Original Research

The Therapy-Related Symptom Checklist for Children as a Method for Monitoring Symptoms in Chinese Children With Cancer: Linguistic Validation and Cross-Cultural Adaptation

Hasan Alelayan, M.S.N., R.N.∗†, Huangliang Wen, M.S.N., R.N.∗†, Hui Li, B.S.N., R.N.†, Jing Ge, B.S.N., R.N.§, Wei Han, M.D.§, Xiaoyan Liao, Ph.D., R.N.∗†

∗Nursing Department of Zengcheng Branch, Nanfang Hospital, Southern Medical University, Guangzhou, China
†School of Nursing, Southern Medical University, Guangzhou, China
‡Nursing Department, the First People’s Hospital of Kashgar Prefecture, Kashgar, China
§Pediatric Department, Nanfang Hospital, Southern Medical University, Guangzhou, China

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A B S T R A C T

Background: Children with cancer commonly experience severe symptoms. These may be managed by routine monitoring of their occurrence and severity using a validated tool. Aim: This study aimed to translate and culturally validate a simplified Chinese version of the Therapy-Related Symptom Checklist for Children (TRSC-C). Design: Qualitative method. Participants and setting: We recruited children with cancer from a pediatric department of a tertiary hospital in Guangzhou, China. Methods: We used forward and backward translation by bilingual translators and standardized cognitive interviewing for linguistic validation and to check cross-cultural adaptation. A panel of experts assessed content validity.

Results: Agreement was reached on cultural applicability, suitability for intended purpose, and clarification of the pre-test version. The content validity was good (indices ranged from 0.80-0.90). Fifteen Chinese children with cancer (aged 8-18 years) were included in cognitive interviews. The cognitive debriefing showed that the instrument was easy to understand and appropriate for monitoring symptoms in children with cancer. Some words were adjusted following participants’ comments.

Conclusions: The simplified Chinese version of the TRSC-C was semantically and conceptually equivalent to the original version. Children between 8-18 years old can use this instrument to report symptoms and share their experiences about their disease and treatment.

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fectively (Bradford et al., 2020; Montgomery et al., 2020). Several instruments have been used to measure therapy-related symptoms experienced by children with cancer, such as the Symptom Distress Scale and the Memorial Symptom Assessment Scale (Dupuis et al., 2012). Child-friendly approaches are needed to support children with cancer and their parents in communicating with health care providers about distressing symptoms. The calibrated 30-item Therapy-Related Symptom Checklist for Children (TRSC-C) was designed to detect symptom occurrence and severity during treatment (Williams et al., 2012). The tool has good psychometric properties (Cronbach's alpha = 0.91) and can detect differences in essential aspects of child development across age and sex. It is highly correlated with quality-of-life measures (r = −0.68) and functional status (r = −0.32) of children with cancer (Williams et al., 2012; Williams et al., 2015a). The primary advantage of the TRSC-C is that it is child-friendly, with each item of the tool having at least two terms that help describe symptoms in simpler words. Second, the TRSC-C can be used as a proxy measure, reducing the burden on children. Third, it is successful in capturing symptom clusters, which is a new and important area for pediatric oncology patients in managing and treating cancer (Williams et al., 2015b). Fourth, the checklist allows symptoms to be systematically monitored across time. With the ease of completion, it works well in clinical settings (Williams et al., 2012).

