

A Mixed-Methods Study using Cognitive Debriefing to Assess the Content Validity of a New Health and Functioning Measure for Tobacco and/or Nicotine Product Users

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Introduction and Objectives

- Measuring self-reported changes in health and functioning is crucial to assess changes in the health status of individuals who switch from cigarettes to potentially less harmful tobacco- and nicotine-containing products (TNP), and to inform tobacco harm reduction strategies.
- To date, there are no established smoking-related quality of life (QoL) measures that have proved to be sensitive enough to detect changes in health and functioning in otherwise healthy smokers who switch to potentially less harmful TNPs.
- As part of the **ABOUT** Toolbox (Assessment of Behavioral Outcomes related to Tobacco and nicotine products) initiative [1], we develop a new fit-for-purpose measure to assess the impact of potentially less harmful TNPs on health and functioning and its possible related constructs, such as health-related QoL (HRQoL) or generalized perceptions of health.
- Between 2018 and 2021, a literature review, concept elicitation studies with TNP users (one focus group study in the US, and two in-depth interview studies in Germany and Japan), a global Delphi Panel, and expert panel meetings lead to the development of a conceptual framework and a draft version of the ABOUT™-Health and Functioning measure [2, 3].
- This study assessed the face, content validity, and early measurement properties of the draft ABOUT™-Health and Functioning, using Cognitive Debriefing Interviews (CDI) and Rasch Measurement Theory (RMT) analysis.



Methods

Study Design and participants

Cognitive debriefing interviews were conducted in two waves, in the UK and US, with healthy adult users of:

- cigarettes (n=20, US/UK),
- e-cigarettes (n=20, US),
- heated tobacco products (IQOS™) (n=20, UK),
- smokeless tobacco products (n=10, US), and
- nicotine replacement therapy products (pharmaceutical products) (n=10, UK)

Quotas were set for age, sex at birth, ethnicity, educational level, and time since from which the product was used regularly (daily use).

Wave 1 cognitive debriefing interviews (n=40)

Mixed Methods Interim Analysis and measure updates

Wave 2 cognitive debriefing interviews (n=40)

Final Mixed Methods Analysis and measure finalization

Figure 1. Research design process

Interview and data collection

- 90-minutes semi-structured audio interviews were conducted by a trained qualitative researcher.
- Given the length of the draft measure (195 items), the participants were separated into three groups: each group was debriefed and they completed one part of the measure during the interview and the rest electronically.
- Participants were encouraged to use a “think-aloud” process while completing the measure, with different verbal probes used on item stems, instruction clarity, item comprehension, response options, missing concepts, and overlapping concepts.

Mixed-methods data analysis

- Qualitative: multi-level codes were applied to analyze the transcripts thematically using Atlas.ti.
- Quantitative: small-scale exploratory psychometric analysis in line with RMT was conducted. Targeting, person separation, item discrimination (reliability), item misfit, and local dependence were tested. Descriptive statistics were also provided.
- After each wave, expert panel meetings were held to inform result interpretation and to update the draft measure.



Results



Discussion/Conclusions

Participants

N=80 participants completed the study.

