

## Original Article

# Danish cross-cultural adaptation of the Theoretical Framework of Acceptability questionnaire

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## ABSTRACT

**INTRODUCTION.** Acceptability of healthcare interventions among patients and healthcare professionals is important for effective and efficient implementation in clinical settings. To standardise the assessment of acceptability of healthcare interventions, the Theoretical Framework of Acceptability (TFA) questionnaire was developed. In this study, we aimed to translate and cross-culturally adapt the TFA questionnaire into Danish.

**METHODS.** The TFA was forward- and back-translated and pre-tested in accordance with Beaton's guidelines. Following an iterative process, the pre-final questionnaire was field-tested through cognitive interviews using verbal probing and think-aloud techniques to assess relevance, comprehensiveness and comprehensibility.

**RESULTS.** Following translation, 30 participants (37% female, mean age 61 years) completed cognitive interviews. The population included cardiac arrest survivors and their relatives, patients with hypercholesterolaemia, knee/hip osteoarthritis and patients at risk of heart failure. Five iterative rounds informed adaptations of the Danish version, resolving misinterpretations and improving clarity. Four main issues were identified: 1) structure of the questionnaire, 2) translation of the terms "acceptability" and "intervention", 3) wording of the Likert scale and 4) item-specific interpretation problems.

**CONCLUSIONS.** Following international guidelines, the TFA questionnaire was successfully translated and cross-culturally adapted into Danish, addressing key linguistic and conceptual challenges.

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The acceptability of healthcare interventions, that is, whether those delivering or receiving an intervention understand and perceive it as appropriate, is a crucial determinant of successful implementation and is

important for ensuring adherence and fidelity [1]. As part of the development of an intervention, the Medical Research Council emphasises that assessing feasibility and acceptability is essential for refining the programme theory and optimising the intervention design [1]. In contrast, failing to understand the acceptability of healthcare interventions can result in innovations that are not adopted by healthcare professionals and are difficult to implement in practice [1, 2].

Assessing acceptability in feasibility and intervention studies involves a wide range of methods, from qualitative assessments to objective indicators, such as dropout rates and reasons for discontinuation [3, 4]. However, the lack of a standardised approach can lead to variability in how acceptability is measured and interpreted across studies. The Theoretical Framework of Acceptability (TFA) questionnaire, developed by Sekhon et al. in 2022, assesses acceptability based on seven domains: affective attitude, burden, perceived effectiveness, ethics, intervention coherence, opportunity cost and self-efficacy [3, 5].

The TFA has been widely adopted in healthcare research [5, 6], but a cross-cultural adaptation to the Danish context is required to ensure reliable and valid evaluations of acceptability. Instruments developed in other cultural settings may lose meaning or introduce bias through literal translation if cultural and linguistic nuances are overlooked [7-9]. Therefore, a rigorous translation and adaptation process ensuring linguistic, semantic and conceptual equivalence is essential to maintain content validity [10]. Accordingly, the objective of this study was to translate and cross-culturally adapt the TFA questionnaire into Danish, ensuring semantic and conceptual equivalence to preserve content validity.

## Methods

### Design

This was a systematic translation and cross-cultural adaptation of the TFA questionnaire from English to Danish following Beaton's guideline [11]. Cognitive interviews were performed guided by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guide [12], and reporting followed the Consensus-based Standards for the Selection of Health Measurement Instrument (COSMIN) study design checklist for patient-reported outcome measurement instruments [13].

### The original Theoretical Framework of Acceptability questionnaire

The TFA questionnaire provides a standardised assessment of both prospective, concurrent and retrospective acceptability of healthcare interventions, defined as the extent to which an individual receiving or delivering an intervention considers it to be appropriate, based on anticipated or experiential cognitive and emotional responses [3, 5]. The questionnaire was based on an evidence-informed framework developed in 2017, enabling an overview of acceptability operationalised through seven domains, with one question per domain and a final question addressing overall acceptability, totalling eight questions. The domains "affective attitude" and "ethicality" each consist of two item options, from which the researcher selects the one that best fits the intervention. Each item is rated on a five-point Likert scale, ranging from 1 (worst) to 5 (best) (e.g., 1 = strongly disagree, 3 = no opinion, 5 = strongly agree). The item "Intervention coherence" includes an open-ended field for qualitative responses. Several items include square brackets to be completed by the research team before enrolment, allowing for adaptation to the specific intervention [5] ([Supplementary Table S1](#)).

