PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Reliability and Validity of the Chinese version of the Test for Respiratory and Asthma Control in Kids (TRACK) in preschool children with asthma: a prospective validation study
AUTHORS	Zhang, Jing; Zhao, Liebin; Zhao, Deyu; Chen, Zhimin; Li, Shenghui; Zhang, Hao; Zhang, Lei; Yuan, ShuHua; Tang, Mingyu; Wu, YuFen; Zhong, Wenwei; Xu, Juan; Zhao, Li; Liu, Shi Ying; Zhang, Lei; Hong, Jianguo; Yin, Yong

VERSION 1 - REVIEW

REVIEWER	Dong In Suh Associate Professor, Seoul National University College of Medicine, South Korea
REVIEW RETURNED	06-Aug-2018

GENERAL COMMENTS	This is a well-organized manuscript that appropriately focused on the validity and reliability of the Chinese version TRACK questionnaire. This study consisted of two main procedure, linguistic validation with cognitive debriefing and the clinical reliability/validity evaluation. Although the latter part is well described and analyzed, the former part, especially the cognitive debriefing, needs to be described more in detail, instead of stating "No change was made after the pre-testing." According to the original version of TRACK in English, every brand-name of systemic steroid containing drugs was listed. Does the modified Chinese version of TRACK also list the brand name of drugs? according to the authors manuscript, only a broad description on the high dose corticosteroids and intravenous corticosteroids were mentioned without naming the specific various brand names. The general person may not understand what the "high dose of inhaled corticosteroids" means. Although previous articles did not show specific scores on each subject, higher scores in the Chinese version may ascribe to the higher score of the question number 5. In the method section, the author would mention clearly that physicians did not know what score the caregiver has given to their subjects' asthma control. Is there any difference between the international GINA and the Chinese asthma guideline? Is there any discrepancy in the

	treatment plan between the two guidelines that the physician has to make? Does this can make an influence on the result? The authors would better to explain why the scores of follow-up visit can cause higher scores than those of initial visit in the discussion session. Finally, can it be possible for the authors to post the Chinese version of TRACK as a supplement material? It can help to spread the TRACK questionnaire in the usual practice.

REVIEWER	FRANCISCO-JAVIER GONZALEZ-BARCALA RESPIRATORY DEPARTMENT, UNIVERSITY HOSPITAL OF SANTIAGO DE COMPOSTELA, SPAIN
REVIEW RETURNED	04-Sep-2018

GENERAL COMMENTS	REVIEW_BMJ_2018_AUG_25378_CHINA_ACT Many thanks for inviting me to review this manuscript, where the authors try to validate the TRACK questionnaire in Chinese IMPORTANCE OF THE QUESTION OR SUBJECT STUDIED The validation of a TRACK questionnaire could be useful to improve the measurement of health of asthma children in China The objectives are clearly stated. ADEQUACY OF APPROACH The experimental design seems, in general, adequate. However, there are some weak points: -In the paragraph “Study Population” the age range of the included patients should be clearly stated -The sample size should be justified -The main inclusion / exclusion criteria should be clearly shown in the current paper. Now there is a reference to reference 18 where there seems to be some important differences in the inclusion criteria (e.g. age less than 18 years, etc). The study is acceptable from an ethical point of view, and the statistical treatment seems adequate RESULTS The results are clearly presented I think that it is necessary to show how many patients rejected to take part in this study. Were they different than those who accepted? The response rate is important to evaluate the validity of the results. DISCUSSION: The discussion is relevant and supported by the data presented REFERENCES The references are rather old, 63% being older than 5 years. There are some references only available in Chinese (2, 3, 21, 22), so it is difficult to understand outside of China. ABSTRACT

	The abstract is adequate and well structured

REVIEWER	Ueli Bollag Switzerland, retired
REVIEW RETURNED	09-Sep-2018

GENERAL COMMENTS	This is a meticulously planned and executed study. The introduction paragraph flows logically from preventive aspects of asthma to the situation in preschool children, the different treatment options in preschool children, to the different questionnaires for the control of asthma and the description of the TRACK questionnaire. The translation of the English version of TRACK into Chinese and back in a blinded manner is convincing. When I first read about the caregivers selected for the assessment of TRACK I questionned whether these caregivers were representative for China. However the authors mentioned this honestly as a main limitation of this study. The discussion neatly focusses on the comparison of TRACK with e.g. theC-Act (Chinese version of Childhood Asthma control test). I am not competent to report on the corectness of statistics applied by the authors.

