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Cultural Adaptation and Psychometric Properties of the Chinese Burden of Treatment Questionnaire (C-TBQ) in Primary Care Patients with Multi-Morbidity

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3 **Questionnaire (C-TBQ) in Primary Care Patients with Multi-Morbidity**
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Key Messages

- Multi-morbidity is associated with significant societal and personal burdens
- Treatment burden results from an excessive workload required to manage health
- Generic instruments to assess treatment burden in multi-morbidity are needed
- The Chinese Burden of Treatment Questionnaire (C-TBQ) is valid and reliable

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For Peer Review

Abstract

Background

The Burden of Treatment Questionnaire (TBQ) assesses the impact of a patient's treatment workload on their quality of life

Objectives

The aim was to translate and validate the TBQ on Chinese primary care patients with multi-morbidity.

Methods

The English TBQ was translated and back-translated using professional translators. Cognitive debriefing interviews were performed on 15 patients. The resulting instrument was tested on 200 primary care patients with multi-morbidity (>1 chronic disease) to examine its psychometric performance including exploratory factor analysis, confirmatory factor analysis, internal consistency and reliability. EQ-5D-5L, SF-6D, WONCA COOP Charts and the Global Health Rating Scale were used to assess convergent and divergent validity.

Results

Median age of the respondents was 62 years (range 22-95 years) with a median of 4 conditions. The median TBQ total score was 16 (interquartile range 7.25-30). There was a significant floor effect (>15%) observed for all items. Spearman's correlations was >0.4 for all items demonstrated adequate internal construct validity. TBQ global score correlated with number of conditions ($p=0.034$), EQ-5D-5L ($p<0.001$), SF-6D ($p<0.001$), and the Feelings ($p=0.004$), Daily activities ($p=0.003$) and Social activities ($p<0.001$) domains of the WONCA COOP. There was no significant correlation between global health rating and TBQ global scores ($p=0.298$). Factor analysis demonstrated a three-factor structure. There was good internal consistency (Cronbach's alpha = 0.842) and good test-retest reliability (ICC = 0.830).

Conclusion

The newly translated Chinese version of the TBQ appears to be valid and reliable for use in Cantonese-speaking, adult primary care patients with multi-morbidity.

Keywords: Chronic Disease, Multi-morbidity, Primary Care, Psychometrics, Quality of Care, Quality of Life

Cultural Adaptation and Psychometric Properties of the Chinese Burden of Treatment Questionnaire (C-TBQ) in Primary Care Patients with Multi-Morbidity

Background

Multi-morbidity, often defined as having two or more chronic illnesses, is an important priority for health services research¹. With multi-morbidity now exceeding single morbidity², there are growing concerns that disease-centred healthcare models may result in over treatment and increased risks for adverse events in patients with multi-morbidity^{3,4}. The World Health Organization recognizes patients with multi-morbidity as being more vulnerable⁵. They have higher risks of polypharmacy, adverse drug events, medication nonadherence⁶ and more complex patterns of service use⁷. Patients are typically older, may have cognitive impairments or poorer health literacy⁸. Multi-morbidity is associated with greater psychological distress, depression, anxiety, and poorer health-related quality of life (HRQOL)^{9,10}.

Patient experience studies have revealed that patients with multi-morbidity often encounter burdens not only from their symptoms, but also from the activities needed to maintain health¹¹. Managing health requires time and effort, which if excessive, can result in unintentional consequences¹¹. 'Treatment burden' is an emerging concept which refers to the patient workload resulting from their treatments and disease-related self-care¹². 'Patient capacity' is the ability to cope with the illness and treatment burden¹³. Excessive treatment burden has been associated with reduced therapeutic adherence, increased hospitalization rates and mortality¹⁴.

There are currently several instruments that assess treatment burden for specific conditions, but burden can result from both individual diseases as well as from a combination of diseases, hence the need for instruments that can assess treatment burden generically^{15,16}. To date, there have been five instruments developed to measure treatment burden in patients with multi-morbidity^{15,17-20}. Each has its own merits and shortcomings including length, applicability, language and scope²⁰.