### Setting and participants

The study was conducted at the Department of Cardiology, Odense University Hospital, Denmark. Participants were recruited and thereafter interviewed by DBJ and CME from October to December 2024 using purposive sampling to ensure variation in key characteristics (age, sex and education). Eligible respondents were native

Danish-speaking patients or relatives aged  $\geq 18$  years who had participated in an intervention study (e.g., a feasibility, pilot or randomised controlled trial).

## Data collection and analysis

### *Translation and cross-cultural adaptation*

We followed the five steps of Beaton's guide [11]: 1) forward translation from English to Danish, 2) synthesis of the translated version, 3) back translation by a native English speaker to Danish, 4) review and consensus by a multidisciplinary committee of the back-translated version, and 5) completion of a pre-final questionnaire for pretesting (Table 1). Cognitive interviews were conducted to evaluate the pre-final questionnaire [12]. Each step is elaborated below.

**TABLE 1** Overview of the translation and cross-cultural adaption process of the Theoretical Framework of Acceptability (TFA) questionnaire.

Step	Description
Consent	Permission to use the original TFA acceptability questionnaire was sought by contacting the original author, who was invited to engage in the process. As no response was received, the questionnaire was used in accordance with the Creative Commons Attribution 4.0 International License [5]
Forward translation	3 independent translators each performed a Danish version of the questionnaire based on the original version. All were native Danish speakers fluent in English
Synthesis	The 3 forward-translated versions were merged into a single synthesised version. Discrepancies were discussed and resolved through consensus among translators
Multidisciplinary committee review	A multidisciplinary committee of 4 participants, all familiar with the TFA construct, reviewed the synthesised version. The committee assessed face validity, clarity, cultural appropriateness and wording
Back translation	A native English speaker, unfamiliar with the original instrument and underlying construct, back-translated the synthesised version to English
Back translation review	A consensus meeting was held to reconcile the back-translated version with the original TFA acceptability questionnaire. A language model supported interpretation of key terms, e.g., "Acceptability". A pre-final questionnaire was finalised for pre-testing
Pretesting	The pre-final questionnaire was tested through cognitive interviews using think-aloud and verbal probing techniques. Participants with variation in age, sex and health conditions were represented in all rounds. Adjustments were made between rounds. Relevance, comprehensiveness and comprehensibility were achieved after 5 rounds, n = 30 interviews in total
Proofreading	The final version was proofread to correct minor linguistic and formatting errors
Final documentation	A written document summarised the translation process, methodological choices and key decisions

### *Forward translation, synthesis, back translation and consensus*

- 1) Three independent forward translations were conducted by DBJ (familiar with the construct of "acceptability") and CME and SMB (unfamiliar), all native Danish speakers fluent in English.
- 2) The translations were synthesised into a single version and reviewed by a multidisciplinary committee familiar with the construct (a PhD student with a nursing background, a psychologist with a PhD and two

professors: background in nursing and physiotherapy). The committee assessed face validity, clarity, cultural appropriateness and wording discrepancies. A symmetric translation approach prioritising conceptual equivalence was applied [9, 10, 14].

3) A native English speaker, blinded to the original version and unfamiliar with the construct, performed the back translation to ensure conceptual fidelity [13].

4) Discrepancies were resolved through harmonisation [10]. An artificial intelligence language model (ChatGPT4; chatgpt.com) assisted in clarifying specific terminology (e.g., “acceptability”) through nuanced linguistic interpretations.

All changes were documented, and a pre-final questionnaire was prepared for cognitive interviews [13].

#### **Pretesting, cognitive interviews**

To evaluate face and content validity and ensure cross-cultural adaptation, the pre-final questionnaire was tested through cognitive interviews, a qualitative method used to evaluate how individuals understand and respond to survey items [13]. Interviews were conducted individually, either online via Zoom or in person at the Department of Cardiology. Participants were purposively sampled from four different diagnostic groups and varied in age, sex, educational level and clinical characteristics [13, 15]. All were enrolled in ongoing intervention studies (feasibility, pilot or randomised controlled trial) involving cardiac arrest survivors and relatives, patients with hypercholesterolemia, knee/hip osteoarthritis or at risk of heart failure (**Table 2**). Participants completed a paper version while being observed, followed by a structured interview using think-aloud and verbal probing techniques ([Supplementary Table S2](#)) [12].

