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Patients' adherence-related beliefs about inhaled steroids: application of the Chinese version of the Beliefs about Medicines Questionnaire-specific in patients with asthma

Qingqing Cai, MS^{a*}, Ling Ye, MD^{b*}, Robert Horne, PhD^c, Jing Bi, MS^b, Qing Xu, MS^a, Xiaofen Ye, MS^a, Aifang Yang, MS^d, Meiling Jin, MD^b, Xiaoyu Li, PhD^a, and Qianzhou Lv, MS^a

^aDepartment of Pharmacy, Zhongshan Hospital, Fudan University, Shanghai, PR China; ^bDepartment of Respiratory, Zhongshan Hospital, Fudan University, Shanghai, PR China; ^cUCL School of Pharmacy, University College London, London, United Kingdom; ^dDepartment of Pharmacy, Worker's Medical Clinic, Macau, PR China

ABSTRACT

Objective: The main objective of the present study is to evaluate the psychometric properties of the Chinese version of Beliefs about Medicines Questionnaire-specific among asthma patients; and to assess the association between patients' belief and adherence to inhaled corticosteroid therapy. **Methods:** A cross-sectional survey was carried out in the asthma clinic of Zhongshan Hospital, to Fudan University (Shanghai, China) between April 2016 and March 2018. The Beliefs about Medicines Questionnaire-specific was translated into Chinese according to international guidelines. Internal consistency, test-retest reliability, and confirmatory factor analysis were calculated to validate the Beliefs about Medicines Questionnaire-specific. The relationship between the adherence and the belief subscale were assessed using Kruskal–Wallis test. **Results:** Two hundred and seventeen patients were recruited in this study. The Beliefs about Medicines Questionnaire-specific was deemed reliable based on the results of Cronbach's alpha coefficient and test-retest intraclass correlation coefficient (ICC, ICC = 0.759). Confirmatory factor analysis showed acceptable model fit for the two-factor model. Patients' compliance was closely related to their belief about inhaled corticosteroid. The adherence rates were highest for the accepting groups, and lowest for the skeptical groups. Higher adherence was significantly associated with higher necessity-concerns differential ($p = .001$) and lower concern ($p = .004$). **Conclusions:** The Chinese version of the Beliefs about Medicines Questionnaire-specific can be used as a reliable tool by the clinicians to identify beliefs and behaviors of individual to improve adherence in Chinese patients.

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Beliefs about medicines; adherence; asthma; psychometrics properties; questionnaire

Introduction

Asthma is a chronic airways inflammatory disease which affects up to 30 million people in China, and approximately 330 million people worldwide [1]. The increasing prevalence of asthma has become a serious public health problem and causes an adverse socio-economic burden. Asthma cannot be cured, but can be controlled with appropriate management [2]. Current management guidelines recommend inhaled corticosteroid (ICS) as an initial maintenance treatment for persistent asthma [3]. Regular application of ICSs can significantly reduce the proportion of hospitalized patients with asthma attacks by 80% [4]. However,

nonadherence is a prevalent and important reason that leads to poor asthma control [5,6]. It has been estimated that adherence rates to ICS in adults with chronic asthma varies from 30% to 80% [7].

Many factors exert their impact on patients' adherence to the prescribed medicine. Among them, patients' belief and attitude toward the medicines have been shown to be a modifiable factor that has a strong predictive effect on adherence [8,9]. Several studies indicated that people who had stronger beliefs in the necessity of taking medicine were more inclined to adhere to the prescription [10,11]. In contrast, those who were more concern about the side effects or the

CONTACT Meiling Jin, MD ✉ Jinjin.meiling@zs-hospital.sh.cn Department of Respiratory Medicine, Zhongshan Hospital, Fudan University, Shanghai 200032, PR China; Xiaoyu Li ✉ lixiaoyulxb@sina.com; Qianzhou Lv ✉ lv.qianzhou@zs-hospital.sh.cn Department of Pharmacy, Zhongshan Hospital, Fudan University, Shanghai 200032, PR China.

*These authors contribute equally to this work.

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dependence liability were more likely to have intentional nonadherence [12]. Thus, identifying the modifiable problematic belief and behaviors of individual may be a useful tool for the clinicians to improve the patients' adherence to asthma controller therapy [13].