The Burden of Treatment Questionnaire (TBQ) developed by Tran, Ravaud et al is a patient-reported measure that assesses the consequences of medical interventions against the patient's self-perceived ability to cope. The original 13-item TBQ was developed in France, but its application was limited to patients within the French healthcare system. A more comprehensive 15-item English version was subsequently developed and validated for use in a broader range of settings¹⁷. The strength of the English TBQ is that it measures a number of aspects of treatment burden including the economic burdens. Its main weakness is it has only been validated on a relatively young, healthy and well-educated subject population^{17,20}. Hong Kong

1 has a pluralistic healthcare system where patients use both public and private services with
2 80% of primary care delivered in the private sector and 80% of tertiary care in the public sector.
3 The English TBQ was selected for translation and adaptation due to its comprehensiveness in
4 assessing various aspects of treatment burden (including financial burdens) with relevant items
5 for Hong Kong's pluralistic health setting.
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11 Translating a pre-existing instrument into a different language, and evidence of its
12 psychometric properties are needed to support the validity and reliability of the instrument to
13 ensure that the attributes being measured are conceptually equivalent to the original. This
14 process enables cross-cultural comparisons. It is also important to ensure a translated
15 instrument is culturally relevant and acceptable to the target population.
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21 The aim of this study was to perform a translation and cultural adaptation of the TBQ from
22 English to Chinese for use in Hong Kong, and explore the psychometric properties in a sample
23 of Chinese primary care patients with multi-morbidity. The findings will provide evidence to
24 support future observational studies on treatment burden to inform medical education and
25 improve quality of care.
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30 **Methods**

31 *Translation and cultural adaptation of the TBQ*

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33 Procedures as recommended by the International Society for Pharmacoeconomics and
34 Outcomes Research (ISPOR) task force were followed²¹. Permission was obtained from the
35 TBQ authors and MAPI Trust (holders of the copyright). Two professional translators
36 performed the forward and backward translations. Two bilingual local primary care providers
37 reconciled discrepancies between the back translation and original English version.
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44 Cognitive debriefing interviews were conducted on 15 Cantonese Chinese speaking patients
45 with a balanced sampling of ages and genders to assess for clarity, relevance and
46 interpretation. Two bilingual authors reviewed the results and made final modifications to the
47 instrument.
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51 *Subject Sampling and Recruitment for Psychometric Testing of the C-TBQ*

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53 Subjects were recruited from a government-funded General Out-Patient Clinic (GOPC) of the
54 Hong Kong Hospital Authority (HA). The HA is a governmental body responsible for the
55 delivery of approximately 80% of chronic disease care in Hong Kong²². Eligible subjects
56 with multi-morbidity were identified using a screening checklist of 20 common chronic
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1 diseases²³. Exclusion criteria included aged <18 years; unable to understand Cantonese;
2 refusal to participate; or too ill to give consent.
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5 *Study Instruments*

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8 *Chronic disease count* is a commonly used measure of multi-morbidity and was defined as
9 the simple unweighted enumeration of the number of diseases present²⁴. To assess the
10 number of diseases, subjects were asked to self-complete a checklist of 20 chronic conditions
11 (**Supplementary Material 1**) derived from the Hong Kong Primary Care Morbidity Survey
12 2007-2008²³. Those with two or more chronic diseases were identified as having multi-
13 morbidity.
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19 *Burden of Treatment Questionnaire (TBQ) English version* is a 15-item questionnaire that
20 assesses the patient's workload to maintain their health and its impact on quality of life¹⁷.
21 Each item is scored from 0-10 with total scores ranging from 0 (no burden) to 150 (high
22 burden). The instrument was validated for multi-setting use^{15,17}.
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26 *Short-form Six-dimension (SF-6D)* is a preference-based measure of health, with a six-
27 dimensional health state classification (physical health, role limitation, bodily pain, vitality,
28 mental health, and social functioning) that quantifies a patient's health for each dimension,
29 against a set of preference-based weights obtained from representative samples of general
30 population²⁵⁻²⁷. Values are between 0 (death) and 1 (full health). The SF-6D utility score was
31 calculated using the Hong Kong Chinese SF-6D value set²⁶. The minimum important
32 difference (MID) value of the SF-6D is 0.033²⁸.
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39 *EuroQol Five-dimension Five-level Questionnaire (EQ-5D-5L)* is a standardised instrument
40 with five items representing five dimensions (mobility, self-care, usual activities,
41 pain/discomfort, and anxiety/depression) and a visual analogue scale (VAS) from 0-100. It
42 provides a single index value for health status²⁹⁻³². The EQ-5D-5L utility score was
43 calculated based on the EQ-5D-5L value set for China³³. The MID value of the EQ-5D-5L
44 for the Chinese scoring algorithm is 0.058³⁴.
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50 *Global Health Rating Scale* is a single item scale that asks subjects to rate their current
51 general health status on a five-point scale from Excellent to Poor. This item was extracted
52 from the Chinese SF-12v2 that has been validated in Hong Kong³⁵.
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56 *WONCA/COOP Chart* is an instrument used to assess functional status in primary care^{36,37}. It
57 contains six charts relating to physical fitness, feelings, daily activities, social activities,
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1 change in health and overall health, rated on a five-point scale. The instrument has been
2 validated in Hong Kong³⁸.

