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Original Article

Development and validation of a Chinese translated questionnaire: A single simultaneous tool for assessing gastrointestinal and upper respiratory tract related illnesses in pre-school children

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التقييم المتزامن للأمراض ذات الصلة بالجهازين الهضمي والتنفسي في الأطفال الصغار ويمكن تطبيقها على سكان ماليزيا الصينيين والدول الأخرى الناطقة بالصينية.

الكلمات المفتاحية: التنمية؛ إسهال؛ الاستبانة؛ الأمراض ذات الصلة بالجهاز التنفسي؛ التحقق من الصحة

الملخص

أهداف البحث: الأطفال عرضة للأمراض المعدية التي تأتي من أقرانهم في الحضانات، ورياض الأطفال، ومراكز الرعاية النهارية. بينت بعض الدراسات أن تناول الكائنات الدقيقة النافعة يقلل من عدد الإصابات بتلك الأمراض، الأمر الذي يؤدي إلى التقليل من الغياب ومن تناول المضادات الحيوية. مع التوجه للتركيز الأقل على والتفضيل الأقل لأخذ عينات الدم من الصغار، فإن الكثير من البيانات القابلة للقياس الكمي يتم الحصول عليها فقط من الدراسات الاستقصائية والاستبيانات. يبلغ ٢٥٪ من سكان ماليزيا من أصل صيني. استهدفنا تطوير أداة واحدة يمكن من خلالها إجراء تقييمات متزامنة لأمراض ذات صلة بالجهازين الهضمي والتنفسي لدى الأطفال الصينيين الصغار.

طرق البحث: تمت ترجمة الاستبانات المصادق عليها باللغة الإنجليزية، التي تشمل بيانات متعلقة بالديموغرافيا والسجلات الصحية الشهرية إلى اللغة الصينية. وتمت المصادقة على نسختي الترجمة؛ من الصينية إلى الإنجليزية ومن الإنجليزية إلى الصينية.

النتائج: أظهرت الاستبانات الديموغرافية والشهرية الصحية، مؤشري صلاحية مستوى كلي للبند مستواهما ٠.٩٩و ٠.٩٧على التوالي، بينما أظهرت النسخ الصينية المترجمة مؤشري صلاحية مستوى كلي للبند مستواهما ٠.٩٧ و٠.٩٨على التوالي. كما تم الحصول على مؤشر صلاحية عملية الاستجابة للبند بمستوى ١.٠٠ لهذه الاستبانة من ٣٠ من المجيبين مما يدل على أن البنود كانت واضحة ومفهومة.

الاستنتاجات: أظهرت هذه الدراسة مستوى جيدا من مؤشر الصلاحية في النسخة المترجمة الصينية، مما يدل على أنها أداة صالحة وموثوق بها لاستخدامها في

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Abstract

Objectives: Children are prone to contagious illnesses that come from peers in nurseries, kindergartens, and day care centres. The administration of probiotics has been reported to decrease the episodes of such illnesses, leading to decreased absences and consumption of antibiotics. With less emphasis on, and preferences for, blood collection from young subjects, quantifiable data are merely obtained from surveys and questionnaires. Malaysia has a population which is 25% ethnic Chinese. We aimed to develop a single tool that enables simultaneous assessments of both gastrointestinal and respiratory tract-related illnesses among young Chinese children.

Methods: The English-language validated questionnaires using data about demographics and monthly health records were translated into the Chinese language. Both forward and backward translated versions were validated.

Results: The developed demographic and monthly health questionnaires showed an overall item-level content validity index (I-CVI) of 0.99 and 0.97, respectively; while the translated Chinese versions showed I-CVI of 0.97 and 0.98, respectively. Item-level of response process validity index of 1.00 for this questionnaire was obtained from 30

respondents inferring that the items were clear and comprehensible.

Conclusions: This study showed acceptable levels validity in the Chinese translated version, illustrating a valid and reliable tool to be used for simultaneous assessment of gastrointestinal and respiratory tract-related illnesses in young children that is applicable for Malaysia's Chinese population and other Chinese-speaking nations.

Keywords: Development; Diarrhoea; Questionnaire; Respiratory tract-related illnesses; Validation

Introduction

Malaysia has a population which is 25% ethnic Chinese, while the Chinese language is currently the second most spoken in the world. The numbers of Chinese researchers are increasing by three-fold from 0.5 million back in 1995 until 1.5 million researchers in 2007[1] with publications among Chinese researchers increasing 64-fold in peer-reviewed scientific papers.[2] China also marks the fastest growth of 18.7% in global filings of intellectual property in 2014−2015.[3] Among studies registered globally, almost 90% of the clinical trials have been conducted in China.[4] Thus, a translated Chinese version would benefit many. In this study, we aimed to develop a single tool that enables simultaneous assessments of both gastrointestinal and respiratory-related illnesses among preschool or young children in Chinese populations.