REVIEWER	Anke Huels Emory University, Atlanta, GA, USA
REVIEW RETURNED	03-Dec-2018

GENERAL COMMENTS	In this paper, the authors investigated the reliability and validity of the Chinese version of the Test for Respiratory and Asthma Control in Kids (TRACK) in preschool children with asthma. General comments: The topic of the manuscript is interesting and very important. However, since there are many mistakes in wording and grammar, many sentences and paragraphs are hard to understand. The authors might consider making use of a professional language editing service. Furthermore, the statistical methods and the results should be explained in more detail so that the reader can better understand what is done and why it is done that way. Specific comments: • Abstract: The objective should be clarified. If I understand it correctly, the TRACK was designed to monitor asthma control in children younger than 5 years. The following points should be clear from the abstract: 1) Why do we care about a new test for asthma control in Chinese children, 2) What was done (TRACK was translated to Chinese, reliability and validity was tested). • Abstract, conclusions: “The study extends the validity and reliability of the Chinese version of TRACK.” From the manuscript I assumed that the authors proposed a Chinese version of TRACK. Or did they use an existing Chinese version? If they proposed a Chinese version, I do not understand what is meant by the conclusion – particularly by “extend”. Or is this just a mistake in wording? • Article summary: • 1 – please check the grammar of this sentence,

	• 2 – which assessment tool is currently used in China? The name of the tool should be mentioned here. Even after reading the whole manuscript I don't know to which part of the manuscript the authors are referring to. • 3 – "the Chinese version was slightly revised" I thought they are proposing a Chinese version of TRACK within this manuscript. Or do they mean "The original TRACK was slightly revised according to the guidelines in China"? • 5 – Not sure if this can really be called a strength of the study. Of course, it is more convenient if smartphone applications are used instead of paper, but I'm not sure if it is necessary to mention this in the article summary. • Introduction, p.5, lines 9-11: "The morbidity …" - please check grammar • Introduction, p.6, lines 27-34: The objectives should be clarified. It should be mentioned that first, a Chinese version of TRACK is proposed and then it is validated. The second sentence is totally unclear and should be rewritten. • Methods, p.6, line 53: wording! The authors probably mean "systematic" and not "systemic" • Methods, p.8, line 29: "modified Chinese version of TRACK was considered to be more suitable for less than 5 years of children" – Do the authors mean "children younger than 5 years"? • Methods, p.8, line 33 "representing the study population" – I'm pretty sure that only 10 participants cannot represent the study population. I think it's just a wrong wording. Please clarify. • Methods, p.8, line 36: The authors should provide a reference after the TRACK's copyright owner. Otherwise, it is unclear who the copyright owner is. • Methods, p.8, line 43: I'm not an expert in this, but is it really enough that the caregivers agree to participate in the study? Is it really not necessary the patients' parents agree as well? • Statistical analysis, p.9, line 20: "with a specified condition or clinical variables" – This sentence is unclear. Please rewrite. • Statistical analysis, p.9, lines 42 ff.: The methods described for the validity need to be described in more detail. In general, the authors mention all the statistical methods they used, but did not mention, why the methods were used and what was the aim of the single analyses. Therefore, it is hard to understand the purpose e.g. behind using a factor analysis with a Varimax rotation. • Statistical analysis, p.9, lines 47 ff.: The term "construct validity" is uncommon and not defined. What's the difference to "validity"? • Reliability, p.12, line 7: What is meant by "consistency reliability"? All the number mentioned in the results for the different validation approaches are not interpreted. It remains unclear to the reader if e.g. a "consistency reliability" of 0.63 is high or low and what does that mean (same for the KMO values and factor loads)? • Discriminant Validation, p. 12, lines 52-54: The first sentence is unclear. The authors might mean "from" instead of "among", but that doesn't fix the whole sentence. Please rewrite. • Table 3, the table is unclear. They present the samples sizes in a row, which is labeled as "median (IQR)". Furthermore, it is not necessary to show the test statistic and the degrees of freedom. The p-value should be sufficient. • Discussion, p. 15, lines 27-31: "Because the 5 items … "- Please rewrite and clarify this sentence. Why was the original TRACK not designed to be internally consistent? I'm a bit surprised and it would be nice to see a reference for this. "especially the item 5 that …" – I have no idea how this fits to the first part of the sentence.

	• Discussion, p.15, line 37: “older” instead of “greater” • Discussion, p.15, line 37: Don’t start a sentence with “also” • Discussion, p.17, lines 7-11: What is the advantage of a quantitative evaluation? Please explain in more detail. • Discussion, p.18, line 39: “has not been” • Discussion, p.18, line 46-48: “Because if the limitations …” – I think I understand what the authors wanted to say with this sentence. However, it needs to be rewritten and the grammar / wording needs to be corrected. • Discussion, p.18, lines 50-53: “We have been conducting a more thorough and comprehensive clinical study to further confirm the cutoff point that can be used and promoted in China.” Has this already been published or are you including this data in this manuscript? If not, I would suggest to leave this sentence out.

VERSION 1 – AUTHOR RESPONSE

Response to Reviewer 1:

Thank you for your comments.Our answer to your points are as follows.

Reviewer: 1

Reviewer Name: Dong In Suh

Institution and Country: Associate Professor, Seoul National University College of Medicine, South Korea

Please state any competing interests or state ‘None declared’: Nothing to declare

This is a well-organized manuscript that appropriately focused on the validity and reliability of the Chinese version TRACK questionnaire.

