

# Translation and Cultural Adaptation of adult PROMIS Physical Function Short Forms into Simplified Chinese

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## Research

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# Abstract

**Background:** The Patient-Reported Outcomes Measurement Information System (PROMIS) has been proven to be an effective and efficient measurement tool and has entered its global promotion phase. Our research team was authorized by the PROMIS Health Organization to translate five adult Patient-Reported Outcomes Measurement Information System (PROMIS) physical function short forms (4a, 6b, 8b, 8c, and 8c 7-Day) to ensure the conceptual and semantical equivalence to the source and pretest them in a Chinese population for cultural adaptation.

**Methods:** The translation was conducted following the Functional Assessment of Chronic Illness Therapy (FACIT) methodology, which mainly includes forward translation, reconciliation, back-translation, expert reviews, cognitive testing, and linguistic validation, etc. And cognitive interview was used to pretest the translated items in Chinese patients with cancer and a healthy population.

**Results:** The translation process was relatively smooth, except for some translated versions that slightly altered some word choices or sentence structures. Subsequent pre-testing of the Simplified Chinese short forms showed that clarifying or laying emphasis on the time frame in the instructions was needful, and two sets of response categories and one item stem needed some slight revisions due to cultural or language discrepancies.

**Conclusion:** The translation and linguistic validation of five adult PROMIS physical function short forms into Simplified Chinese have been completed, and field testing, calibration, and psychometric testing are pending.

## 1. Introduction

Cancer is one of the leading causes of death worldwide. Based on data of the National Central Cancer Registry of China, about 4 million new cancer cases and 3 million cancer deaths were registered in China in 2015 [1]. The increased prevalence of cancer and prolonged cancer survival have increased the burden of surveillance and management of symptoms and therapeutic responses of Chinese patients with cancer [2, 3]. Cancer and its treatment can lead to various physical, psychological, and social health disorders [4]. Among them, physical function issues are one of the essential causes of other disorders. They negatively impact the patients' quality of life and disease prognosis [5].

Objective indices or clinician-reported outcomes like hand-grip strength [6], Eastern Cooperative Oncology Groups [7, 8], Activities of Daily Life [9, 10], etc., have been used as assessment standards of the physical functioning of patients with cancer in China; meanwhile, patients' opinions have been seriously neglected. However, practitioners and researchers have realized that some health-related symptoms or functions and their impact on life as reported directly from the patients should be considered [11]. Additionally, discrepancies were observed between clinician-reported and patient-reported outcomes (PROs) [12, 13], indicating the importance of patient-reported data during clinical decision-making. PROs refer to health-related information, including information on physical health, mental health, social health, satisfaction with clinical treatment, etc., which is reported directly by patients, without interpretation from a physician or others [14]. Collecting PROs has multiple benefits, such as efficiently facilitating patient-clinician communication [15], enhancing the comprehension and confidentiality of clinical data [16], assisting the medical decision-making process [17], and reducing patients' anxiety [18]. It has been revealed that patients with cancer reported more frequent or severe treatment-related toxicities than in clinicians' reports [12, 13, 19, 20]. As a result, routinely collecting and using PROs is increasingly being acknowledged in clinical cancer care [21-24].

The Patient-Reported Outcomes Measurement Information System (PROMIS), funded by the National Institutes of Health since 2004 [25], is a measuring system that consists of over 300 measures that have been developed and validated based on the Item Response Theory. It was designed for both patients with chronic conditions and the general population to self-measure and report various health status domains [26]. It can be performed in multiple forms, such as fixed-length paper questionnaires (short forms or profiles) or computerized adaptive testing (CAT) [27, 28]. The original English version of PROMIS tools and several translated versions have proven to have good reliability, validity, responsiveness, comparability, and a light measurement burden [28-30]. PROMIS physical function (PF) measures were designed to assess one's self-reported capability of physical activities, including the functioning of the upper extremities, lower extremities, and central regions, as well as some daily activities [31]. Prior studies demonstrated that PROMIS physical function short forms (PF-SFs) have good psychometric properties, and PROMIS scores are strongly associated with other recognized legacy measures [32-34]. Therefore, it is expected that the PROMIS PF-SFs will better assess the physical function disorders of Chinese patients with cancer.

