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Reliability and Validity of Chinese version of the Test for Respiratory and Asthma Control in Kids (TRACK) in preschool children with asthma

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Running title: Validation of Chinese version of TRACK

Abstract

Objective This study aimed to validate the 5-item Chinese version, the Test for Respiratory and Asthma Control in Kids (TRACK) to monitor asthma control in preschool children.

Design Prospective validation study.

Setting and participants A total of 321 preschool children with asthma completed the study from December 2017 to January 2018 in China.

Method: The TRACK was translated to Chinese by using translation and back translation. Caregivers of preschool children with symptoms consistent with asthma, completed the TRACK at 2 clinic visits in 4-6 weeks. Physicians completed a Global Initiative for Asthma (GINA)-based asthma control survey at both visits. Responsiveness of the TRACK to assess the change of asthma control status, reliability and discriminant validity were evaluated.

RESULTS: The internal consistency reliability of the Chinese version of TRACK was 0.63 and 0.71 at both visits, respectively (Cronbach's α). The test-retest reliability was 0.62 for children whose physician's evaluation according to GINA was the same at both visits (N=206). There was a significant difference between the TRACK of the children in different asthma control categories ($p<0.001$). Children who received a recommendation for stepped-up in therapy from their physician had lower score on TRACK than children who received "maintained or stepped-down therapy" ($p<0.001$).

CONCLUSION: The study extends the validity and reliability of the Chinese version of TRACK. Changes in TRACK scores effectively reflected the asthma control of preschool children and guided further treatment.

Trial registration number NCT02649803

Key word: Asthma, Asthma control, Preschool children, Questionnaire, Reliability, Validity

Article summary

Strengths and limitations of this study

1. This is the first time to validate the Chinese version of TRACK in preschool children with asthma in China.
2. The Chinese version of TRACK was superior over the current assessment tool for asthma control status in preschool children in China.
3. The Chinese version of the TRACK was slightly revised and included "high dose of inhaled corticosteroids (ICS) and intravenous corticosteroids (IVCS)" to item 5 of TRACK according to the guidelines (2016) in China.
4. Only children with asthma younger than 5 years were included, and patients with other recurrent wheezing diseases or older than 5 years old were excluded.
5. This is the first study to use smartphone application to collect and download the follow-up information.

Introduction

Since 1990, the prevalence of asthma in children has been increasing in China. The prevalence of children's asthma in 0-14 years old was 1.07% in the year 1990, 1.97% in 2000 and 3.02% in 2010, leading to a major public health problem.[1–3] The morbidity of different age groups was different, 1.77%, 4.15% and 2.82% were under 2 years old, 3-5 years old and 6-14 years old, respectively in China.[3] Preschool children (those aged 5 years or younger) have significantly higher morbidity of asthma than other age groups. There are 48% of preschool children reporting an asthma attack in the preceding year.[4] The annual rate of emergency department visits and hospital admissions are higher than that of other age groups.[5] Preschool children with asthma have permanent lung function deficit at 6 years of age, persisting till the early and middle adulthood.[6] Asthma management in preschool children is complex, where the effects of different therapies in varied phenotypes remain unclear and several confounders affect the treatment response in asthma. As a result, preschool children with asthma require more health-care service and cause greater economic burden.

Poor treatment adherence is one of the most significant risk factors for children with asthma.[7] Because of the lack of an effective caregiver-reported asthma control assessment tool for the preschool children, caregivers usually underestimate their asthma symptoms, and hence is considered as one of the most important reasons for the poor treatment compliance.[8] The assessment of the control level of the children with asthma remains an essential link in the whole process of follow-up and treatment of the chronic disease. Current guidelines emphasized the assessment of asthma control including clinical asthmatic manifestations and lung function screening.[9] The preschool children are too young to complete the lung function test, so the level of asthma control assessment of the preschool children mostly depends on their caregivers' feedback. Thus, determining the level of control in these children remains challenging. Over the past few years, many questionnaires have been put forwarded to evaluate the patients' asthma control level in children aged 4 to 11 years[10], 5 to 17 years[11], and adolescents as well as adults[12, 13]. GINA and NAEPP (National Asthma Education and Prevention Program) emphasized 2 domains of asthma control including risk and impairment. However, most existing asthma control questionnaires cannot be used for children under 5 years old and can only assess the frequency of respiratory symptoms and rescue medication usage.[13–15]

A simple, applicable, accessible and validated tool is urgently needed for preschool children with asthma in China. In 2007, Murphy et al. developed a new assessment tool 'Test for Respiratory and Asthma Control in Kids (TRACK)' for children under 5 years old, covering the risk and impairment domains. This caregiver-reported questionnaire contains 5 items. Each item is given a score of 0-20 points based on 5-point Likert-type scale for a total score of 0-100. The reliability of TRACK was greater than 0.7 in both development as well as validation samples. Also it correctly classified the respiratory control levels in approximately 80% of preschool children with asthma and the cutoff point was 80. [16] Changes in TRACK scores of 10 or more points represent clinically meaningful changes in respiratory control status in young children with respiratory symptoms consistent with asthma and should alert healthcare providers to re-evaluate asthma management.[17] However, the questionnaire has not been validated in Chinese young children.

Hence, in the present study, the reliability and validity of the Chinese version of TRACK and consistency between TRACK and the asthma control levels assessed according to the GINA for preschool children were measured. We hypothesized that the Chinese version of TRACK significantly reflected the control level of the preschool children with asthma and was compatible with the GINA.

METHODS

The study was approved by the ethics committee of the Shanghai General Hospital, Shanghai, China and Shanghai Children's Medical Center, Shanghai, China and all the caregivers of the patients provided written informed consent before initiating the study. The trial was registered as NCT02649803 on ClinicalTrials.gov. The study protocol had been published on the BMJ open.[18]

Study design and setting

This prospective, multicenter, observational study was conducted from December 2017 to February 2018 at Shanghai General Hospital (Shanghai), Shanghai Children's Medical Center (Shanghai), Nanjing Children's Hospital (Nanjing), The Children's Hospital (Hangzhou) and 14 community hospitals in the Pudong district of Shanghai. All community healthcare providers involved in this clinical study received systemic training before the initial patient enrollment. Only qualified healthcare providers participated in this study.

Study Population

The caregivers of the preschool children with asthma in the 'Pediatric asthma control under a community management model in China' clinical study program who were invited and visited to the study site to participate were given a brief description of the study. The inclusion and exclusion criteria were already published[18]. The patient's caregiver had already been instructed to install the application (APP) on their smartphone and learned how to use it. We checked whether the caregivers filled in the TRACK and reminded the children to complete it in the back-end of the software every month to make sure their compliance. The caregivers filled the TRACK on their smartphone before they entered the consulting room. Caregivers should read and write in Chinese.

TRACK questionnaire

The caregiver-completed the TRACK that contained 5 items to monitor the respiratory control in children less than 5 years. The TRACK included frequency of respiratory symptoms (such as wheezes, cough, shortness of breath), nighttime awakenings, activity limitations in the past 4 weeks, frequency of rescue medicine use in the preceding 3 months, and oral corticosteroid use in the previous year. The score for the response to each item ranged from 0-20, and the scores for the individual items were added to obtain the final TRACK score. The total score of the TRACK questionnaire was 100.[16]

The English version of TRACK questionnaire was translated to Chinese version according to the previously published international test commission guidelines.[19, 20] First, the forward translation was performed independently by two native Chinese speakers who were fluent in English and also pediatricians with public health background. The consensus version was obtained after discussion by the two translators. Second, the backward translation of the consensus version into English version was performed by two translators who were blinded to the procedures of the forward translation. Finally, a thorough comparison of the original, translated and back translated versions was conducted by an expert committee for conceptual equivalence. Then, the pre-final consensus version was established.

Although the Chinese version of the TRACK tries to keep consistent with the original version of the questionnaire, its content has been partially adjusted. The modified Chinese version of the TRACK was slightly revised for item 5 of the pre-final consensus version after communicating with Prof. Murphy, the original author of the TRACK. 'How often does your child take a high dose of inhaled corticosteroids (ICS) and intravenous corticosteroids (IVCS) for breathing problems when not controlled by other medications?' was added as item 5. The treatment of asthma more likely recommended the use of ICS to reduce or avoid the usage of systemic corticosteroids and Children with asthma can be upgraded to a higher dose of ICS, leukotrienes (LTRA) or minimum dose of oral glucocorticoids after the failure of the third level treatment based on the guidelines (2016) in China[21]. Some children with severe asthma attack will be prescribed with intravenous corticosteroid follow the guidelines (2016) in China, so we also add intravenous corticosteroid to the item 5 as a complement. Thus, the modified Chinese version of TRACK was considered to be more suitable for less than 5 years of children with asthma in China [22]. A final Chinese version was generated after the pre-final version was pre-tested on the caregivers of 10 patients' representing the study population. No change was made after the pre-testing. Ten caregivers participating in the pre-testing of the pre-final version did not subsequently take part in the study itself. All steps were completed in cooperation with the TRACK's copyright owner.

Data Collection

After the agreement of the caregivers' participation in this study, they were initially prompted to fill out the TRACK by using the APP on their smartphone and were followed-up after 4-6 weeks. Physicians were blinded to the caregiver's responses at the baseline and follow-up visits. Patients' asthma control level was assessed by the physician according to the GINA for children under 6 years old. It was assessed by 4 items including the frequency of daytime symptoms, nocturnal symptoms, usage of the rescue drug (bronchodilators), and limited degree of daily activities in the past 4 weeks. According to the GINA, patients were divided into 3 groups as controlled,

partly controlled and uncontrolled.[9]

Patient and Public Involvement statement

No patients or public were involved in the present study design. Patients' caregivers were involved in the study by actively completing the questionnaires on their smartphones during the 2 months. A results-report will be sent to the study participants.

STATISTICAL ANALYSIS

Statistical analysis was conducted by SPSS 21.0 (IBM SPSS Statistics, NY, USA). Categorical data were expressed as the number of participants (or proportion) with a specified condition or clinical variables. The Kolmogorov-Smirnov test was used to examine the normality of the distribution of the data. Median and quartiles were adopted to describe non-normally distributed data. The group difference was calculated using the Kruskal-Wallis test, as the data was non-normally distributed. *P* values less than 0.05 was considered statistically significant.

Reliability

Cronbach's α coefficient was used to assess the internal consistency reliability for the scale. The test–retest reliability of the TRACK questionnaire was evaluated using Pearson correlation coefficients by comparing the scores at the baseline and follow-up visits in the children whose physicians reported that the asthma control status according to the GINA was unchanged between the two visits.

Validity

The construct validity was evaluated using a factor analysis with a Varimax rotation. The fit of the model was examined through the assumptions of factor analysis. Thus, the Kaiser-Meyer-Olkin (KMO) test was measured. In addition, the Bartlett's test of sphericity revealed the original correlations between the variables. Construct validity was analyzed among the children with asthma at baseline. For the discriminant validation tests, the children were divided into groups according to their differences in respiratory control derived from the 2 criteria measures. The first part of the TRACK's discriminant validation was assessed by comparing the TRACK scores with the 3 categories based on the GINA definition of control (controlled, partly

controlled and uncontrolled). The second part of the TRACK's discriminant validation was assessed by comparing the TRACK scores of the 3 categories of treatment decisions during the end of the visit (stepped-up in therapy, no change, stepped-down in therapy).

Screening accuracy

The screening accuracy of the TRACK as a tool to identify children with respiratory control problems was evaluated by using the Receiver Operating Characteristic (ROC) curve analysis. The criterion measure of respiratory control was based on the GINA guideline. The children were grouped as two group, not well controlled group (partly controlled and uncontrolled) versus controlled group, to detect children with any uncontrolled symptoms of asthma as far as possible. In addition, sensitivity, specificity, positive and negative predictive values, false-positive rate, accuracy and the area under the ROC curve were calculated to explore the optimal cutoff point for screening purposes.

RESULTS

Demographics

A total of 340 caregivers were recruited in the study. Of these, 321 (94.4%) caregivers completed the follow-up visit and their TRACKs were finally enrolled in the study (Figure 1). Most of the caregivers were female (84.1%), aged 25-44 years old (81.3%), and were graduated from college or higher (77.9%). The patients' age distribution was as follows: 40(12.5%) <24 months, 165(51.4%) between 25 and 48 months, and the remaining 116(36.1%) between 49-60 months. Ninety percent of the children were reported with controlled status of asthma by their caregivers. The characteristics of the patients at baseline were presented in Table 1.

Table 1. Caregiver and Children Demographic Characteristics

Characteristics	Study group (n=321)
Gender *n (%)*	
Boy	227 (70.7)

Girl	94 (29.3)
Age in months[a] *(months)*	44.1 (35.6, 51.9)
0-24 months *n (%)*	40 (12.5)
25-48 months *n (%)*	165 (51.4)
49-60 months *n (%)*	116 (36.1)
Age at first wheezing episode[a] *(months)*	18 (11, 29)
Atopic dermatitis *n (%)*	206 (64.2)
Allergy rhinitis *n (%)*	236 (73.5)
Food allergy *n (%)*	80 (24.9)
Family atopy *n (%)*	152 (47.4)
Caregiver gender *n (%)*	
Male	51 (16.0)
Female	270 (84.1)
Caregiver age *n (%)*	
18-24	48(15.0)
25-34	174 (54.2)
35-44	87 (27.1)
≥45	12 (3.7)
Caregiver education *n (%)*	
Not a high school graduate	23 (7.2)
High school graduate	48 (15.0)
College graduate or higher	250 (77.9)
Caregiver disease control rating *n (%)*	
Controlled	289 (90.0)
Uncontrolled	32 (10.0)

[a]Median and quartiles (median (25%, 75%))

Reliability

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. The intraclass correlation for test-retest reliability was 0.63 (95%CI, 0.52-0.73, Pearson) for the preschool children with asthma whose physician's evaluated according to the GINA were the same at both visits (n=206).

Construct Validation

The KMO values were found to be 0.75 at the baseline visit and were considered to be satisfactory. Bartlett's test of sphericity gave a χ^2=350.88 (P<0.001). The items of the Chinese version of the TRACK loaded on the same factor. The factor loads of each item of the TRACK ranged from 0.23 to 0.82 (Table 2).