As far as we know, no pediatric symptom measures have yet been translated into simplified Chinese. A recent study used the Chinese version of the Patient-Reported Outcomes Measurement Information System Pediatric Measures to measure physical, emotional, and social functions and symptoms (fatigue and pain; Liu et al., 2019). However, the tool was not designed to assess the occurrence and severity of symptoms during cancer treatment for children. The TRSC-C was established in English and validated in the U.S. pediatric population (Williams et al., 2012). It has been widely used in many countries (Williams et al., 2015a; Williams et al., 2014; Williams et al., 2012), but has not been translated into simplified Chinese. To use an instrument in another culture or language, a translation should be followed by cross-cultural adaptation (Guillem et al., 1993). A comprehensive method should be used to establish equivalence between the original and the translated versions for any self-report measure. Alongside linguistic validation, cultural adaptation is essential to maintain the authenticity of the content across cultures at a conceptual level (Beaton et al., 2000). Cognitive debriefing, which may help to identify potential issues and how respondents understand and respond to items, is used to check the cultural adaptation and pre-test instruments (Woolley et al., 2004). A cognitive debriefing should be conducted after translation to ensure that the items are worded consistently and that respondents can answer them successfully (Wild et al., 2005). This study aimed to develop a simplified Chinese version of the TRSC-C using linguistic validation, content validation, and cultural adaptation.

**Methods**

**Translation and Cultural Adaptation of the TRSC-C**

The Therapy-Related Symptom Checklist for Children (TRSC-C; Williams et al., 2012) contains seven factors and 30 items. The factors are as follows: (1) nutrition-related; (2) psychosocial/central nervous system; (3) oropharyngeal; (4) bone marrow toxicity/neuropathy; (5) skin/other toxicities; (6) neurotoxicities; and (7) respiratory/other symptoms. The child or their proxy scores the severity of each symptom experienced since the last treatment, using a five-point Likert-type scale: 0 (no symptoms), 1 (a little bit), 2 (quite a bit), 3 (a lot), and 4 (a whole lot). Space on the form is available to add relevant symptoms. Each item is child-friendly, for example, “do not feel very hungry” and “do not feel like eating” are listed under the item on loss of appetite. The TRSC-C score ranges from 0 to 120. A higher average rating means more severe symptoms at greater frequency. Two rigorous guidelines (Bonomi et al., 1996; Wild et al., 2005) were followed to develop the simplified Chinese version of the TRSC-C. Sometimes, the two guidelines complemented each other. If there was any discrepancy between them, the stricter guideline was followed. The following steps from both guidelines were therefore adopted:

**Step 1: Preparation**

Dr Williams, the original developer of the TRSC-C, was contacted, and authorization was obtained to translate the TRSC-C into simplified Chinese. We then started to recruit a bilingual team for forward and backward translations, and experts to evaluate the content validity. The experts had to have more than 5 years of work experience in pediatric oncology. We asked the translators to use simple and clear wording to ensure that it would be understandable by the largest possible number of children with cancer.

**Step 2: Forward translation**

Two translators independently translated the original version of the TRSC-C into simplified Chinese. Both the translators were native Chinese and highly trained in written and spoken English. The translators also measured the degree of difficulty in translating each item on a scale from 0 to 10 (0 = no difficulty and 10 = total difficulty).

**Step 3: Reconciliation of items**

A consensus panel including a methodologist (XL), a pediatric oncologist (WH), a pediatric nursing specialist (JG), and an English professor compared the two forward translated versions and synthesized them into a single version. This included evaluating the table of item definitions and reviewing the original and the simplified Chinese versions in consensus meetings. Specific translatability issues were pointed out and discussed, until a consensus was reached.

**Step 4: Backward translation**

A native English speaker proficient in Chinese and blinded to the original version back-translated the synthesized forward-translated version into English to ensure content equivalence. The translator also assessed the difficulty of retranslating each item on a scale of 0-10. The consensus panel checked the translation for missing or misleading words between the original and the backward-translated version. The backward translation was also sent back to the original developer to review.

**Step 5: Expert review**

The experts were requested to judge whether items of the TRSC-C-C were relevant and comprehensible, by measuring relevance, simplicity, clarity, and ambiguity using a four-point ordinal scale (Supplementary Table S1). A focus group interview was then hosted to provide in-depth discussion of the checklist.