A number of instruments were developed to explore nonadherence and medication belief, such as the Morisky Medication Adherence Scale (MMAS-8) developed by Morisky et al. [14], and the Beliefs about Medicines Questionnaire (BMQ) developed by Horne et al. [15]. The BMQ consists of two sections: BMQ-specific and BMQ-general which can be used independently or simultaneously. The BMQ-specific (Necessity-Concern Framework) is shown to be more strongly associated with the medication adherence than BMQ-general [15]. It has good psychometric properties and has been validated among various samples [16], including asthma [15,17]. So far, the BMQ has been conducted in Chinese patients with atrial fibrillation undergoing warfarin therapy without validation [18]. However, when an instrument was applied in a different language, translation discrepancies arising between different language versions, thus conceptual equivalence between the original version and target language needs to be achieved in order to ensure the comprehensibility of the instrument [19]. Thus, psychometric testing of the translated scale is needed in various settings.

The objective of our study is to evaluate the validity and reliability of the Chinese version of the BMQ-specific questionnaire among patients with asthma and to assess patients' belief about ICS and its association with adherence.

Methods

Study design

The study was designed to be a cross-sectional survey carried out in the asthma clinics of a large teaching hospital (Zhongshan Hospital, Fudan University, Shanghai) between April 2016 and March 2018. Inclusion criteria were: 1. Age older than 18 years with a diagnosis of asthma; 2. Taking ICS alone or combined with long-acting beta agonists (LABA) to control asthma for at least one month. Patients were excluded if they had a diagnosis of chronic obstructive pulmonary disease or other significant respiratory disease. All patients were informed of the objective of the study, and then signed a written consent approved by the Ethics Committee of Zhongshan Hospital, Fudan University before inclusion.

All of the participants completed the questionnaire during a face-to-face interview, which was carried out by a trained pharmacist. The questionnaire contains four parts: 1. History information form (socio- demographic data: age, sex, education background, etc.; medication date; clinical: the first onset age of asthma, duration of asthma, etc.); 2. The MMAS-8 scale; 3. the BMQ-specific; In addition, a random sample of 23 patients with asthma were asked to complete the scale again to assess the test-retest reliability of the BMQ-specific scale. Finally, the relationship between patients' beliefs and adherence were assessed.

Measures

BMQ-specific

The BMQ-specific was translated into Chinese according to an internationally recommended procedure [19]. Two Chinese pharmacists translated the English version of the BMQ-specific into Chinese. Then, the Chinese BMQ-specific was translated back to English by a bilingual pharmacist blind to the original version. The comparison of the two versions of BMQ-specific resulted in minor discrepancies. We therefore considered the translation satisfied our needs. The final version was submitted to 20 asthma patients who finished the questionnaire without difficulty understanding under the direction of the researchers.

The BMQ-specific is a 10- item questionnaire with two scales, of which 5 items for each scale assess the specific personal beliefs about the necessity and concerns of prescribed medication use [15]. Responses were scored on a five-point Likert scale where 1 = strongly disagree, 2 = disagree, 3 = uncertain, 4 = agree and 5 = strongly agree. The total scores range from 5 to 25 for both of the necessity and concerns subscales. Patients with a subscale score above 15 were classified as high necessity or concern, and vice versa [20]. The patient's belief in the concept represented by the scale is positively correlated to the score he gets. A necessity-concerns differential ranging from -20 to 20 can also be calculated by subtracting the concerns subscale scores from the necessity subscale. It is considered as an indicator of the way that patients weigh their necessity and concern of taking the medication. Higher perceived necessity and/or lower concerns is indicated as higher differential scores, which implies higher likelihood of adherence [21].

To assess the association between medication belief and adherence, four attitude groups were created based on the patient's necessity and concern: 1. high

Table 1. Patient characteristics.

Variables	All (n = 217)
Age, years, mean $\pm$ SD	48.05 $\pm$ 16.33
Duration of regular ICS treatment, years, mean $\pm$ SD	3.87 $\pm$ 4.93
Gender (N, %)	
Male	101 (46.5%)
Female	116 (53.5%)
Education level (N, %)	
Primary studies	12 (5.5%)
Secondary studies	28 (12.9%)
Senior high studies	42 (19.4%)
University studies	135 (62.2%)
Occupation (N, %)	
Physical labor	11 (5.1%)
Office work	113 (52.1%)
Housewife/Retired	86 (39.6%)
Student	7 (3.2%)
Age of asthma onset (N, %)	
<18-year old	61 (28.1%)
18–45 years of age	98 (45.2%)
> 45-year old	58 (26.7%)
Duration of asthma (N, %)	
< 5 years	90 (41.5%)
5–10 years	26 (12.0%)
>10 years	101 (46.5%)
MMAS-8 score, mean (SD)	5.91 (1.79)
High	40 (18.4%)
Medium	69 (31.8%)
Low	108 (49.8%)

necessity scores and low concern scores imply “Accepting”; 2. high necessity scores and high concern scores imply “Ambivalent”; 3. low necessity scores and high concern scores imply “Indifferent”; and 4. low necessity scores and high concern scores imply “Skeptical” [11,22].