Table 2 Loadings of the TRACK

Items	Item Loadings
1	0.82
2	0.83
3	0.82
4	0.55
5	0.48

Eigen value: 2.38, Variance explained: 52.51%

Discriminant Validation

The TRACK scores were significantly different among children categorized according to the GINA, which was evaluated by the physicians at baseline (P<0.001) and follow-up (P<0.001) visits to support the discriminant validity of the TRACK scores.

The TRACK scores were the highest among those with controlled rating and the lowest among the uncontrolled rating (Table 3). Children who were recommended for a stepped-up therapy by their physician had significantly lower score on the TRACK at baseline and follow-up than children who had maintained and stepped-down therapy (P<0.001,Table 4).

Table 3 Comparison of the TRACK score according to control levels of asthma as defined by GINA.

	Control rating by GINA			
	Controlled	Partly Controlled	Uncontrolled	Chi-squared, df, P
Baseline TRACK score Median (IQR)	95 (85-100) n=197	80 (70-85) n=87	75 (65-85) n=37	89.2, 2, < 0.001
Follow-up TRACK score Median (IQR)	90 (85-100) n=207	80 (72.5-87.5) n=89	70 (57.5-77.5) n=25	104.2, 2, < 0.001

Table 4 Comparison of the TRACK scores of subsets differing in physician's therapy by GINA-based control

	Change in therapy			
	Stepped Down	No Change	Stepped Up	Chi-squared, df, P
Baseline TRACK score Median (IQR)	90 (85-100) n=58	85 (80-95) n=246	65 (60-75) n=17	40.7, 2, < 0.001
Follow-up TRACK score Median (IQR)	90 (85-100) n=41	90 (80-95) n=273	40 (40-60) n=7	21.1, 2, < 0.001

Screening Accuracy

The baseline and follow-up TRACK scores showed that the screening ability of the scale across all scores (0-100) provided an area under the ROC curve of 0.81 (Figure 2) and 0.83 (Figure 3). To distinguish "controlled" patients from "partly controlled

and uncontrolled" patients, the TRACK cutoff point of 85 provided the most consistent balance between sensitivity and specificity at baseline (sensitivity 81.4% and specificity 72.1%) and follow-up visits (sensitivity 80.7% and specificity 71.5%). The screening accuracy of the TRACK scores at different cutoff points at baseline and follow-up visits are presented in Tables 5 and 6.

Table 5 Screening accuracy of the TRACK scores at baseline visit

Cut-off points	Odds Ratio	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	False-positive rate (%)	Accuracy (%)
65	8.74	18.6	97.5	65.5	82.1	34.5	67.0
70	7.65	29.0	94.9	68.0	78.3	32.0	69.5
75	6.82	43.6	89.9	71.7	73.0	28.3	72.0
80	8.14	62.1	83.3	77.7	77.8	22.3	75.1
85	11.33	81.5	72.1	86.1	64.7	13.9	75.7
90	8.63	87.9	54.3	87.7	54.8	12.3	67.3

PPV: Positive Predictive Value; NPV: Negative Predictive Value

Table 6 Screening accuracy of the TRACK scores at follow-up visit

Cut-off points	Odds Ratio	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	False-positive rate (%)	Accuracy (%)
65	4.54	22.8	99.0	70.0	92.9	30.0	72.0
70	3.37	30.7	96.6	71.7	83.3	28.3	73.2
75	3.73	44.7	93.7	75.5	82.8	24.5	77.0
80	2.61	64.0	86.5	81.3	72.3	18.6	78.5
85	2.72	80.7	71.5	87.1	60.9	13.0	74.8

90	2.43	90.4	49.3	90.3	50.0	9.7	63.9

PPV: Positive Predictive Value; NPV: Negative Predictive Value

Discussion

To our knowledge, this is the first time that the Chinese version of TRACK has been validated in preschool children with asthma in China. Also this is the first study to unite several hospitals in China to manage pediatric asthma and to use smartphone applications to collect and download the follow-up information[18]. Results showed that the TRACK demonstrated good reliability and validity. Responsiveness to the changes in asthma control over time demonstrated the utility of the questionnaire.

In this study, the reliability was obtained from internal consistency using Cronbach's α coefficient. The Cronbach's α coefficient for TRACK was 0.63 and 0.71 at both visits, respectively. When the item 5 (OCS, 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. Because the 5 items of the TRACK were not designed to be internally consistent, especially the item 5 that measures the risk domain of asthma remained extremely important for the inclusion. The Chinese version was modified by adding the high dose ICS and IVCS to item 5 based on the guidelines (2016) in China. The risk domain demonstrated by the study showed that the recent severe asthma exacerbations are important independent predictors of future severe exacerbations in children with severe or difficult-to-treat asthma and should be considered when establishing asthma management plans.[23] In the original version of TRACK, Cronbach's α coefficients varied from 0.64 to 0.75.[16] In the Spanish and Turkish version of the TRACK, Cronbach's α coefficients varied from 0.74 to 0.76 in the questionnaire.[24, 25] Compared with other versions of the TRACK, the reliability of the Chinese version was similar and acceptable. Discriminant validity was evaluated by the differences in the TRACK among children with controlled, partly controlled and uncontrolled asthma according to the GINA and the children whose baseline visit resulted in a stepped-up, stepped-down or no change in therapy. Our results with respect to the discriminant validity of the TRACK are consistent with

those reported by Chipps et al. The study recruited 438 caregivers of asthmatic children under 5 years old and completed the TRACK at 2 clinic visits. Physicians completed the guidelines-based respiratory-control survey at both visits and were asked whether the visit resulted in a change in therapy. The results showed significant differences in the mean TRACK scores among children categorized according to the physicians' NAEPP-based control table ratings at baseline and follow-up, change in therapy and control status, supporting the discriminant validity of the TRACK scores. The internal consistency reliability at baseline and follow-up and the test-retest reliability of the TRACK findings are consistent with our study results.[26] These present studies extended the validity and reliability of the TRACK by demonstrating its responsiveness to change in respiratory control status over time in children with asthma under 5 years old. Taken together, these results showed that the questionnaire demonstrated good validity, which was consistent with other versions.

As a common assessment tool for asthma control, Chinese version of Childhood asthma control test (C-ACT) is widely used to assess the asthma control levels of children aged 4-11 years in China.[10] But this assessment requires both children as well as their caregivers to complete it together, while TRACK can be completed by the caregivers independently. The items of C-ACT are sometimes difficult for the younger children and even greater than 4 years to understand. Also, the C-ACT is not suitable for children under 4 years due to relatively high prevalence of asthma in childhood. Although the impairment domain of the TRACK evaluation was similar to the C-ACT, but the specific description was not the same. The impairment evaluation domain of the TRACK contains 2-time dimensions (including the past 4 weeks and the past 3 months). However, the C-ACT only evaluates the conditions over the past 4 weeks. The C-ACT also does not include the evaluation of risk factors of asthma. Therefore, the TRACK questionnaire was more appropriate for the clinical evaluation of asthma control level in children under 5 years than the C-ACT.

Another method for assessing preschool children's asthma control, that is widely accepted and used in China, is according to the GINA by physicians. In our study, the

TRACK showed a good area under the ROC curve relative to the GINA-based ratings of asthma control. The GINA recommended to use well-controlled, partly-controlled and uncontrolled, three different levels of qualitative assessment.[9] However, the ideal asthma control assessment tool should be based on the objective quantitative evaluation and differentiate the control level. Therefore, we need an objectively quantified assessment tool to assess the control level of children's asthma. Therefore, these requirements were met by the TRACK and so considered it as a good choice.

In the initial Murphy's study, a cutoff point of 80 provided the best balance between sensitivity and specificity for discriminating between patients with uncontrolled versus controlled asthma. In patients with a TRACK score of less than 80, the need for further evaluation or treatment adjustment should be considered.[16] Other language versions of the TRACK questionnaire also used 80 as the cutoff point.[24, 25] In present study, a cutoff score of 85 provided reasonable screening statistics both at the baseline and follow-up visits. This higher value in our study was probably because of our ROC curve that was relative to the GINA-based ratings of asthma control rather than the NAEPP-based ratings in other studies.[16, 24, 25] Kaya et al evaluated the consistency between the TRACK and the asthma control levels as evaluated by the GINA and NAEPP guidelines in preschool children. When 80 was taken as the cut-off value for the TRACK, the compatibility rate of asthma control levels between the TRACK and GINA and TRACK and NAEPP were 71.0% and 76.4%, respectively. Control levels of 29.0% of patients were not compatible with GINA and 23.6% of patients were not compatible with NAEPP in this study. The inconformity rate of GINA was higher than that of NAEPP.[27] The main difference between the GINA and NAEPP is that if the daytime symptoms were more than once a week, any activity limitation due to asthma, the reliever needed more than once a week or if any night-time symptom in the last month, the patient was considered not accepted as controlled according to the GINA. However, the NAEPP defined patients as uncontrolled for up to one occurrence of a night-time symptom in a month, 2 days daytime symptoms in a week, 2 days short-acting β2 agonist use for symptom control

in a week and/or one exacerbation in a year. In terms of asthma control, the requirement of the GINA-based assessment was higher than the NAEPP for children under 5 years. TRACK was developed based on the NAEPP asthma management guidelines. This was the explanation for the increased optimal cutoff point to 85 in Chinese version of the TRACK in our study. Other reasons for the discordance of the cut-off point may be the fact that the guidelines evaluated asthma control in three categories, controlled, partly controlled and uncontrolled, whereas TRACK divided patients into two groups, controlled and uncontrolled. When we performed the data analysis, we defined the uncontrolled group as uncontrolled and partly controlled children according to GINA. Overall the findings from our study support the initial study finding that TRACK scores lower than 80 will identify children with suboptimal asthma or respiratory control.

The main limitation of our study was that the caregivers were with relatively higher educational background. Although this study was a multicenter cohort study, it was mainly limited to Shanghai, Hangzhou and Nanjing. Most of the caregivers are from the above or nearby cities. As these are the most developed cities in China, the educational level is relatively higher than the underdeveloped Mid-west areas. The Chinese version of the TRACK, which should be promoted in China in the future needs to be further validated by more different levels of regional participation in the country. Another limitation is that NAEPP has no Chinese version and not been applied in China, and so the physicians in China mainly used the GINA to assess the situation of asthma control in children and adjusted the treatment. So, we only used the GINA-based asthma control assessment and treatment adjustment in the analysis. Because of the limitations of the amount and region of the cases in our study, the optimal cutoff point in this paper is unable to fully represent the level in whole China. 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.

In conclusion, the results of this study provided evidence on the reliability and validity of the Chinese version of the TRACK in assessing asthma control in

preschool children. The TRACK compensates the insufficiency of the other assessment tools for preschool children in China. The promotion and application of the TRACK in China can guide the caregivers and physicians to assess the level of asthma control in children conveniently and effectively, and further guide the clinical treatment change.

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Contributors JGH, YY and LBZ contributed to the conception and design of the study, revising the draft critically for important intellectual content. JZ and SHL contributed to data analysis and drafting the submitted article. JGH, DYZ and ZMC

contributed to the translation, data acquisition, interpretation of outcomes. JGH and YY contributed to crucial revision of the draft for important intellectual content and providing final confirmation of the revised version to be published and getting the permission of the original questionnaire. DYZ, ZMC, HZ, JZ, SSY, YFW, WWZ and LZ contributed to following up the patients, collecting extracting and analyzing the data. All authors contributed to data analysis, drafting the manuscript, amending the paper and being responsible for all aspects of the work. All the data could be accessed to all of the authors assured the accuracy of the reported data.

Competing of interests None declared.

Ethics approval Ethical approval for the study was granted by the Shanghai First People's Hospital Research ethics committee(2018KY001) and Shanghai Children's Medical Center Research ethics committee(SCMCIRB-K2016037).

Patient consent Parental/Guardian consent obtained.

Data sharing statement Extra data are available by emailing the corresponding author.

REFERENCES

1 The National Cooperative Research Group on Childhood Asthma. A nationwide survey on the state of asthma in a population of 0–14-year-old children. *Chin J Tuberc Respir Dis* 1993;16:64–68.

2 Chen Y. A nationwide survey in China on prevalence of asthma in urban children. *Zhonghua Er Ke Za Zhi* 2003;41(2):123–27.

3 The National Cooperative Group on Childhood Asthma, Institute of Environmental Health and Related Products. Third nationwide survey of childhood asthma in urban

areas of China. *Zhonghua Er Ke Za Zhi* 2013;51(10):729–35.

4 Garner R, Kohen D. Changes in the prevalence of asthma among Canadian children. *Health Rep* 2008;19(2):45–50.

5 Lougheed MD, Garvey N, Chapman KR, et al. The Ontario Asthma Regional Variation Study: Emergency department visit rates and the relation to hospitalization rates. *Chest* 2006;129(4):909–17.

6 Grad R, Morgan WJ. Long-term outcomes of early-onset wheeze and asthma. *J Allergy Clin Immunol* 2012;130(2):299–307.

7 Xiang L, Zhao J, Zheng Y, et al. Uncontrolled asthma and its risk factors in Chinese children: A cross-sectional observational study. *J Asthma* 2016;53(7):699–706.

8 Sonney JT, Gerald LB, Insel KC. Parent and child asthma illness representations: A systematic review. *J Asthma* 2016;53(5):510–16.

9 The Subspecialty Group of Respiratory Diseases, The Society of Pediatrics, Chinese Medical Association, The Editorial Board, Chinese Journal of Pediatrics. 2017 GINA Report, Global Strategy for Asthma Management and Prevention. *Chin J Pediatr* 2016;54(3):167-181.

10 Liu AH, Zeiger R, Sorkness C, et al. Development and cross-sectional validation of the Childhood Asthma Control Test. *J Allergy Clin Immunol* 2007;119(4):817–25.

11 Skinner EA, Diette GB, Algatt-Bergstrom PJ, et al. The Asthma Therapy Assessment Questionnaire (ATAQ) for children and adolescents. *Dis Manag* 2004;7(4):305–13.