**Step 6: Cognitive interviewing**

This step aimed to evaluate: (1) whether the participants understood the item; (2) whether the participants understood the item as expected; and (3) how the participants viewed the item and its response options. We recruited a convenience sample of children diagnosed with cancer from a 2500-bed tertiary hospital in Guangzhou, China. The inclusion criteria for participation in the study were children: (1) diagnosed with cancer and undergoing active treatment; (2) aged between 8 and 18 years; and (3) able to...
Table 1
Cognitive Interview Questions

<table>
<thead>
<tr>
<th>Overall Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did you have any difficulty in understanding these items?</td>
</tr>
<tr>
<td>2. Which items were offensive or annoying to you?</td>
</tr>
<tr>
<td>3. Was there anything else that should have been included related to your symptoms?</td>
</tr>
<tr>
<td>4. Do you have any other comments regarding this checklist?</td>
</tr>
<tr>
<td>Items</td>
</tr>
<tr>
<td>5. Please answer each item below and select a proper answer for each item.</td>
</tr>
<tr>
<td>6. Please explain the meaning of this item (or kid-friendly term) in your own words.</td>
</tr>
<tr>
<td>7. Please look at the item: “after oncology treatment,” what do you think about it?</td>
</tr>
<tr>
<td>Response Options</td>
</tr>
<tr>
<td>8. What option did you select, and why?</td>
</tr>
<tr>
<td>9. Are the response options “no symptoms, a little bit, quite a bit, a lot, a whole a lot” adequate for these items?</td>
</tr>
</tbody>
</table>

Table 1: Cognitive Interview Questions

Speaking and reading Chinese. The exclusion criteria were children: (1) diagnosed with chronic diseases such as diabetes or asthma; or (2) having cognitive problems or psychiatric disorders. The children’s clinical and treatment data were extracted from medical records. Before the survey, the researchers explained the study’s purposes and procedures to all eligible children. The children were also told that their personal and medical information would be kept confidential, and the data would only be reported in aggregated form. Previous studies suggest that a newly translated measure should be tested for cognitive equivalence by the key in-country person on a group of 5-15 respondents in the target language (Wild et al., 2005). In this study, the interviews mainly focused on young children (8-10 years old), both boys and girls, because they typically have more reading problems and a lower level of cognitive function than older children (Liu et al., 2013). When no new topics were identified, data saturation was considered to have been reached. The consensus panel reassessed the saturation decision.

Cognitive interviews were conducted by the primary researchers (the first and second authors). They are completing a Ph.D. and M.S.N. and have the necessary academic training in conducting qualitative research such as interviews and focus groups. The interviewers also conducted a couple of practice interviews before this study under the supervision of the corresponding author. A cognitive debriefing form was provided as a tool for interviewing. Field notes were taken during the interviews. Finally, the corresponding author checked the notes and interview report to ensure that all issues had been addressed. The interviewers were fluent in Chinese and had no prior relationship with the participants. The interviewers explained the purpose and the procedure to participants and used respondent debriefing to verify that the questions were understood as intended on a semantic and conceptual level. Each participant was asked to answer the simplified Chinese version of the TRSC-C before the interview. The interviewers then checked the participants’ responses to each item and began the face-to-face interview using standardized questions for each item (Table 1). Participants were asked to give verbal feedback on the difficulties involved in any items. This was followed by specific questions about the instructions on the measures and the different answer options, and the participants’ understanding of each item. Participants also were asked to suggest alternative wording for any difficult or confusing items. The cognitive interviews were conducted in a meeting room in the pediatric department. Simplified Chinese was the data collection language. Neither audio nor video recording was used to collect the data. Further interviews were carried out after adjusting confusing words emerging from the earlier interviews.

Step 7: Review of cognitive debriefing and finalization

A consensus panel experienced in questionnaire design decided whether to maintain or change item wording based on the cognitive debriefing. During this step, differences that may influence the clarity of the checklist and individual items were discussed and resolved, to create a final version of the questionnaire (Supplementary Figure S1).

