



Japanese translation of the Functional Assessment of Cancer Therapy-Breast + 4 (FACT-B + 4) following international guidelines: a verification of linguistic validity

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Abstract

Background For breast cancer patients, postoperative lymphedema and upper limb movement disorders are serious complications that absolutely reduce their quality of life (QOL). To evaluate this serious complication, we used “Quick Dash” or “FACT-B”, which can assess a patient's physical, social, emotional, and functional health status. To evaluate their breast cancer surgery-related dysfunction correctly, “FACT-B + 4” was created by adding four questions about “arm swelling” and “tenderness”. We have translated it into Japanese according to international translation guidelines.

Methods At the beginning, we contacted FACT headquarters that we would like to create a Japanese version of FACT-B + 4. They formed the FACIT Trans Team (FACIT) following international translation procedures, and then, we began translating according to them. The steps are 1: perform “Forward and Reverse translations” to create a “Preliminary Japanese version”, 2: request the cooperation of 5 breast cancer patients and “conduct a pilot study” and “questionnaire survey”, and 3: amendments and final approval based on pilot study results and clinical perspectives.

Result In Step1, FACIT requested faithful translation of the words, verbs, and nouns from the original text. In Step2, patients reported that they felt uncomfortable with the Japanese version words such as “numb” and “stiffness” and felt that it might be difficult to describe their symptoms accurately. In Step3, we readjusted the translation to be more concise and closer to common Japanese language, and performed “Step1” again to ensure that the translation definitely retained the meaning of the original.

Conclusion A Japanese version of FACT has existed until now, but there was no Japanese version of FACT-B + 4, which adds four additional items to evaluate swelling and pain in the upper limbs. This time, we have created a Japanese version that has been approved by FACT.

keywords Breast cancer · FACT-B · FACT-B+4 · QOL

Background

Breast cancer is the most common malignant tumor in women, and according to the 2019 national cancer registry data in Japan, there were approximately 95,000 breast cancer patients that year, and the number of patients is increasing year by year. Breast cancer treatment is multidisciplinary and combines surgical therapy, drug therapy, and radiation therapy. As prognosis is improving due to developments in imaging technology and drug therapy, future challenges will be to improve cancer survivorship, such as improving post-treatment quality of life (QOL) and help patients return to society.

Some of the major treatment complications that trouble breast cancer survivors are surgery-related complications, such as lymphedema and postoperative pain. In particular, cases involving axillary dissection are accompanied by many side effects, such as pain due to causalgia, lymphedema caused by intercostobrachial nerve damage, limited shoulder movement, and numbness. These complications not only cause pain and functional impairment, but also cause mental stress and significantly impair daily living activities [1–6]. It has been reported that lymphedema occurs in 5.6% of patients who undergo sentinel lymph-node biopsy, and in 20% of patients who undergo axillary dissection, and a meta-analysis has also shown that patients who undergo dissection are approximately four times more likely to develop lymphedema [7, 8]. Treatment for lymphedema includes compression therapy with elastic garments and bandages, manual drainage, and lymphatic anastomosis, but none of these methods is very effective, and many patients suffer from lymphedema for a long time after surgery. As far as we know, there are no prospective studies comparing QOL considering lymphedema in patients who underwent sentinel node biopsy and axillary dissection, yet axillary dissection clearly increases the rate of lymphedema and thus decreases QOL.

In recent years, clinical studies have examined new surgical techniques for prevention of lymphedema, such as reducing the extent of axillary dissection [9, 10], sentinel node biopsy-guided axillary dissection in patients with negative lymph nodes after preoperative chemotherapy [11, 12], and tailored axillary surgery [13–18]. However, the long-term outcome of lymphedema incidence, and the extent to which these procedures improve the patient's QOL, are unclear. In addition, there are still cases that require lymphatic dissection, and prevention of lymphedema and early intervention for lymphedema is a future challenge, for which a scale to determine the impact of lymphedema is needed [1, 19].