1. This study consisted of two main procedure, linguistic validation with cognitive debriefing and the clinical reliability/validity evaluation. Although the latter part is well described and analyzed, the former part, especially the cognitive debriefing, needs to be described more in detail, instead of stating "No change was made after the pre-testing."

Response: The statement "No change was made after the pre-testing" was corrected as “A final Chinese version was generated after the pre-final version was pre-tested on the caregivers of 10 patients’ caregivers followed by interviews to ensure that the translation was comprehensible and applicable to the patient population. In the last step of the process, the final version was prepared for validation.”(P9, line 16-24)

2. According to the original version of TRACK in English, every brand-name of systemic steroid containing drugs was listed. Does the modified Chinese version of TRACK also list the brand name of drugs? according to the authors manuscript, only a broad description on the high dose corticosteroids and intravenous corticosteroids were mentioned without naming the specific various brand names. The general person may not understand what the "high dose of inhaled corticosteroids" means.

Although previous articles did not show specific scores on each subject, higher scores in the Chinese version may ascribe to the higher score of the question number 5.

Response: We are very sorry for negligence of this part.

"'How often does your child take a high dose of inhaled corticosteroids (ICS) （nebulized budesonide 1 mg/dose, daily inhalations or other equivalent ICS) and systemic corticosteroids (oral prednisone, oral prednisolone, intravenous methylprednisolone, intravenous hydrocortisone succinate) for breathing problems when not controlled by other medications?' was added as item 5." was added.(P8, line 49-57)

3. In the method section, the author would mention clearly that physicians did not know what score the caregiver has given to their subjects' asthma control.

Response: We have added in the "Data Collection" part in the Method section as "Physicians were blinded to the caregiver's responses to the TRACK on their smartphone at the baseline and follow-up visits."(P10, line 19-21)

4. Is there any difference between the international GINA and the Chinese asthma guideline? Is there any discrepancy in the treatment plan between the two guidelines that the physician has to make? Does this can make an influence on the result?

Response: The most part of the Chinese asthma guideline and the GINA are same in the diagnosis, assessment and treatment of children with asthma. The purpose of the China asthma Guideline is to better promote the GINA standard in China. Therefore, it will not have an impact on the results of the study in China. The only difference is the treatment of breathing problems of children with asthma by recommending using inhaled corticosteroids and systematic corticosteroids as well. We have made a slightly modified to the TRACK in the end.

5. The authors would better to explain why the scores of follow-up visit can cause higher scores than those of initial visit in the discussion session.

Response: We have checked the original data again. From table 2 and table 3, we found that there appeared to be a tendency for follow-up visit scores was higher than initial . We carried out a further statistical analysis of these two sets of non-normal distribution data. The median number of the initial TRACK score for preschool children with asthma was 90, and the median score at the follow-up visit was 90. There was no significant difference between two scores by using Wilcoxon signed rank test (z=-0.219, p=0.827).

6. Finally, can it be possible for the authors to post the Chinese version of TRACK as a supplement material? It can help to spread the TRACK questionnaire in the usual practice.

Response: It's a very important suggestion. We have posted it as Table 1 in the manuscript.(P9, Table 1)

Response to Reviewer 2:

Thank you very much for your comments and suggestions.We have revised the manuscript as follows.

Reviewer: 2

Reviewer Name: FRANCISCO-JAVIER GONZALEZ-BARCALA

Institution and Country: RESPIRATORY DEPARTMENT, UNIVERSITY HOSPITAL OF SANTIAGO DE COMPOSTELA, SPAIN

Many thanks for inviting me to review this manuscript, where the authors try to validate the TRACK questionnaire in Chinese

IMPORTANCE OF THE QUESTION OR SUBJECT STUDIED

The validation of a TRACK questionnaire could be useful to improve the measurement of health of asthma children in China

The objectives are clearly stated.

ADEQUACY OF APPROACH

1. The experimental design seems, in general, adequate. However, there are some weak points:

-In the paragraph “Study Population” the age range of the included patients should be clearly stated

Response: We have added “male or female outpatient ≤ 5 years old” in the “Study population” section.(P10,line 31)

2. -The sample size should be justified

Response: We have added “Sample size for validation studies should be greater than 5-10 times the number of variables. Tabachnik and Fidell suggested having at least 300 cases required for factor analysis. We used these recommendations to determine our sample size” in the part of “study population”.(P7, line 21)

3. -The main inclusion / exclusion criteria should be clearly shown in the current paper. Now there is a reference to reference 18 where there seems to be some important differences in the inclusion criteria (e.g. age less than 18 years, etc).

Response: We have re-written this part according to the reviewer’s suggestion as following.(P7, line 19-39)

Inclusion criteria: Patients will be eligible to participate if all the following criteria apply: (1) male or female outpatient <6 years old, (2) diagnosed with asthma according to the Guidelines for the Diagnosis and Optimal Management of Asthma in Children (3) consent obtained by subject's parent or guardian and (4) subjects or subject's caregiver has a smartphone at their disposal.