Content Validity

Content validity was assessed by asking experts to measure relevance, simplicity, clarity, and ambiguity of each item of the TRSC-C on a four-point ordinal scale. The expert opinions from the content validity forms were used to calculate content validity indices (CVI), including item CVI (I-CVI) and scale CVI (S-CVI) (DeVon et al., 2007). I-CVI and S-CVI are crucial for an instrument to assess health outcomes or support clinical decision-making (Almanasreh et al., 2019). I-CVI was calculated as the number of experts who scored three or four on the item as a proportion of the total number of experts (Ayre and Scally, 2014; Zamanzadeh et al., 2015). I-CVI values range from 0 to 1. I-CVI >0.79 was considered acceptable (DeVon et al., 2007). Both the universal agreement (UA) among the experts (S-CVI/UA) and the average CVI (S-CVI/Ave) methods were used to measure the S-CVI (DeVon et al., 2007). The number of items with an I-CVI of 1 was divided by the total number of items to calculate the S-CVI/UA (Zamanzadeh et al., 2015). The sum of the I-CVI values was divided by the total number of items to calculate the S-CVI/Ave (Zamanzadeh et al., 2015). S-CVI/UA values ≥0.80 and S-CVI/Ave ≥0.90 were considered to indicate excellent content validity (Ayre and Scally, 2014; Zamanzadeh et al., 2015). The percentage of items unanswered and the proportion of respondents attempting all the items were also recorded (Reito et al., 2017). We used Excel (Microsoft Office, 2007) to analyze the data.

Ethical Consideration

Ethical approval was obtained from the Nanfang Hospital Ethical Committee (NFEC-202006-K6-01). Informed consent was obtained from parents or proxies, and assent was obtained from children. A complete description of the study was provided to all participants and their proxies to obtain written informed consent. The surveys were completed anonymously. This research adhered to the principals of the Declaration of Helsinki.

Results

Linguistic Validation of the Simplified Chinese Version of the TRSC-C

The difficulty scores from the bilingual team were low for both forward (1.56 ± 0.58) and backward translations (1.64 ± 0.55). Most of the items offered a straightforward translation during the translation procedures with only slight discrepancies linked to a particular word choice or child-friendly words. For example, at step...
3 reconciliation, the forward-translations of the item “loss of appetite (not feeling hungry; eat less, not feel like eating),” which were given as “貪食 (不覺得餓; 飲食減少; 吃不下)” in translation 1 and “沒有食欲 (不覺得餓; 吃得少; 不喜歡東西)” in translation 2 were synthesized as “貪食 (不覺得餓; 吃得少; 吃不下).” The forward-translations of the item “bruising (dark spots on the skin, bruise easily),” which was “瘀斑 (皮肤出现瘀斑; 容易瘀青)” in translation 1 and “瘀伤 (皮肤出现黑色斑点; 易瘀伤)” in translation 2, were synthesized as “瘀斑 (皮肤出现黑色斑点; 容易瘀青).” There is no single or plural form in Chinese, so for the item “numbness in fingers/toes,” “手指節” was translated as “手指節 (腳趾極),” which is typically used like the plural form in English. The consensus panel reached agreement on the cultural applicability, suitability for intended use, and clarification of the synthesized items in the checklist.

Content Validity of the Simplified Chinese Version of the TRSC-C

A team of 10 Chinese professional experts (four pediatric oncologists and six pediatric oncological nurses) was invited to assess the content validity of the simplified Chinese version of the TRSC-C. The characteristics of the experts are shown in Table 2. There was a high percentage (93%-100%) of agreement on the acceptability of the content of the instrument among the experts. At the item level, all the items had an I-CVI of more than 0.80 for the four criteria (Supplementary Table S2). At the scale level, the S-CVI/UA was 0.90 (relevance), 0.93 (clarity), 0.80 (simplicity), and 0.83 (unambiguity), and the S-CVI/Ave was 0.98 (relevance), 0.99 (clarity), 0.97 (simplicity), and 0.97 (unambiguity; Table 3). The findings indicate that the simplified Chinese version of the TRSC-C has good content validity for measuring symptoms in Chinese children with cancer. One expert suggested adding a new item (weight gain) to the instrument because of the administration of corticosteroids in patients with pediatric cancer. After an in-depth discussion, the consensus panel decided not to add this because they considered that weight gain is not common. If a child gained weight, they could use the space provided in the checklist to report the symptom.