12 Juniper EF, O'Byrne PM, Ferrie PJ, et al. Measuring asthma control. Clinic

questionnaire or daily diary? *Am J Respir Crit Care Med* 2000;162(4 Pt 1):1330–34.

13 Nathan RA, Sorkness CA, Kosinski M, et al. Development of the asthma control test: A survey for assessing asthma control. *J Allergy Clin Immunol* 2004;113(1):59–65.

14 Juniper EF, Gruffydd-Jones K, Ward S, et al. Asthma Control Questionnaire in children: Validation, measurement properties, interpretation. *Eur Respir J* 2010;36(6):1410–16.

15 Vollmer WM, Markson LE, O'Connor E, et al. Association of asthma control with health care utilization and quality of life. *Am J Respir Crit Care Med* 1999;160(5 Pt 1):1647–52.

16 Murphy KR, Zeiger RS, Kosinski M, et al. Test for respiratory and asthma control in kids (TRACK): A caregiver-completed questionnaire for preschool-aged children. *J Allergy Clin Immunol* 2009;123(4):833-9.e9.

17 Zeiger RS, Mellon M, Chipps B, et al. Test for Respiratory and Asthma Control in Kids (TRACK): Clinically meaningful changes in score. *J Allergy Clin Immunol* 2011;128(5):983–88.

18 Xu J, Yin Y, Zhang H, et al. Paediatric asthma control under a community management model in China: A protocol for a prospective multicentre cohort study. *BMJ Open* 2017;7(8):e015741.

19 Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine* 2000;25(24):3186–91.

20 Guillemin F. Cross-cultural adaptation and validation of health status measures. *Scand J Rheumatol* 1995;24(2):61–63.

21 The Subspecialty Group of Respiratory Diseases, The Society of Pediatrics, Chinese Medical Association, The Editorial Board, Chinese Journal of Pediatrics. Guideline for the diagnosis and optimal management of asthma in children(2016). *Chin J Pediatr* 2016;54(3):167–81.

22 Hong J. Modified Chinese version of the Test for Respiratory and Asthma Control in Kids (TRACK) and its clinical value. *Chinese Journal of Practical Pediatrics* 2018;33(3):192–95.

23 Haselkorn T, Zeiger RS, Chipps BE, et al. Recent asthma exacerbations predict future exacerbations in children with severe or difficult-to-treat asthma. *J Allergy Clin Immunol* 2009;124(5):921–27.

24 Rodríguez-Martínez CE, Nino G, Castro-Rodriguez JA. Validation of the Spanish version of the Test for Respiratory and Asthma Control in Kids (TRACK) in a population of Hispanic preschoolers. *J Allergy Clin Immunol Pract* 2014;2(3):326-31.e3.

25 Buyuktiryaki B, Sahiner UM, Yavuz ST, et al. Validation of the Turkish version of "Test for Respiratory and Asthma Control in Kids (TRACK)" questionnaire. *J Asthma* 2013;50(10):1096–101.

26 Chipps B, Zeiger RS, Murphy K, et al. Longitudinal validation of the Test for Respiratory and Asthma Control in Kids in pediatric practices. *Pediatrics* 2011;127(3):e737-47.

27 Kaya A, Erkocoglu M, Akan A, et al. TRACK as a complementary tool to GINA and NAEPP guidelines for assessing asthma control in pre-school children. *J Asthma*

2014;51(5):530–35.

Figure 1 Flow diagram for the selection of participants

Figure 2 ROC curve for the baseline TRACK scores

Figure 3 ROC curve for the follow-up TRACK scores

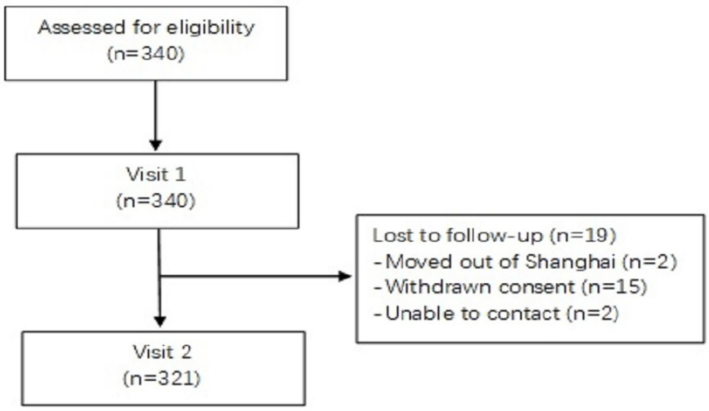

Figure 1 Flow diagram for the selection of participants

317x238mm (300 x 300 DPI)

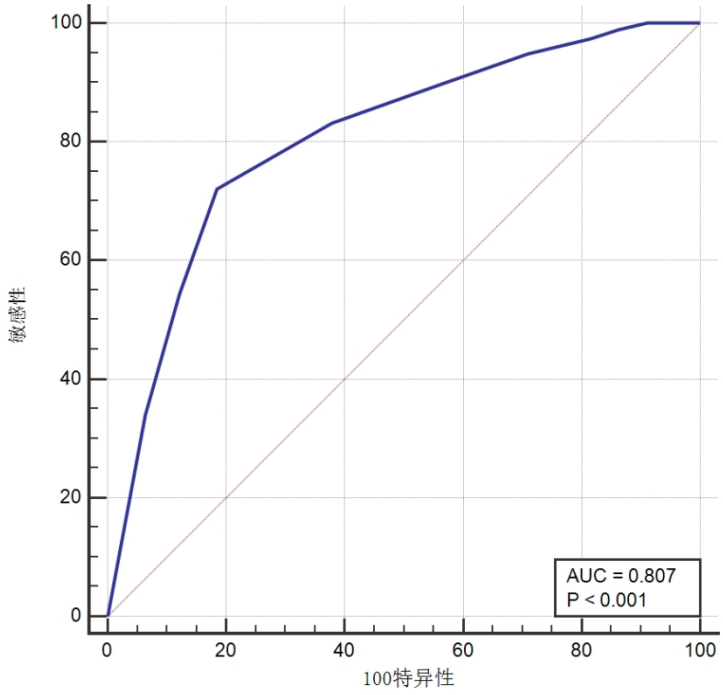

Figure 2 ROC curve for the baseline TRACK scores

101x76mm (300 x 300 DPI)

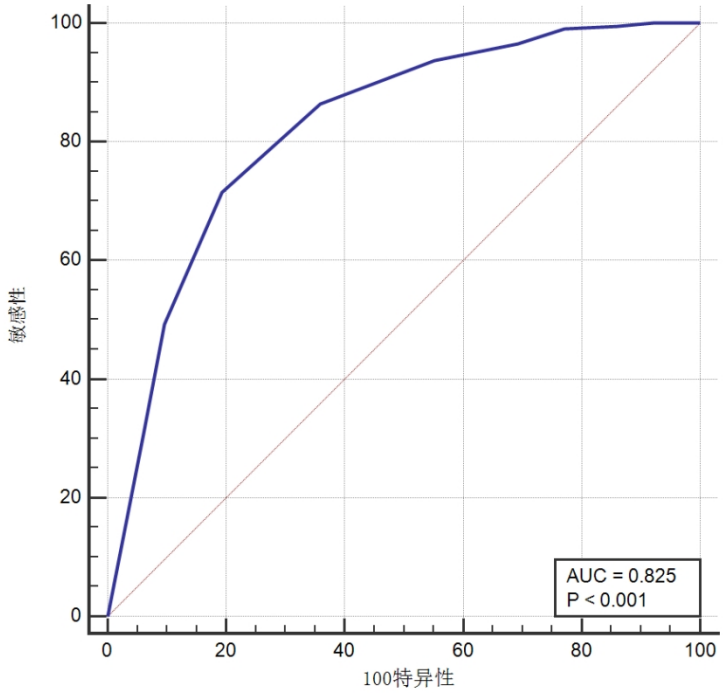

Figure 3 ROC curve for the follow-up TRACK scores

101x76mm (300 x 300 DPI)

Reporting checklist for diagnostic test accuracy study.

Based on the STARD guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STARD reporting guidelines, and cite them as:

Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig L, LijmerJG Moher D, Rennie D, de Vet HCW, Kressel HY, Rifai N, Golub RM, Altman DG, Hooft L, Korevaar DA, Cohen JF, For the STARD Group. STARD 2015: An Updated List of Essential Items for Reporting Diagnostic Accuracy Studies.

		Reporting Item	Page Number
	#1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	2
	#2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	2
	#3	Scientific and clinical background, including the intended use and clinical role of the index test	4
	#4	Study objectives and hypotheses	5
Study design	#5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	5-6
Participants	#6	Eligibility criteria	6

	#7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	6
	#8	Where and when potentially eligible participants were identified (setting, location and dates)	5
	#9	Whether participants formed a consecutive, random or convenience series	5-6
Test methods	#10a	Index test, in sufficient detail to allow replication	5-6
	#10b	Reference standard, in sufficient detail to allow replication	6
	#11	Rationale for choosing the reference standard (if alternatives exist)	7
	#12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	7
	#12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	7
	#13a	Whether clinical information and reference standard results were available to the performers / readers of the index test	8
	#13b	Whether clinical information and index test results were available to the assessors of the reference standard	8
Analysis	#14	Methods for estimating or comparing measures of diagnostic accuracy	8
	#15	How indeterminate index test or reference standard results were handled	9
	#16	How missing data on the index test and reference standard were handled	8
	#17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	8
	#18	Intended sample size and how it was determined	8
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	#20	Baseline demographic and clinical characteristics of participants	9
	#21a	Distribution of severity of disease in those with the target condition	9
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	#22	Time interval and any clinical interventions between index test and reference standard	9
Test results	#23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	10
	#24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	10
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BMJ Open

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

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Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Respiratory medicine

Keywords:	Asthma < THORACIC MEDICINE, asthma control, questionnaire, preschool children, Reliability, Validity

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

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Running title: Validation of the Chinese version of TRACK

Abstract

Objective 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.

Design Prospective validation study.

Setting and participants A total of 321 preschool children with asthma completed the study from December 2017 to January 2018 in China.

Method TRACK was translated to Chinese using translation and back translation. Caregivers of preschool children with symptoms consistent with asthma completed TRACK at 2 clinic visits over 4-6 weeks. Physicians completed a Global Initiative for Asthma (GINA)-based asthma control survey at both visits. The responsiveness of TRACK to assess the change in asthma control status, reliability and discriminant validity were evaluated.

Result The internal consistency reliability of the Chinese version of TRACK was 0.63 and 0.71 at the first and second visits, respectively (Cronbach's α). The test-retest reliability was 0.62 for children whose physician's evaluation was the same at both visits, according to GINA (N=206). There was a significant difference between TRACK scores for children in different asthma control categories ($p<0.001$). Children who received a recommendation for stepped-up therapy from their physician had lower scores on TRACK than children who received maintaince or stepped-down therapy ($p<0.001$).

Conclusion This study verifies the validity and reliability of the Chinese version of TRACK. Changes in TRACK scores effectively reflected the asthma control of preschool children and guided further treatment.

Trial registration number NCT02649803

Keywords: Asthma, Asthma control, Preschool children, Questionnaire, Reliability, Validity

Article summary

Strengths and limitations of this study

1. 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.
2. Tests of the validity and reliability of the Chinese version of TRACK were conducted in a Chinese multicentre.
3. TRACK's discriminant validation was assessed by comparing the TRACK scores with 3 categories based on the GINA definition of the control and by comparing the TRACK scores of the 3 categories of treatment decisions at the end of the visit.
4. Only children younger than 5 years old with asthma were included, and patients with other recurrent wheezing diseases or who were older than 5 years old were excluded.
5. The main limitation of our study is that the caregivers had relatively high educational backgrounds.

Introduction

Since 1990, the prevalence of asthma in children has increased in China. The prevalence of asthma in children 0-14 years old was 1.07% in 1990, 1.97% in 2000 and 3.02% in 2010, leading to a major public health problem. The prevalence has been remarkably increasing since 1998. The current prevalence of children with asthma likely increased from 2017 to 2019.[1] 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[2].The annual rate of emergency department visits and hospital admissions are higher than that of other age groups.[3] Preschool children with asthma have permanent lung function deficits at 6 years of age that persist until early and middle adulthood.[4] Asthma management in preschool children is complex, while the effects of different therapies in varied phenotypes remain unclear, and several confounders affect the asthma treatment response. As a result, preschool children with asthma require more health-care services and cause a greater economic burden.

Poor treatment adherence is one of the most significant risk factors for children with asthma.[5] Due to the lack of an effective caregiver-reported asthma control assessment tool for preschool children, caregivers usually underestimate their asthma symptoms, and this is considered as one of the most important reasons for poor treatment compliance.[6] The assessment of the control level of children with asthma remains an essential link in the process of follow-up and treatment of this chronic disease. Current guidelines emphasize the assessment of asthma control that include clinical asthmatic manifestations and lung function screening.[7] Preschool children are too young to complete the lung function test, so the level of asthma control assessment of these children mostly depends on their caregivers' feedback. Thus, determining the level of control in these children remains challenging. Over the past few years, many questionnaires have been given to evaluate the patients' asthma control level in children aged 4 to 11 years,[8] 5 to 17 years,[9]and adolescents as well as adults.[10 11] GINA (Global Initiative for Asthma) and NAEPP (National Asthma Education and Prevention Program) emphasized 2 domains of asthma control, including risk and impairment.

However, most existing asthma control questionnaires cannot be used for children under 5 years old and can only assess the frequency of respiratory symptoms and rescue medication usage. [11,12]

A simple, applicable, accessible and validated tool is urgently needed for preschool children with asthma in China. In 2007, Murphy et al. developed a new assessment tool 'Test for Respiratory and Asthma Control in Kids (TRACK)' for children under 5 years old, covering the risk and impairment domains. This caregiver-reported questionnaire contains 5 items. Each item is given a score of 0-20 points based on 5-point Likert-type scale for a total score of 0-100. The reliability of TRACK was greater than 0.7 in both development and validation samples. It correctly classified the respiratory control levels in approximately 80% of preschool children with asthma, and the cut-off point was 80. [13] TRACK score changes of 10 or more points represent clinically meaningful changes in respiratory control status in young children with respiratory symptoms consistent with asthma, and healthcare providers should be alerted to re-evaluate asthma management.[14] However, the questionnaire has not been validated in young Chinese children.