Exclusion criteria: Patients will not be eligible to participate if any of the following exclusion criteria are present: (1) differential diagnosis of asthma such as congenital heart disease, gastro-oesophageal reflux, bronchopulmonary dysplasia or bronchiolitis obliterans; (2) allergy to any inhaler cortical steroid; (3) other diseases that could interfere with the study results judged by the clinicians; or (4) participation in any analogous clinical study within 3 months.

The study is acceptable from an ethical point of view, and the statistical treatment seems adequate

RESULTS

The results are clearly presented

4. I think that it is necessary to show how many patients rejected to take part in this study. Were they different than those who accepted? The response rate is important to evaluate the validity of the results.

Response: 'Only 7 cases that met the inclusion and exclusion criteria were unwilling to take part in the study.' was added in the results.(P12, line 32-34)

DISCUSSION:

The discussion is relevant and supported by the data presented

REFERENCES

5. The references are rather old, 63% being older than 5 years.

There are some references only available in Chinese (2, 3, 21, 22), so it is difficult to understand outside of China.

Response:

（1）References 2 and 3 are the results of the two largest recent epidemiological surveys of childhood asthma in China. No relevant English articles have been published. We reviewed the literature again and found that a recent meta-analysis of the epidemiology of childhood asthma in China had been published. We have made adjustments to this part of the reference. (Ref: Guo X, Li Z, Ling W, et al. Epidemiology of childhood asthma in mainland China (1988-2014): A meta-analysis. Allergy Asthma Proc 2018;39(3):15-29.)

（2）References 21 is the Guideline for asthma in children in Chinese (2016).References 22 is Dr. Jianguo Hong's first introduction of the Chinese version of TRACK to the pediatricians in China. Dr.

Hong is the correspondent author of this manuscript. Do you think if we can keep these two references in this paper?

（3）At the same time, we have supplemented the references section by adding nearly 5 years of literature.

ABSTRACT

The abstract is adequate and well structured

Response to Reviewer 3:

Special thanks to you for your comments.

Reviewer: 3

Reviewer Name: Ueli Bollag

Institution and Country: Switzerland, retired

This is a meticulously planned and executed study. The introduction paragraph flows logically from preventive aspects of asthma to the situation in preschool children, the different treatment options in preschool children, to the different questionnaires for the control of asthma and the description of the TRACK questionnaire. The translation of the English version of TRACK into Chinese and back in a blinded manner is convincing. When I first read about the caregivers selected for the assessment of TRACK I questionned whether these caregivers were representative for China. However the authors mentioned this honestly as a main limitation of this study. The discussion neatly focusses on the comparison of TRACK with e.g. the C-Act (Chinese version of Childhood Asthma control test). I am not competent to report on the corectness of statistics applied by the authors.

Response:We are pleased that you reviewed our manuscript.Thank you for your recognition of it.For the statistical analysis part, we have cooperated with researchers with professional background in statistics in the process of study.

Response to reviewer 4:

We appreciate you assigning such qualified comments to our manuscript. Your efforts and insights were a tremendous help to us during the revision.

Reviewer: 4

Reviewer Name: Anke Huels

Institution and Country: Emory University, Atlanta, GA, USA

In this paper, the authors investigated the reliability and validity of the Chinese version of the Test for

Respiratory and Asthma Control in Kids (TRACK) in preschool children with asthma.

General comments:

The topic of the manuscript is interesting and very important. However, since there are many mistakes in wording and grammar, many sentences and paragraphs are hard to understand. The authors might consider making use of a professional language editing service. Furthermore, the statistical methods and the results should be explained in more detail so that the reader can better understand what is done and why it is done that way.

Specific comments:

- Abstract: The objective should be clarified. If I understand it correctly, the TRACK was designed to monitor asthma control in children younger than 5 years. The following points should be clear from the abstract: 1) Why do we care about a new test for asthma control in Chinese children, 2) What was done (TRACK was translated to Chinese, reliability and validity was tested).

Response: We have revised it to “Of the limited existing asthma control questionnaires that are available for children under 5 years old, most only assess the impairment domain of asthma control in China. This study aimed to translate the English version of TRACK (Test for Respiratory and Asthma Control in Kids) into Chinese and validate it to monitor asthma control in preschool children.”(P3, line 11-18)

- Abstract, conclusions: “The study extends the validity and reliability of the Chinese version of TRACK.” From the manuscript I assumed that the authors proposed a Chinese version of TRACK. Or did they use an existing Chinese version? If they proposed a Chinese version, I do not understand what is meant by the conclusion – particularly by “extend”. Or is this just a mistake in wording?

Response: We are sorry for the mistake in wording. At present, we haven’t started using the Chinese version of TRACK. The sentence was modified to ‘The study verifies the validity and reliability of the Chinese version of TRACK’.(P3, line 49-50)

- Article summary:

- 1 – please check the grammar of this sentence,

Response: This sentence has been rewritten as ‘This is the first study to validate a Chinese version of the Test for Respiratory and Asthma Control in Kids (TRACK) for preschool children with asthma.’(P4, line 13-15)

- 2 – which assessment tool is currently used in China? The name of the tool should be mentioned here. Even after reading the whole manuscript I don’t know to which part of the manuscript the authors are referring to.