Cognitive Debriefing of the Simplified Chinese Version of the TRSC-C

The cognitive interviews were conducted during September and October 2019. The pre-test version of the instrument was examined by 15 children with cancer, of whom nine (60%) were male, and 10 (66.7%) were between 8-10 years old. Table 2 shows the characteristics of the participants. No participants subsequently refused to participate, withdrew consent, or dropped out. The average time required to complete the instrument was approximately 25 minutes. The interviews revealed that most items of the TRSC-C were quickly and easily understood. The participants also understood the response categories and instructions well. They seldom deferred or revised previous answers. Some of the child-friendly terms were modified because of difficulties understanding or because the words were ambiguous for young children. Table 4 shows the child-friendly terms modified by this process. The participants were generally satisfied with the checklist because it accurately expressed their concerns. They highlighted the importance of the checklist because severe symptoms can occur following chemotherapy, and a tool for monitoring symptoms at home is particularly useful.

Discussion

To our knowledge, this is the first study to develop a simplified Chinese version of the TRSC-C. Linguistic validation and cultural adaptation of the simplified Chinese version of the TRSC-C were used to preserve the original instrument’s qualitative nature. Our findings suggest that the simplified Chinese version of the TRSC-C achieved semantic and conceptual equivalence to the original version, had good content validity, and was easy to understand and appropriate for monitoring symptoms in children with cancer. One of the study strengths is the adequate number of experts used to explore content validity. Another is that we enrolled young children (mainly 8-10 years old) to evaluate the cultural adaptation of the instrument through cognitive interviewing.

The forward and backward translations of the TRSC-C were not complicated because the TRSC-C consists of typical symptoms in pediatric oncology patients, appropriate response options, and guidance. The child-friendly language used in the English version is considered easy to understand for most children and adolescents aged 8-18 years. Terms were only modified when this was considered unavoidable following both reconciliation and cognitive debriefing and was required to improve comprehension and accuracy of wording. Slight differences in words and child-friendly terms emerged in the translation process, such as alternative forms of words, direct translation versus paraphrasing, and scientific versus spoken form. Some English words or phrases may have two or more counterparts in Chinese (Liu et al., 2013; Madi & Badr, 2019), which leads to a complex translation process to select the most relevant and correct equivalent term (for example, bruise can be “瘀伤,” “瘀斑,” or “瘀青” in Chinese). Comparing the spoken (vernacular) and the written (classical) forms was also a challenge in translating the TRSC-C into simplified Chinese. In general, children may not be familiar with the standard term and usually prefer the argot. Spoken Chinese is also more child-friendly. For example, “feel lazy” was translated into “乏力” (written Chinese). However, the experts replaced it with “不想动” (don’t want to move), which is the spoken form for “feel lazy.” The final translation was agreed to provide terminology and words that would be understood by children, parents, healthcare providers, and teachers.
The content validity of the full simplified Chinese version of the TRSC-C was acceptable at both item and scale level. This suggests that the checklist is relevant for evaluating symptoms in Chinese children with cancer. To confirm understanding, we used the respondent debriefing method in standardized cognitive interviews. Our methodology was consistent with previous studies (Liu et al., 2013). For the Spanish version of the TRSC-C, five children with cancer and their parents evaluated the ease of completion. However, the authors failed to report detailed findings (Williams et al., 2014). Children’s answers rely on their cognitive levels, so some younger children did not clearly understand some terms during the cognitive interviews. Terms containing complicated words or ambiguous definitions were quickly recognized by the children and this prompted some adjustments to the text. For example, “气短” for “shortness of breath” was not clearly understood by one child during the interview, and was replaced by “气促”, as suggested by the child.