The Functional Assessment of Cancer Therapy (FACT) questionnaire is often used to assess QOL as a measure of the overall health of cancer patients [20]. Other current methods for assessing patient QOL include the SF-36, DASH, and the EORTC QOL-C30. These are self-report questionnaire tools for determining arm and shoulder disability and the impact of lymphedema on physical, functional, and social aspects. However, there has been concern that these assessment tools may not adequately assess breast cancer-related lymphedema, upper limb dysfunction, and sensory impairment. [21–24]. Concerns that this did not accurately reflect the QOL of cancer patients led to the creation of the FACT-B, which focused more on breast cancer treatment, and the FACT-B + 4, which included four additional questions on arm mobility [25–27]. FACT-B + 4 has been translated and used in 27 countries around the world for the evaluation of postoperative lymphedema in breast cancer. However, there is no Japanese translation of FACT-B + 4.

Therefore, we initiated the translation of the FACT-B + 4 in accordance with established translation processes, and report that we have verified the linguistic validity and created a Japanese version of the FACT-B + 4 which has been approved by FACT.

Methods

Overview

The translation process was prepared and approved in cooperation with the “FACIT Trans Team (FACIT)” in accordance with international guidelines for translation procedures. The translation process consisted of three steps: (1) forward translations, back translations, and preparation of a provisional Japanese version; (2) pre-testing with the help of five breast cancer patients; and (3) revisions based on pre-test results and clinical perspectives, and final approval. The Japanese translation was created after linguistic validation of the Japanese version (Table 1).

The implementation period was from September 2022 to June 2023, and all authors of this paper were involved to the same extent in the review of the forward translation and the preparation of the Japanese draft, the review of the back-translation and the preparation of the tentative Japanese translation, the review of the pre-test results, and the proposal of the final Japanese translation.

Table 1 The translation process follows the international translation guidelines provided by the FACIT Trans Team

1. Forward translation; Translate from English into Japanese and this translation should be provided by a native Japanese
2. Reconciler; Once you have Fwd1 and Fwd2 translations, you'll need to send it to a third translator. He is also a native Japanese speaker, who will review the English source and the two forward translations and either choose one of the translations or choose a new translation, depending on what that person thinks is most appropriate
3. Back translation; Send the reconciler version only to a fourth translator (do not send the English original), who will provide a back translation (BT) of the item from Japanese back into English. The back-translator should be a native English speaker, if possible
4. FACIT Comments; They will review the steps, as well as the back translations, and provide FACIT comments
5. Review FACIT Comments and Finalized Translation
6. Literal Back translation of final; This is meant to be word-for-word translation: the English translation of the Final that upholds the exact or primary meaning of each word used in the item
7. Polished Back translation of final; This is meant to be the English translation of the Final that reflects what the item is saying in essence. This is what patients who speak the target language will understand when they read this item
8. Harmony check, Debrief notes and Post Test Final

Forward translation, back-translation, revision, and preparation of a tentative Japanese version

After the creation of the Japanese draft through forward translation, back-translation, and discussions between the developers of the original version and our research team, the Japanese draft was approved by FACT in June 2023.

First, two native Japanese speakers independently prepared Japanese translations of FACT-B + 4. A third translator created a temporary forward translation based on these Japanese translations. FACIT required that “The back-translator should be a native English speaker”. Therefore, we asked two people who were based in the U.S. and familiar with the English language to be the back-translators. For the back-translation, the original English text was withheld, and only the Japanese translation determined by forward translation was disclosed to them, and they back-translated the Japanese text into English.

The results were returned to FACT and evaluated by the secretariat as to whether the back-translated English deviated from the original version or not. Based on the results, the Japanese version was reviewed and revised by the co-authors, and a Japanese translation was prepared in response to FACT's review. Then, the Japanese translation was prepared in response to the FACT review, and a literal back-translation (“a word-for-word translation: the English translation of the Final that upholds the exact or primary meaning of each word used in the item”) and a polished back-translation (“an English translation of the Final that reflects what the item is saying in essence. This is what patients who speak the target language will understand when they read this item”). The Japanese version was completed, and this

process was repeated for all revisions of the Japanese draft, and a provisional Japanese translation was prepared.

Harmony check, debrief notes, and post-test final version

Cognitive debriefing was conducted as a pre-test for potential users of the tentative Japanese version. Cognitive debriefing is an interview process to confirm that the meaning of the questions is understood and culturally acceptable, and was conducted by the principal investigator through individual interviews with five breast cancer patients who volunteered to participate in the study. Specifically, we asked the patients to rephrase the questions and choices in the tentative Japanese translation in their own words to confirm their understanding of the text and language, and to provide feedback on the difficulty of answering the questions and the difficulty of understanding the text.