Response: We use the GINA criteria to assess the asthma control of preschool children.We have mentioned this in the discussion part, ‘Another method for assessing preschool children's asthma control that is widely accepted and used in China is GINA, which is administered by physicians.’(P18, line 28-30)

- 3 – “the Chinese version was slightly revised” I thought they are proposing a Chinese version of TRACK within this manuscript. Or do they mean “The original TRACK was slightly revised according to the guidelines in China”?

Response: The original TRACK was slightly revised according to the guidelines in China(2016). Because of the limitation of the bullet points,we have deleted this point.

- 5 – Not sure if this can really be called a strength of the study. Of course, it is more convenient if smartphone applications are used instead of paper, but I’m not sure if it is necessary to mention this in the article summary.

Response: After carefully consideration, we have deleted it.

- Introduction, p.5, lines 9-11: “The morbidity …” - please check grammar

Response: We have rewritten this part to ‘Preschool children (those aged 5 years or younger) have significantly higher morbidity from asthma than other age groups. In addition, there are 4.27 exacerbations per 10 person-years of preschool children in a population-based cohort study’.(P5,line 19-24)

- Introduction, p.6, lines 27-34: The objectives should be clarified. It should be mentioned that first, a Chinese version of TRACK is proposed and then it is validated. The second sentence is totally unclear and should be rewritten.

Response: We have rewritten this part to ‘The purpose of this study was to propose and validate a Chinese version of TRACK to measure asthma control in preschool children. This questionnaire can be used as a complement to the limited asthma control assessment tools that are currently available for children under 5 years old with asthma in China.’

(P6,line 35-42)

- Methods, p.6, line 53: wording! The authors probably mean “systematic” and not “systemic”

Response: We are sorry for our incorrect writing.(P7, line 5)

- Methods, p.8, line 29: “modified Chinese version of TRACK was considered to be more suitable for less than 5 years of children” – Do the authors mean “children younger than 5 years”?

Response: We have revised it to ‘children younger than 5 years old’.(P9, line 16)

• Methods, p.8, line 33 “representing the study population” – I’m pretty sure that only 10 participants cannot represent the study population. I think it’s just a wrong wording. Please clarify.

Response: The 10 participants just met with all the inclusion and exclusion criteria, so we cannot use “representing the study” here. We have deleted this phrase.(P9, line 16-18)

• Methods, p.8, line 36: The authors should provide a reference after the TRACK’s copyright owner. Otherwise, it is unclear who the copyright owner is.

Response: The reference was marked.(P9, line 28)

• Methods, p.8, line 43: I’m not an expert in this, but is it really enough that the caregivers agree to participate in the study? Is it really not necessary the patients’ parents agree as well?

Response: Because it’s a registered clinical research, the participants need to sign the informed consents before the study begins according to the protocol. We need to get the agreement form the caregivers first.

• Statistical analysis, p.9, line 20: “with a specified condition or clinical variables” – This sentence is unclear. Please rewrite.

Response: We have rewritten this sentence to ‘Descriptive statistics were applied to illustrate the general characteristics of the included participants.’(P10, line 47-49)

• Statistical analysis, p.9, lines 42 ff.: The methods described for the validity need to be described in more detail. In general, the authors mention all the statistical methods they used, but did not mention, why the methods were used and what was the aim of the single analyses. Therefore, it is hard to understand the purpose e.g. behind using a factor analysis with a Varimax rotation.

Response: We have rewritten this part as following.

There are a number of different measures that can be used to validate tests, one of which is construct validity. Construct validity is used to determine how well a test measures what it is supposed to measure. Then an Exploratory Factor Analysis produces the dimension of differentiation that is used in order to confirm or not the questionnaire construct validity. To determine if the questionnaire was suitable for factor analysis, two statistical tests were used. The first is the criterion KMO (Kaiser-Meyer Olkin Measure of Sampling Adequacy, KMO), which examines sample sufficiency, and the latter is the Bartlett’s test of sphericity, which examines it is examined if the items of the questionnaire are inter-independent. It has been suggested that if the KMO is greater than 0.6 and the Bartlett’s Test of Sphericity must be significant at $\alpha < 0.05$ then the factorability of the correlation matrix is assumed. Exploratory Factor Analysis was then conducted with 5 items using principal component analysis extraction and Varimax rotation. The minimum factor loading cut off point was 0.4. Construct validity was analysed among the children with asthma at baseline. (P11, line 24-49)

• Statistical analysis, p.9, lines 47 ff.: The term “construct validity” is uncommon and not defined. What’s the difference to “validity”?

Response: “There are a number of different measures that can be used to validate tests, one of which is construct validity. Construct validity is used to determine how well a test measures what it is supposed to measure” was added to the “Validity”part. (P11, line 24-28)

• Reliability, p.12, line 7: What is meant by “consistency reliability”? All the number mentioned in the results for the different validation approaches are not interpreted. It remains unclear to the reader if e.g. a “consistency reliability” of 0.63 is high or low and what does that mean (same for the KMO values and factor loads)?