MMAS-8

The adherence to ICS was assessed using the validated Chinese version of the MMAS-8 [23]. It is a self-report questionnaire with 8 items, of which seven yes/no question for items from 1 through 7 and one 5-point Likert scale (1 = Never; 0.75 = Rarely once; 0.5 = In a while sometimes; 0.25 = Usually; 0 = All the time) [14]. MMAS-8 scores range from 0 to 8, with MMAS-8 score of <6 indicates low adherence, a score of 6 to <8 indicates medium adherence, and a score of 8 indicates high adherence [14].

Statistical analysis

The analysis of general data of the objects was carried out on SPSS 23.0 program. The data is described by mean $\pm$ SD, frequency and percentage. A Kruskal–Wallis test was performed to determine significant association between adherence groups and belief subscale and the necessity-concerns differential and between adherence and BMQ attitudinal groups. Mann–Whitney *U* tests were used to determine which groups differed.

The scale reliability is indicated by Cronbach’s alpha coefficient. Cronbach’s alpha coefficients of 0.7 are considered satisfactory [24], but coefficients that are more than 0.5 is considered acceptable [25]. The test–retest of the scale was assessed using intraclass correlation coefficient (ICC). An ICC greater than 0.6 indicates good test–retest reliability [26]. The scale construct validity was tested using confirmatory factor analysis. It was conducted using Amos 16.0 software to evaluate the underlying factor structure of BMQ-specific. Absolute fit indices such as the Chi-square statistic, the Goodness of Fit Index (GFI), Comparative Fit Index (CFI), the root-mean-square error of approximation (RMSEA), and the standardized root mean squared residual (SRMR) were used to test whether the data set account for the two-factor model. For the Chi-square statistic, a cutoff value close to 3 has been suggested. For the GFI and CFI, a value >0.90 has been accepted [27]. For the SRMR, values equal or inferior to 0.08 indicating a good fit [28]. For the RMSEA, a value equal or inferior to 0.08 was considered to reflect good fit [29].

Results

Sample characteristics

A total of 217 patients with asthma were recruited in the present study. Patient characteristics are summarized in Table 1. 53.5% were female and the mean ($\pm$ SD) age of the participants recruited was 48.05 $\pm$ 16.33, ranging from 18 to 85 years. Approximately 94.5% had an education level above the primary studies (12.9% secondary studies, 19.4% senior high studies and 62.2% university studies), and more than half of them works in the office. 45.2% patients were firstly diagnosed with asthma aging from 18 to 45. Nearly half of them (46.5%) suffered from asthma for more than 10 years.

The mean MMAS-8 score was 5.91 $\pm$ 1.79. 18.4% (40 of 217), 31.8% (69 of 217) and 49.8% (108 of 217) of patients had high, medium, and low adherence, respectively.

BMQ measure

Patients were more concerned about the necessity of the prescribed ICS (mean 17.34 SD 2.80) compared to their concern about potential adverse effects of the ICS (mean 15.98 SD 3.04). The mean necessity-concerns differential was 1.36 ($\pm$ 4.15), ranging from -9 and 13. About 31.8% of the patients have negative values for the necessity-concerns differential. Among