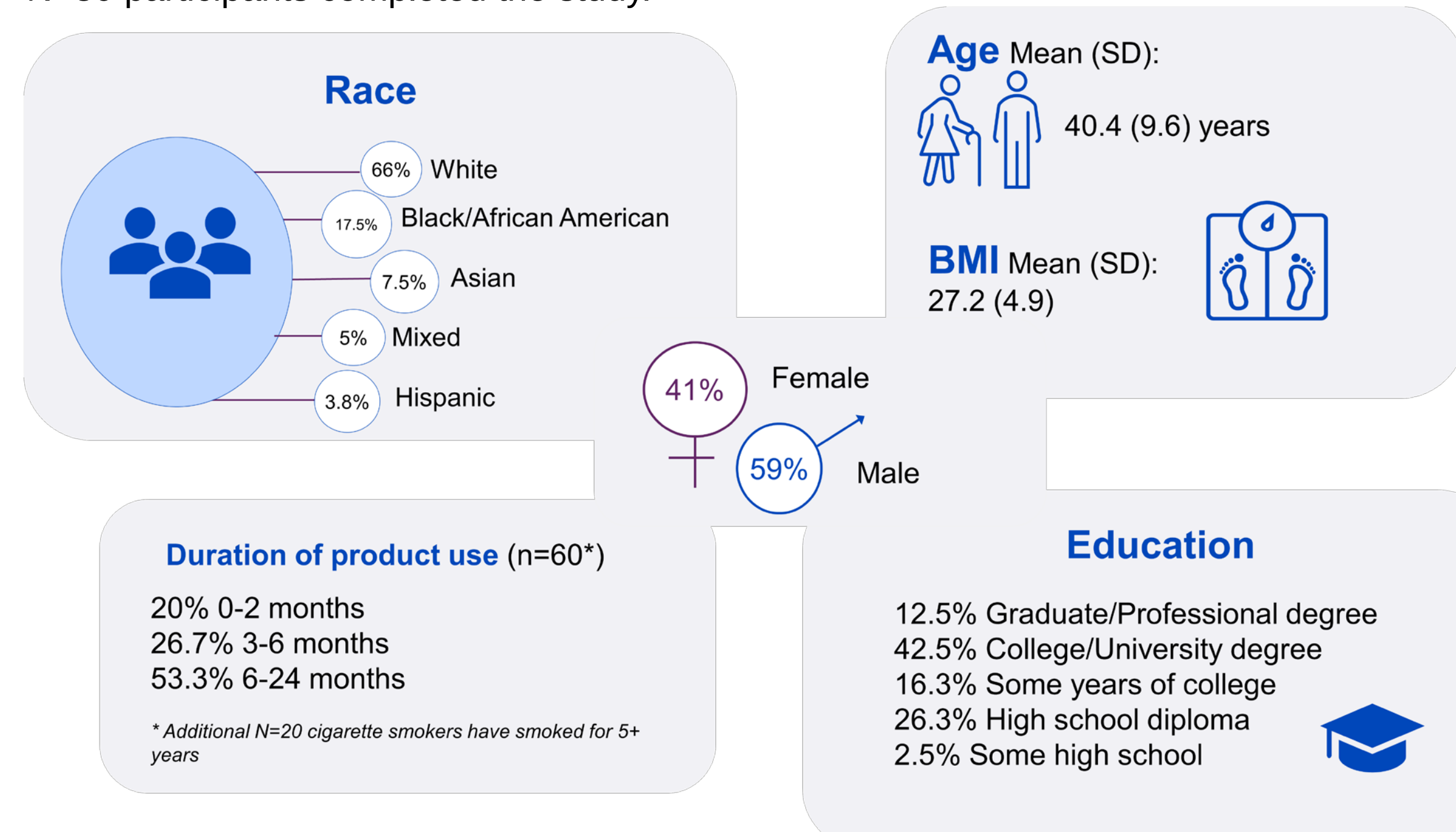


Figure 2. Overview of sample characteristics

General measure feedback

- The participants generally endorsed the content of the measure and provided positive feedback: “*I think they all relate to issues important to me. Breathing is something that is important to me, obviously*” (Smokeless tobacco user, participant ID C-01-115).
- Overall, the instructions and items were clear, relevant, and appropriate across all TNP user groups (cigarettes, e-cigarettes, smokeless tobacco, NRT, IQOS).

Item-level feedback

Qualitative feedback on the measure content lead to revision and adjustments in item wordings and scale names after each wave (e.g., “yellow or brown nails” was revised to “stained nails” for respondent’s skin colour appropriateness, “gastrointestinal health” was renamed to “digestive health” for general understandability).

Recall period

A 7-day recall period was tested in Wave 1, and a 4-week recall period was tested in Wave 2. The scales performed consistently for both recall periods; however, the 7-day recall period had less of a ceiling effect.

Response scales

Different types of response continuums were chosen according to suitability to each scale (i.e., severity, frequency, difficulty, bother, and change). Health scale was scored on a severity continuum in Wave 1 and a frequency continuum in Wave 2. Quantitative evidence and expert feedback led to retaining the severity continuum. No consistent issues were identified for the response continuum chosen for the remaining scales.

Conceptual overlap

Conceptual overlap between some items was identified through both qualitative and quantitative evidence. No items were removed as the evidence suggested that all items posed were important to some TNP users. Further the evidence was not conclusive in the small sample to make decisions ahead of further psychometric validation steps.

The “breathing during daily activity scale,” which overlapped conceptually with the “breathing difficulty” scale, was removed in its entirety, based on (i) quantitative evidence suggesting “breathing difficulty” to perform better; (ii) no overwhelming qualitative evidence suggesting that one scale was more poorly understood than the other; and (iii) the expert panel endorsement of “breathing difficulty” over “breathing during daily activities.”