Response: We have rewritten these 2 parts.

Reliability (P13, line 39-P14, line 8)

The internal consistency reliability was 0.63 at baseline and 0.71 at follow-up, respectively (Cronbach’s α). When item 5 [OCS (Oral corticosteroids), IVCS or ICS use in the past 12 months] was deleted, the internal consistency reliability was increased to 0.73 at baseline and 0.75 at follow-up. At baseline, the Cronbach’s α value was below the recommended reliability for a multi-item scale of 0.7. The internal consistency reliability was adversely affected by item 5 of TRACK.The intraclass correlation for test-retest reliability was 0.63 (95%CI, 0.52-0.73, Pearson) for the preschool children with asthma whose physicians evaluated according to the GINA were the same at both visits (n=206). The test- retest reliability value seen in this study could be considered “good” but not “excellent.” The time period between the baseline and follow-up was 4-6 weeks and that was designed to evaluate the changes in asthma control. Because the clinical respiratory symptoms of preschool children with asthma changed frequently, 4-6 weeks may not be an optimal time interval to evaluate test-retest reliability, which ultimately affects the results.

Construct Validation (P14, line 12-28)

The KMO values were found to be 0.75 at the baseline visit and were considered to be satisfactory (>0.6), indicating that the sample size was large enough to assess the factor structure. Bartlett’s test of sphericity, an indicator of the strength of relationships among variables, gave a $\chi 2=350.88$ ($P<0.001$). The procedures generated a Kaiser–Meyer–Olkin value for each construct that was above 0.6 with a significant Bartlett’s test of sphericity value, indicating that the data were sufficient to proceed with factor analysis. Then the Exploratory Factor Analysis was then conducted. The items of the Chinese version of the TRACK loaded on the same factor. The 5 items explained 52.51% of the variance. The factor loads of each item of the TRACK ranged from 0.48 to 0.83 (Table 3).

• Discriminant Validation, p. 12, lines 52-54: The first sentence is unclear. The authors might mean “from” instead of “among”, but that doesn’t fix the whole sentence. Please rewrite.

Response: We have rewritten it to ‘The TRACK scores were significantly different across the 3 groups of children (controlled, partly controlled, or uncontrolled) categorized according to the GINA’.(P14, line 50-52)

• Table 3, the table is unclear. They present the samples sizes in a row, which is labeled as “median (IQR)”. Furthermore, it is not necessary to show the test statistic and the degrees of freedom. The p-value should be sufficient.

Response: The table3 and table4 was revised. The test statistic, the degrees of freedom and ‘media (IQR)’were deleted.(P15, Table 4 and Table 5)

• Discussion, p. 15, lines 27-31: “Because the 5 items … “- Please rewrite and clarify this sentence. Why was the original TRACK not designed to be internally consistent? I’m a bit surprised and it would be nice to see a reference for this. “especially the item 5 that …” – I have no idea how this fits to the first part of the sentence.

Response: The 5 items of the TRACK are consistent with the NAEPP asthma management guidelines for both the impairment domain of control assessment (i.e., asthma symptoms, use of rescue medications, night-time awakenings, and the effect of asthma on everyday functioning) and the risk domain of control assessment (i.e., oral corticosteroid courses in the past 12 months). As such, the TRACK instrument supports the premise that respiratory and asthma control is a multidimensional construct.[13](P16,line 49-60)

• Discussion, p.15, line 37: “older” instead of “greater”

Response: We have changed ‘greater’ to ‘older’.(P18, line 10)

• Discussion, p.15, line 37: Don’t start a sentence with “also”

Response: We have used ‘Meanwhile’ instead of ‘also’.(P18, line 10)

• Discussion, p.17, lines 7-11: What is the advantage of a quantitative evaluation? Please explain in more detail.

Response: ‘ The asthma control assessment tool quantifies asthma controlled as a continuous variable and provides a numeric value to distinguish between control and uncontrolled asthma. If the physician or caregiver can knows the specific score, they can have a clearer understanding of asthma control and facilitate comparison between different periods. ’ was added to this part.(P18, line 41-49)

• Discussion, p.18, line 39: “has not been”

Response: We have added ‘has’ in the sentence. We apologized for the mistake. (P20, line 22)

• Discussion, p.18, line 46-48: “Because if the limitations …” – I think I understand what the authors wanted to say with this sentence. However, it needs to be rewritten and the grammar / wording needs to be corrected.

Response: We have rewritten it to ‘Due to the limited number of cases and regional constraints, the optimal cut-off point for this paper cannot fully represent the level of the whole of China. ’(P20, line 30-32)

• Discussion, p.18, lines 50-53: “We have been conducting a more thorough and comprehensive clinical study to further confirm the cutoff point that can be used and promoted in China.” Has this already been published or are you including this data in this manuscript? If not, I would suggest to leave this sentence out.

Response: The clinical study to further confirm the cutoff point of the TRACK has not been promoted in China. This sentence was deleted.