The primary purposes of this research included:

- a. Translating five PROMIS PF-SFs into Simplified Chinese to ensure the conceptual and semantical equivalence to the source
- b. Pretesting and culturally adapting the translated versions in Chinese adult patients with cancer and healthy populations

## 2. Methods

### 2.1 Authorization

Authorization was obtained from the PROMIS Health Organization (PHO) to translate five PROMIS PF-SFs into Simplified Chinese, including PF-SFs 4a, 6b, 8b, 8c, and 8c 7-Day derived from the PROMIS item bank version 2.0. All the translation documentations, including contents of each SF (title, guidance, item stems, answer options), translation records, and cognitive debriefing, were submitted to the PROMIS Statistical Center (PSC) for review and approval.

### 2.2 Procedure

This study adopted the FACIT translation methodology that is recommended by the PROMIS Instrument Development and Validation Scientific Standards (Version 2.0) [35] to translate and adjust the measures. The main steps of the translation and cultural adaptation are shown in Table 1.

#### Table 1

#### **Brief introduction of the main steps of the FACIT translation methodology**

Steps	Objective of each step
Independent translations	To translate the original items into the target language by two native speakers of the target language, independently
Reconciliation	To reconcile the two forward translation versions by another native speaker of the target language
Back-translation	To translate the reconciled version back into the original language by a native English-speaking translator
Expert reviews	To review the above steps and select the best translation of each item or provide a better alternative by three linguistic or medical experts, who are native speakers of the target language, independently
Finalization	To review each item's translation history and consider comments from the Translation Project Manager (TPM) to determine the final translation by a Language Coordinator (LC), a native of the target language; and then provide its literal back-translation and polished back-translation  The LC should justify any discrepancies between the final version and reconciled version or expert's recommendation.
Finalization Quality assurance	To perform a quality review by the PSC based on the preceding steps collated by the TPM to ensure consistency with previous translations, other languages, and between items
Pre- testing and validation	To pretest the version that is formatted and typeset by two proofreaders in native target users to verify its accuracy and equivalence to the source (each item will need at least 5 participants.)
Analysis of participants' comments and validation of the translation	Compilation of the participants' comments and summarization of the issues by the TPM; review and provision of corresponding solutions by the LC; verification of the consistency between the proposed solutions, source text, and other languages by the TPM.

## 2.3 Translation and cultural adaptation process

### 2.3.1 Step 1: forward translation

Two bilingual healthcare professionals who were proficient in English, with Chinese as their native language, independently performed a forward translation of the titles, guidance, item stems, and answer options. Both translators were provided with a spreadsheet of item definitions and potential item-specific translatability issues summarized by PROMIS.

### **3.2.2 Step 2: reconciliation**

Another bilingual translator, a Chinese native, reconciled the two forward translated versions after reviewing the spreadsheet above. This step aimed to address discrepancies between the two forward translations and acquire a version that could better convey the original intention of the item by selecting one of them, creating a hybrid version, or even offering a new translation.

### **2.3.2 Step 3: back-translation**

The reconciled version was subsequently translated back into English by a translator who was bilingual and fluent in both languages. The translator was blinded to the source instruments and item definitions and was asked to back-translate without any embellishment to retain the original meanings to the greatest extent. Then, the Translation Project Manager (TPM) found differences between the original and the back-translated version and clarified the original meaning of the items for the next step of expert reviews.

### **2.3.4 Step 4: expert reviews**

Three native Chinese experts separately reviewed all the above steps and chose the most accurate and appropriate translation for each item or provided an alternative translation that was better than the existing ones. They were all healthcare professionals with doctoral or master's degrees. The TPM evaluated their comments and identified potential issues with the recommended translations. Then, all the information above was collated into the Item History document for the Language Coordinator (LC) to make final decisions.

### **2.3.5 Step 5: finalization**

The LC, who also a native Chinese, determined the final translation after considering all the historical translations and comments. He/she justified any discrepancy between the final version and the reconciled choice or expert's recommendation. Next, the LC performed both literal and polished back translation based on the finalization.

### **2.3.6 Step 6: Harmonization and quality assurance**

The TPM preliminarily assessed the final translation's accuracy and equivalence by comparing the back-translations with the source text and completed the documenting. All the material was then submitted to the PSC to ensure consistency with previous translations, other languages, and between items. Finally, the SFs were formatted, typeset, and proofread independently by two proofreaders before a reconciled version was generated.