Item refinement

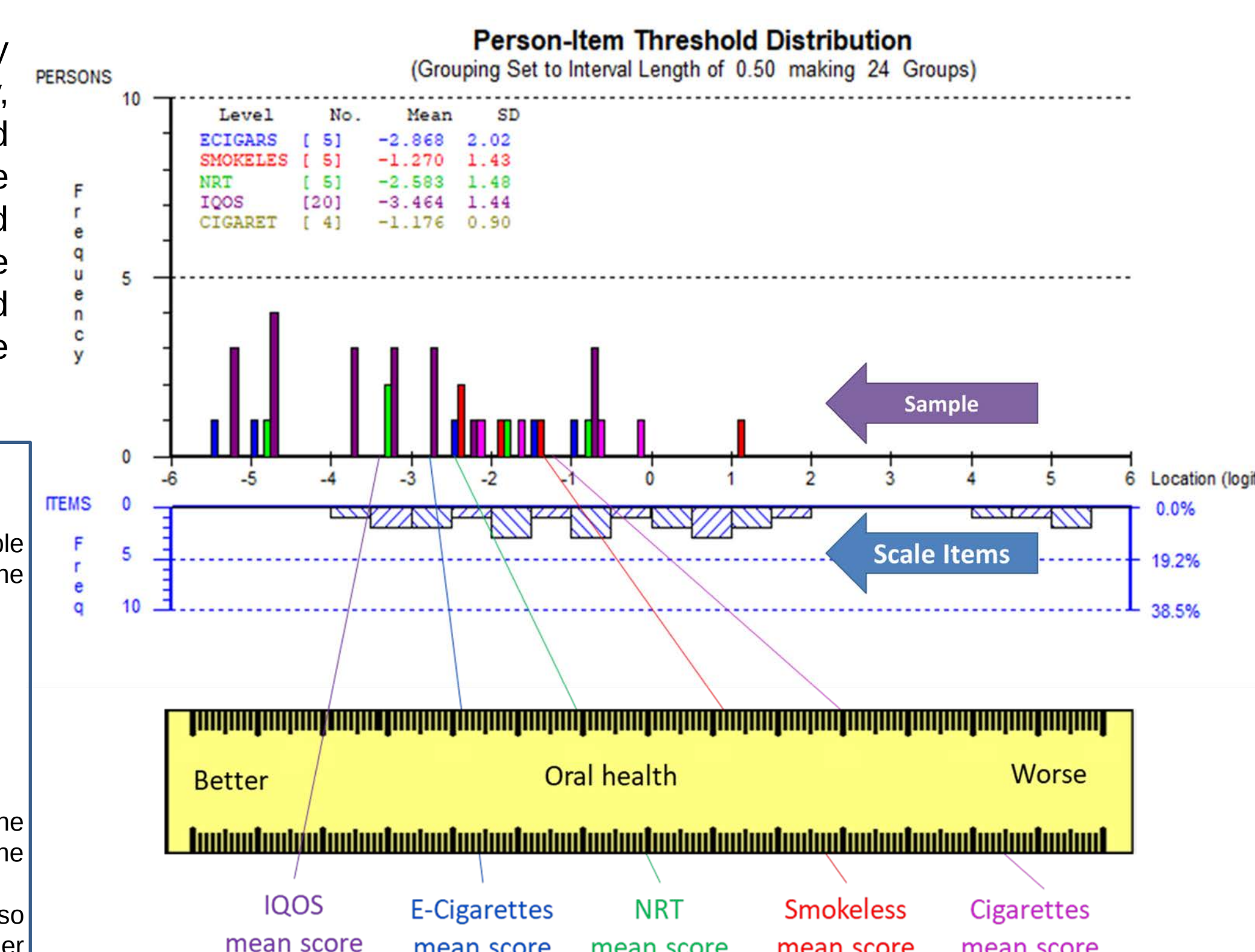
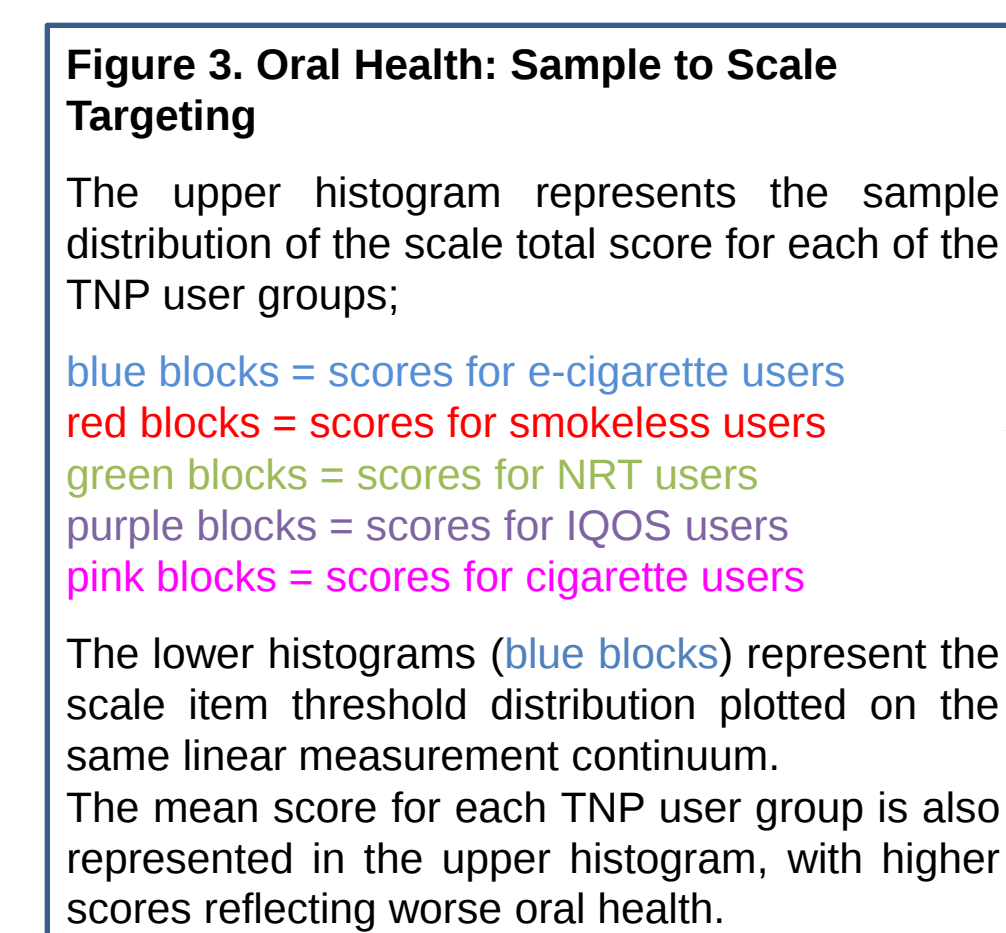
Three scales were removed (i.e., digestive health, cardiovascular health, and tiredness and sleep health) because (i) entire scales were not reflective of issues related to TNP use (based on qualitative feedback and expert panel meetings), and (ii) quantitative evidence showed poor reliability across both waves, skewed data, and poor targeting. Specific items were however retained and moved to the “general health” scale.