3 4 5 6 *Data Collection*

7
8 A field worker approached patients in the waiting room and screened for multi-morbidity
9 using the checklist. Patients with \geq two conditions were invited to participate. The field
10 worker explained the study, obtained consent and administered the questionnaire. Subjects
11 were re-contacted two weeks later to collect data for test-retest reliability. The first interview
12 was face-to-face. The second interview was telephone-administered.

13 14 15 16 17 *Statistical Analysis*

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19 Descriptive statistics (median, inter-quartile range, and percentage of floor and ceiling
20 effect), and the floor and ceiling of the C-TBQ item and global scores were determined. For
21 the C-TBQ, the floor is the *least* amount of burden whilst the ceiling is the *greatest* (a reverse
22 of most HRQOL instruments). The floor and ceiling effect is the proportion of patients who
23 achieved the worst or the best possible scores, with 15% used as the threshold for having a
24 significant effect³⁹.

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26 Internal construct validity was assessed using item-total scale correlation with scores >0.4
27 demonstrating adequate correlation⁴⁰.

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29 Convergent validity was assessed using Spearman's rho correlation to test against health
30 utility, WONCA/COOP and General Health Rating scores, and number of diseases. It was
31 hypothesised that patients with higher numbers of chronic diseases would have more
32 treatment burden, and an increase in treatment burden would be associated with poorer
33 HRQOL (reflected by lower SF-6D and EQ-5D-5L scores).

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35 Sensitivity was determined by performing known-group comparisons of the C-TBQ total
36 score between subjects with different numbers of diseases using independent t-test or analysis
37 of variance, where appropriate. As older people are more likely to have more morbidity,
38 analyses were adjusted for confounding effects due to age. Regression coefficients and
39 corresponding p-values were used to measure the effect of the number of diseases (>4 , 4, 3
40 versus 2 as reference category) on the C-TBQ and HRQOL scores. It was hypothesised that a
41 higher number of diseases would be associated with increased burden, with and without
42 adjusting for age⁴¹.

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44 Test-retest reliability was assessed by examining the intra-class correlation coefficient (ICC)
45 of the C-TBQ global score with an ICC >0.7 indicating good reproducibility⁴².

Exploratory factor analysis (EFA) utilizing a principal component method with varimax rotation was used to explore dimensionality and the underlying factor structure, and to compute factor Eigenvalues. Factors with Eigenvalues >1 were retained. Individual rotated factor loadings and the Cronbach's alpha if each individual item were removed were estimated. Goodness-of-fit of the factor structure derived by EFA were subsequently assessed using confirmatory factor analysis (CFA). Goodness-of-fit index (GFI)⁴³, adjusted goodness-of-fit index (AGFI)⁴³, root mean square error of approximation (RMSEA)⁴⁴, and comparative fit index (CFI) were used to assess the model goodness-of-fit, and were considered adequate if: 1) $RMSEA \leq 0.08$; 2) $GFI \geq 0.90$; 3) $AGFI \geq 0.80$; and 4) $CFI \geq 0.95$.

Internal consistency of the C-TBQ was assessed using Cronbach's alpha with cut-off scores ≥ 0.7 indicating adequate internal consistency⁴².