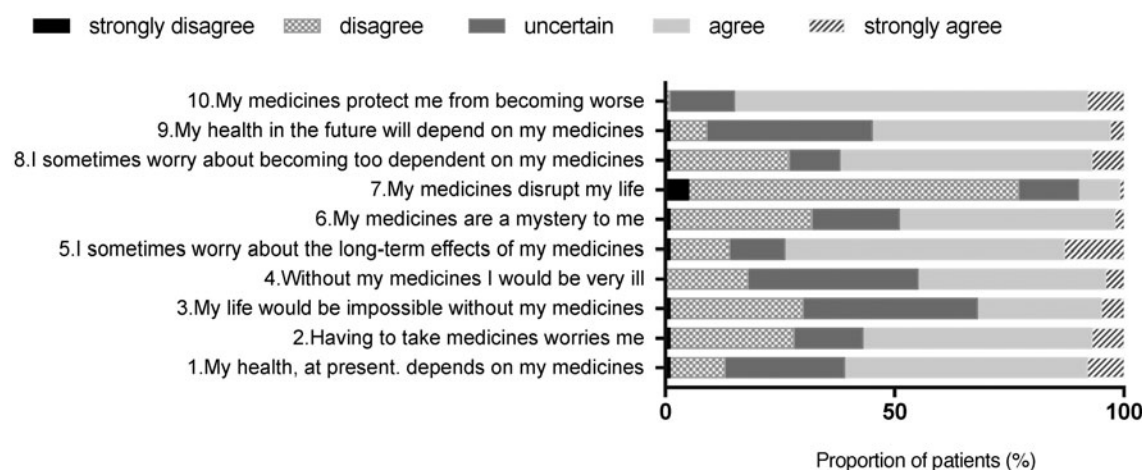


Figure 1. Distribution of each item of BMQ-specific.

217 research candidates, high necessity for medication was present in 159 patients (73.3%) while high concerns about medication was noted in 129 patients (59.4%). 162 patients (74.7%) worried about the long-term effect of medication, 135 patients (62.2%) worried about becoming too dependent on the medicines, and 183 patients (84.3%) accepted that ICS protects them from becoming worse. The distribution of each item of the BMQ is shown in Figure 1.

Reliability

The internal consistent reliability (Cronbach's alpha) for BMQ-Concern and BMQ-Necessity were 0.698 and 0.784, respectively. It indicates moderate reliability of the Chinese version of BMQ-specific. The highest item-to-total correlation coefficient for BMQ-Necessity and BMQ-Concern were 0.685 and 0.583, respectively. Cronbach's alpha increases to 0.727 when item 6 was deleted, and slightly higher (0.796) when item 10 was deleted.

Reproducibility

A total of 23 patients completed the scale 2–4 weeks later. The ICC of the Chinese version BMQ-specific was 0.759, which shows satisfactory reliability and stability.

Construct validity: Factor analysis

Confirmed factor analysis was conducted to evaluate the underlying factor structure of BMQ-specific. Absolute fit indices including the Chi-square statistic, the Goodness of Fit Index (GFI), the root-mean-square error of approximation (RMSEA), and the based standardized root mean squared residual

Table 2. Results of confirmatory factor analysis (CFA).

Goodness of fit index	Recommended value	Model using full sample ($N = 217$)
χ^2	N/A	78.092
df	N/A	35
χ^2/df	≤ 3.0	2.231
GFI	> 0.9	0.928
CFI	> 0.9	0.917
RMSEA	≤ 0.08	0.075
SRMR	≤ 0.08	0.074

χ^2 : Chi-square; df : degrees of freedom; GFI: goodness of fit index; CFI: comparative fit index; RMSEA: root mean square error of approximation; SRMR: standardized root mean squared residual.

(SRMR) were used to test the hypothesis that the data set in this study would fit the two-factor model. The ratio of χ^2 to df (degrees of freedom) was 2.231, which falls well within the range of 2–5; GFI was 0.928 and the SRMR was 0.074. The RMSEA was 0.075. The fit indices showed that the model had an acceptable fit with the data (Table 2). In the model, all items had standardized factor loadings greater than 0.4, except for item 10 (0.38) and item 6 (0.29) (Figure 2).

Relationship between adherence and belief

Patients' compliance was closely related to their belief about ICS. Higher adherence was significantly associated with higher necessity-concerns differential ($p = .001$) and lower concern ($p = .004$) (Table 3), however, there was no significance between these groups on the necessity ($p = .051$). The means and standard deviations for BMQ-specific measures by adherence group were shown in Table 3. As for the adherence rates and MMAS-8 score between different belief groups, the adherence rates by MMAS-8 was highest for the accepting, and lowest for the skeptical groups (Figure 3). The mean MMAS-8 score (6.5 ± 1.5) was highest in the accepting group and