Based on the results of the pre-test, the Japanese translation was subjected to a final check by FACT to ensure that it did not deviate from the purpose and meaning of the original version of FACT-B + 4, and received final approval for use in clinical studies.

Results.

We worked with FACIT to translate the text, using spreadsheets of words created based on international translation guidelines (Fig. 1). The steps of the translation process and the results are shown in Fig. 2. In this section, the process of translation is illustrated using the phrase “Movement of my arm on this side is painful” from FACT-B + 4 as an example.

FACT-B+4-Greek-III

Note to translators: this questionnaire is a general quality of life questionnaire that will be answered by both women and men. Please be gender inclusive (both masculine and feminine) throughout.

Also, please keep in mind that the recall period is the past 7 days and that the responses to the questions are “not at all,” “a little bit,” “somewhat,” “quite a bit,” and “very much.”

Q6	
Eng	On which side was your breast operation? Left / Right (please circle one)
Fwd 1	
REC	
BT	
FACIT Comments	(for FACIT use only!)
Rev	
Final	
Literal BT of Final	
Polished BT of Final	
Harmo Issues	(for FACIT/LC use only!)
Post Harmo Final	If different from original final. Please add rows below and provide “Polished” and “Literal” BT’s
Post Proofing	If different from original final.
Final	Please add rows below and provide “Polished” and “Literal” BT’s
Debrief. Notes	(for FACIT/LC use only!)
Post Test Final	If different from original final. Please add rows below and provide “Polished” and “Literal” BT’s

Fig. 1 We perform translation using this word spreadsheet

Forward translations

Two native Japanese speakers prepared Japanese translations of the questionnaire items. A third translator created a temporary forward translation based on these Japanese translations. As a result, it was decided that “I feel pain when I move the arm of the person who had the surgery” was appropriate.

Back translations

Since “The back-translator should be a native English speaker, if possible” was required for this course, we asked two persons who currently live and work in the United States for more than 7 years (with native-level English, of course) to perform the back-translation. The original English text was withheld, and only the Japanese translation determined by forward translation was made available to them, and they back-translated it into English. As a result, a back-translation of “There is pain when you move the arm on the side of the surgery”.

The results were returned to FACT and evaluated by the secretariat

All translations were requested to faithfully translate the original words, verbs, and nouns. In addition, difficulty with Japanese translations, such as “numb” and “stiffness”, and difficulty in paraphrasing the question sentences were reported. Based on these results, the co-authors reviewed and revised the Japanese version again, and the revised Japanese version was evaluated by FACIT with feedback. After that, a literal back-translation and a polished back-translation were prepared, and the revised translation was evaluated as a tentative translation without problem.

Harmony check

Considering the process that led to the creation of the provisional Japanese version of FACT-B + 4, FACIT requested a harmonization check to pilot test it with five breast cancer patients. To carry out the harmonization check, a pilot test was conducted with five breast cancer patients using the provisional Japanese version of FACT-B + 4. Because of they are recruited as volunteers, they were met without compensation. Afterward, they were asked to complete a questionnaire to verify its linguistic validity. We recruited volunteers from Okayama University Hospital who had

B10	
Eng	Movement of my arm on this side is painful
Fwd 1	手術をした側の腕を動かすと痛みがあります
Fwd 2	患側を動かすと痛みがある。
REC	手術をした方の腕を動かすと痛みがある。
BT	There is pain when you move the arm on the side of the surgery.
FACIT Comments	The JPN should be in the first person singular “when I move my arm”. Surgery is not present in the source. Please refer to item definitions for acceptable translation alternatives and try to remain as faithful to the source as possible while maintaining the natural flow of the language.
Rev	Following the comments, I changed the subject to first person singular and removed the word “surgery”.
Final	こちらの腕を動かすと痛みがある
Literal BT of Final	It is painful when I move my arm on this side
Polished BT of Final	There is pain when I move my arm on this side
Harmo Issues	(for FACIT/LC use only!)
Post Harmo Final	If different from original final. Please add rows below and provide “Polished” and “Literal” BT’s
Post Proofing Final	If different from original final. Please add rows below and provide “Polished” and “Literal” BT’s
Debrief. Notes	(for FACIT/LC use only!)
Post Test Final	If different from original final. Please add rows below and provide “Polished” and “Literal” BT’s

Fig. 2 This is the actual translation process of “Movement of my arm on this side is painful”