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.

METHODS

The study was approved by the ethics committee of the Shanghai General Hospital, Shanghai, China and Shanghai Children's Medical Center, Shanghai, China, and all caregivers of patients provided written informed consent before study initiation. The trial was registered as NCT02649803 on ClinicalTrials.gov. The study protocol has been published on BMJ open. [15]

Study design and setting

This prospective, multicentre, observational study was conducted from December 2017 to February 2018 at Shanghai General Hospital (Shanghai), Shanghai Children's Medical Center (Shanghai), Nanjing Children's Hospital (Nanjing), The Children's

Hospital (Hangzhou) and 14 community hospitals in the Pudong district of Shanghai. All community healthcare providers involved in this clinical study received systemic training before initial patient enrolment. Only qualified healthcare providers participated in this study.

Study Population

The caregivers of preschool children with asthma in the 'Paediatric asthma control under a community management model in China' clinical study programme who visited the study site and were invited to participate were given a brief description of the study.[15]Inclusion criteria: Patients will be eligible to participate if all the following criteria apply: (1) male or female outpatient ≤ 5 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 sample size for validation studies should be greater than 5-10 times the number of variables.[16] Tabachnik and Fidell suggested having at least 300 cases required for factor analysis.[17] We used these recommendations to determine our sample size.

The patient's caregiver had already been instructed to install the application (APP) on their smartphone and to learn how to use it. We determined whether the caregivers completed TRACK and reminded the children to complete it in the back-end of the software every month to ensure compliance. The caregivers completed TRACK on their smartphone before they entered the consulting room. Caregivers should be able to read and write in Chinese.

TRACK questionnaire

The caregiver completed the TRACK questionnaire that contained 5 items to monitoring the respiratory control in children less than 5 years. TRACK includes the frequency of respiratory symptoms (such as wheezes, cough, shortness of breath), night-time awakenings, activity limitations in the past 4 weeks, the frequency of rescue medicine use in the preceding 3 months, and oral corticosteroid use in the previous year. The score for the response to each item ranges from 0-20, and the scores for the individual items are added to obtain the final TRACK score. The total score of the TRACK questionnaire is 100.[13]

The English version of the TRACK questionnaire was translated to the Chinese version according to the previously published international test commission guidelines.[18] First, the forward translation was performed independently by two native Chinese speakers who are fluent in English and are also paediatricians with a public health background. The consensus version was obtained after discussion by the two translators. Second, the backward translation of the consensus version into English version was performed by two translators who were blinded to the procedures of the forward translation. Then, a thorough comparison of the original, translated and backward translated versions was conducted by an expert committee for conceptual equivalence. Finally, the pre-final consensus version was established.

Although the Chinese version of TRACK tries to remain consistent with the original version of the questionnaire, its content has been partially adjusted. The modified Chinese version of TRACK was slightly revised for item 5 of the pre-final consensus version after communicating with Prof. Murphy, the original author of the TRACK. ‘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 systematic corticosteroids (oral prednisone, oral prednisolone, intravenous methylprednisolone, intravenous hydrocortisone succinate) for breathing problems when not controlled by other medications?’ was added as item 5. The treatment of asthma more likely recommended the use of ICS to reduce or avoid the usage of

systematic corticosteroids, and children with asthma can be upgraded to a higher dose of ICS, leukotrienes (LTRA) or minimum dose of oral glucocorticoids after failure of the third level of treatment based on the guidelines (2016) in China[7]. Some children with a severe asthma attack will be prescribed intravenous corticosteroid to follow the guidelines (2016) in China, so we also added intravenous corticosteroid to item 5 as a complement. Thus, the modified Chinese version of TRACK was considered to be more suitable for children younger than 5 years old with asthma in China[19]. A final Chinese version was generated after the pre-final version was pre-tested on the caregivers of 10 patients, 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. Ten caregivers participating in the pre-testing of the pre-final version did not subsequently take part in the study itself. All steps were completed in cooperation with TRACK's copyright owner [13].The Chinese version of TRACK is presented in Table 1.

Table 1. Chinese version of TRACK

	分值				
	20 分	15 分	10 分	5 分	0 分
在过去 4 周内，孩子受到呼吸问题（如喘息、咳嗽或呼吸短促）的困扰有多频繁？	根本没有 ☐	1～2 次 ☐	每周 1 次 ☐	任一周 2～3 次 ☐	任一周 4 次或更多次 ☐
在过去 4 周内，孩子因呼吸问题（喘息、咳嗽、呼吸短促）在晚上醒来有多频繁？	根本没有 ☐	1～2 次 ☐	每周 1 次 ☐	任一周 2～3 次 ☐	任一周 4 次或更多次 ☐
在过去 4 周内，孩子的呼吸问题（如喘息、咳嗽或呼吸短促）在多大程度上干扰其玩耍、上学或进行同龄儿童应该进行的平常活动的能力？	根本没有 ☐	轻微 ☐	中等 ☐	大 ☐	极大 ☐
在过去 3 个月内，您需要使用快速缓解药物（特布他林、沙丁胺醇）来治疗孩子的呼吸问题（喘息、咳嗽、呼吸短促）有多频繁？	根本没有 ☐	1～2 次 ☐	每周 1 次 ☐	任一周 2～3 次 ☐	任一周 4 次或更多次 ☐

在过去 12 个月内，孩子需要全身糖皮质激素（口服泼尼松或泼尼松龙、注射甲泼尼龙或琥珀酸氢化可的松）或加用局部糖皮质激素（高剂量）来治疗其他药物无法控制的呼吸问题的频次？	从来没有 ☐	1 次 ☐	2 次 ☐	3 次 ☐	4 次或更多次 ☐

Data Collection

After the caregivers had agreed to participate in this study, they were initially prompted to fill out TRACK using the APP on their smartphone, and follow-up occurred after 4-6 weeks. Physicians were blinded to the caregivers' responses to TRACK on their smartphone at the baseline and follow-up visits. Patients' asthma control levels were assessed by the physician according to GINA for children under 6 years old. These levels were assessed by 4 items, including the frequency of daytime symptoms, nocturnal symptoms, usage of the rescue drug (bronchodilators), and limited degree of daily activities in the past 4 weeks. According to GINA, patients were divided into 3 groups: controlled, partly controlled and uncontrolled.[7]

Patient and Public Involvement statement

No patients or the public were involved in the present study design. Patients' caregivers were involved in the study by actively completing the questionnaires on their smartphones over the course of 2 months. A results-report will be sent to the study participants.

STATISTICAL ANALYSIS

Statistical analysis was conducted by SPSS 21.0 (IBM SPSS Statistics, NY, USA). Descriptive statistics were applied to illustrate the general characteristics of the included participants. The Kolmogorov-Smirnov test was used to examine the normality of the distribution of the data. Median and quartiles were adopted to describe non-normally distributed data. The group difference was calculated using the Kruskal-Wallis test, as the data were non-normally distributed. *P* values less than 0.05 were considered statistically significant.

Reliability

Internal consistency is the extent to which a group of items measure the same construct, as evidenced by how well they vary together or intercorrelate. Cronbach's α coefficient was used to assess the internal consistency reliability for the scale. We conducted test-retest analysis to assess the temporal stability of TRACK, i.e., whether the questionnaire was reliable in eliciting the same response at the initial (test) and at the second visit 4-6 weeks later (retest). The test–retest reliability of the TRACK questionnaire was evaluated using Pearson's correlation coefficients by comparing the scores at the baseline and follow-up visits in the children whose physicians reported that the asthma control status according to GINA was unchanged between the two visits.

Validity

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 to confirm 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 if the items on 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. For the discriminant validation tests, the children were divided into groups according to their differences in respiratory control derived from the 2 criteria measures. The first part of TRACK's discriminant validation was assessed by comparing the TRACK scores with the 3 categories based on the GINA definition of control (controlled, partly controlled and uncontrolled). The second part

of TRACK's discriminant validation was assessed by comparing the TRACK scores of the 3 categories of treatment decisions during the end of the visit (stepped-up in therapy, no change, stepped-down in therapy).

Screening accuracy

The screening accuracy of TRACK as a tool to identify children with respiratory control problems was evaluated using the Receiver Operating Characteristic (ROC) curve analysis. The criterion measure of respiratory control was based on the GINA guidelines. The children were grouped in two groups, not well controlled (partly controlled and uncontrolled) versus controlled, to detect children with any uncontrolled symptoms of asthma as far as possible. In addition, sensitivity, specificity, positive and negative predictive values, false-positive rate, accuracy and the area under the ROC curve were calculated to explore the optimal cut-off point for screening purposes.

RESULTS

Demographics

Only 7 cases that met the inclusion and exclusion criteria were unwilling to take part in the study. A total of 340 caregivers were recruited for the study. Of these participants, 321 (94.4%) caregivers completed the follow-up visit, and their TRACKs were finally enrolled in the study (Figure 1). Most of the caregivers were female (84.1%) who were aged 25-44 years old (81.3%) and had graduated from college or higher (77.9%). The patients' age distribution was as follows: 40 (12.5%) <24 months, 165 (51.4%) between 25 and 48 months, and the remaining 116 (36.1%) between 49 and 60 months. Ninety percent of the children were reported with controlled status of asthma by their caregivers. The characteristics of the patients at baseline are presented in Table 2.

Table 2. Caregiver and Children Demographic Characteristics

Characteristics	Study group (n=321)
Gender *n (%)*	
Boy	227 (70.7)
Girl	94 (29.3)
Age in months[a] *(months)*	44.1 (35.6, 51.9)
0-24 months *n (%)*	40 (12.5)

25-48 months *n (%)*	165 (51.4)
49-60 months *n (%)*	116 (36.1)
Age at first wheezing episode[a] *(months)*	18 (11, 29)
Atopic dermatitis *n (%)*	206 (64.2)
Allergy rhinitis *n (%)*	236 (73.5)
Food allergy *n (%)*	80 (24.9)
Family atopy *n (%)*	152 (47.4)
Caregiver gender *n (%)*	
Male	51 (16.0)
Female	270 (84.1)
Caregiver age *n (%)*	
18-24	48(15.0)
25-34	174 (54.2)
35-44	87 (27.1)
≥45	12 (3.7)
Caregiver education *n (%)*	
Not a high school graduate	23 (7.2)
High school graduate	48 (15.0)
College graduate or higher	250 (77.9)
Caregiver disease control rating *n (%)*	
Controlled	289 (90.0)
Uncontrolled	32 (10.0)

[a]Median and quartiles (median (25%, 75%))

Reliability

The internal consistency reliability was 0.63 at baseline and 0.71 at follow-up (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 them according to GINA to be 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 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

The KMO values were found to be 0.75 at the baseline visit, which is considered 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 χ^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. Exploratory Factor Analysis was then conducted. The items of the Chinese version of TRACK loaded on the same factor. The 5 items explained 52.51% of the variance. The factor loads of each item of TRACK ranged from 0.48 to 0.83 (Table 3).

Table 3 Loadings of TRACK

Items	Item Loadings
1	0.82
2	0.83
3	0.82
4	0.55
5	0.48

Eigen value: 2.38, Variance explained: 52.51%

Discriminant Validation

The TRACK scores were significantly different across the 3 groups of children (controlled, partly controlled, or uncontrolled) as categorized according to GINA, and this was evaluated by the physicians at baseline (P<0.001) and follow-up (P<0.001) visits to support the discriminant validity of the TRACK scores. The TRACK scores were the highest among those with a controlled rating and the lowest among those with an uncontrolled rating (Table 4). Children who were recommended for stepped-up

therapy by their physician had significantly lower scores on TRACK at baseline and follow-up than children who had maintained or stepped-down therapy (P<0.001, Table 5).

Table 4 Comparison of TRACK scores according to control levels of asthma as defined by GINA

	Control rating by GINA			
	Controlled	Partly Controlled	Uncontrolled	P
Baseline TRACK score	95 (85-100) n=197	80 (70-85) n=87	75 (65-85) n=37	＜0.001
Follow-up TRACK score	90 (85-100) n=207	80 (72.5-87.5) n=89	70 (57.5-77.5) n=25	＜0.001

Table 5 Comparison of TRACK scores of subsets differing in physician's therapy by GINA-based control

	Change in therapy			
	Stepped Down	No Change	Stepped Up	P
Baseline TRACK score	90 (85-100) n=58	85（80-95） n=246	65 (60-75) n=17	＜0.001
Follow-up TRACK score	90 (85-100) n=41	90 (80-95) n=273	40 (40-60) n=7	＜0.001

Screening Accuracy

The baseline and follow-up TRACK scores showed that the screening ability of the scale across all scores (0-100) provided an area under the ROC curve of 0.81 (Figure 2) and 0.83 (Figure 3). To distinguish "controlled" patients from "partly controlled and uncontrolled" patients, the TRACK cut-off point of 85 provided the most consistent balance between sensitivity and specificity at the baseline (sensitivity 81.4% and specificity 72.1%) and follow-up visits (sensitivity 80.7% and specificity 71.5%). The screening accuracy of the TRACK scores at different cut-off points at the baseline and follow-up visits are presented in Tables 6 and 7.