Gastrointestinal illnesses among infants and young children are a worldwide concern, with over two million hospitalizations of children under five years of age for diarrhoea where it is commonly defined as three or more loose or watery stools in the last 24 h. However, respiratory illnesses are currently the most common acute diseases in children with no available effective treatments or prophylaxes.[5] In Malaysia, diarrhoea and seasonal respiratory illness are among the most common diseases found to affect children, with diarrhoea being identified as one of the top five leading causes of death in children aged 1−19 years in the 1970s−1980s.[6−8] Children who are attending day care centres are at 1.5−3.0 times higher risk of gastrointestinal and respiratory tract infections than those cared for at home or in small family care groups.[9]

Five guidelines are routinely adopted in translation processes: preparation, translation, pretesting, revising and documentation.[10] A desired questionnaire is developed for data collection prior to translation. Pretests of the developed questionnaires aim to identify concepts or constructs that are specific to a certain language or culture (emic). Based on the pretest results, the questionnaire is revised to avoid conceptual bias and to achieve construct equivalence which represents the same underlying latent concept in different languages. Final decisions on revisions are made and the translated documents are then finalized and documented.

There are five general sources of evidence to support the validity of any research tools: 1) content, wherein items of research tools completely represent the measured outcomes; 2) response process, wherein subjects understand the items of research tools correctly; 3) internal structure, wherein acceptable reliability and factor structure is demonstrated; 4) relations to other variables, wherein correlation exists among other tools that measure similar outcomes; and, 5) consequences, wherein interpretation of scores justify a difference.[11,12] In this study, we investigated two sources of evidence of the newly developed instrument, namely content validity and response process validity.

Materials and Methods

Two main phases were involved: i) Phase I: development of tools/instruments; and ii) Phase II: translation and validation (Figure 1). In the development stage, relevant contents and information related to diarrhoea and respiratory-related illnesses were identified, generated, written, and assembled into a usable instrument. This was performed via focus groups, expert opinions, clinical observations, theory, literature reviews, and interviews.[13] The translation and validation processes involved expert reviews on the developed contents.[14] The finalized version was subsequently pretested among the targeted population through face validation. The final version of the developed questionnaires will be used in a clinical study that has been approved by the Human Ethics Committee of Universiti Sains Malaysia (USM) (approval number USM/JEPeM/14100354) based on the Declaration of Helsinki, and was registered under ClinicalTrials.gov (registration number NCT02434042).

Phase I: Development and validation of questionnaires

Development of questionnaires

We aimed to develop two questionnaires, namely Basic Lifestyle and Demographic Questionnaire (BLDQ) and Monthly Health Questionnaire (MHQ) (Supplementary files S1−S4). BLDQ was developed to collect demographic information such as age, sex, BMI, and history of illnesses. MHQ was designed for gathering information on monthly health for occurrences of gastrointestinal and/or respiratory illnesses. A focus group was created that comprised eight students, all guided by research team members to express their ideas and opinions, that were screened by the research team members to gather relevant ideas. Information was also gathered from clinical observations to describe all the symptoms occurring during diarrhoea and respiratory-related illnesses.

Literature reviews were used to construct symptoms for respiratory-related illnesses: namely, rhinitis, nasal blockage, sore throat, cough, common cold, and fever[15] and symptoms for acute diarrhoea: namely, fever, bloody stools and vomiting.[16]