VERSION 2 – REVIEW

REVIEWER	Dong In Suh Seoul National University College of Medicine
REVIEW RETURNED	29-Jan-2019

GENERAL COMMENTS	Most parts were appropriately revised. page 7, line 35: inhaler cortical steroid -> inhaled corticosteroid page 9 & page 10: systematic -> systemic

REVIEWER	FRANCISCO-JAVIER GONZALEZ-BARCALA UNIVERSITY OF SANTIAGO DE COMPOSTELA SPAIN
REVIEW RETURNED	28-Jan-2019

GENERAL COMMENTS	REVIEW_BMJ_OPEN_TRACK_QUESTIONNAIRE IMPORTANCE OF THE QUESTION OR SUBJECT STUDIED The rationale for performing the study is adequate. The information provided (the use of The TRACK test) is well known in different countries, however it is new for Chinese people On page 33, line 30, it is stated: “it correctly classified the respiratory control”. I don´t know what respiratory control is, what does it mean? The objectives are clearly stated ADEQUACY OF APPROACH Experimental design seems adequate. My main concern is the accuracy of asthma diagnosis at this age. It is well known that there are transient wheezers who never become asthmatics In the inclusion criteria there are some minor weak points: -The age range of inclusion should be clearly defined. It is stated ≤5 years old, but the lower age limit is not clearly shown. -The guidelines for the diagnosis of asthma need a reference The statistical analysis seems adequate Acceptable from an ethical point of view RESULTS

	According to the data presented in table 2 there are some patients with allergy rhinitis and food allergy, however, the criteria for these diagnoses should be clearly defined in the methods section Page 41, lines 10-20: this paragraph is more discussion than results Page 41, line 29: the meaning of this symbol "□" should be explained. The title of table 3 is "loadings of the TRACK", however the meaning of loadings is not defined Page 42, line 15-16: why children whose treatment was stepped-up have such low TRACK score at the follow-up?. It should be explained in the discussion section Table 1 may well be written in Chinese, hence it is difficult to understand outside of China. DISCUSSION The discussion should be shortened. The current discussion is rather long and difficult to read Page 44, lines 39-43: there are some mistakes in the Cronbach´s coefficient cited from references 13,22-23. E.g., from reference 13 it is cited 0.64-0.75, however it should be 0.71-0.75 Page 46, line 58-59: The conclusions are clear and supported by the data presented REFERENCES The references are rather old (61% older than 5 years) The references 7 and 19 are available only in Chinese GRAMMAR AND STYLE English language should be checked by a native English speaker ABSTRACT Adequate and well structured

VERSION 2 – AUTHOR RESPONSE

Response to Reviewer 1:

We are particularly grateful to you for your comments.

Reviewer 1:
Reviewer Name: Dong In Suh
Institution and Country: Seoul National University College of Medicine, Korea
Please state any competing interests or state 'None declared': None declared

Most parts were appropriately revised.
page 7, line 35: inhaler cortical steroid -> inhaled corticosteroid

page 9 & page 10: systematic -> systemic

Response: We apologize for these errors and have corrected them. (Page 31, line 49; Page 33, line 14 and line 21)

Response to Reviewer 2:

Your comments were very helpful for the revision of our manuscript.

Reviewer 2:

Reviewer Name: FRANCISCO-JAVIER GONZALEZ-BARCALA

Institution and Country: UNIVERSITY OF SANTIAGO DE COMPOSTELA, SPAIN

Please state any competing interests or state ‘None declared’: NONE DECLARED

REVIEW_BMJ_OPEN_TRACK_QUESTIONNAIRE

IMPORTANCE OF THE QUESTION OR SUBJECT STUDIED The rationale for performing the study is adequate.

The information provided (the use of The TRACK test) is well known in different countries, however it is new for Chinese people

On page 33, line 30, it is stated: “it correctly classified the respiratory control”. I don´t know what respiratory control is, what does it mean?

Response: We apologize for our unclear expression. We have corrected the text as follows: “In screening for control problems, TRACK showed a good area under the receiver operating characteristic (ROC) curve relative to the NAEPP-based ratings of asthma control. TRACK correctly classified the asthma control levels in approximately 80% of preschool children with asthma, and the cutoff point was 80.” (Page 30, line 24-32)

My main concern is the accuracy of asthma diagnosis at this age. It is well known that there are transient wheezers who never become asthmatics

Response: Recurrent wheezing occurs in a large proportion of children 5 years of age or younger, typically in conjunction with viral upper respiratory tract infections. Diagnosis of asthma in children under 5 years of age can be challenging. In this study, we used the below information to diagnose asthma according to GINA: the young child had a history of 3 or more episodes of wheezing per year, wheezing or coughing that occurs with exercise, laughing or crying in the absence of an apparent respiratory infection, clinical improvement with 2–3 months of controller treatment (regular low-dose inhaled corticosteroids), and worsening after cessation. Your suggestion was very helpful, and we have added this information to the manuscript. (Page 31, line 33-41)

The age range of inclusion should be clearly defined. It is stated ≤5 years old, but the lower age limit is not clearly shown.