Table 6 Screening accuracy of TRACK scores at the baseline visit

Cut-off points	Odds Ratio	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	False-positive rate (%)	Accuracy (%)
65	8.74	18.6	97.5	65.5	82.1	34.5	67.0
70	7.65	29.0	94.9	68.0	78.3	32.0	69.5

75	6.82	43.6	89.9	71.7	73.0	28.3	72.0
80	8.14	62.1	83.3	77.7	77.8	22.3	75.1
85	11.33	81.5	72.1	86.1	64.7	13.9	75.7
90	8.63	87.9	54.3	87.7	54.8	12.3	67.3

PPV: Positive Predictive Value; NPV: Negative Predictive Value

Table 7 Screening accuracy of TRACK scores at the follow-up visit

Cut-off points	Odds Ratio	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	False-positive rate (%)	Accuracy (%)
65	4.54	22.8	99.0	70.0	92.9	30.0	72.0
70	3.37	30.7	96.6	71.7	83.3	28.3	73.2
75	3.73	44.7	93.7	75.5	82.8	24.5	77.0
80	2.61	64.0	86.5	81.3	72.3	18.6	78.5
85	2.72	80.7	71.5	87.1	60.9	13.0	74.8
90	2.43	90.4	49.3	90.3	50.0	9.7	63.9

PPV: Positive Predictive Value; NPV: Negative Predictive Value

Discussion

To our knowledge, this is the first time that the Chinese version of TRACK has been validated in preschool children with asthma in China. Additionally, this is the first study to unite several hospitals in China to manage paediatric asthma and to use smartphone applications to collect and download follow-up information. [15] The results showed that TRACK demonstrated good reliability and validity. Responsiveness to the changes in asthma control over time demonstrated the utility of the questionnaire.

In this study, reliability was obtained from internal consistency using Cronbach's α coefficient. The Cronbach's α coefficient for TRACK was 0.63 and 0.71 at the first visit and at follow-up, respectively. When item 5 (OCS, 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. The 5 items of 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] The Chinese version was modified by adding high dose ICS and IVCS to item 5 based on the guidelines (2016) in China. The risk domain demonstrated by the study showed that recent severe asthma exacerbations are important independent predictors of future severe exacerbations in children with severe or difficult-to-treat asthma and should be considered when establishing asthma management plans.[20 21] In the original version of TRACK, Cronbach's α coefficients varied from 0.64 to 0.75.[13] In the Spanish and Turkish versions of TRACK, Cronbach's α coefficients varied from 0.74 to 0.76 in the questionnaire.[22 23] Compared with other versions of TRACK, the reliability of the Chinese version was similar and acceptable. Discriminant validity was evaluated by differences in TRACK among children with controlled, partly controlled and uncontrolled asthma according to GINA and children whose baseline visit resulted in a stepped-up, stepped-down, or maintained therapy. Our results with respect to the discriminant validity of TRACK are consistent with those reported by Chipps et al. [24]The study recruited 438 caregivers of asthmatic children under 5 years old and completed TRACK at 2 clinic visits. Physicians completed the guidelines-based respiratory-control survey at both visits and were asked whether the visit resulted in a change in therapy. The results showed significant differences in the mean TRACK scores among children categorized according to the physicians' NAEPP-based control table ratings at baseline and follow-up, change in therapy and control status, thus supporting the discriminant validity of the TRACK scores. The internal consistency reliability at baseline and follow-up and the test-retest reliability of the TRACK findings are consistent with our study results.[24] These present studies extend the validity and reliability of TRACK by demonstrating its responsiveness to change in respiratory control status over time in children with asthma under 5 years old. Taken together, these results showed that the questionnaire demonstrated good validity, which is consistent with other versions.

As a common assessment tool for asthma control, the Chinese version of the Childhood asthma control test (C-ACT) is widely used to assess the asthma control

levels of children aged 4-11 years in China.[5, 8, 25] However, this assessment requires both children and their caregivers to complete it together, while TRACK can be completed by caregivers independently. The items of C-ACT are sometimes difficult for younger children and even those older than 4 years to understand. Meanwhile, the C-ACT is not suitable for children under 4 years due to the relatively high prevalence of asthma in childhood. Although the impairment domain of the TRACK evaluation was similar to the C-ACT, the specific description was not the same. The impairment evaluation domain of TRACK contains 2 time dimensions (including the past 4 weeks and the past 3 months). However, C-ACT only evaluates conditions over the past 4 weeks. C-ACT also does not include the evaluation of risk factors of asthma. Therefore, the TRACK questionnaire was more appropriate for the clinical evaluation of asthma control levels in children under 5 years than C-ACT.

Another method for assessing preschool children's asthma control that is widely accepted and used in China is GINA, which is administered by physicians. In our study, TRACK showed a good area under the ROC curve relative to GINA-based ratings of asthma control. GINA recommends to use well-controlled, partly controlled and uncontrolled, three different levels of qualitative assessment.[7] However, the ideal asthma control assessment tool should be based on objective quantitative evaluation and differentiate the control level. The asthma control assessment tool quantifies asthma control as a continuous variable and provides a numeric value to distinguish between controlled and uncontrolled asthma. If the physician or caregiver knows the specific score, they can have a clearer understanding of asthma control and facilitate comparison between different periods. Therefore, we need an objectively quantified assessment tool to assess the control level of children's asthma. These requirements were met by TRACK, and therefore it is considered good choice.

In Murphy's initial study, a cut-off point of 80 provided the best balance between sensitivity and specificity to discriminate between patients with uncontrolled versus controlled asthma. In patients with a TRACK score of less than 80, the need for further

evaluation or treatment adjustment should be considered.[13] Other language versions of the TRACK questionnaire also used 80 as the cut-off point.[22 23] In the present study, a cut-off score of 85 provided reasonable screening statistics both at the baseline and follow-up visits. This higher value in our study was most likely due to our ROC curve that was relative to the GINA-based ratings of asthma control rather than the NAEPP-based ratings in other studies.[13 22 23] Kaya et al. evaluated the consistency between TRACK and asthma control levels as evaluated by the GINA and NAEPP guidelines in preschool children. When 80 was taken as the cut-off value for TRACK, the compatibility rate of asthma control levels between TRACK and GINA and TRACK and NAEPP were 71.0% and 76.4%, respectively. Control levels of 29.0% of patients were not compatible with GINA, and 23.6% of patients were not compatible with NAEPP in this study. The inconformity rate of GINA was higher than that of NAEPP.[26] The main difference between GINA and NAEPP is that if the daytime symptoms were more than once a week, if any activity limitation was due to asthma, if the reliever needed more than once a week or if any night-time symptom in the last month, the patient was considered not accepted as controlled according to GINA. However, the NAEPP defined patients as uncontrolled for up to one occurrence of a night-time symptom in a month, 2 days of daytime symptoms in a week, 2 days of short-acting β2 agonist use for symptom control in a week and/or one exacerbation in a year. In terms of asthma control, the requirements of the GINA-based assessment were higher than those of NAEPP for children under 5 years. TRACK was developed based on the NAEPP asthma management guidelines. This was the explanation for the increased optimal cut-off point to 85 in the Chinese version of TRACK in our study. Other reasons for the discordance of the cut-off point may be the fact that the guidelines evaluated asthma control in three categories, controlled, partly controlled and uncontrolled, whereas TRACK divided patients into two groups, controlled and uncontrolled. When we performed data analysis, we defined the uncontrolled group as uncontrolled and partly controlled children according to GINA. Overall, the findings

from our study support the initial study finding that TRACK scores lower than 80 will identify children with suboptimal asthma or respiratory control.

The main limitation of our study is that the caregivers had relatively high educational backgrounds. Although this study was a multicentre cohort study, it was mainly limited to Shanghai, Hangzhou and Nanjing. Most of the caregivers are from the abovementioned cities or nearby cities. As these are the most developed cities in China, the educational level is relatively high compared to the underdeveloped Mid-west areas. The Chinese version of TRACK, which should be promoted in China in the future, needs to be further validated by different levels of regional participation in the country. Another limitation is that NAEPP has no Chinese version and has not been applied in China, so the physicians in China mainly use GINA to assess the situation of asthma control in children and to adjust the treatment. Therefore, we only used the GINA-based asthma control assessment and treatment adjustment in the analysis. Due to the limited number of cases and regional constraints, the optimal cut-off point for this paper cannot fully represent the whole of China.

In conclusion, the results of this study provided evidence on the reliability and validity of the Chinese version of TRACK in assessing asthma control in preschool children. TRACK compensates for the insufficiency of other assessment tools for preschool children in China. The promotion and application of TRACK in China can guide caregivers and physicians to conveniently and effectively assess the level of asthma control in children, further guiding clinical treatment change.

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Contributors JGH, YY and LBZ contributed to the conception and design of the study, revising the draft critically for important intellectual content. JZ and SHL contributed to data analysis and drafting the submitted article. JGH and JZ contributed to the translation, data acquisition, and interpretation of outcomes. JGH and YY contributed to crucial revision of the draft for important intellectual content, provided final confirmation of the revised version to be published, and obtained permission of the original questionnaire. DYZ, ZMC, HZ, JZ, LZ, SHY, MYT, YFW, WWZ, JX, LXZ, SYL and LZ contributed to following up with patients, and collecting, extracting and analysing the data. All authors contributed to data analysis, drafting the manuscript and amending the paper, and all are responsible for all aspects of the work. All authors could access all of the data to assure accuracy of the reported data.

Competing of interests None declared.

Ethics approval Ethical approval for the study was granted by the Shanghai First People's Hospital Research ethics committee(2018KY001) and Shanghai Children's Medical Center Research ethics committee (SCMCIRB-K2016037).

Patient consent Parental/Guardian consent obtained.

Data sharing statement Extra data are available by emailing the corresponding author.

Figure 1 Flow diagram for the selection of participants

Figure 2 ROC curve for baseline TRACK scores

Figure 3 ROC curve for follow-up TRACK scores

References

1. 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. Bloom CI, Nissen F, Douglas IJ, et al. Exacerbation risk and characterisation of the UK's asthma population from infants to old age. *Thorax* 2018;73(4):313-20.

3. Karaca-Mandic P, Jena AB, Joyce GF, et al. Out-of-pocket medication costs and use of medications and health care services among children with asthma. *JAMA* 2012;307(12):1284-91.

4. Grad R, Morgan WJ. Long-term outcomes of early-onset wheeze and asthma. *J Allergy Clin Immunol* 2012;130(2):299-307.

5. Xiang L, Zhao J, Zheng Y, et al. Uncontrolled asthma and its risk factors in Chinese children: A cross-sectional observational study. *J Asthma* 2016;53(7):699-706.

6. Sonney JT, Gerald LB, Insel KC. Parent and child asthma illness representations: a systematic review. *J Asthma* 2016;53(5):510-6.

7. Subspecialty Group of Respiratory Diseases SoPCMA, Editorial Board CJoP. [Guideline for the diagnosis and optimal management of asthma in children(2016)]. *Zhonghua Er Ke Za Zhi* 2016;54(3):167-81.

8. Liu AH, Zeiger R, Sorkness C, et al. Development and cross-sectional validation of the Childhood Asthma Control Test. *J Allergy Clin Immunol* 2007;119(4):817-25.

9. Skinner EA, Diette GB, Algatt-Bergstrom PJ, et al. The Asthma Therapy Assessment Questionnaire (ATAQ) for children and adolescents. *Dis Manag* 2004;7(4):305-13.

10. Juniper EF, O'Byrne PM, Ferrie PJ, et al. Measuring asthma control. Clinic questionnaire or daily diary? *Am J Respir Crit Care Med* 2000;162(4 Pt 1):1330-4.

11. Nathan RA, Sorkness CA, Kosinski M, et al. Development of the asthma control test: a survey for assessing asthma control. *J Allergy Clin Immunol* 2004;113(1):59-65.

12. Juniper EF, Gruffydd-Jones K, Ward S, et al. Asthma Control Questionnaire in children: validation, measurement properties, interpretation. *Eur Respir J* 2010;36(6):1410-6.

13. Murphy KR, Zeiger RS, Kosinski M, et al. Test for respiratory and asthma control in kids (TRACK): a caregiver-completed questionnaire for preschool-aged children. *J Allergy Clin Immunol* 2009;123(4):833-9 e9.

14. Zeiger RS, Mellon M, Chipps B, et al. Test for Respiratory and Asthma Control in Kids (TRACK): clinically meaningful changes in score. *J Allergy Clin Immunol* 2011;128(5):983-8.

15. Xu J, Yin Y, Zhang H, et al. Paediatric asthma control under a community management model in China: a protocol for a prospective multicentre cohort study. *BMJ Open* 2017;7(8):e015741.

16. MacCallum RC, Widaman KF, Preacher KJ, et al. Sample Size in Factor Analysis: The Role of Model Error. *Multivariate Behav Res* 2001;36(4):611-37.

17. Tabachnic BG, Fidell LS. Using Multivariate Statistics. 5th edition. Boston, MA: Pearson

Education. Inc. 2007.

18. Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine (Phila Pa 1976)* 2000;25(24):3186-91.

19. Hong JG. Modified Chinese version of the Test for Respiratory and Asthma Control in Kids (TRACK) and its clinical value. *Chinese Journal of Practical Pediatrics* 2018;33(3):4.

20. Haselkorn T, Zeiger RS, Chipps BE, et al. Recent asthma exacerbations predict future exacerbations in children with severe or difficult-to-treat asthma. *J Allergy Clin Immunol* 2009;124(5):921-7.

21. Turner SW, Murray C, Thomas M, et al. Applying UK real-world primary care data to predict asthma attacks in 3776 well-characterised children: a retrospective cohort study. *NPJ Prim Care Respir Med* 2018;28(1):28.

22. Rodriguez-Martinez CE, Nino G, Castro-Rodriguez JA. Validation of the Spanish version of the Test for Respiratory and Asthma Control in Kids (TRACK) in a population of Hispanic preschoolers. *J Allergy Clin Immunol Pract* 2014;2(3):326-31 e3.

23. Buyuktiryaki B, Sahiner UM, Yavuz ST, et al. Validation of the Turkish version of "Test for Respiratory and Asthma Control in Kids (TRACK)" questionnaire. *J Asthma* 2013;50(10):1096-101.

24. Chipps B, Zeiger RS, Murphy K, et al. Longitudinal validation of the Test for Respiratory and Asthma Control in Kids in pediatric practices. *Pediatrics* 2011;127(3):e737-47.

25. Leung TF, Ko FW, Sy HY, et al. Identifying uncontrolled asthma in young children: clinical scores or objective variables? *J Asthma* 2009;46(2):130-5.