**Limitations**

This study had some limitations. First, we did not examine the psychometric properties of the checklist. Our future work will focus on testing the reliability and validity of the instrument. Second, children who took part in the cognitive interviews might not have experienced all symptoms at the time of the interviews. Children’s understanding of symptoms might be based on their developmental level (Liu et al., 2013) and experience. Younger children might therefore find it easier to understand symptoms that they had experienced, and misunderstandings may result in underreporting or overlooking a symptom. The young children did not report difficulty in understanding symptoms that they had not experienced but a larger sample size may help reduce potential bias. Future research should investigate therapy-related symptoms in the target population among a larger sample.

**Conclusions**

In response to the need to monitor the occurrence and severity of therapy-related symptoms in children with cancer, we translated the TRSC-C into simplified Chinese, following rigorous guidelines. A panel of experts evaluated the content validity of the instrument. Cognitive interviewing was used to ensure cross-cultural adaptation and suitability of the simplified Chinese version of the TRSC-C to assess symptoms in Chinese children with cancer. We found that the simplified Chinese version of the TRSC-C was appropriate for this purpose. Health care practitioners, researchers, parents, and teachers may use the instrument to monitor and record symptoms among Chinese children with cancer undergoing cancer therapy. It will help them to better understand symptoms, and plan and modify interventions to achieve the best outcome for these children.

**Clinical Implications**

The tool is useful for health practitioners, clinical researchers, pediatric oncology nurses, and parents to monitor the occurrence and severity of therapy-related symptoms. This will support successful symptom management and medication education throughout treatment. The tool may also be helpful for safety assessment during drug development in Chinese-speaking populations.

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**Supplemental materials**


**References**


**Table 4**

Modification of the Chinese Version of the Therapy-Related Symptom Checklist After the Cognitive Interview

<table>
<thead>
<tr>
<th>Item</th>
<th>Pretest Version/English Equivalent</th>
<th>Cognitive Interview</th>
<th>Final Version/English Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeling sluggish (feel very tired, feel lazy)</td>
<td>感觉乏力 (非常疲倦; 用尽精力) (feeling sluggish feel very tired, feel lazy)</td>
<td>二位年轻儿童不能理解“乏力”；一位儿童建议使用“疲倦”，而不是“乏力”</td>
<td>感觉疲倦 (非常疲倦; 不想动) (feeling tired; feeling lazy)</td>
</tr>
<tr>
<td>Difficulty sleeping (hard to go to sleep, hard to stay asleep)</td>
<td>失眠 (入睡困难; 很难熟睡) (insomnia (difficult to fall asleep, hard to sleep)</td>
<td>一位儿童建议“失眠”被理解得更容易</td>
<td>失眠 (入睡困难; 很难熟睡)</td>
</tr>
<tr>
<td>Shortness of breath (hard to breathe, breath faster)</td>
<td>气促 (呼吸困难; 呼吸急促) (shortness of breath (dyspnea; rapid breathing)</td>
<td>一位儿童不知道“气促”意味着什么</td>
<td>气短 (呼吸困难; 呼吸急促) (shortness of breath (dyspnea; rapid breathing)</td>
</tr>
</tbody>
</table>


Williams, A. R., Williams, D. D., Williams, P. D., Almi, F., Hesham, H., Donley, B., & Kheirbek, R. E. (2015a). The development and application of an oncology Therapy-Related Symptom Checklist for Adults (TRSC) and Children (TRSC-C) and e-health applications. Biomedical Engineering Online, 14(Suppl 2), S1.


