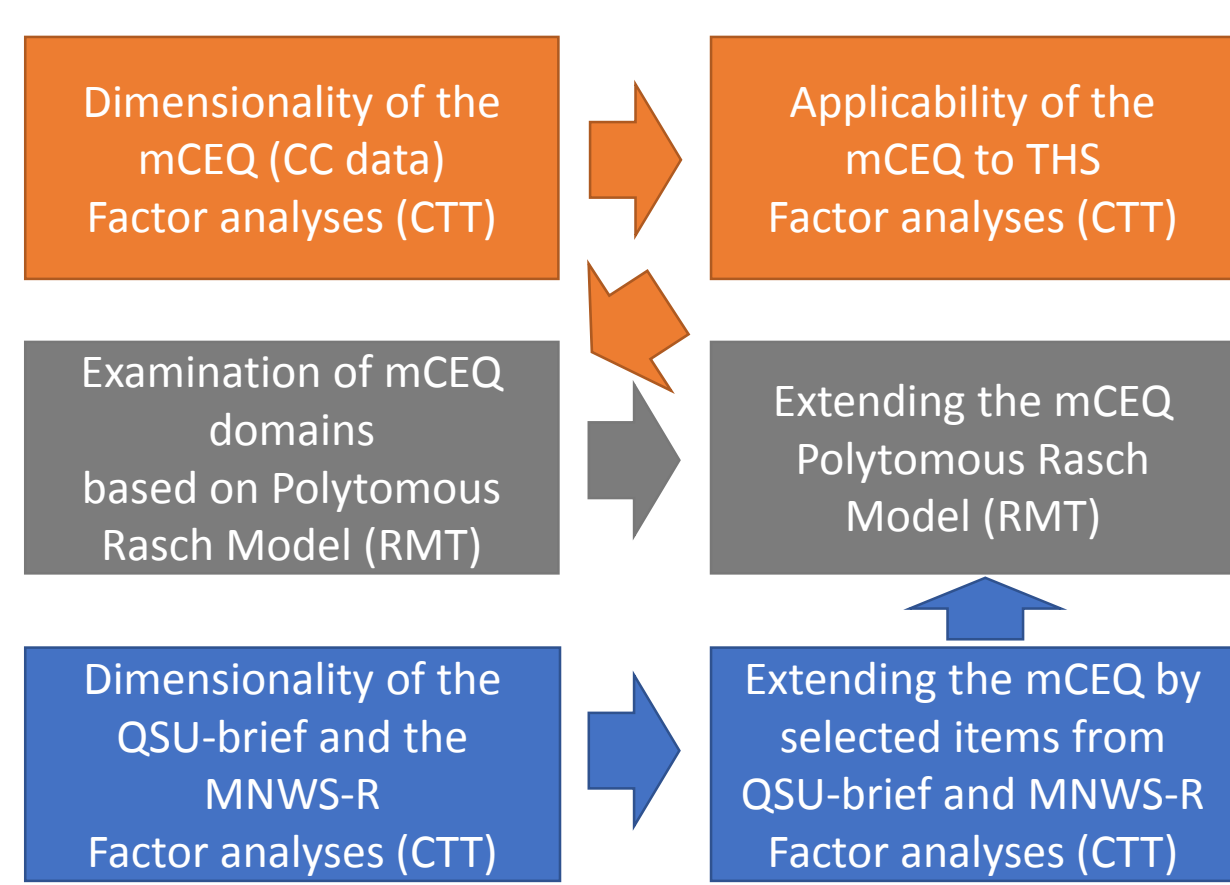


Figure 3: Sequence of Analyses. CC: Conventional Cigarette; CTT: Classical Test Theory; RMT: Rasch Measurement Theory; THS: Tobacco Heated System