Response: Asthma cases were diagnosed by the paediatric respiratory specialist according to GINA, and those that did not meet the exclusion criteria were included in the study. The minimum age limit is not set in GINA for children 5 years and younger. For consistency, we did not set a lower age limit for inclusion criteria.

The guidelines for the diagnosis of asthma need a reference

Response: We diagnosed these children with asthma according to GINA, and we have cited a reference for it. (Page 31, line 33)

Acceptable from an ethical point of view

RESULTS

According to the data presented in table 2 there are some patients with allergy rhinitis and food allergy, however, the criteria for these diagnoses should be clearly defined in the methods section

Response: Thank you for your comment; we have neglected this aspect in our paper. The following text was added to the methods section: “Atopic dermatitis was diagnosed by a senior dermatologist by examining the skin and reviewing the children’s medical histories. The diagnosis of allergy rhinitis was established by a senior ENT consultant according to Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines.[15] Food allergy was diagnosed by an allergist-immunologist based on a number of factors, such as symptoms, family history, skin and blood test, elimination test and oral food challenge before making a diagnosis.” (Page 31, line 54-60; Page 32, line 4-6)

Page 41, lines 10-20: this paragraph is more discussion than results Page 41, line 29: the meaning of this symbol “□” should be explained.

Response: We have moved this paragraph to the discussion section. (Page 41, line 6-16)

The symbol is χ^2. (Page 38, line 8)

The title of table 3 is “loadings of the TRACK”, however the meaning of loadings is not defined

Response: We defined this item in Table 3 as follows. (Page 38, line 21-34)

Items	Item Loadings
Frequency of respiratory symptoms in the past 4 weeks	0.82
Frequency of sleep disrupted in the past 4 weeks	0.83
Activity limitations in the past 4 weeks	0.82
Frequency of rescue medicine use in preceding 3 months	0.55
Systemic corticosteroids or high-dose ICS use in the previous year	0.48

Page 42, line 15-16: why children whose treatment was stepped-up have such low TRACK score at the follow-up? It should be explained in the discussion section

Response: These asthmatic children completed TRACK at 2 clinical visits in 4-6 weeks. In Table 5 and Table 6, the children with lower TRACK scores who needed stepped-up treatment was not the data of the same patient before and after treatment; it was the percentage of the total patients. This information can reflect the children who were recommended for a stepped-up therapy by their

physician who had a significantly lower score than those who either maintained or stepped-down therapy. TRACK can be used to help the physician to guide clinical treatment.

Table 1 may well be written in Chinese, hence it is difficult to understand outside of China.

Response: As another reviewer proposed, we included the standard Chinese version of TRACK in the article to facilitate its standardization, promotion and application in China.

DISCUSSION

The discussion should be shortened. The current discussion is rather long and difficult to read

Response: We agree, thank you for the comment. We have now improved the organization of the discussion section and shortened it in the revised manuscript.

Page 44, lines 39-43: there are some mistakes in the Cronbach´s coefficient cited from references 13,22-23. E.g., from reference 13 it is cited 0.64-0.75, however it should be 0.71-0.75

Response: We apologize for this error; we have corrected it. (Page 40, line 35-36)

The conclusions are clear and supported by the data presented

REFERENCES
The references are rather old (61% older than 5 years) The references 7 and 19 are available only in Chinese

Response: We have updated the references. Because TRACK was invented in 2009, translation and clinical applications were performed in other countries a few years ago; therefore, some of the references are from a slightly earlier time. China needs this clinical application now, as we are hoping to catch up to the international clinical trend.

References 7 is the Children's Asthma Guideline in China (2016). The purpose of this Chinese version of the Children's Asthma Guideline is to promote the GINA standard in China efficiently. After comparing the Chinese version of the Children's Asthma Guideline with GINA carefully and confirmed the consistency of the two guidelines, I corrected the reference to GINA.

Reference 19 is a citation by Dr. Jianguo Hong, who was the first person to introduce the Chinese version of TRACK to paediatricians in China. Dr. Hong is the correspondent author of this manuscript. If possible, we would like to keep this reference in our manuscript.

GRAMMAR AND STYLE
English language should be checked by a native English speaker

Response: We have again sent the manuscript to AJE for editing to help us improve the language of the manuscript.

ABSTRACT
Adequate and well structured

Correction: *Reliability and validity of the Chinese version of the Test for Respiratory and Asthma Control in Kids (TRACK) in preschool children with asthma: a prospective validation study*

Zhang J, Zhao L, Zhao D, *et al*. Reliability and validity of the Chinese version of the Test for Respiratory and Asthma Control in Kids (TRACK) in preschool children with asthma: a prospective validation study. *BMJ Open* 2019;9:e025378. doi: 10.1136/bmjopen-2018-025378

This article was previously published with error in authorship.
Jing Zhang and Liebin Zhao are co-first authors and Jianguo Hong and Yong Yin are co-corresponding authors.

BMJ Open 2019;**9**:e025378corr1. doi:10.1136/bmjopen-2018-025378corr1