Table 2 Characteristic of patients who participated in this pilot test

	Age	Breast cancer side	Clinical stage	Subtype	Neoadjuvant chemotherapy	Breast surgery	Adjuvant therapy
1	49	Left	T1bN0M0	Triple negative	No	Bp+SNB	RT
2	43	Left	TisN0M0	Luminal	No	Bp+SNB	RT
3	49	Left	T2N0M0	HER2 positive	Yes	Bt+SNB	Trastuzumab
4	72	Left	T1cN0M0	Luminal	No	Bp+SNB	AI+RT
5	59	Right	T1cN1M0	Luminal	Yes	Bt+Ax	AI+CDK4/6

undergone breast cancer surgery and were willing to assist in the creation of the Japanese translation. A pre-test was conducted with the patients who agreed to participate in this project.

The characteristics of these patients are detailed in Table 2 and include the following: age, breast cancer surgery method, history of breast cancer drug therapy treatment, and years since breast cancer surgery.

Rows 3 - 15: Please enter all information English.			
パイロットテスト実施場所（国、都道府県市町村、場所名を記入してください）			
面接実施日 - dd/mm/yyyy			
患者の使用言語			
面接時の年齢			
性別（「男性」か「女性」を選択）			
出生国			
活動状況（以下の説明に基づき、患者さんに自身の活動レベルを評価していただきます）			
0.症状はなく、普段と同じように活動している 1.多少症状があるものの、昼間起きている間に床について休む必要は 2.床について休む必要があるのは、昼間起きている時間の50%以下である 3.昼間起きている時間の50%以上は床について休む必要がある 4.寝たきりである			
患者さんは指定されたすべての条件を満たしている（「はい」か「いいえ」を選択）			

面接担当者の注意事項	一般的な質問	患者さんの回答（「はい」か「いいえ」を選択）	英訳
質問票の中で、「わかりにくい」と回答された項目について患者さんに質問してください。できる限り回答者に協力して、わかりにくい項目をすべて記載するようにしてください。当該項目がわかりにくかった理由や、わかりにくいと感じた理由を尋ねてください。	質問票の項目の中でわかりにくいものはありませんか。「いいえ」の場合は、次の質問にスキップしてください。 わかりにくかった項目の番号を記入し、その理由を述べてください。また、どのように言い換えればよいと思いますか。 質問票の中にご自分とは無関係な項目、あるいは失礼だと感じた項目はありましたか。「いいえ」の場合は、次の質問にスキップしてください。 ご自分とは無関係な項目、あるいは失礼だと感じた項目の番号と、その理由を述べてください。また、どのように言い換えればよいと思いますか。 ご自分の病歴に関する事項で、ほかにもこの質問票に加えるべきだと思う項目はありますか。「いいえ」の場合は、次の質問にスキップしてください。 このアンケートにどのような項目を加えるべきだと思いますか。		

項目に関する質問

面接担当者の注意事項これから、いくつかの項目を特に取り上げて質問させていただきます。正しい回答と誤った回答というものはありません。単にあなたのご意見をお聞きしたいだけです。質問された表現がどのような意味をもつかを自分なりにお答えいただければ幸いです。この質問票は英文を邦訳したものです。訳文に問題があるかどうかを判断する際の助けとして、あなたのご意見を求めているわけです。同じような質問を繰り返し尋ねたり、わかりきったことと思われるような質問をしたりすることがあります。これは、あなたがわからないと思って尋ねているのでも、ひっかき問題を出しているのでもありません。質問票の項目に必要な修正を加えられるよう、これらの項目についてできる限り多くの情報を得ようとしていることを、どうぞご理解ください。

項目番号	項目	質問	患者さんの回答（日本語）	英訳
Q6	乳がんの手術をしたのはどちら側ですか？ 左/右（丸で囲んでください）	この項目の意味をご自分の言葉で説明してください。		
B10	手術	この項目のこの言葉はどのような意味だと思いますか。		
B11	こちらの図を動かすと痛みがある	回答としてどれを選びましたか。それはなぜですか。		
B12	痛み	この項目のこの言葉は何を指していると思いますか。		
B13	こちらの図の動く範囲は不十分だ	この項目の意味をご自分の言葉で説明してください。		
B14	こちらの図のしびれがある	回答としてどれを選びましたか。それはなぜですか。		
B15	しびれがある	この感傷を説明してください。		
B16	こちらの図に位置がある	回答としてどれを選びましたか。それはなぜですか。		
B17	位置	この感傷を説明してください。		