Missing concepts

N=8 items were added based on qualitative feedback related to missing concepts relevant to TNP use, such as “difficulty to breath when lying down.”

RMT analysis

The RMT analysis largely supported the scales’ reliability, sample-to-scale targeting, and discrimination potential across the TNP user groups. It informed decisions on early item and scale refinements when synthesized with qualitative feedback and the expert opinion.



Version post-CDI

The ABOUT™-Health and Functioning measure version following both waves of cognitive debriefing interviews comprised 146 items (including 12 items in a conditional checklist), broken down into the following domains and scales:

6 health domains

- appearance,
- oral health,
- throat and voice,
- coughing breathing & lung health,
- general health,
- breathing difficulty.

3 Functioning domains

- working life,
- social functioning,
- well-being.

1 additional domain

- bother with smell.

Each domain was completed by a set of global severity items, assessing severity of the impact of TNP use, and transition global items, assessing change since switching from cigarettes to another TNP.

For all scales, both 7-day and 4-week recall periods were retained, to be selected according to future study objectives and designs.

COVID-19 impact on responses

A majority of participants stated that the ongoing COVID-19 situation has impacted their responses (n=38). The most frequently reported domains/questions impacted by COVID-19 was attributed specifically to items within the “social functioning” domain, due to lockdown restrictions, meaning that TNP users did not deal with social situations with friends/family to the same extent as prior to the pandemic.

This study provides early supporting evidence of the measure content relevance, clarity, and ease of completion of the new ABOUT™-Health and Functioning. It comprises 10 scales (146 items) covering different health concepts, as well as different functioning concepts.

Mixed-methods evidence, including qualitative interviews, quantitative analysis, and expert panel meetings, was used to guide the selection of the response continuum, recall periods, and the refinement of specific items. This could better match the underlying domain of each scale, with the aim of developing and validating a measure fit-for-purpose to assess change in health and functioning among users of a broad range of TNPs, addressing an important gap in available measures.

Next steps

The qualitatively validated measure will be administrated in a large multi-national web-based survey to assess its psychometric proprieties, which will further establish and confirm the final item content and inform decisions on item reduction and the scoring structure of the measure.

As all measures are part of the ABOUT™ Toolbox, the validated ABOUT™-Health and Functioning will be made available to the scientific community through PROQOLID™ and will be freely available for non-commercial use.

References

- Chrea C, et al. Developing fit-for-purpose self-report measures for assessing consumer responses to tobacco and nicotine products: the ABOUT™ Toolbox initiative [version 1; peer review: 2 approved]. *FL000Research* 2018, 7:1278 <https://doi.org/10.12688/FL000Research.16810.1>
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- Afolalu EF, et al. Qualitative Health and Functioning Concept Elicitation Interviews in Japanese Users of Heated Tobacco Products. 2021. Oral virtual presentation at the Society for Research and Nicotine and Tobacco Virtual Conference. <https://www.pmscience.com/resources/docs/default-source/smt-2021/smt-2021-poster-esther-afolalu.pdf?>