Results

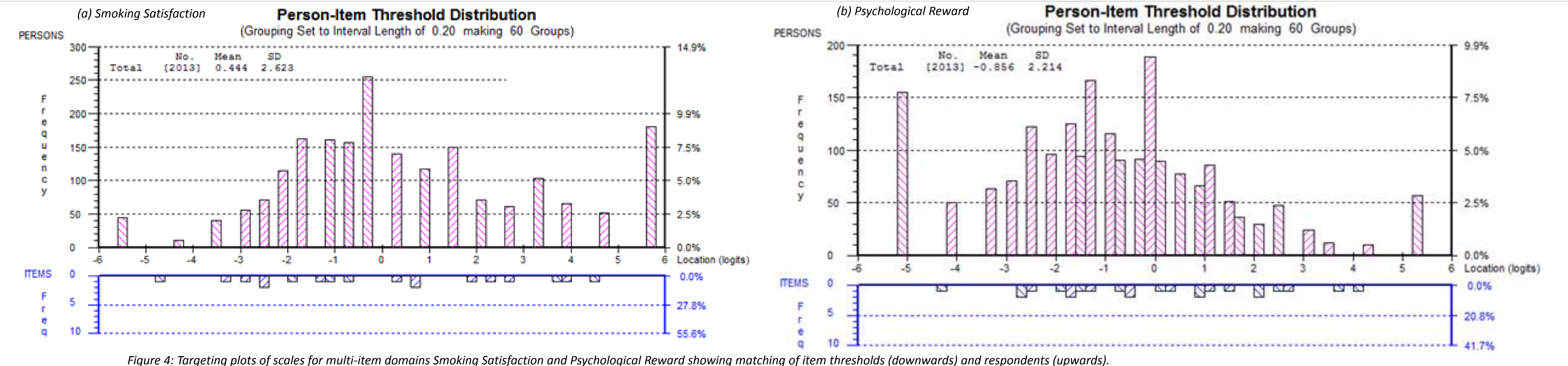


Figure 4: Targeting plots of scales for multi-item domains Smoking Satisfaction and Psychological Reward showing matching of item thresholds (downwards) and respondents (upwards).

Classical Test Theory (CTT) - Factor analyses

- The factor analyses confirmed the three multi-item domains of the mCEQ for both cigarette and THS, showing that the mCEQ is applicable to THS.
- Integration of items from QSU-brief and the MNWS-R: Based on the analysis of the dimensionality of the QSU-brief and the MNWS-R, as well as on content-related considerations, items were selected for potential extension of the mCEQ. However, combined factor analyses of the mCEQ and the additional items revealed no real potential to extend or improve the mCEQ.

Rasch Measurement Theory (RMT) - Polytomous Rasch Model

- Items of the multi-item domains Smoking Satisfaction and Psychological Reward (excluding item #8, *hunger*) were found to work as scales, meeting the requirements of RMT with good targeting (Figure 4) and high reliability (Person-Separation Index and Rasch reliability of 0.90 and 0.89, respectively).
- For Aversion (items #9, *dizzy*; #10, *nauseous*) strong floor effects were identified, implying poor targeting (i.e., low suitability of items to differentiate between respondents and, by implication, different products). Thus, a conclusive psychometric assessment was not possible and the scale was of very limited use in discriminating between respondents and products, suggesting they should be interpreted as single items.
- Integration of items from QSU-brief and the MNWS-R: The potential to expand the domain of Aversion by adding items from other instruments was explored and showed that neither the QSU-brief nor the MNWS-R were suitable sources of additional items as their conceptual basis appeared to be too different from that of the mCEQ. The same applies to the two single-item domains (Craving Reduction, Enjoyment of Sensation), which could not be extended either.

The scales assessing the domains of Smoking Satisfaction and Psychological Reward (after excluding item #8, *hunger*) qualify for being analyzed and scored using the Rasch model. Hierarchy of items within the two multi-item domains was demonstrated (Figure 5).

Analyses of differential item functioning (DIF, testing for item equivalence) revealed good comparability across responses to different products. In terms of equivalence across US and Japanese respondents, there was some indication of DIF requiring corrective action.