最後の質問

この質問票に関して他にご意見・ご提案があればお聞かせください。（「はい」か「いいえ」を選択）

このプロジェクトにご協力いただき、ありがとうございました。あなたのコメントは、本質問票の日本語版が正しく翻訳され、国際的に利用可能となるの

Fig. 3 The contents of the harmony check question

The contents of the questionnaire are shown in Fig. 3. The questions used in the harmony check were as follows, and included questions about the clarity of the Japanese text in the provisional Japanese version of FACT-B + 4, as well as questions about the respondents' interpretations

of the Japanese and the reasons for their answers in the questionnaire (Fig. 3).

Questions about the clarity of the Japanese text in the provisional Japanese version of FACT-B + 4.

•Did you find any of the items in the questionnaire difficult to understand?

•Did you find any items in the questionnaire that were not relevant to you or that you felt were rude?

Questions about the respondents' interpretations of the Japanese and the reasons for their answers.

•Q6: What do you think is the meaning of this item in the Japanese version of FACT-B + 4?

•Q6: Please explain in your own words the meaning of this item, what do you think this word surgery means?

•B10: Which of the following did you choose as your answer? Why is that? Pain: What do you think this word means?

•B11: Please explain the meaning of this item in your own words.

•B12: I have numbness in my arm on this side. Which of the following did you choose as your answer and why?

•B13: I have numbness on this side of my arm.

•B13: There is stiffness in this arm. Which of the following did you choose as your response? And explain this feeling.

As a result, the patients reported difficulty with Japanese translations, such as “numb” and “stiffness”, and difficulty in paraphrasing the questions. Finally, based on the preliminary test results, the original developer, the Japanese translation team, and the back-translation team reviewed the proposed revisions, made minor modifications to make the wording more concise and closer to everyday language, and created the final Japanese translation, which was approved by FACIT (Fig. 4). As a result, the Japanese version was approved for

use in the FACT-B + 4 website, and the Japanese version was serialized in the Language Availability section of the FACT-B + 4 website.

Discussion

There are several tools commonly used to assess upper limb function and quality of life (QOL), including Quick DASH, FACT-B + 4, EORTC QLQ-C30, and SF-36. Quick DASH and SF-36 are designed to assess upper limb impairment and disability in patients with upper limb problems or disorders affecting the upper limb, with a particular focus on upper limb-related pain, range of motion, and functional ability in daily living. In contrast, EORTC QLQ-C30 and FACT-B + 4 are comprehensive tools used to assess the QOL of breast cancer patients, encompassing multiple questions that address physical, social, emotional, and functional aspects. FACT-B + 4 is an enhanced version of FACT-B, specifically modified to more accurately assess side effects related to breast cancer surgery, such as upper limb swelling and pain.

In accordance with international guidelines for translation procedures, we created the Japanese translation together with the original developer team (FACIT) and obtained approval for use of the Japanese version of FACT-B + 4. On the FACT-B + 4 website, they mention that “Available translations of the FACT-B + 4 can be obtained by registering for permission. Users are not permitted to translate the

FACT-B + 4 (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

ADDITIONAL CONCERNS		Not at all	A little bit	Some-what	Quite a bit	Very much
B1	I have been short of breath.....	0	1	2	3	4
B2	I am self-conscious about the way I dress.....	0	1	2	3	4
B3	One or both of my arms are swollen or tender.....	0	1	2	3	4
B4	I feel sexually attractive.....	0	1	2	3	4
B5	I am bothered by hair loss.....	0	1	2	3	4
B6	I worry that other members of my family might someday get the same illness I have.....	0	1	2	3	4
B7	I worry about the effect of stress on my illness.....	0	1	2	3	4
B8	I am bothered by a change in weight.....	0	1	2	3	4
B9	I am able to feel like a woman.....	0	1	2	3	4
B10	I have certain parts of my body where I experience pain....	0	1	2	3	4
Q6	On which side was your breast operation? Left Right (please circle one)					
B10	Movement of my arm on this side is painful.....	0	1	2	3	4
B11	I have a poor range of arm movements on this side.....	0	1	2	3	4
B12	My arm on this side feels numb.....	0	1	2	3	4
B13	I have stiffness of my arm on this side.....	0	1	2	3	4