### **2.3.7 Step 7: Cognitive debriefing and linguistic validation**

The formatted SFs of the Simplified Chinese version were then pretested among native Chinese speakers living in the Chinese Mainland to verify if the translated items were conceptually and semantically equivalent to the English source. As the PROMIS PF-SF 8b involves all the guidance, answer options, and items of SFs 4a and 6b, cognitive interviews included only SFs 8b, 8c, and 8c 7-Day (24 items). As requested by the PHO, each item was debriefed by at least 5 participants, and each participant answered a maximum of 35 items [35]. Meanwhile, considering that items

of SFs 8c and 8c 7-Day were similar and unsuitable to be debriefed on same participants, the acceptable sample size for the cognitive interview was at least 10. Purposive sampling was conducted to recruit both patients with cancer and healthy participants with diverse physical function levels and demographic characteristics (e.g., gender, age, education, etc.). The inclusion criteria included: a) patients diagnosed with any cancer; b) aged between 18 and 70 years; c) able to speak Mandarin and read Simplified Chinese; d) with clear consciousness, no expressive or mental problems; and e) consent to participate in this study. The exclusion criteria were: a) patients with terminal-stage cancer (predicted survival  $\leq 6$  weeks) or in a critical condition; b) patients with any condition that might preclude completing the questionnaires or interview. The patient enrollment ensured a balance in the participants' age and gender distribution, and that  $\geq 2$  interviewees for each item had at most a junior high school degree. The participants were from the medical oncology ward of Fudan University Shanghai Cancer Center. The head nurse of the ward reviewed the patients' medical records to recommend eligible persons and informed them of the study's purposes and contents before including them. Healthy participants were recruited from the logistic or service departments of the cancer center and Fudan University.

Participants were required to fill the dispatched SFs independently. Simultaneously, the interviewer observed their reactions and completion speed. A semi-structural interview was conducted using a self-designed script template (Table 2) to obtain the participants' overall comments, impressions on each part of the questionnaires, and additional suggestions. The interviews were recorded both with paper and audio after obtaining permission from the participants.

## **Table 2**

### **The script template of the cognitive interview**

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impression

After completing this questionnaire, did you find any questions challenging to understand? If yes, please specify which one and why.

Are there any questions you deem irrelevant to physical function? If yes, tell me which one and why.

Are there any expressions in this questionnaire that makes you feel uncomfortable or inappropriate? If yes, tell me which one and why.

Do you offer any alternative wordings for the problematic items you have identified?

Do you think these questions are adequate to measure your physical function, or would you like to add any new questions to this questionnaire?

3e

Please repeat the instructions in your own words.

At this reminder of the 7-day recall period. What do you think about it? Were your answers all the same in this time frame?

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options

Please explain these five choices in your own words.

Did you tell me the discrepancies between these two choices?

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Please repeat this item in your own words (or How did you comprehend this item?).

How did you select your answer? Please tell me about your thinking process of this item.

Did you explain the meaning of this word (or phrase) in your own words?

Does this item need any improvement in its wording? If yes, tell me your specific advice.

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3e detection

Do you have any other problems or advice on the questionnaire?

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### **2.3.8 Main step 8: analysis of participants' comments and finalization of the translation**

Within 24 to 48 hours after each interview, the audio recording material was transcribed verbatim. Qualitative data of the earlier interviews was preliminarily analyzed in time and guided the subsequent interviews such as providing inspiration for the interviewer on specific probing questions. After all initial interviews for an item were completed, the TPM collated participants' comments for the item and summarized the issues. The LC reviewed the issues and proposed corresponding solutions. The TPM then ensured that the solutions were consistent with the source.

### **2.3.9 Ethics**

This study was approved by the Ethics Review Committee of Fudan University Shanghai Cancer Center (file No. 1808190-14). All participants received oral and written messages about the study and their rights. They were guaranteed anonymity. Written consent to participate was obtained from all participants. The whole research process strictly followed the ethical principles of qualitative research, and respectful interactions were ensured to protect the vulnerable patients.