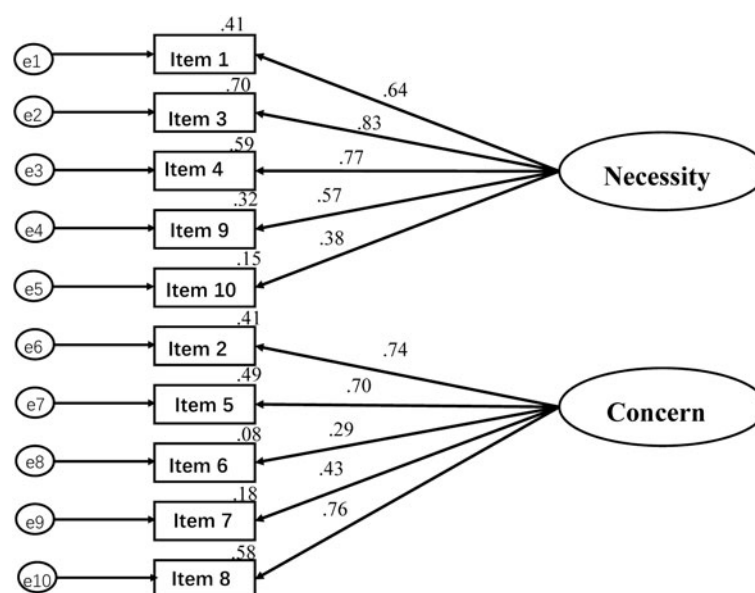


Figure 2. Confirmatory Factor Analysis of the Chinese version of BMQ-specific for asthma patients (with items' standardized regression weight and uniqueness). For all items, all factor regression weights are significant with a p values of less than .001.

Table 3. Mean $\pm$ standard deviations scores and results of Kruskal–Wallis test for BMQ-specific measures by different adherence groups.

	Low adherence	Median adherence	High adherence	p
Necessity	16.88 $\pm$ 2.60	17.81 $\pm$ 2.82	17.75 $\pm$ 3.13	.051
Concern	16.28 $\pm$ 2.85	16.42 $\pm$ 3.01	14.42 $\pm$ 3.17	.004
Necessity–Concerns Differential	0.61 $\pm$ 3.97	1.39 $\pm$ 3.91	3.35 $\pm$ 4.41	.001

lowest in the skeptical group (4.8 ± 2.1). The mean MMAS-8 score was (5.9 ± 1.6) and (6.1 ± 1.8) for the ambivalent group and indifferent group, respectively. A significant difference in the MMAS-8 score was observed between the accepting and skeptical group ($p = .000$), and the accepting group and ambivalent group ($p = .027$) as well.

Discussion

In this study, we assessed the validity and reliability of the BMQ-specific among asthma patients in China. To the best of our knowledge, this is also the first study to validate this scale in Chinese patients. The Chinese version BMQ-specific is reliable with the Cronbach's alpha for BMQ-Concern and BMQ-Necessity, which are 0.698 and 0.786, respectively. These value is comparable to what has been obtained using the original English version from asthma patients with Cronbach's alpha of 0.75 and 0.80, respectively [15]. The results from an Italian version assessed the BMQ-specific in asthma patients obtained Cronbach's alpha for BMQ-Concern and BMQ-

Necessity of 0.70 and 0.65, respectively [30]. These studies generated similar Cronbach's alpha results.

Confirmed Factor analysis show that the Chinese version of the BMQ-specific has the same factorial structure as the original scale in asthma patients. Acceptable model fit indices were found for the two subscales. All standardized regression weight (factor loadings) were great than 0.4, except item 10 of the necessity factor with factor loadings a slightly lower than 0.4, and item 6 of the concern factor far below 0.4. The low factor loadings of item 6 could be due to the word “mystery” has multiple meanings in Chinese. And linguistic differences exist when it's been translated. This has also been reported in the Scandinavian translation [31]. Indeed, a low factor loading of 0.21 for item 6 has also been reported among HIV patients in the French version of BMQ [32].