CFA was performed using LISREL 8.80 (Scientific Software International, Inc., Lincolnwood, IL, USA). Other statistical analyses were performed using STATA 13.0.

Results

Instrument translation and adaptation

Table 1 shows the characteristics of the cognitive debriefing participants. The C-TBQ took an average of 10.2 minutes to complete and was easy to comprehend. Modifications for use on Hong Kong Chinese patients are summarised in **Supplementary Material 2**.

Supplementary Material 3 outlines the iterative steps taken to reconcile the translation.

Supplementary Material 4 contains the final version of the C-TBQ and back-translated English TBQ (Hong Kong version) registered with Mapi Research Institute.

Psychometric testing of the C-TBQ

The median age of subjects ($N=200$) was 62 (range 22 to 95) years with a median of four conditions (**Table 1**). Subjects with no chronic disease were not sampled as it was thought that the TBQ would not be relevant. A significant floor effect was found for all items. All correlations between items and global scores scored >0.4 demonstrating adequate internal construct validity (**Table 2**).

Factor analysis. EFA using the principal component method with varimax rotation extracted three factors with eigenvalues ≥ 1.0 on which all 15 items loaded significantly (and exclusively), and explained 51.091% of the total variations (**Table 2**). The three-factor CFA model derived by EFA met the criteria for demonstrating adequate goodness-of-fit ($RMSEA=0.0747$; $GFI=0.89$; $AGFI=0.85$; $CFI=0.95$).

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2 *Known group comparisons.* Analyses were conducted on patients with two, three, four and >
3 four conditions. There was a significant difference in mean C-TBQ global scores between
4 patients with different numbers of multi-morbidities ($p=0.049$). Further analyses were
5 conducted on patients with two or three (Mean=18.1, SD=16.5), four or five (Mean=23.6,
6 SD=20.7), and >five chronic conditions (Mean=27.2, SD=20.4). There was a significant
7 difference in mean C-TBQ global scores between groups indicating that patients with more
8 conditions had higher C-TBQ scores (**Table 3**). Using a MID value of 0.033 for SF-6D score,
9 the differences in SF-6D scores between groups were meaningful. However, using an MID
10 value 0.058, the differences in EQ-5D-5L scores between groups were not meaningful. **Table**
11 **4** shows the effect of the number of morbidities on the C-TBQ and other HRQOL scores
12 controlling for age. Patients with >four conditions had significantly higher C-TBQ global
13 scores, poorer EQ-5D-5L scores and EQ-5D VAS scores than those with only two.
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23 *Reliability.* The C-TBQ was internally consistent (Cronbach's alpha =0.842), and reliable
24 (ICC=0.830) demonstrating good test-retest reliability.
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Convergent validity. **Table 5** summarizes the correlations between the C-TBQ, health utility
scores, WONCA/COOP scores, General Health Rating scores, and multi-morbidities. C-TBQ
global scores negatively correlated with the EQ-5D-5L ($r= -0.280$, $p <0.01$), EQ-5D VAS ($r=$
 -0.311 , $p <0.01$), and SF-6D ($r= -0.303$, $p <0.01$), but positively correlated with
WONCA/COOP feelings ($r= 0.205$, $p <0.01$), daily activities ($r= 0.212$, $p <0.01$), social
activities ($r= 0.290$, $p <0.01$), overall health ($r= 0.200$, $p <0.01$), and the number of diseases
($r= 0.150$, $p <0.05$). A weak correlation ($r= 0.074$, $p >0.05$) was observed between global
health rating and C-TBQ global score.

41 **Discussion**

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Our study found that Chinese patients with multi-morbidity aged from 25 to 83 years could
understand, correctly interpret and respond to all the items of the C-TBQ, however, an
introductory sentence explaining 'treatment burden' was needed it was an unfamiliar concept.
Treatment burden is a relatively novel Western concept and our Chinese patients had never
thought of health care as work. Once explained, they easily understood the analogy. Most
subjects completed the questionnaire in less than 10 minutes with the exception of an 83-
year-old respondent, indicating that more time might be needed when administering the
instrument on elderly patients. For some items, exemplars were added to enhance reliability.
For example, we added 'such as eating less sugar and eating more vegetables' to Item 5 to
promote the understanding of 'dietary modification'.