## 3. Results

### 3.1 Steps 1 to 6: translation process

The translations of the titles, instructions, answer categories, and items involved in the five short forms from step 1 to step 5 mostly maintained consistent except in few cases where the word choices or sentence structures were changed slightly, while retaining the original meaning of the sentences. Since step 6 was performed in the PSC to ensure consistency with previous translated versions, other languages if applicable, or between items, and proofreading for formatting was required, while other translators in steps 1 to 5 did not need to consider the overall harmonization of various PROMIS measures; therefore, the discrepancies between the final translations from the PSC and the translations generated in steps 1 to 5 were obvious. For example, when compared to the translations of steps 1 to 5 ("物理功能"), the final translation of the title, "physical function" was "躯体功能," which was consistent. Both translations could essentially convey the source meaning; however, that from PSC was considered whether it was consistent with some previous mature translated PROMIS measures. In addition, the PSC made great efforts in performing quality control of translation details. For example, translated versions of the phrase "carrying groceries" (involved in item PFB1 and PFA5 of physical function short form 8b) in steps 1 to 5 included "超市购物袋" or "购物袋," which indicated that the object to be carried was a supermarket shopping bag without laying emphasis on the content. Although the LC took the advice based on the back-translation to change it into "物品" to convey that the object was some kind of good, the PSC further revised it to "食品," which further defined the groceries as foodstuff, which turned out to be more specific and close to the context of daily life activities.

### 3.2 Steps 7 to 8: cultural adaptation process

Since our cognitive interview was conducted simultaneously with other studies involving short forms about fatigue, pain intensity, anxiety and depression, etc. that were administered to the same subjects, and to avoid increasing each interviewee's burden, we increased our sample size. This also helped to prevent an early loss of concentration and interest in the interview, given that not merely questions about the physical functioning were asked. Fourteen subjects were interviewed. Each participant was debriefed on 1 to 2 of our

**Table 3**

**Demographic and clinical information of the participants (n=14)**

riefed m(s)	Gender	Age (years)	Level of education	Employment status	Occupation type	Residential area	Financial stress	Clinical diagnosis
3b	Female	66	□	Retired	□	Urban	□	Stage IV breast cancer
3b, 8c	Female	50	□	In employment	□	Urban	□	Stage III colorectal cancer
3b	Female	33	□	In employment	□	Urban	□	Stage III breast cancer
3b	Male	42	□	In employment	□	Rural	□	Healthy
3b	Male	51	□	In employment	□	Rural	□	Healthy
3c	Female	33	□	In employment	□	Urban	□	Stage IV breast cancer
3c	Male	25	□	In employment	□	Rural	□	Stage IV rhabdomyosarcoma
3c	Female	55	□	In employment	□	Urban	□	Healthy
3c	Male	43	□	In employment	□	Rural	□	Healthy
7-Day	Male	58	□	In employment	□	Rural	□	Stage III gastric cancer
7-Day	Female	48	□	In employment	□	Urban	□	Stage II breast cancer
7-Day	Male	48	□	In employment	□	Rural	□	Stage IV gastric cancer
7-Day	Female	35	□	In employment	□	Urban	□	Healthy
7-Day	Female	55	□	Retired	□	Urban	□	Healthy

Notes: Level of education: □ Junior high school or below, □ High school / technical secondary school, □ Higher vocational education, □ Undergraduate education; Occupation type: □ Administrative staff, □ Workers, □ Services or commerce, □ Agriculture; Financial stress: □ None, □ A little, □ Some, □ Quite a lot

The results showed that items of the PROMIS PF-SFs 4a, 6b, 8b, 8c, and 8c 7-Day were generally completed quickly by the participants. Participants seldom hesitated when answering the questions, and they answered all questions. However, four respondents changed their answer to an item during the interview; they explained that they did not think more carefully when answering the questions for the first time.

The interview data indicated that most instructions, response options, and items in the target short forms were well understood by most of the participants. For response options or items that needed revisions indispensably, a second cognitive interview was conducted with eight different participants, which involved the preliminary revised versions. A third cognitive interview was conducted with five more participants to help in determining the final revision. Two participants (No. 3 and No. 8) were uncertain about the time frame at the beginning when they responded to SF 8c, which was designed to assess the users' current PF level; participant No. 8 further recommended that some words should be added to remind respondents about the record period. Unlike the English predicate tense that can remind respondents that the questions are focused on the present moment, Chinese verbs do not have this kind of hints; we considered the advice of respondent No. 8 to further clarify the time frame in similar questionnaires (SFs 4a, 6b, 8b, and 8c). One respondent (No. 10) forgot to read the reminder of the recall period of PF-SF 8c 7-Day; this made us to further highlight the related words. After revising or emphasizing the time frame cues, we consulted the second-round interviewees and found that most of them supported the revisions on the time frame as they found them to be more eye catching and helpful. All the aforementioned information pointed to the importance of providing more clarity to the instructions of the translated versions.