The mean score of the necessity and concern subscale about ICS are 17.34 ± 2.80 and 15.98 ± 3.04 , respectively. The patients appear to prefer more on middle categories than extreme categories as shown in the distribution of each item of BMQ-specific. The degree of “agreement” or “disagreement” may be influenced by the patients' perceptions of the illness and asthma conditions. As mentioned by Horne, the beliefs about the treatment necessity are directly related to illness perceptions, and the concerns might reflect perceptions and experiences of classes of treatment [33]. Patients with relative high perception of illness and severe asthma are more likely to have a stronger agreement on the necessity of ICS treatment. Patients who had received long-term treatment with

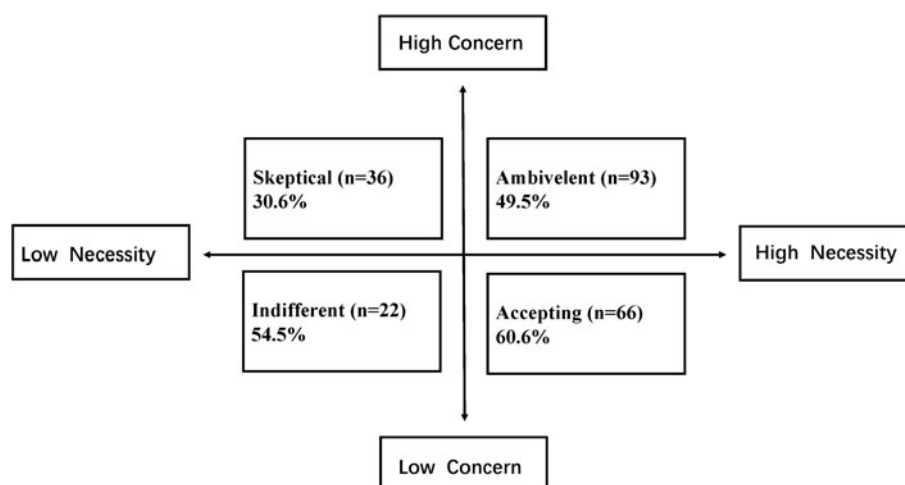


Figure 3. Distribution of patients among the four medication belief groups and percentage of adherent patients according to MMAS-8 in each group.

ICS and with mild and/or newly diagnosed asthma are more likely to express more concerns about ICS treatment.

As for the adherence with different belief groups, the adherence rates are highest for the accepting group, and lowest for the skeptical groups. A significant difference in the MMAS-8 score is observed between the accepting group and skeptical group. Comparable results are obtained in the study of adherence to ICS from Netherlands asthma patients by Menckeborg et al. [22]. In contrast, a significant difference in the MMAS-8 score is also observed between the accepting group and ambivalent group, which supports the hypotheses that high concern would influence patients' adherence.

Van Steenis et al. [11] showed that higher necessities related to higher self-reported adherence. However, the present study found a positive relationship between adherence and necessity-concerns differential, and a negative correlation between adherence and concerns. This is in accordance with the findings from a meta-analysis inclusive 94 papers about the necessity-concern framework and adherence [34]. It also suggests that the necessity-concerns differential is a significant positive predictor of adherence [12,32]. Patients seem to have intentional nonadherence when they believe the risks of taking medicine exceed the benefits [12]. Low adherence may be a choice between patients' benefits and risks. They are being irresolute between the beliefs about the necessity of ICS for asthma maintenance and the concern about the long-term adverse effects perceiving in the future [35]. Thus, it tends to be more important to focus on the concerns than on the necessity flawed attempt to improve compliance.

The relationship between adherence and asthma control has been widely discussed in the literature [6,36,37]. Many studies suggested that better asthma control was significantly associated with higher adherence [6,38]. Data from a recent meta-analysis showed that daily inhaled ICS had superior effects on lung function, airway inflammation, asthma control and reliever use than intermittent inhaled ICS [39]. It is also suggested that better asthma control is more likely to have better clinical outcomes, such as less asthma exacerbations, less hospitalizations than those with poorer control [38]. Thus, it's important to focus on patient's belief to achieve a higher adherence and a better asthma control.

Despite the important implication of our findings, several limitations of our study should be noted. Firstly, our data comes from a cross-sectional survey. It can only evaluate the patients' adherence at a certain time, but adherence to ICS changed over time [36]. Secondly, the data on the adherence was self-reported. The patients were recruited from specialist clinics, which could result in overestimation of adherence [38]. However, in view of the study design, self-report was the most appropriate approach of assessing adherence behavior.

Conclusions

The Chinese version of the BMQ-specific was demonstrated to have acceptable reliability and validity. In addition, our study shows patients' beliefs about medication have a significant impact on the treatment adherence that related to asthma control. Thus, the Chinese version of the BMQ-specific can be used as a reliable tool by the clinicians to identify beliefs and

behaviors of individual to improve adherence in Chinese speaking patients.

Disclosure statement

The authors have no competing interests to report.

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