26. Kaya A, Erkocoglu M, Akan A, et al. TRACK as a complementary tool to GINA and NAEPP guidelines for assessing asthma control in pre-school children. *J Asthma* 2014;51(5):530-5.

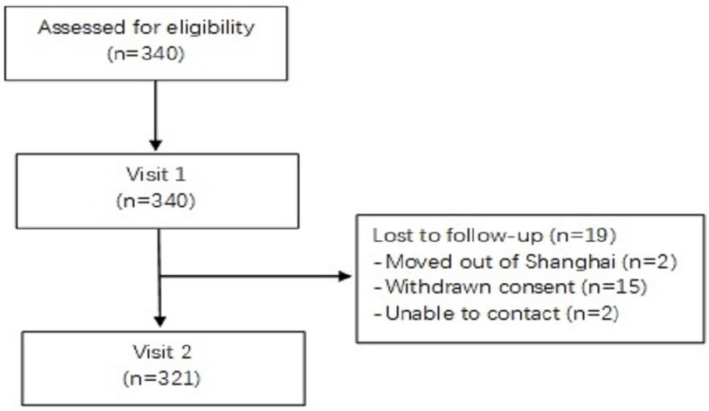

Figure 1 Flow diagram for the selection of participants

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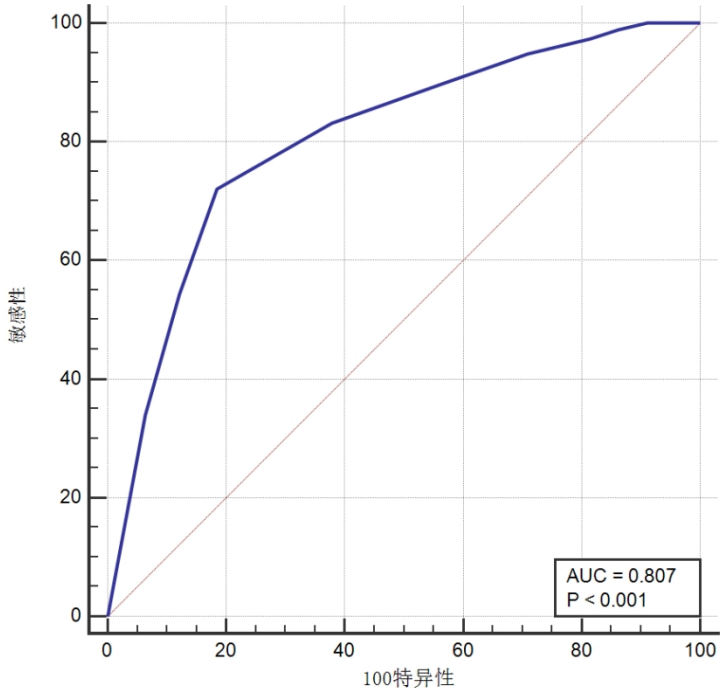

Figure 2 ROC curve for the baseline TRACK scores

101x76mm (300 x 300 DPI)

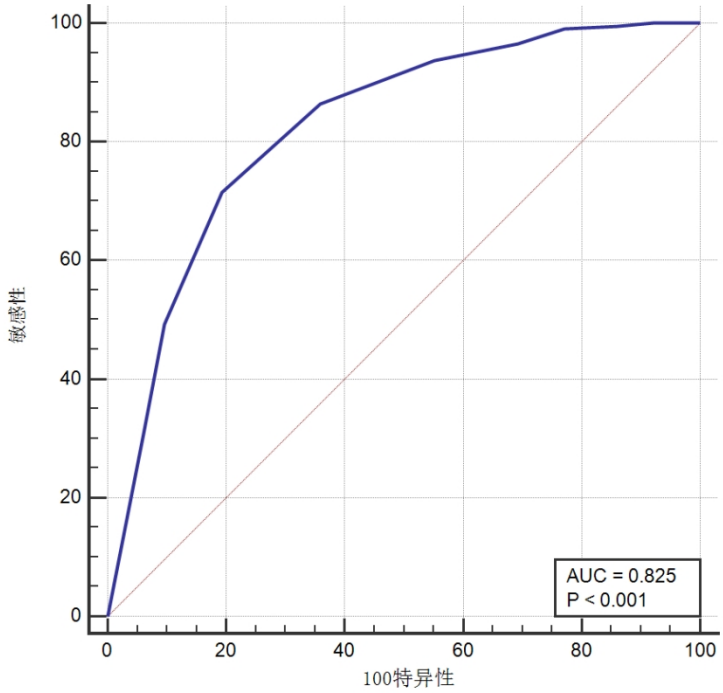

Figure 3 ROC curve for the follow-up TRACK scores

101x76mm (300 x 300 DPI)

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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

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Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Respiratory medicine

Keywords:	Asthma < THORACIC MEDICINE, Asthma control, Preschool children, Questionnaire, Reliability, Validity

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

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ABSTRACT

Objective The limited existing asthma control questionnaires that are available for children 5 years of age or younger in China mostly assess only the impairment domain of asthma control. Here, the English version of the Test for Respiratory and Asthma Control in Kids (TRACK) was translated into Chinese and validated for its application in asthma control in preschool children.

Design Prospective validation study

Setting and participants A total of 321 Chinese preschool children suffering from asthma completed the study from December 2017 to February 2018.

Method The TRACK translation into Chinese employed the translation and back translation technique. The caregivers of the preschool children with asthma symptoms completed the TRACK during two clinical visits over 4-6 weeks. Moreover, the physicians completed a Global Initiative for Asthma (GINA)-based asthma control survey at both visits. The utility of the TRACK for assessing the change in asthma control status and its reliability and discriminant validity were evaluated.

Results The Chinese version of the TRACK showed internal consistency reliability values of 0.63 and 0.71 at each visit, respectively (Cronbach's α). The test-retest reliability was 0.62 for individuals whose GINA-based assessment results were the same at both visits (N=206). The TRACK scores for the children in the various asthma control categories were significantly different (P<0.001). Children recommended for increased treatment by the physicians had lower TRACK scores than those recommended for no change in treatment or decreased treatment (P<0.001).

Conclusion The study verifies the validity and reliability of the Chinese version of the TRACK. Changes in the TRACK scores effectively reflected the level of asthma control in preschool children and guided further treatment strategies.

Trial registration number NCT02649803

Key words: Asthma, Asthma control, Preschool children, Questionnaire, Reliability, Validity

ARTICLE SUMMARY

Strengths and limitations of this study

1. The present study was the first to validate the Chinese version of the Test for Respiratory and Asthma Control in Kids (TRACK) for preschool children with asthma.
2. The study sample was recruited from the Yangtze River Delta region, represented by Jiangsu, Zhejiang and Shanghai, where the incidence of asthma in children has increased rapidly over the last 10 years.
3. Only children 5 years of age or younger with asthma were included, and patients with other recurrent wheezing diseases were excluded.
4. The main limitation of this study was that the caregivers had relatively high educational backgrounds, which may limit the surveys applicability to other underdeveloped provinces in China.

INTRODUCTION

Since 1990, the prevalence of asthma in paediatric patients has remarkably increased in China. The prevalence in children aged 0-14 years was 1.07% in 1990, 1.97% in 2000 and 3.02% in 2010, resulting in a major public health problem. The prevalence of asthma has been increasing steadily since 1998, and the prevalence of children with asthma has likely increased from 2017 to 2019.[1] Preschool children (those aged 5 years or younger) present significantly higher morbidity from asthma than those in other age groups. In addition, there were 4.27 exacerbations per 10 person-years in preschool children in a population-based cohort study.[2] The annual rate of emergency department visits and hospital admissions is higher than that of other age groups.[3] Preschool childhood wheezing may reflect a progressive decline in lung function that could extend into adulthood and an elevated risk of chronic obstructive pulmonary disease (COPD) when accompanied with atopy.[4] Asthma management in preschool children is complex, as the effects of different therapies for varied phenotypes remain unclear, and several confounders can affect the treatment response. As a result, preschool children with asthma require a large amount of healthcare resources, resulting in a high economic burden.

Poor treatment adherence represents a significant risk factor in children with asthma.[5] Because of the lack of an effective caregiver-reported asthma control assessment tool for preschool children, caregivers usually underestimate the child's asthma symptoms; this is one of the primary reasons for poor treatment compliance.[6] Evaluation of the asthma control level in children with asthma remains an essential factor in the follow-up and treatment of this chronic disease. Current guidelines emphasize the assessment of asthma control, including clinical asthmatic manifestation assessments and lung function screening.[7] Preschool-aged children are too young to complete a lung function test; therefore, asthma control assessments of these individuals are mostly dependent on caregiver feedback. Thus, assessing the control level in these individuals remains challenging. Over the past few years, many questionnaires have been proposed to evaluate asthma control in 4- to 11-year[8]- and 5- to17-year[9]-old children, as well as in adolescents and adults.[10] The Global Initiative for Asthma (GINA) and the National Asthma Education and Prevention Program (NAEPP) have emphasized two asthma

control domains: risk and impairment. However, most existing asthma control questionnaires cannot be used for children under 5 years old and assess only the frequency of respiratory symptoms and rescue drug usage.[11]

A simple, efficient and validated tool is urgently needed for preschool children with asthma in China. In 2007, Murphy et al. developed a new assessment tool called the "Test for Respiratory and Asthma Control in Kids (TRACK)" for children 5 years of age and younger, covering the risk and impairment domains. This caregiver-reported questionnaire contains 5 items. Each item is assigned a score of 0-20 points based on a 5-point Likert scale for a total of 0-100 points. The reliability of the TRACK was greater than 0.7 in the development and validation samples. While screening for control issues, the TRACK displayed a good area under the receiver operating characteristic (ROC) curve based on the NAEPP-based evaluation of asthma control. The TRACK correctly classified asthma control levels in approximately 80% of preschool-age individuals with asthma, and the cutoff point was 80.[12] TRACK score alterations ≥10 points are clinically significant for respiratory control in young children showing respiratory symptoms indicating asthma and should trigger a re-evaluation of asthma management.[13] However, the questionnaire has not been validated in China.

The current study aimed to propose and validate a Chinese version of the TRACK to evaluate asthma control in preschool children. This questionnaire can be used as a complement to the limited asthma control assessment tools that are currently available in China for children 5 years of age or younger with asthma.

METHODS

The study was approved by the ethics committee of the Shanghai General Hospital, Shanghai, China, and Shanghai Children's Medical Center, Shanghai, China. All caregivers provided signed informed consent before study initiation. The trial is registered as NCT02649803 on ClinicalTrials.gov. The study protocol has been published in *BMJ Open*.[14]

Study design and setting

The current prospective, multicentre, observational trial was carried out from December 2017 to February 2018 at Shanghai General Hospital (Shanghai), Shanghai Children's Medical Center (Shanghai), Nanjing Children's Hospital (Nanjing), The Children's Hospital (Hangzhou) and 14 community hospitals in Pudong District, Shanghai. The staff of all the community hospitals contributing to the present trial received systematic training prior to patient enrolment.

Study population

The caregivers of the preschool children with asthma in the "Paediatric asthma control under a community management model in China" clinical study programme who were invited and visited the study site to participate were given a concise description of the trial.[14] The inclusion criteria were as follows: (1) the child was an outpatient ≤ 5 years of age and of either sex; (2) the child received a diagnosis of asthma based on the GINA criteria (a history of 3 or more times of wheezing attack per year in the absence of obvious respiratory infection; exercise-, laughing- or crying-induced wheezing or coughing; clinical improvement with 2-3 months of regular low-dose inhaled corticosteroids (ICSs), and symptom worsening after ICS cessation); (3) the child's parent or guardian provided consent; and (4) the caregiver had access to a smartphone. The exclusion criteria were as follows: (1) the child had congenital heart disease, gastro-oesophageal reflux, bronchopulmonary dysplasia or bronchiolitis obliterans; (2) the child had a previous allergic reaction to an ICS; (3) the child presented other ailments that could potentially interfere with the study data according to the physician; and (4) the child was involved in a similar trial in the past 3 months.

Atopic dermatitis was diagnosed by a senior dermatologist by examining the skin and reviewing the child's medical records. The diagnosis of allergy rhinitis was established by a senior ear, nose, and throat (ENT) consultant according to Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines.[15] A food allergy was diagnosed by an allergist-immunologist based on a number of factors, such as symptoms, family history, skin and blood tests, elimination tests and oral food challenge.

The sample size in validation studies should exceed 5-10 times the number of parameters.[16] Tabachnik and Fidell proposed that ≥300 cases were required for a factor assessment.[17] These recommendations were used for the sample size determination.

The caregivers were trained to use the study application (APP) installed on their smartphones. We monitored whether the caregivers completed the TRACK report and reminded the users to complete the report every month to ensure compliance. The caregivers completed the TRACK report on their smartphone before they entered the consultation room. The caregivers were able to read and write in Chinese.

TRACK questionnaire

The caregiver-reported TRACK contained 5 items to monitor respiratory control in children 5 years of age or younger. The TRACK included the frequency of respiratory manifestations (such as wheezing, coughing and shortness of breath), night-time awakenings, activity limitations in the last 4 weeks, the frequency of rescue medicine utilization in the preceding 3 months, and oral corticosteroid administration in the past 12 months. Scores for various items ranged between 0 and 20, and the total score of the TRACK questionnaire was 100.[12]

The English version of the TRACK was translated into Chinese following previously established guidelines.[18] First, a forward translation was carried out independently by two native Chinese speaking investigators with English fluency who were paediatricians with a public health background to produce a consensus version. Second, the consensus version was back-translated into English by two blinded professional translators. Finally, the original, translated and back-translated versions were thoroughly compared by a committee of experts for conceptual equivalence. Then, a pre-final consensus version was obtained.