**TABLE 2** Participants characteristics.

<i>Characteristics</i>	
Total participants, N	30
Women, n (%)	11 (37)
Age, mean (range), yrs	61 (21-82)
Age $\geq$ 65 yrs, n (%)	8 (26.7)
<i>Patient population and related study/intervention, n (%)</i>	
Cardiac arrest survivors <sup>a</sup>	5 (17)
Relatives of cardiac arrest survivors <sup>a</sup>	9 (30)
Patients with hypercholesterolaemia <sup>b</sup>	4 (13)
Elderly and obese patients at risk of developing heart failure <sup>c</sup>	9 (30)
Patients with knee and hip osteoarthritis: GLA:D programme <sup>d</sup>	3 (10)
<i>Educational level, n (%)</i>	
Primary education	2 (6.7)
Lower secondary education	3 (10)
Upper secondary/vocational education	12 (40)
Bachelor's degree	8 (26.7)
Higher education: master's degree or above	5 (16.7)

a) Patients included from a feasibility study with out-of-hospital cardiac arrest survivors and their relatives (unpublished).

b) Patients included from a pilot study with patients with hypercholesterolaemia (NCT05758779).

c) Patients included from a randomised controlled trial involving elderly and obese patients at risk of developing heart failure (NCT05084235).

d) Patients included from an intervention study including patients with knee- or hip osteoarthritis (GLA:D programme) [16].

The interviews assessed understanding, relevance and clarity of items, response options and instructions [10, 13, 17]. Participants were asked to suggest alternative wording for unclear items. If  $\geq 20\%$  identified an issue with an item, revisions were made iteratively by DBJ, CME and BBO [9, 12, 18]. Each round included participants with diverse backgrounds. Cultural adjustments followed a symmetrical translation approach, prioritising meaning and naturalness over literal equivalence. Once items were considered relevant and understandable, the final version was proofread for linguistic accuracy [9, 10, 13, 14].

### Ethics

This study complied with the Declaration of Helsinki [19], and was approved by the Danish Data Protection Agency, Southern Denmark Region, no. 24/48766. All participants received written and verbal information and provided written consent.

*Trial registration:* not relevant.