A group of experts, including the sponsor of the study, colleagues and clinicians, reviewed the gathered information, commented, and determined new and important information that was absent, but needed, and/or removal of non-relevant
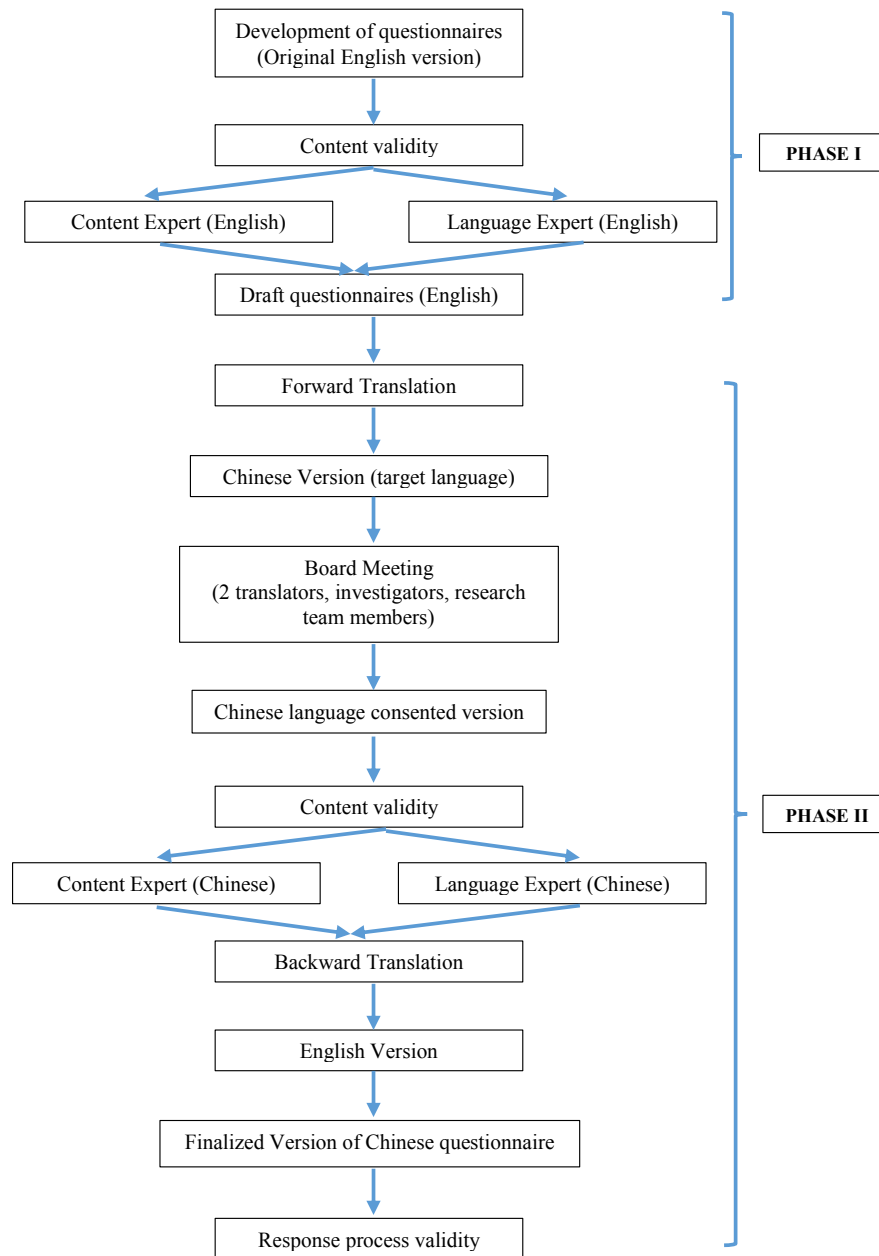
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┌─────────────────────────────────┐
│  Development of questionnaires   │
│    (Original English version)    │
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                ▼
┌─────────────────────────────────┐
│         Content validity         │
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        ↙                 ↘
┌──────────────────┐  ┌──────────────────┐
│ Content Expert   │  │ Language Expert  │
│   (English)      │  │    (English)     │
└──────────────────┘  └──────────────────┘
        ↘                 ↙
┌─────────────────────────────────┐
│  Draft questionnaires (English)  │
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PHASE I

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┌─────────────────────────────────┐
│        Forward Translation       │
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                ▼
┌─────────────────────────────────┐
│   Chinese Version (target        │
│        language)                 │
└─────────────────────────────────┘
                │
                ▼
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│          Board Meeting           │
│ (2 translators, investigators,   │
│    research team members)        │
└─────────────────────────────────┘
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                ▼
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│  Chinese language consented      │
│           version                │
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│         Content validity         │
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┌──────────────────┐  ┌──────────────────┐
│ Content Expert   │  │ Language Expert  │
│   (Chinese)      │  │    (Chinese)     │
└──────────────────┘  └──────────────────┘
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┌─────────────────────────────────┐
│       Backward Translation       │
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│          English Version         │
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│  Finalized Version of Chinese    │
│         questionnaire            │
└─────────────────────────────────┘
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┌─────────────────────────────────┐
│     Response process validity    │
└─────────────────────────────────┘
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PHASE II

Figure 1: Process flow of questionnaire development. Schematic diagram of the development of questionnaires in English (Phase I) and translation and validation of questionnaires in Chinese (Phase II).

information from the instrument.[14] Responses and feedback were collected, summarized and the questionnaire was revised, producing a draft of BLDQ and MHQ in English.