1 Similar to other treatment burden questionnaires, there was a significant floor effect²⁰. This
2 may have been due to the sample frame. Participants were primary care patients with
3 relatively milder diseases, receiving government-subsidised care. Many were elderly,
4 unemployed or retired, and hence may not have experienced the burden of ‘taking time off
5 work to attend medical visits’. Further studies on different patient populations, particularly
6 those with greater complexity or those who are encumbered with significant out-of-pocket
7 costs may reveal a different pattern of scores. A lack of a ceiling effect indicates that the C-
8 TBQ may be better for monitoring burden deterioration.
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10 As hypothesised, the C-TBQ global score strongly correlated with disease number, all health
11 utility scores and most of the WONCA/COOP domain scores. A recent review found
12 treatment burden was associated with the cumulative effect of an increased workload
13 resulting from a higher number of conditions¹¹. Similarly, recent study which found a 3.4-
14 unit reduction in the EQ-VAS score for each additional condition⁴¹. Conversely, there was
15 only a weak correlation between C-TBQ scores the Global Health Rating scale. This suggests
16 that the C-TBQ correlates better with measures that capture the impact of illness on daily
17 functioning than those assessing the patient’s perception of their health.
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19 Although the English TBQ was found to be uni-dimensional, factor analysis of the C-TBQ
20 demonstrated a three-factor structure. This may have potential implications for instrument
21 scoring. The structure of the C-TBQ suggested three domains of treatment burden. Factor 1
22 related to the direct burdens of receiving health care such as drug treatments, investigations
23 and medical visits. Item TBQ7 (inconveniencing friends and family) also loaded on this
24 factor, possibly because much of this burden may be related to transportation issues to attend
25 medical appointments. Factor 2 related to administrative and financial burdens, whilst Factor
26 3 was lifestyle-related including item TBQ8 on being a ‘reminded that they had health
27 problems’.
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29 The internal consistency and test-retest reliability of the C-TBQ were comparable to the
30 French and English versions^{15,17}.
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32 *Strengths and Limitations*

33 A key strength of this study was our subject sampling. We used a representative sample of
34 primary care patients with multi-morbidity including a large proportion of elderly patients,
35 with a median of four conditions.
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37 There were also limitations. Subjects were recruited by convenience sampling from a single
38 site where health care was delivered by specialist family physicians in a government-
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1 subsidized health care setting. Selection bias may impact the floor and ceiling effect
2 measurements in this study and the pattern of burden observed. A future larger scale study
3 with subjects across a broader age range, from both public and private settings are
4 recommended to examine the prevalence, risk factors, mediators, and moderators of
5 treatment burden.
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10 This instrument focussed specifically on treatment burdens related to chronic disease care in
11 Western medicine health care settings and further modifications to the C-TBQ may be needed
12 to include aspects of treatment burden resulting from Chinese Medicine. Further testing is
13 recommended to assess the instrument's performance in other Chinese-speaking health care
14 populations such as in China or Taiwan, or in secondary and tertiary settings.
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20 **Conclusions**

21 In settings such as Asia, where patients may be less likely to verbally disagree with their
22 doctors, admit to non-compliance, or disclose that they cannot cope, a treatment burden
23 questionnaire can potentially be useful for identifying at-risk patients, and help facilitate better
24 patient-centred doctor-patient interactions. Treatment burden scores can be used to promote or
25 evaluate shared decision-making interventions. Our study found that the Chinese TBQ is valid,
26 reliable and sensitive, and provides evidence to support its use in larger scale epidemiological
27 studies and health services research.
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39 Thi Tran for giving us permission to translate and adapt their Burden of Treatment
40 Questionnaire. The questionnaire is copyrighted to Phillippe Ravaud, and administered by the
41 Mapi Research Trust.
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48 **Compliance with ethical standards**

49 All authors declare that they have no competing interests.
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51

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58 **Ethical approval**

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For Peer Review

Table 1. Subject characteristics for the cognitive debriefing interviews and psychometric testing of the Chinese Burden of Treatment Questionnaire (TBQ)