### Results

#### Forward and back translation

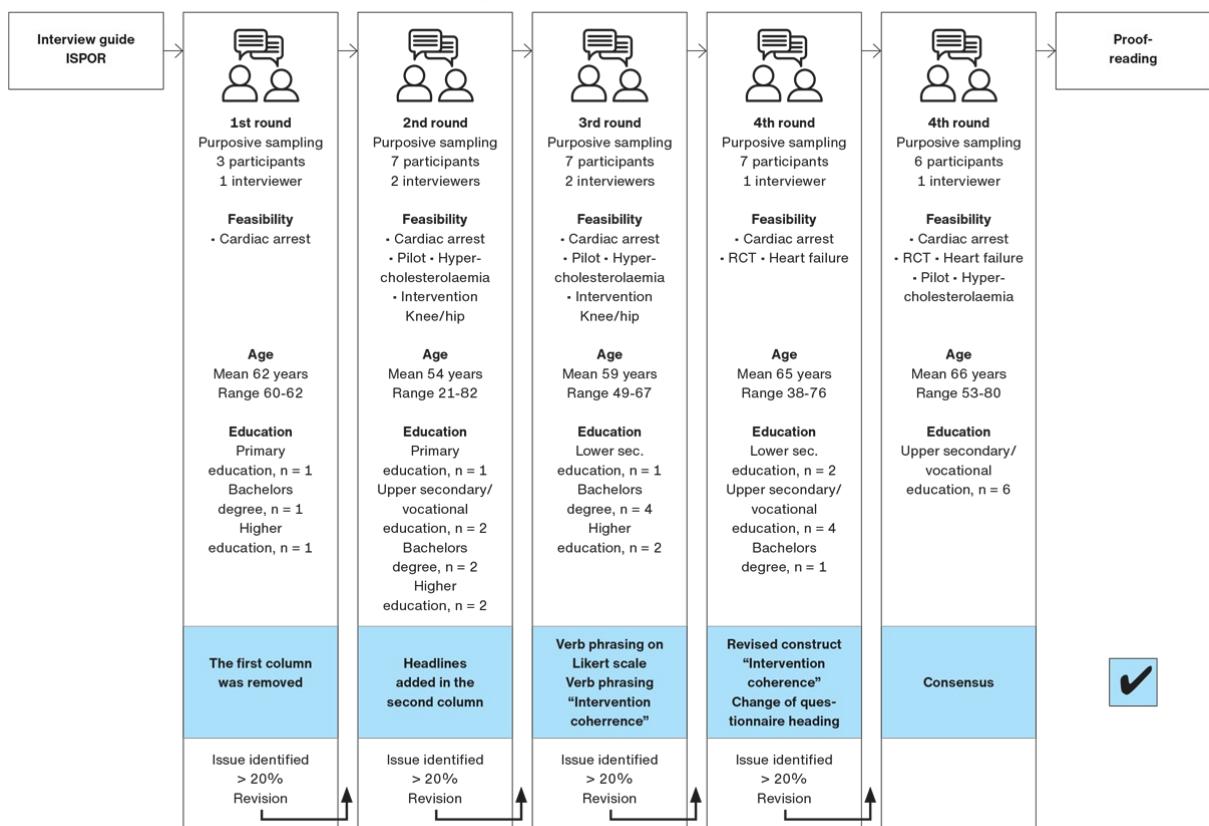
Three forward translations and one back translation were performed. Given the lack of a direct Danish

equivalent, “General acceptability” resulted in the Danish adaptation “Overordnet accept [Overall acceptance]”. Although the back-translation of four domain labels (“Affective attitude”, “Burden”, “Intervention coherence” and “Self-efficacy”) showed discrepancies, the Danish wordings were accepted as conceptually aligned with the original intent. In the original questionnaire, the item “Intervention coherence” included an open-ended field; however, the multidisciplinary committee decided to remove it to enhance feasibility (standardising quantitative measures for use in large samples at the expense of qualitative feedback).

### Cognitive interviews

A total of 30 participants were included in five interview rounds (Table 2, **Figure 1**). Five individuals declined participation (due to time constraints/other commitments).

**FIGURE 1** Overview of the iterative process employed in the cognitive interview.



ISPOR = International Society for Pharmacoeconomics and Outcomes Research.

The participants found the questionnaire relevant, feasible and easy to understand, with all items being completed, and face validity was considered good. The original English questionnaire's two-column format (with researcher instructions in the left column) confused some participants, which led to the removal of the first column (Table 3, [Supplementary Table S3](#)).

**TABLE 3** Overview of the original Theoretical Framework of Acceptability (TFA) questionnaire, and summary of revisions for the Danish TFA questionnaire items<sup>a</sup>.

TFA construct	Explanation of the construct	Summary of revisions
Affective attitude	How an individual feels about the intervention	2 alternative items were evaluated: "Comfortable" was replaced with a "like/dislike" scale for consistency. Emotional discomfort with the original item led to slight rewording, and the Danish term for "intervention" was replaced by "project"
Burden	The perceived amount of effort which is required to participate in the intervention	Minor adjustments were made to the item phrasing. The verb "to engage with" was replaced with "to participate in" to improve clarity
Ethicality	The extent to which the intervention has good fit with an individual's value system	The item heading was simplified to "consequences". Participants expressed confusion over "ethical/moral", but the item was retained with clarified wording
Perceived effectiveness	The extent to which the intervention is perceived as likely to achieve its purpose	Item phrasing was modified to distinguish it from "intervention coherence". Introductory text was added to enhance conceptual clarity
Intervention coherence	The extent to which the participant understands the intervention and how it works	The original item was misunderstood as a question of effectiveness. Rewritten to focus on how the intervention components contribute to its goal. Open-text field was removed
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention	Minor linguistic adjustments. No major revisions were required based on cognitive interview feedback
Opportunity costs	The extent to which benefits, profits or values must be given up to engage in the intervention	No changes were made. Item was well understood across participants
General acceptability	The overall acceptability of the intervention	A heading was added for clarity. "Acceptability" was difficult to translate directly; the phrase "samlet set" ["overall"] was added to contextualise meaning. Likert scale wording was modified to reduce negative connotation

a) Acceptability definition according to the TFA framework: a multifaceted construct which reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experiential cognitive and emotional responses to the intervention.