Content validity (English version)

The questionnaires in English were first pretested among a small group of experts (10 experts), that are well-versed in English and have expertise on the contents of the question-naires. All experts were required to independently rate each question and item with "YES" and "NO", where "YES" was given a score of one and "NO" was given a score of zero according to a binary scoring system.[17] The content validity index (CVI) was calculated in two forms; I-CVI (Item-level Content Validity Index) for individual items, where the number of experts answering "YES" was divided by the

number of total experts involved, and S-CVI (Scale-level Content Validity Index) for the overall scale, where I-CVI for all items are summed. S-CVI are computed in two ways; namely, S-CVI/Ave (averaging calculation method) and S-CVI/UA (universal agreement calculation method). S-CVI/Ave was calculated from total I-CVI value divided by the total number of items; whereas, S-CVI/UA was calculated by summing the number of items that had 100% agreement and dividing that by the total number of items.[18]

Phase II: Translation and validation of questionnaires

The translation process to produce the questionnaires in two languages (source and target) utilizes a decentring technique involving paraphrasing and translation between

source and target languages.[19] Forward- and backward-translations were applied in the translation process for both questionnaires. The BLDQ and MHQ in English were translated into Chinese by two independent translators: a bilingual researcher and a qualified linguistic expert. In order to achieve high quality translation, the reliability, fluency and appropriateness of the translated instrument were heavily emphasized.[20]

Forward translation

Forward translation involved translating the English questionnaires into Chinese (target language) by two certified independent bilingual translators. One of the translators was knowledgeable about health care terminologies and the content of the questionnaires in both languages, while the other translator has such capabilities in addition to proficiency in informal phrases, slang and jargon, idiomatic expressions and emotional terms commonly used in the Chinese community.[20] These are needed to comprehensively envelop coherent medical aspects with cultural nuances of informal conversations. The translated Chinese questionnaires were presented at the board meeting, for comparison with the original English version to identify any ambiguities and discrepancies of words, sentences and meanings. Ambiguities and discrepancies were discussed and resolved using a committee-consensus approach to produce a reconciled version of the translated questionnaire. All revisions made were documented.

Content validity (Chinese version)

The translated questionnaires (in Chinese) was subsequently pretested by another 10 experts who are well versed in Chinese and knowledgeable about the content of the questionnaires. Emphases were given to appropriateness of content, and language validity for wording, sentence, style and communication effects.[10] All experts were required to independently rate each question and item with "YES" or "NO", where scores were given according to a binary scoring system as described earlier. The content validity index (CVI) was calculated based on the comments and feedback from the experts.

Back translation

Upon amendment, the translated questionnaires (Chinese; target language) were subsequently translated backward into the source language (English). Two independent translators with qualifications as described previously were recruited, with the exception that they are well-versed in English (source language) instead, to translate the Chinese versions of the questionnaires into English. They were completely blind to the original version of the questionnaires and the questionnaires being back-translated.[21] Two different versions of English-translated questionnaires were discussed and reconciled for any discrepancies and ambiguities. The Chinese version was revised and modified. All revisions and modifications were done by consensus among all the translators, investigators and research team members. All revisions made were documented. Final versions of the questionnaires in English and Chinese were pretested for response process validity.

Response process validation

Response process validity is also known as surface validity, logical validity or appearance validity.[22] It was defined as "Do respondents understand the questions to mean what we intend them to mean?".[23] It was carried out by the target group and technically untrained observers who determined the validity of the measurement procedure or domains.

Response process validation was assessed by 30 volunteers recruited from the target population who will be responding to this instrument. A written informed consent was obtained from all the volunteers before assessment. Those recruited were parents and primary caregivers of pre-school children. They evaluated the instructions, response format and the items of questionnaires for clarity. Similar to content validation, all 30 volunteers were required to independently rate each question and item with "YES" or "NO", where scores were given according to a binary scoring system as described earlier. Those who rated "NO" were requested to provide suggestions for amendment and clarity. All feedbacks were Response process Validity index was calculated to determine the quality of the translated questionnaires.