Cognitive debriefing subjects (n=15)				
	Participant no.	Age (years)	Gender	Completion Time (mins)
Chinese Instrument -Version 1	1	34	M	36
	2	54	F	72
	3	55	M	47
	4	56	F	41
	5	25	M	13
Chinese Instrument -Version 2	6	46	F	6
	7	78	F	15
	8	78	M	13
	9	75	M	13
	10	76	M	12
Chinese Instrument -Version 3 (final)	11	83	M	18
	12	37	F	9
	13	52	M	10
	14	54	F	9
	15	64	M	5
		57.8		21.3
Psychometric testing subject characteristics (N=200)				
Demographic, % (n)		Total (N = 200)		
Age, median (Interquartile range)		62 (56-67) years		
Gender				
Female		55.0 % (110)		
Male		45.0 % (90)		
Number of chronic conditions				
1		0.0 % (0)		
2		17.5 % (35)		
3		27.5 % (55)		
4		22.5 % (45)		
>4		32.5 % (65)		
Median (Interquartile range)		4 (3-5)		

Table 2. Descriptive statistics and exploratory factor analysis of each TBQ item

Item number	Item description	Median (IQR)	Floor (%)	Ceiling (%)	Spearman's rho correlation	Rotated factor loading			Cronbach's alpha (if item deleted)
						Factor 1	Factor 2	Factor 3	
TBQ_1a	The problems related to the discomfort caused by your medications (tablets, inhalers, eye drops, injections) such as: pain, taste, shape, size, and bruising.	0 (0-2)	65.0	0.5	.592**	0.681	0.020	0.108	0.833
TBQ_1b	The problems caused by how many times a day you need to take your medications (for example: once per day, twice per day, three times per day).	0 (0-2)	66.0	0.5	.626**	0.782	0.103	0.014	0.831
TBQ_1c	The problems caused by the effort you need to make to remember to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...).	0 (0-0)	76.5	1.0	.552**	0.724	0.122	0.101	0.833
TBQ_1d	The problems caused by the precautions you need to take when taking your medications (for example: taking them at specific times of the day or with meals, not being able to do certain things after taking medications, such as driving or lying down...).	0 (0-1)	69.5	0.5	.596**	0.746	0.170	0.246	0.826
TBQ_2a	The problems related to having to go for regular lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated inconveniences.	0 (0-3.75)	53.0	2.5	.674**	0.650	0.248	0.272	0.823
TBQ_2b	The problems related to self-monitoring (for example: taking your blood pressure or checking your blood sugar): frequency, time spent and associated inconveniences.	0 (0-2)	67.5	0.5	.582**	0.488	0.162	0.356	0.831

1										
2										
3	TBQ_2c	The problems related to doctor or allied health visits:	0 (0-4)	47.0	1.5	.649**	0.443	0.420	0.289	0.825
4		frequency and time spent for these visits, or difficulties in								
5		finding the healthcare centres.								
6										
7	TBQ_2d	The problems related to your relationships with your	0 (0-0)	81.5	1.0	.484**	0.484	0.314	0.033	0.837
8		doctors, nurses and other allied health professionals (for								
9		example: feeling not listened to enough or not taken								
10		seriously).								
11										
12	TBQ_2e	The problems related to arranging medical appointments	0 (0-2)	61.0	1.5	.664**	0.149	0.584	0.477	0.828
13		(for example: doctor's visits, lab tests and other exams), and								
14		reorganizing your schedule around these appointments.								
15										
16	TBQ_3	The problems related to the administrative burden	0 (0-3)	60.0	2.5	.549**	0.057	0.802	0.060	0.838
17		associated with your healthcare (for example: the time and								
18		effort you take to fill in forms for hospitalizations, insurance								
19		claims, reimbursements and/or obtaining social services)?								
20										
21	TBQ_4	The problems related to the financial burden associated with	0.5 (0-5)	50.0	1.5	.680**	0.252	0.737	0.122	0.830
22		your healthcare (for example: out of pocket expenses or								
23		expenses not covered by insurance)?								
24										
25	TBQ_5	The problems related to having to modify your diet, reduce	0 (0-3)	49.5	0.5	.562**	0.259	0.087	0.716	0.832
26		your alcohol intake or stop smoking as recommended by								
27		your doctor (for example: avoiding certain foods, eating less								
28		sugar, eating more vegetables...)?								
29										
30	TBQ_6	The problems related to needing to exercise more as	0 (0-4)	50.5	1.0	.542**	0.143	0.141	0.764	0.835
31		recommended by your doctor (for example: walking, jogging,								
32		swimming...)?								
33										
34	TBQ_7	The things you need to do to look after your health may	0 (0-0)	83.0	1.0	.426**	0.401	0.363	0.039	0.837
35		sometimes cause your family, friends and co-workers								
36		inconvenience (for example: needing help from family to								
37		administer injections at home, needing help from friends to								
38		get to and from doctors' appointments, needing co-workers								
39		to cover for you so that you can go to your doctors'								
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appointments...), how much does it impact your relationships with them?