As for the answer categories, 6/10 interviewees considered that "有点儿难" (translation for "With a little difficulty") cannot be distinguished from "有点难" (translation for "With some difficulty"), which involved SFs 8b and 8c. Considering the proposals of the first-round interviewees, translation team members and a previous study [36] where similar answer categories of PROMIS were translated into Simplified Chinese, we replaced "有点儿难" with "几乎不难," which means "almost no difficulty," "basically no difficulty," or "with little difficulty" in Chinese. Similarly, "有点难" in SF 8c 7-Day was replaced with "有点难," since 2/5 interviewees also commented on it for the same reason. However, in the second cognitive interview, 4/8 participants opposed the revision since they thought that "有点难" was too close to "不难," which is the translation of the first option, "without any difficulty". We then presented a total of six alternative sets of answer categories for the third-round interviewees to choose from; all the five interviewees agreed that "有点难" should be changed to "相对难," which refers to "relatively difficult".

Item PFA11 ("Are you able to do chores such as vacuuming or yard work?") from SF 8b was considered as not widely applicable for Chinese people; 3/5 participants identified that it had cross-cultural issues. They deemed that "吸尘" ("vacuuming") was uncommon in Chinese families, and they suggested that it should be changed to "扫地" ("sweeping the floor"). One of them also said that not every family in China had a yard and suggested that "院子活" (the translation of "yard work") should be adapted to "收拾屋子," which means "to tidy up a room". We considered the participants' suggestions and presented the revised version to the second-round interviewees, but found that some of them observed a discrepancy between the revisions and original words. We performed a third cognitive interview to offer more alternative activities and further probe the respondents' perspectives. Similar cleaning activities differed with participants. For example, two respondents thought that sweeping the floor was more tiring than vacuuming, while two had contrary views. Therefore, we replaced "吸尘" with a more general and inclusive concept ("打扫"), which referred to cleaning activities, such as vacuuming, sweeping or mopping the floor, wiping tables, etc. As for "收拾屋子," 3/5 third-round interviewees suggested that "收拾屋子" ("tidy up the house") had a bit more workload than "收拾屋子" ("tidy up the room") and was closer to "院子活" ("yard work"). Therefore, we adapted "院子活" to "收拾屋子" for the Chinese population. Revisions of the cultural adaptation process are shown in Table 4.

The items also had some problems that originated from the English source. First, some items were not unidimensional enough, meaning that the examples may have been affected by not only one's PF, but by other factors as well, which may have biased the respondents' answers. For instance, one patient (No. 1) selected her answer as "Unable to do" for "Are you able to run errands and shops?" (Item PFA53) because her white blood cell

count was low, showing that she was not suitable for shopping. She also believed that running errands required both a good PF and normal cognitive function. Second, some examples were not concrete enough. For instance, Item PFA5 asked that "Does your health now limit you in lifting or carrying groceries?" and 4/5 deemed that the weight of the groceries was vague and needed clarification. Third, multiple examples in one item were not same-level activities. Specifically, for Item PFA1 ("Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?"), two respondents (No. 9 & 11) insisted that running itself is a strenuous sport. Since all the aforementioned problems also exist in the original entry, we did not modify these items.

#### **Table 4**

#### **Revisions made after the first-round cognitive interview**

Involved short forms	Involved parts	English source	Chinese Version/English Equivalent	Final Chinese Version/English Equivalent	Reasons for Revision
PROMIS physical function 4a, 6b, 8b and 8c	Instruction	(It hasn't emphasized a time frame for answering items)	--	(Add a sentence "XXXXXXXXXX [...]"/"Please respond to the items depending on your current health status..." below the instruction and at the top left of the form and add a black - edged text box to emphasize on it.)	Two participants in the first-round interview especially confirmed the time frame to the interviewer when they began answering the items, and one of them suggested adding a relevant reminder. Considering that Chinese verbs do not have tense cues like the English verbs involved in the items, the advice was taken. All the participants of the second-round interview approved the revision.
PROMIS physical function 8c 7-Day	Instruction	Thinking about the past 7 days...	XXXXXXXX7... / Think back to the last seven days..	(Add a black - edged text box to emphasize on the text.)	One participant missed the reminder of the recall period and that influenced his choices. This revision involved making the reminder more prominent. All the participants of the second-round interview agreed to the revision.
PROMIS physical	Answer categories	Without any difficulty,	XXXXXXXXXXXXXXXXXXXXXXXXXXXX / With no	XXXXXXXXXXXXXXXXXXXXXXXXXXXX / With no	Six of 14 participants claimed that there was a