Results

Phase I: Development and validation of questionnaires

Development of questionnaires

Literature search indicated that symptoms commonly associated with respiratory-related illnesses were rhinitis, nasal blockage, sore throat, cough, common cold, and fever. Discussions from focus groups yielded additional symptoms such as runny nose, sneezing, wheezing, hoarseness, mucus production and vomiting, while acute diarrhoea included main symptoms of fever, bloody stools, and vomiting. Further discussions from focus groups yielded additional symptoms such as abdominal pain, dehydration, nausea, loss of appetite, dizziness, and rectal pain. Colour of stool during diarrhoea was also included in the questionnaire as colour changes may occur indicating other underlying causes of diarrhoea.

Initially, the administration of antibiotics was set as an exclusion criterion to exclude subjects who were administered antibiotics prior to the trial. However, based on the opinions of experts, such an exclusion criterion was deemed unethical as children should not be forbidden to take antibiotics when it has been prescribed and is necessary. Thus, this exclusion criterion was removed. Initially, the duration (number of days) of symptoms for both diarrhoea and respiratory-related illnesses were not included. Upon discussion with focus groups and opinions from experts, this information was deemed important and has thus been included.

Content validity (English version)

The contents of both questionnaires (BLDQ (S1 File); MHQ (S2 File)) were validated for content and language by 10 experts. The BLDQ consisted of 38 items in four different sections (Table 1 (i)). Some minor modifications have been performed upon reconciliation of the draft questionnaires. In section C (Child's health details), the phrase "Participant's health details" was changed into a more specific term

"Child's health details". In section D (Child's lifestyle), the phrase "Currently have pets or small animals at home" was changed to "Currently have pets or small animals at home? If yes, please state" for better clarify and specificity.

Content validation produced an overall validity index of over 0.80, with a universal agreement index (S-CVI/UA) of 1.00 for both sections A and B, and 0.91 and 0.86 in sections C and D, respectively. An average index (S-CVI/Ave) of 1.00 for sections A and B, and 0.99 for sections C and D were obtained (Table 1 (i)). The MHQ comprised of 72 items categorized into four sections (Table 1 (ii)). An average index (S-CVI/Ave) of over 0.80 was obtained from all four sections. A universal agreement index (S-CVI/UA) of 0.40 was obtained for section A, and 1.00, 0.98 and 0.83 for sections B, B (I) and B (II), respectively.

Phase II: Translation and validation of questionnaires

Forward and backward translation

The reconciliation process indicated that the forward translated Basic Lifestyles and Demographic Questionnaire did not require further modifications during back-translation (back to English). The five items in the Monthly Health Questionnaire required minor modifications and rephrasing during the reconciliation of the forward translation. Meanwhile, no adjustment was needed in either questionnaire based on a comparison between the back translated and the original English versions.

Content validity (Chinese version)

Content validation was also conducted for the forward translated questionnaires (Chinese version). In the BLDQ (S3 File), content validation produced an overall validity index of over 0.80, with S-CVI/UA of 1.00 for all four sections A, B, C

and D. An index of 1.00 for S-CVI/Ave was obtained for all four sections as well (Table 2 (i)). Meanwhile, the S-CVI/Ave index of over 0.80 was obtained from all four sections for the MHQ (Table 2 (ii)). S-CVI/UA index of 0.80 was obtained for section A, and 1.00, 0.93 and 0.94 for sections B, B (I) and B (II), respectively.

Response process validity

Response process validation was performed using the finalized version of the translated questionnaires with a total of 30 volunteers from a target population who were parents with pre-school children and literate in Chinese. Similar to content validity, computation of response process validity also included Item-level Validity Index (I-VI), Scale-level Validity Index (S-VI), S-VI/UA, S-VI/Ave and the average proportion of items judged clear/comprehensible across 30 respondents. All items showed an index of 1.00 for all the sections of all questionnaires studied (Table 3).

Discussions

Cross-cultural translation and validation involve more than a literal translation that is crucial to produce a valid and suitable questionnaire or instrument, applicable in different target populations from different cultures and languages.[24] A new questionnaire or instrument can be adapted from the established ones or developed from scratch. Here, we developed a new questionnaire that is suitable to measure occurrences of diarrhoea and respiratory-related illnesses among children in Malaysia. During development of the questionnaires, ideas and contents were gathered from expert opinions, literature reviews, and discussions in focus groups.

The translation process was challenging as the words in the source language have no equivalent words in the target

Table 1: Content validity index for (i) Basic Lifestyle and Demographic Questionnaire (BLDQ) and[26] (ii) Monthly Health Questionnaire (MHQ) in English version by ten respondents.