The term "intervention" was not fully assimilated into everyday Danish, and was therefore replaced by "projekt" [project]. Participants suggested changes to the wording of certain Likert scale options (for "Affective attitude", "Ethicality" and "General acceptability"). This resulted in a conceptual adjustment to response options to ensure clearer language and a more even distribution of response categories.

Verbal probing identified that participants perceived the items "Perceived effectiveness" and "Intervention coherence" as overlapping, both of which were interpreted by participants as questions about effectiveness. To address this and ensure fidelity to the underlying concept of "Intervention coherence" (i.e., understanding the intervention's aim and internal alignment), a conceptual translation approach was applied. Verbal probing identified a risk of response bias, as participants mistakenly selected the neutral option for "Perceived effectiveness" when intending to indicate "no effect". To address this, a brief introductory sentence was added, and this appeared to improve response accuracy and content validity [12] ([see final version, Supplementary Table S1](#)).

## Discussion

This study translated and cross-culturally adapted the TFA questionnaire into Danish, ensuring semantic and conceptual equivalence. The iterative translation process was essential for refining several items and confirming content validity in the Danish context. Cognitive interviewing is widely recommended in translation guidelines, although sample size and composition may vary depending on the need for clarification and refinement [9, 10, 12, 18]. Guided by ISPOR's recommendations [12], five iterative rounds were necessary to resolve issues related to "Intervention coherence" and "Perceived effectiveness". A recent study on the translation and cognitive testing of the Swedish version of the TFA observed similar conceptual challenges [6]. The participants in this study struggled to interpret items such as "Acceptable" and "Ethical consequences", highlighting difficulties in key domains [6] and aligning with our findings. Thus, as part of the translation and validation of the TFA, there is a need for careful wording, piloting and discussion of ambiguous items across cultural contexts.

The translation process highlighted difficulties among participants in understanding and articulating the multifaceted construct, resulting in several interview rounds. Verbal probing was used as the primary technique

during the interviews, although it requires more interviewer training than the think-aloud method [18]. Maintaining participants in the think-aloud process was challenging, as responses often shifted towards personal experiences rather than item interpretation [18]. Conducting mock interviews beforehand might have helped identify these issues [12]. As only two interviewers conducted the interviews, training was integrated into the process. This allowed for the detection of semantic inconsistencies and revealed a potential risk of response bias across repeated interviews [13].

Including participants from four interventions allowed us to assess the tailored item formulations inserted in square brackets by each study's researchers. Although this approach provides flexibility, the cognitive interviews demonstrated potential threats to response validity when the inserted descriptions lacked clarity. To ensure clarity and relevance, we recommend pre-testing the intended wording in the target population. Likewise, the Swedish translation of TFA, as revealed through cognitive interviews, showed that not all items were applicable across interventions [6]. Similar to our findings, the authors recommend selecting or modifying items depending on the context and population. This further supports the original TFA developers' guidance on adapting item formulation while preserving conceptual intent [5].

### Strength and limitations

A notable strength was adherence to recommended guidelines, an iterative approach and a relatively high number of cognitive interviews, which strengthened content validity. Additionally, the diverse study population of patients and relatives, varying in age, sex, and clinical characteristics, improved the relevance of findings. Only a few participants had low levels of education, which may limit transferability to populations with limited health literacy. Back-translation was conducted by a single native English speaker. Finally, although the inter-rater reliability of the original TFA has been assessed [5], further evaluation of measurement properties is needed.

### Conclusions

The TFA questionnaire was successfully translated and cross-culturally adapted into Danish, addressing key semantic and conceptual challenges. The Danish version of the TFA questionnaire may be applied to assess acceptability in feasibility studies within a Danish context.

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**Supplementary material** [a07250547-supplementary.pdf](https://ugeskriftet.dk/dmj/a07250547-supplementary.pdf)

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