function 4a, 6b, 8b, 8c and 8c 7-Day		With a little difficulty, With some difficulty, With much difficulty, Unable to do	difficulty, With a little difficulty, With some difficulty, Very difficult, Unable to do	difficulty, With a little difficulty, Relatively difficult, Very difficult, Unable to do	little difference between "○○○○" and "○○○○". All the participants in third- round interview agreed to the final revision.
PROMIS physical function 8c and 8c 7- Day	Answer categories	No difficulty at all, A little bit of difficulty, Some difficulty, A lot of difficulty, Can't do because of health	○○○○○○○○○○○○○○○○○○○○ ○○○○○○○○ / With no difficulty, With a little difficulty, With some difficulty, Very difficult, Can't do because of health	○○○○○○○○○○○○○○○○○○○○ ○○○○○○○○ / With no difficulty, With a little difficulty, Relatively difficult, Very difficult, Can't do because of health	Two participants claimed that there was too little difference between "○○○○" and "○○○○". Two second- round interviewees thought that the words "○○ ○○○○" ("because of health") were redundant since the premise was already provided in the item stem, while 5 out of 8 third-round interviewees preferred to reserve them since they could further remind the respondents.
PROMIS physical function 8b	Item PFA11	Are you able to do chores such as vacuuming or yard work?	○○○○○○○○○○○○○○○○○○○○ / Can you do household chores like vacuuming or yard work?	○○○○○○○○○○○○○○○○○○○○ ○○ / Can you do household chores such as cleaning or tidying up the house?	Three participants of the first-round interview deemed that the use of a vacuum cleaner ("○○") is not very common in Chinese families, and they suggested that it should be replaced with "○○" ("sweep the floor"). The second- and third- round interviewees' opinions on the workload

of "[]" or of other cleaning activities compared to "[]" differed. One first-round interviewee thought that not every family in China has a yard ("[] ") and suggested that it should be changed to "[]" ("a room"). Three out of 5 third-round interviewees thought that "[]" ("tidy up the house") had a bit more workload than "[]" ("tidy up the room"), and was closer to "[]" ("yard work").

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## 4. Discussion

This study described the process and results of the translation and cross-cultural adaptation. The FACIT translation methodology recommended by the PROMIS Instrument Development and Validation Scientific Standards Version 2.0 [35], which requires international cooperation between the United States and Chinese research teams, played a significant role.

Although the cognitive interview was time-consuming and labor-intensive, its results were fruitful. It can effectively improve the comprehensibility and cultural appropriateness of the translated measures and further ensure the quality of collected data. Think-aloud interview and probing are two main techniques of conducting cognitive interviews [37]. In this study, we mainly used a self-designed semi-structure interview script, which consisted of probing questions, to obtain the participants' reactions, comprehension, and perspectives of the items and to help us find discrepancies between their understanding and original intentions of the questions [38]. Consistent with a similar study, our findings suggested that words in the Chinese cultural context were not enough to describe many levels of a subjective feeling like in English language. Sometimes, the literal translation of a set of answer categories into Chinese did not maintain the differentiation degree of the original English options, and the tense-free issue of Chinese verbs may have confused the respondents about the time frame of the questions, compared to the English versions. Moreover, some activities mentioned in the original measures, like vacuuming, are still not very common in China. Many respondents preferred items that matched their own trait level. Some respondents felt that some items were irrelevant if they were too easy or too difficult for them (e.g., Patient No.3 reacted to Item PFC12 with a look of shock: "I haven't done this kind of manual labor yet. How can I answer this question? Most of the time I just help look

after the kids, or do a few simple chores. Who do you think can do manual labor for two hours straight?"); this was consistent with the findings by Schnohr et al [39]. This also highlights the advantage of the PROMIS measurements, which can be administered by CAT that can automatically select questions which match a subject's trait level, and then efficiently and precisely give us a test result.