Items	(i) BLDQ (38 items) section				(ii) MHQ (72 items) section			
	A	B	C	D	A	B	B (I)	B (II)
S-CVI/Ave	1.00	1.00	0.99	0.99	0.88	1.00	0.99	0.93
S-CVI/UA	1.00	1.00	0.91	0.86	0.40	1.00	0.98	0.83
Average proportion of items	1.00	1.00	0.99	0.99	0.88	1.00	0.99	0.93

S-CVI (Scale-level Content Validity Index); UA (Universal Agreement calculation method); Ave (Averaging calculation method); S-CVI/UA (Scale-level Content Validity Index, Universal Agreement calculation method); S-CVI/Ave (Scale-level Content Validity Index, Averaging calculation method); Average proportion of items judged relevant across the ten respondents.

Table 2: Ratings on item scale by ten respondents for the translated BLDQ and MHQ in Chinese.

Items	(i) BLDQ (38 items) section				(ii) MHQ (72 items) section			
	A	B	C	D	A	B	B (I)	B (II)
S-CVI/Ave	0.98	0.96	0.98	0.97	0.94	1.00	0.97	0.99
S-CVI/UA	0.80	0.87	0.82	0.86	0.80	1.00	0.93	0.94
Average proportion of items	0.98	0.96	0.98	0.97	0.94	1.00	0.97	0.99

S-CVI (Scale-level Content Validity Index); S-CVI/UA (Scale-level Content Validity Index, Universal Agreement calculation method); S-CVI/Ave (Scale-level Content Validity Index, Averaging calculation method) UA (Universal Agreement calculation method); Ave (Averaging calculation method).

Table 3: Response process validity index for the BLDQ and MHQ in Chinese.

Items	(i) BLDQ (38 items) section				(ii) MHQ (72 items) section			
	A	B	C	D	A	B	B (I)	B (II)
S-VI/Ave	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
S-VI/UA	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Average proportion of items	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00

Scale-level Validity Index (S-VI); Universal Agreement calculation method (S-VI/UA); Averaging calculation method (S-VI/Ave); average proportion of items judged clear/comprehensible across 30 respondents.

language, while the meaning of the original version needed to be preserved and retained. The BLDQ and MHQ were translated by local Chinese linguistic experts, with cooperation from the investigators, to assure that the Chinese translations retained the original meaning of the English-version questionnaires. Content validations showed a good, clear understanding of the contents and the languages used. This indicated that the translation process was culturally-valid and reliable to be used with the target population. Reliability refers to the accuracy of a translated version from the perspective of semantic equivalence, technical accuracy, and textual completeness. The translated version should be stylistically appropriate, culturally acceptable by the target population and should have the same communicative effect as the source language. A content validity index of 0.8 or higher for a new tool is deemed acceptable and applicable.[17,25] In this study, the BLDQ and MHQ showed an overall CVI of over 0.95, indicating the contents were highly relevant to represent the measured outcome for the Chinese population. The original questionnaires (English) and the translated version (Chinese) showed a high CVI, indicating similar patterns and good agreement between both English and Chinese versions. The back translated version (from Chinese back-translated to English) only required minor amendments, indicating clarity and the absence of discrepancies and/or ambiguities.

A response process validity index of 1.0 obtained from the pilot testing involving 30 respondents that represented future potential subjects (parents of pre-school children), indicated the suitability for use among the Chinese-speaking population. In addition, the subjects involved in this process were randomly selected, thus minimizing selection bias.

Conclusions

To our knowledge, both BLDQ and MHQ are the first instruments that are developed, translated and validated in Chinese, to collect children's background information and to evaluate the occurrence and prevalence of diarrhoea and respiratory-related illnesses in young children during probiotic administration. This instrument is also simple, easily understood and could be applied to subjects from other age groups with minimal alterations.

Abbreviations: BLDQ, Basic Lifestyle and Demographic Questionnaire; MHQ, Monthly Health Questionnaire; I-CVI, item-level content validity index; S-CVI, Scale-level Content Validity Index; UA, Universal agreement calculation method; Ave, Averaging calculation method; S-CVI/UA, Scale-level content validity index, universal agreement calculation method; S-CVI/Ave, Scale-level content validity index, averaging calculation method.

Conflict of interest

The authors declare no competing financial or conflict of interest.

Authors' contribution

MTL, JZX and ASYL conceived and designed the questionnaires. ASYL, SBC and MTL performed the recruitment and pilot study. ASYL, MSBY and YYL analysed the data. ASYL, MTL and MSBY wrote the manuscript.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jtumed.2017.11.003.

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