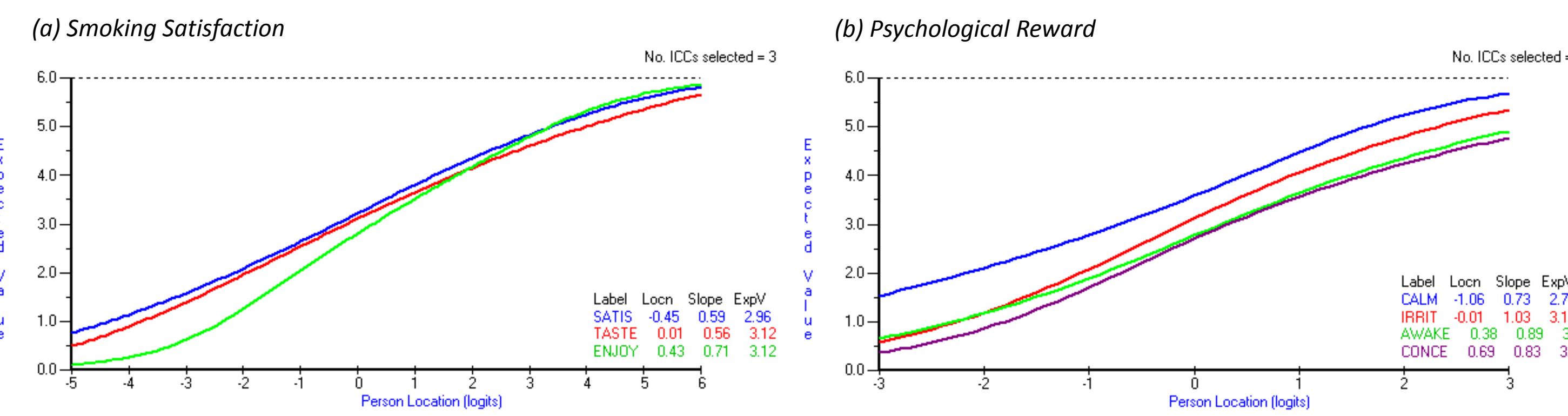


Figure 5: Hierarchy of items for multi-item domains Smoking Satisfaction (item #1, satisfaction; item #2, taste; item #12, enjoy) and Psychological Reward (item #4, calm; item #6, less irritable; item #5, awake; item #7, concentrate).

Discussion

The mCEQ is, in principle, applicable to cigarettes as well as to THS. From a CTT perspective, all three multi-item domains could be confirmed. The two multi-item domains of Smoking Satisfaction and Psychological Reward, together consisting of 8 out of the 12 mCEQ items, also met the requirements of RMT after minimal adaptation (excluding one item from Psychological Reward). Despite their brevity, both scales showed few extreme scores (Smoking Satisfaction 10.5%, Psychological Reward 11.2%) implying satisfactory targeting.

The applicability of the mCEQ to cigarette and THS was confirmed for respondents from the US and Japan based on RMT analyses.

The analysis of the extended mCEQ did not reveal any real potential to improve the mCEQ for the single-item domains and Aversion domain.

A possible limitation lies in the analysis of all responses at different time points as if they were coming from independent respondents. Since the main goal of the study was to assess the general applicability of the mCEQ, the possible dependency was deemed non-critical.

In its current form, it is recommended to administer the full mCEQ to assess the self-reported reinforcing effects of cigarettes and the candidate MRTP THS. The two multi-item domains (Smoking Satisfaction and Psychological Reward) can be interpreted at the scale level, whereas the remaining items (one item deleted from Psychological Reward, two items assessing Aversion, one item on Craving Reduction, and one item on Enjoyment of Respiratory Tract Sensation) should be interpreted as single-item measures.

Moving forward, inclusion of a special instruction to remove the ambiguity of the wording 'smoking' and 'cigarettes' not applying to the use of other products is to be considered, or the rewording of items as proposed by Hatsukami et al. (2013) with the Product Evaluation Scale (PES): *Was it satisfying?* instead of *Was smoking satisfying?*

References:

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