Although the Chinese version of the TRACK attempted to maintain consistency with the original version of the questionnaire, its content was partially adjusted. The modified Chinese version of the TRACK was slightly revised for item 5 of the pre-final consensus version after communicating with Prof. Murphy, the original author of the TRACK. The following question was added as item 5: “How often does your child take a high dose of ICSs (nebulized budesonide 1 mg/dose, daily inhalations or other equivalent ICSs)

and systemic corticosteroids (oral prednisone, oral prednisolone, intravenous methylprednisolone, intravenous hydrocortisone succinate) for breathing issues when not controlled by other medications?". The treatment of asthma in China is more likely to involve the use of high-dose ICSs to reduce or avoid the use of systemic corticosteroids based on the GINA data.[7] In addition, some children who experience severe asthma attacks are prescribed intravenous corticosteroids (IVCSs) according to the GINA assessment[7] during emergency treatment hospitals in China. Therefore, we added intravenous corticosteroid use to item 5 as a complement. Thus, the modified Chinese version of the TRACK was considered to be more suitable for children aged 5 years or younger with asthma in China.[19] A final Chinese version was obtained after pre-testing the pre-final version on the caregivers of 10 patients; the pre-tests were followed by interviews to ensure comprehension and applicability to the patient population. At this point, the final version was prepared for validation. The 10 caregivers participating in the pre-test did not participate in the study itself. All steps followed the TRACK's copyright requirements.[12] The Chinese version of the TRACK is presented in Table 1.

Table 1. Chinese version of the TRACK

	分值				
	20 分	15 分	10 分	5 分	0 分
在过去 4 周内，孩子受到呼吸问题（如喘息、咳嗽或呼吸短促）的困扰有多频繁？	根本没有 ☐	1～2 次 ☐	每周 1 次 ☐	任一周 2～3 次 ☐	任一周 4 次或更多次 ☐
在过去 4 周内，孩子因呼吸问题（喘息、咳嗽、呼吸短促）在晚上醒来有多频繁？	根本没有 ☐	1～2 次 ☐	每周 1 次 ☐	任一周 2～3 次 ☐	任一周 4 次或更多次 ☐
在过去 4 周内，孩子的呼吸问题（如喘息、咳嗽或呼吸短促）在多大程度上干扰其玩耍、上学或进行同龄儿童应该进行的平常活动的能力？	根本没有 ☐	轻微 ☐	中等 ☐	大 ☐	极大 ☐
在过去 3 个月内，您需要使用快速缓解药物（特布他林、沙丁胺醇）来治疗孩子的呼吸问题（喘息、咳嗽、呼吸短促）有多频繁？	根本没有 ☐	1～2 次 ☐	每周 1 次 ☐	任一周 2～3 次 ☐	任一周 4 次或更多次 ☐

在过去 12 个月内，孩子需要全身糖皮质激素（口服泼尼松或泼尼松龙、注射甲泼尼龙或琥珀酸氢化可的松）或加用局部糖皮质激素（高剂量）来治疗其他药物无法控制的呼吸问题的频次？	从来没有 ☐	1 次 ☐	2 次 ☐	3 次 ☐	4 次或更多次 ☐

Data collection

After informed consent was obtained, the caregivers were initially prompted to complete the TRACK by using the APP on their smartphones, with a follow-up after 4-6 weeks. The physicians were blinded to the caregivers' responses to the TRACK. The asthma control levels of the patients were evaluated by physicians based on the GINA assessment for children under 5 years of age; the GINA assessed 4 items: the frequency of daytime symptoms, nocturnal symptoms, rescue drug (bronchodilator) usage, and the limitation of daily activities in the past 4 weeks. According to GINA results, the patients were divided into 3 groups, including the controlled, partly controlled and uncontrolled groups.[7]

Patient and public involvement statement

No patients or the public were involved in the present study design. The caregivers were involved in the study by actively completing the questionnaires on their smartphones during the 2-month study period. A results report was sent to the study participants.

STATISTICAL ANALYSIS

SPSS 21.0 (IBM SPSS Statistics, USA) was employed for the statistical analyses. Descriptive statistics were performed for the general participant features. The Kolmogorov-Smirnov test was used to examine the normality of the data distribution. Medians and quartiles were adopted to describe non-normally distributed data. The group difference was calculated using the Kruskal-Wallis test, as the data had a skewed distribution. P <0.05 indicated statistical significance.

Reliability

Cronbach's α coefficient served as a metric for assessing the reliability of the scale. A test-retest analysis was performed to evaluate the temporal stability of the TRACK, i.e., the reliability of identical responses at the first (test) and final visit 4-6 weeks later (retest). The test-retest reliability of the TRACK questionnaire was evaluated using Pearson's correlation coefficient by comparing the scores at baseline and at follow-up in individuals whose physicians indicated that the asthma control status according to the GINA assessment was unchanged between the two visits.

Validity

Construct validity is commonly employed to assess the efficiency of a test to measure what the intended outcome. An exploratory factor analysis produces the dimension of differentiation that is used to confirm the questionnaire construct validity. To determine whether the questionnaire was suitable for factor analysis, the following methods were used. The first was the Kaiser–Meyer–Olkin Measure of Sampling Adequacy (KMO) criterion, which assesses sample sufficiency, and the other was Bartlett's test of sphericity, which examines whether questionnaire items are inter-independent. Generally, a KMO value >0.6 and Bartlett's test of sphericity at $p<0.05$ indicate the factorability of a correlation matrix. An exploratory factor analysis was then performed with 5 items by principal component analysis extraction and varimax rotation, with a minimum factor loading cutoff point of 0.4. Construct validity was analysed among the children with asthma at baseline. For the discriminant validation tests, the children were divided according to their differences in respiratory control based on 2 criteria. The first part of the TRACK's discriminant validation was assessed by comparing the TRACK scores of the 3 categories based on the GINA definition of control (controlled, partly controlled and uncontrolled). The second part of the TRACK's discriminant validation was assessed by comparing the TRACK scores of the 3 categories of treatment decisions at the end of the visit (increased therapy, no change, decreased therapy).

Screening accuracy

The accuracy of the TRACK for identifying individuals presenting respiratory control issues (according to the GINA assessment) was assessed by ROC curve analysis. The children were grouped into two groups, the not well-controlled group (partly controlled

and uncontrolled) and the controlled group, to detect children with any uncontrolled symptoms of asthma as much as possible. In addition, the sensitivity, specificity, positive (PPVs) and negative predictive values (NPVs), false-positive rate, accuracy and the area under the ROC curve were calculated to explore the optimal cutoff point for screening.

RESULTS

Demographics

Only 7 patients who met the eligibility criteria were unwilling to participate in the trial. A total of 340 caregivers were recruited for the study. Of these, 321 (94.4%) caregivers completed the follow-up visit, and their TRACK reports were finally evaluated (Figure 1). Most of the caregivers were female (84.1%), aged 25-44 years old (81.3%), and had graduated from college or obtained a relatively high level of education (77.9%). The patients' age distribution was as follows: <24 months, 40 (12.5%); between 25 and 48 months, 165 (51.4%); and between 49-60 months, 116 (36.1%). A total of 90% of the participants were reported to have a controlled asthma status according to their caregivers. Table 2 summarizes the baseline characteristics of the patients and their caregivers.

Table 2. Caregiver and Patient Demographic Characteristics

Characteristics	Study group (n=321)
Sex *n (%)*	
Male	227 (70.7)
Female	94 (29.3)
Age in months[a] *(months)*	44.1 (35.6, 51.9)
0-24 months *n (%)*	40 (12.5)
25-48 months *n (%)*	165 (51.4)
49-60 months *n (%)*	116 (36.1)
Age at first wheezing episode[a] *(months)*	18 (11, 29)
Atopic dermatitis *n (%)*	206 (64.2)
Allergy rhinitis *n (%)*	236 (73.5)
Food allergy *n (%)*	80 (24.9)
Family atopy *n (%)*	152 (47.4)
Caregiver sex *n (%)*	
Male	51 (16.0)
Female	270 (84.1)
Caregiver age *n (%)*	

18-24	48 (15.0)
25-34	174 (54.2)
35-44	87 (27.1)
≥45	12 (3.7)
Caregiver education *n (%)*	
Not a high school graduate	23 (7.2)
High school graduate	48 (15.0)
College graduate or higher	250 (77.9)
Caregiver disease control rating *n (%)*	
Controlled	289 (90.0)
Uncontrolled	32 (10.0)

[a]Median and quartiles [median (25%, 75%)]

Reliability

The internal consistency reliability values (Cronbach's α) were 0.63 and 0.71 at baseline and follow-up, respectively. After deletion of item 5 [oral corticosteroid (OCS), IVCS or high-dose ICS utilization in the last 12 months], the Cronbach's α values increased to 0.73 and 0.75 at baseline and follow-up, respectively. At baseline, Cronbach's α was less than the value for a multi-item scale (0.7) and negatively influenced by item 5 of the 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 physician evaluations according to GINA were the same at both visits (n=206).

Construct validation

The KMO values were 0.75 at the baseline visit and were considered satisfactory (>0.6), suggesting that the sample size was sufficiently large for assessing the factor structure. In Bartlett's test, a χ^2 =350.88 (P<0.001) was obtained. Moreover, the KMO values for various constructs exceeded 0.6 with Bartlett's test showing significance, suggesting a sufficient amount of data for factor analysis. The exploratory factor analysis was then conducted. The items of the Chinese version of the TRACK showed loading on the same factors. The 5 items explained 52.51% of the variance. The factor loading of each item of the TRACK ranged from 0.48 to 0.83 (Table 3).

Table 3 Loadings of the TRACK

Items	Item Loading
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 the preceding 3 months	0.55
Systemic corticosteroids or high-dose ICS use in the previous year	0.48

Eigen value: 2.38, Variance explained: 52.51%

Discriminant validation

The TRACK scores were significantly different among the controlled, partly controlled, and uncontrolled groups as categorized according to GINA, which was evaluated by the physicians at baseline (P<0.001) and follow-up (P<0.001) visits to support the discriminant validity of the TRACK scores. The TRACK scores showed the highest and lowest values in patients with controlled and uncontrolled ratings (Table 4). Children who were recommended for stepped-up therapy showed significantly lower TRACK scores at baseline and follow-up than those who were recommended for no therapy change or stepped-down therapy (P<0.001, Table 5).

Table 4 TRACK scores based on the control levels of asthma as assessed by the GINA survey.

	Control rating according to the GINA assessment			
	Controlled	Partly Controlled	Uncontrolled	P
Baseline TRACK score	95 (85-100) n=197	80 (70-85) n=87	75 (65-85) n=37	<0.001
Follow-up TRACK score	90 (85-100) n=207	80 (72.5-87.5) n=89	70 (57.5-77.5) n=25	<0.001

Table 5 TRACK scores based on the physicians' recommendations according to GINA-based control

	Change in therapy			
	Stepped Down	No Change	Stepped Up	P
Baseline TRACK score	90 (85-100) n=58	85 (80-95) n=246	65 (60-75) n=17	<0.001
Follow-up TRACK score	90 (85-100) n=41	90 (80-95) n=273	40 (40-60) n=7	<0.001

Screening accuracy

Baseline and follow-up TRACK scores (0-100) produced areas under the ROC curve values of 0.81 (Figure 2) and 0.83 (Figure 3) for screening ability, respectively. To distinguish "controlled" patients from "partly controlled" and "uncontrolled" patients, a TRACK cutoff value of 85 was considered for baseline (sensitivity, 81.4%; specificity, 72.1%) and follow-up visits (sensitivity, 80.7%; specificity, 71.5%). The screening accuracies of the TRACK scores at various cutoff points at baseline and follow-up visits are presented in Tables 6 and 7.

Table 6 The screening accuracy of the TRACK scores at the baseline visit

Cutoff points	Odds ratio	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	False-positive rate (%)	Accuracy (%)
65	8.74	18.6	97.5	65.5	82.1	34.5	67.0
70	7.65	29.0	94.9	68.0	78.3	32.0	69.5
75	6.82	43.6	89.9	71.7	73.0	28.3	72.0
80	8.14	62.1	83.3	77.7	77.8	22.3	75.1
85	11.33	81.5	72.1	86.1	64.7	13.9	75.7
90	8.63	87.9	54.3	87.7	54.8	12.3	67.3

PPV, positive predictive value; NPV, negative predictive value

Table 7 The screening accuracy of the TRACK scores at the follow-up visit

Cutoff points	Odds ratio	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	False-positive rate (%)	Accuracy (%)
65	4.54	22.8	99.0	70.0	92.9	30.0	72.0
70	3.37	30.7	96.6	71.7	83.3	28.3	73.2
75	3.73	44.7	93.7	75.5	82.8	24.5	77.0
80	2.61	64.0	86.5	81.3	72.3	18.6	78.5
85	2.72	80.7	71.5	87.1	60.9	13.0	74.8
90	2.43	90.4	49.3	90.3	50.0	9.7	63.9

PPV, positive predictive value; NPV, negative predictive value

DISCUSSION

To the best of our knowledge, the present study was the first to validate the Chinese version of the TRACK in children 5 years of age or younger with asthma in China. The results showed that the TRACK had good reliability and validity, and the responsiveness to asthma control alterations over time indicated the utility of the questionnaire.

In this study, Cronbach's α values for the TRACK were 0.63 and 0.71 at both visits, respectively. In the original version of the TRACK, Cronbach's α values ranged between 0.71 and 0.75.[12] In the Spanish and Turkish versions of the TRACK, Cronbach's α values ranged from 0.74 to 0.76 in the questionnaire.[20, 21] In comparison with the above versions of the TRACK, the Chinese version had a similar and acceptable reliability. The 5 TRACK items conformed to the NAEPP asthma management guidelines for both the impairment and risk domains of control assessment. The above findings indicated that the TRACK confirmed asthma control to be multidimensional. However, after the deletion of item 5 (OCS, IVCS or high-dose ICS utilization in the preceding 12 months), the internal consistency reliability values increased to 0.73 and 0.75 at baseline and follow-up in this study, respectively. The risk domain assessment demonstrated that recent severe asthma exacerbation is an important independent predictor of future severe exacerbations in paediatric patients suffering from severe or difficult-to-treat asthma and should be taken into consideration in asthma management plans.[22,23] The test-retest reliability was "good" in this work, but it was not "excellent". A total of 4-6 weeks separated the baseline and follow-up visits to allow the evaluation of asthma control changes. Because clinical respiratory symptoms in preschool children with asthma change frequently, 4-6 weeks may not be an optimal time interval to evaluate the test-retest reliability, which could ultimately affect the results.