FACT-B + 4 (Version 4)

過去7日間を対象に、自分の回答として最も適した番号を各項目につき一つ選び、○で囲んでください。

その他心配な点		全くあてはまらない	わずかにあてはまる	多少あてはまる	かなりあてはまる	非常にあてはまる
B1	息切れがする.....	0	1	2	3	4
B2	どのような服をどう着るか、人目が気になる.....	0	1	2	3	4
B3	片方あるいは両方の腕に腫れまたは痛みがある.....	0	1	2	3	4
B4	女性としての魅力があると思う.....	0	1	2	3	4
B5	脱毛に悩まされている.....	0	1	2	3	4
B6	家族の他の者がガンにかかるのではないかと心配である.....	0	1	2	3	4
B7	ストレスがたまると病気に影響が出るのではないかと心配である.....	0	1	2	3	4
B8	体重の変化に悩んでいる.....	0	1	2	3	4
B9	女であると感じることができる.....	0	1	2	3	4
B10	身体の一部に痛みがある.....	0	1	2	3	4
Q6	乳がんの手術をしたのはどちら側ですか? 左 / 右 (丸で囲んでください)					
B10	こちらの腕を動かすと痛みがある.....	0	1	2	3	4
B11	こちらの腕の動く範囲は不十分だ.....	0	1	2	3	4
B12	こちら側の腕にしびれがある.....	0	1	2	3	4
B13	こちらの腕に硬直がある.....	0	1	2	3	4

Fig. 4 Comparison of the Japanese version of FACT-B + 4 approved by FACIT and the original version of FACT-B + 4

FACT-B + 4 without permission from FACIT.org. Translations must undergo a rigorous methodology under the guidance of FACIT.org which includes multiple translators, quality assurance steps and cognitive interviews with patients.” Including the Japanese version, translations have already been created in 29 languages (FACT-B + 4 (facit.org)).

In creating the Japanese translation version, there were many instances where it was pointed out that the translation we considered appropriate did not directly translate the original language of the FACT-B + 4, and it was considered most important that the words of the tool be translated directly into Japanese, so that there would be no differences among the tools rather than just making the translation easy to understand. We found that receiving direct feedback from the potential target population of the scale through pre-testing was extremely important to ensure the linguistic validity of the translation. In other words, it was [21] and polished translation, which is carefully adapted to the cultural background and everyday terminology of the country in question.

Japanese have compulsory education up to junior high school, and it is considered easy for them to understand the Japanese translation of the FACT-B + 4 and answer the survey items. Therefore, when we performed the pre-test on five breast cancer patients to determine whether there were any items on the questionnaire that were difficult to understand, all answered that there were no items that were difficult to understand. However, on the question “What do you think this word means” to verify linguistic validity, all participants seemed to give similar answers to the meanings of everyday words, such as “surgery” and “pain,” but for words that are not often used in everyday life, such as “numbness” and “stiffness,” they gave abstract answers. This included onomatopoeia, such as “tingly” and “prickly” for “numbness,” and for “stiffness,” they gave answers that included subjective opinions, such as “uncomfortable, painful, difficult to move”.

We need to pay attention that this FACT-B + 4 Japanese version has been verified for linguistic validity. In other words, although this FACT-B + 4 Japanese version is evaluated as adequately reflecting the original text linguistically, it may not yet be fully proven whether the scale obtained from this Japanese version shows the same scale as the FACT-B + 4 in other countries. In the future, it will be necessary to conduct validation studies and examine the consistency with the original English version. In other words, to fully ensure that there is cross-cultural validity of the Japanese version of the scale developed in this study, it will be necessary to secure a certain sample size and conduct statistical validation, including an examination of the distribution of SCRQoL and its related factors. In addition, the weighting of the questions may be unique to the Japanese version, which is a topic for future research.

Conclusion

In accordance with international guidelines for translation procedures, a Japanese translation of FACT-B + 4 was prepared, which was approved by the original developer. The importance of obtaining direct feedback from users was confirmed in ensuring the linguistic validity of the translation. We believe that it is important to conduct a validation study of the Japanese translation by conducting a prospective study in the future.

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Declarations

Conflict of interest Dr. Kaori Terata has payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events from Astrazeneca, Lilly, Chugai, Pfizer, and Daiichisan-kyo. Other authors have no conflict of interest.

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