It was also found that some special groups may have specific demands for their PF assessment. For instance, the upper limb functioning of the two upper limbs in patients with breast cancer after surgery may be different; therefore, giving consistent answers to an item may be difficult, and questions concerning their affected limbs may be more suitable. Participants from low-educated groups should also be the focus group of cognitive interviews. In fact, it was suggested that at least two interviewees with a low literacy level or a cognitive impairment should be included during cognitive interviews for PRO questionnaires [40, 41]; this was an inclusion criterion in this study. A prior study found that respondents with a low educational level were more likely to miss an item, give inconsistent answers, miss the instruction of a questionnaire, or be initially reluctant to complete a questionnaire out of shame [41]. We faced similar situations in this study. A respondent (No.10) who missed the hint of the 7-day record period of a SF was a middle-aged man with only a high-school education degree. Respondent No. 8 with an education level below junior high school was very shy and reluctant to answer the questionnaire at the beginning; however, she finally agreed to participate in the interview after encouragement from the interviewer. She changed her original answers severally due to indecision during the cognitive interview. Additionally, the answers of the respondents with a low education level were often negatively affected by their poor thinking and associative ability [39, 42]. For example, respondent No. 1 (female, 66 years old, below junior middle school level) selected the answer "Unable to do" for "Are you able to go up and down stairs at a normal pace?" (Item PFA21) because she always took the elevator at home. Meanwhile, the interviewer had once seen her climb the stairs of the outpatient building from the first floor to the third without any problem.

Summarily, after rigorous translation and cultural adaptation, the Simplified Chinese versions of PROMIS PF-SFs 4a, 6b, 8b, 8c, and 8c 7-Day (Version 2.0) have achieved the cultural context adaptation in China and the conceptual equivalence and semantic equivalence between the Simplified Chinese version and the English source. It can be used for further quantitative validation studies.

## 5. Limitations

First, the sample size was relatively small since a paradigm of qualitative research was used. However, each item was debriefed by at least five subjects [35]. Second, the decisions made by the research team to modify the SFs were based on qualitative data. Nevertheless, extreme caution was taken during any decision-making process. Only items that were considered unclear or problematic by most of the respondents were revised after a careful review of feedbacks. Standardized tables, stored in Word documents were called Item History and were used to collate and compile the periodic results of the entire translation and cultural adaptation process, which enabled the international collaboration team to conveniently compare different members' opinions and reasons before any decision was taken. Subsequent studies should assess the reliability and validity of the SFs in Chinese patients with cancer to ensure their validity in this specific population through psychometric studies.

## 6. Conclusion

This is the first attempt to introduce adult PROMIS PF measures in China. The Simplified Chinese versions of the PROMIS PF-SFs 4a, 6b, 8b, 8c, and 8c 7-Day (Version 2.0) were semantically and conceptually equivalent to the

English sources. They were also culturally appropriate for Chinese adult patients with cancer or healthy persons. Field testing for reliability, validity, and cross-cultural validation of these versions will be conducted in China.

## Abbreviations

CAT: Computer adaptive testing; FACIT: Functional assessment of chronic illness therapy; PHO: PROMIS Health Organization; PROs: Patient reported outcomes; PROMIS: Patient reported outcome measurement information system; PSC: PROMIS Statistical Center; LC: Language coordinator; TPM: Translation Project Manager

## Declarations

### Ethics approval and consent to participate

This study has been approved by the Ethics Reviews Committee of Fudan University Shanghai Cancer Center (file No. 1808190-14).

### Consent for publication

Oral and written consent of participation was obtained from all participants. All the cases were anonymized and numbered during the analysis and reporting phases.

### Availability of data and materials

Not applicable.

### Competing interests

None.

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### Authors' contributions

All authors contributed to the study conception and design. Material preparation and data collection were performed by Yueshi Huang, Xiaoju Zhang, Changrong Yuan and Yang Yang. Data analysis were performed mainly by Yueshi Huang, Xiaoju Zhang, Changrong Yuan and Yang Yang, while other authors all participated in relevant discussions. The first draft of the manuscript was written by Yueshi Huang and Xiaoju Zhang. Other authors commented on the preliminary versions of the manuscript. All authors read and approved the final manuscript. Yueshi Huang and Xiaoju Zhang contributed equally to this work.

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