Another common method for assessing asthma control in preschool children is the GINA assessment, which is widely accepted and used in China and is administered by physicians. Discriminant validity was evaluated by the differences in the TRACK among children with controlled, partly controlled and uncontrolled asthma based on the GINA assessment and the children whose baseline visits prompted a stepped-up, stepped-down or non-changed therapy. Our findings regarding the TRACK's discriminant validity agreed with those of Chipps et al.[24] The study recruited 438 caregivers of children with asthma below 5 years of age for TRACK completion at two clinical visits. Moreover, physicians completed the guidelines-based respiratory control survey and decided whether therapy should be changed. The results showed that the mean TRACK scores were markedly different among the children grouped by the

physicians' NAEPP-based control rating at baseline and follow-up, suggesting a change in therapy and control status and supporting the discriminant validity of the TRACK scores. These studies expanded the TRACK's validity and reliability by demonstrating that it responded to changes in the respiratory control status of individuals with asthma under 5 years of age. Taken together, these results showed that the TRACK has good validity, consistent with other versions.

However, asthma control assessment tools should be based on objective quantitative evaluations and differentiate the control levels. The optimal asthma control assessment tool quantifies asthma control as a continuous variable and provides a numeric value to distinguish between controlled and uncontrolled asthma. If the physician or caregiver knows the specific score, they will have a clearer understanding of asthma control, and it will facilitate comparisons between different periods. Therefore, we need an objectively quantified assessment tool to assess the control level of asthma in children. These requirements were met by the TRACK assessment, and we therefore consider it a complementary assessment tool to the GINA assessment for children under 5 years of age.

In the pioneering work by Murphy and collaborators, a cutoff point of 80 yielded the best balance between sensitivity and specificity for discriminating between controlled and uncontrolled asthma cases. In patients with TRACK scores below 80, a subsequent evaluation or treatment adjustment should be considered.[12] Other versions of the TRACK also used 80 as the cutoff point.[20, 21] Here, a cutoff of 85 yielded acceptable screening statistics at both visits. The elevated value in our study was likely because of our ROC curve that was relative to the GINA-based ratings of asthma control rather than the NAEPP-based ratings used in the other studies.[12, 20, 21] Kaya et al. evaluated the consistency between the TRACK scores and asthma control levels based on the GINA and NAEPP guidelines in pre-school aged children. With 80 as the cutoff point for the TRACK, the compatibility rate of asthma control levels between the TRACK and GINA assessments was 71.0%, while that between the TRACK and NAEPP assessment was 76.4%. The nonconformity rate of the GINA results was higher than that of the NAEPP results.[25] The main difference between the GINA and NAEPP

guidelines is that if the daytime symptoms occurred more than once a week with any activity limitation caused by asthma, and the relief medication was needed more than once a week or any night-time symptom occurred within the ~~last~~ past month, the case was not considered to be controlled based on the GINA guidelines. However, the NAEPP defines cases as uncontrolled when up to one night-time symptom occurs per month, daytime symptoms occur twice within a week, a short-acting β2 agonist for symptom control is required at least 2 days a week and/or one there is at least exacerbation within a year. In terms of asthma control, the requirement of the GINA-based assessment was higher than that of the NAEPP-based assessment for children under 5 years of age. The TRACK was developed following the NAEPP asthma management guidelines, which explains the increased optimal cutoff point of 85 for the Chinese version of the TRACK in our study. Overall, the above findings supported the pioneer report that indicated that TRACK scores below 80 can identify children with uncontrolled asthma or respiratory symptoms.

The main limitation of our study was that the caregivers had relatively high educational backgrounds. Although this study was a multicentre cohort study, it was mainly limited to Shanghai, Hangzhou and Nanjing. Most of the caregivers were from the above or nearby cities. As these are the most developed cities in China, the educational level is relatively higher than that in underdeveloped mid-west areas. The Chinese version of the TRACK, which should be promoted in China in the future, needs to be further validated using different levels of regional participation in the country. Due to the limited number of cases and regional constraints, the optimal cutoff point for this test may not fully represent China as a whole.

In conclusion, these findings demonstrate the reliability and validity of the Chinese version of the TRACK for assessing asthma control in children 5 years of age or younger. The TRACK compensates for the insufficiency of other assessment tools for preschool-aged children in China. The promotion and application of the TRACK in China could help caregivers and physicians evaluate the level of asthma control in children conveniently and effectively and further guide clinical treatment.

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the manuscript, and amending the paper and all take responsibility for all aspects of the work. All the data were accessible to all the authors to ensure the accuracy of the reported data.

Competing interests None declared.

Ethics approval Ethical approval for the study was granted by the Shanghai General Hospital Research Ethics Committee (2018KY001) and Shanghai Children's Medical Center Research Ethics Committee (SCMCIRB-K2016037).

Patient consent Parental/Guardian consent was obtained.

Data sharing statement Additional data can be requested by emailing the corresponding author.

Figure 1 Flow diagram for the selection of participants

Figure 2 ROC curve for the baseline TRACK scores

Figure 3 ROC curve for the follow-up TRACK scores

References

1. 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. Bloom CI, Nissen F, Douglas IJ, et al. Exacerbation risk and characterisation of the UK's asthma population from infants to old age. *Thorax* 2018;73(4):313-20.
3. Perry R, Braileanu G, Palmer T, et al. The Economic Burden of Pediatric Asthma in the United States: Literature Review of Current Evidence. *Pharmacoeconomics* 2019;37(2):155-67.
4. Ma H, Li Y, Tang L, et al. Impact of childhood wheezing on lung function in adulthood: A meta-analysis. *PLoS One* 2018;13(2):e0192390.
5. Xiang L, Zhao J, Zheng Y, et al. Uncontrolled asthma and its risk factors in Chinese children: A cross-sectional observational study. *J Asthma* 2016;53(7):699-706.
6. Sonney JT, Gerald LB, Insel KC. Parent and child asthma illness representations: a systematic review. *J Asthma* 2016;53(5):510-6.
7. Global Strategy for the diagnosis and management of asthma in children 5 years and younger (revised 2018). *Global Initiative for Asthma* Available at: http://www.ginasthma.org.
8. Liu AH, Zeiger R, Sorkness C, et al. Development and cross-sectional validation of the Childhood Asthma Control Test. *J Allergy Clin Immunol* 2007;119(4):817-25.
9. Skinner EA, Diette GB, Algatt-Bergstrom PJ, et al. The Asthma Therapy Assessment Questionnaire (ATAQ) for children and adolescents. *Dis Manag* 2004;7(4):305-13.
10. Alzahrani YA, Becker EA. Asthma Control Assessment Tools. *Respir Care* 2016;61(1):106-16.
11. Voorend-van Bergen S, Vaessen-Verberne AA, de Jongste JC, et al. Asthma control questionnaires in the management of asthma in children: A review. *Pediatr Pulmonol* 2015;50(2):202-8.

12. Murphy KR, Zeiger RS, Kosinski M, et al. Test for respiratory and asthma control in kids (TRACK): a caregiver-completed questionnaire for preschool-aged children. *J Allergy Clin Immunol* 2009;123(4):833-9 e9.
13. Zeiger RS, Mellon M, Chipps B, et al. Test for Respiratory and Asthma Control in Kids (TRACK): clinically meaningful changes in score. *J Allergy Clin Immunol* 2011;128(5):983-8.
14. Xu J, Yin Y, Zhang H, et al. Paediatric asthma control under a community management model in China: a protocol for a prospective multicentre cohort study. *BMJ Open* 2017;7(8):e015741.
15. Brozek JL, Bousquet J, Agache I, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines-2016 revision. *J Allergy Clin Immunol* 2017;140(4):950-58.
16. MacCallum RC, Widaman KF, Preacher KJ, et al. Sample Size in Factor Analysis: The Role of Model Error. *Multivariate Behav Res* 2001;36(4):611-37.
17. Tabachnic BG, Fidell LS. Using Multivariate Statistics. 5th edition. Boston, MA: Pearson Education. Inc. 2007.
18. Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine (Phila Pa 1976)* 2000;25(24):3186-91.
19. Hong JG. Modified Chinese version of the Test for Respiratory and Asthma Control in Kids （TRACK） and its clinical value. *Chinese Journal of Practical Pediatrics* 2018;33(3):192-95.
20. Rodriguez-Martinez CE, Nino G, Castro-Rodriguez JA. Validation of the Spanish version of the Test for Respiratory and Asthma Control in Kids (TRACK) in a population of Hispanic preschoolers. *J Allergy Clin Immunol Pract* 2014;2(3):326-31 e3.
21. Buyuktiryaki B, Sahiner UM, Yavuz ST, et al. Validation of the Turkish version of "Test for Respiratory and Asthma Control in Kids (TRACK)" questionnaire. *J Asthma* 2013;50(10):1096-101.
22. Haselkorn T, Zeiger RS, Chipps BE, et al. Recent asthma exacerbations predict future exacerbations in children with severe or difficult-to-treat asthma. *J Allergy Clin Immunol* 2009;124(5):921-7.
23. Turner SW, Murray C, Thomas M, et al. Applying UK real-world primary care data to predict asthma attacks in 3776 well-characterised children: a retrospective cohort study. *NPJ Prim Care Respir Med* 2018;28(1):28.
24. Chipps B, Zeiger RS, Murphy K, et al. Longitudinal validation of the Test for Respiratory and Asthma Control in Kids in pediatric practices. *Pediatrics* 2011;127(3):e737-47.
25. Kaya A, Erkocoglu M, Akan A, et al. TRACK as a complementary tool to GINA and NAEPP guidelines for assessing asthma control in pre-school children. *J Asthma* 2014;51(5):530-5.

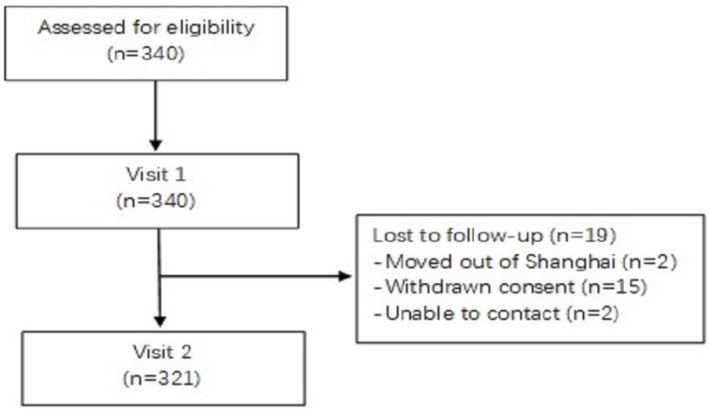

Figure 1 Flow diagram for the selection of participants

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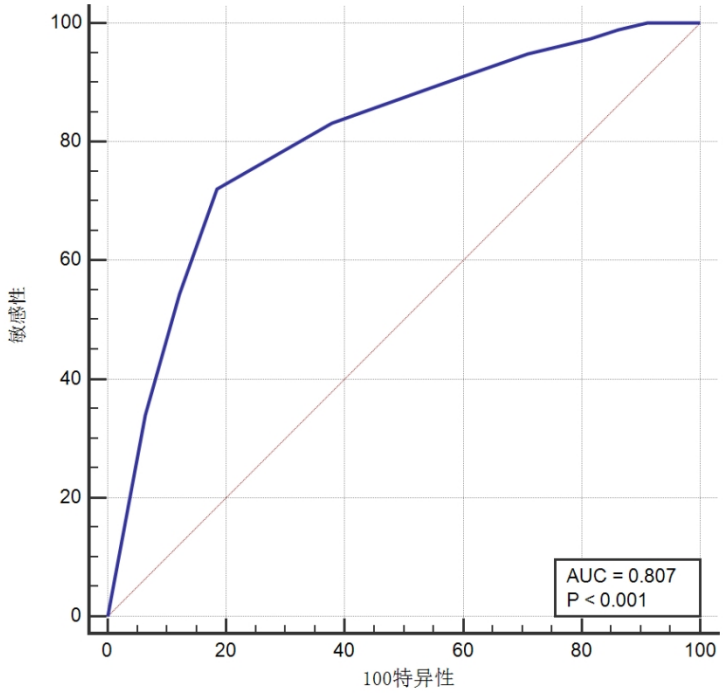

Figure 2 ROC curve for the baseline TRACK scores

101x76mm (300 x 300 DPI)

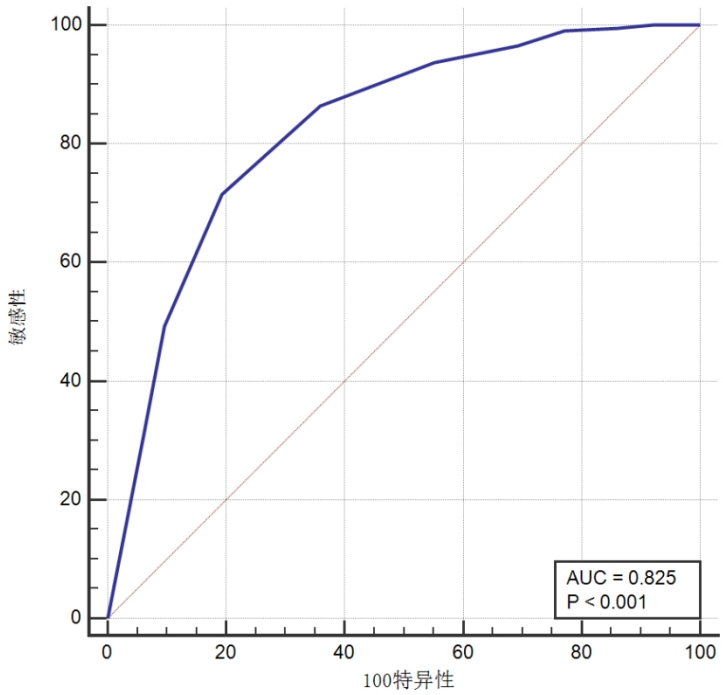

Figure 3 ROC curve for the follow-up TRACK scores

101x76mm (300 x 300 DPI)

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*

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