TBQ_8	'The need for medical healthcare on a regular basis reminds me of my health problems'	0 (0-3.75)	63.5	5.0	.419**	0.012	0.049	0.509	0.854
	TBQ Global score	16 (7.25-30)	11.0	0.5		Factor 1	Factor 2	Factor 3	Total
					Eigenvalue	3.586	2.107	1.971	7.664
					% of variance explained	23.906	14.046	13.139	51.091

Notes:

IQR = Interquartile range; TBQ = The Burden of Treatment Questionnaire

*Correlation is significant at the 0.05 level (2-tailed).

**Correlation is significant at the 0.01 level (2-tailed).

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Table 3. Known group comparisons of TBQ global score and HRQOL scores between groups

	Number of Chronic Conditions (N = 200)					P-value	Number of Chronic Conditions (N = 200)			
	1	2	3	4	>4		2-3	4-5	>5	P-value
	(n = 0)	(n = 35)	(n = 55)	(n = 45)	(n = 65)		(n = 90)	(n = 73)	(n = 37)	
mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD		
TBQ global score	NA	20.5±18.6	16.6±14.9	22.7±19.7	26.2±21.2	0.049*	18.1±16.5	23.6±20.7	27.2±20.4	0.031*
EQ-5D-5L score	NA	0.95±0.12	0.94±0.08	0.94±0.07	0.88±0.11	<0.001*	0.94±0.10	0.93±0.08	0.85±0.12	<0.001*
EQ-5D VAS	NA	82.7±10.4	81.5±10.4	79.7±10.2	74.6±14.2	0.002*	82.0±10.3	80.0±10.5	70.0±14.7	<0.001*
SF-6D score	NA	0.87±0.10	0.84±0.12	0.80±0.10	0.75±0.12	<0.001*	0.85±0.11	0.79±0.11	0.74±0.12	<0.001*
WONCA COOP										
Physical fitness	NA	1.9±1.1	2.4±1.2	2.3±1.0	2.7±1.3	0.028*	2.2±1.2	2.4±1.1	2.8±1.3	0.027*
Feelings	NA	1.2±0.5	1.5±0.7	1.4±0.6	1.6±0.9	0.039*	1.4±0.7	1.5±0.8	1.6±0.7	0.423
Daily activities	NA	1.1±0.4	1.3±0.7	1.2±0.4	1.5±1.0	0.011*	1.2±0.6	1.3±0.7	1.6±1.1	0.018*
Social activities	NA	1.1±0.2	1.2±0.7	1.2±0.7	1.4±0.9	0.106	1.2±0.5	1.3±0.7	1.5±1.0	0.037*
Change in health	NA	2.9±0.6	3.0±0.8	3.0±0.8	2.9±0.9	0.935	2.9±0.7	2.9±0.8	3.0±1.0	0.936
Overall health	NA	2.7±0.7	3.0±0.8	3.1±0.9	3.3±0.9	0.006*	2.9±0.8	3.0±0.9	3.6±0.8	<0.001*
Global health rating	NA	3.0±0.6	2.9±0.7	3.0±0.7	3.2±0.7	0.182	2.9±0.6	3.0±0.7	3.2±0.7	0.111

SD = Standard Deviation; TBQ = The Burden of Treatment Questionnaire; VAS = Visual Analogue Scale; SF-6D = Short-Form 6-Dimensions;

*significant difference at the 0.05 level (2-tailed) by independent t-test or analysis of variance test, where appropriate

Table 4. Effect of the number of co-morbidities on TBQ and HRQOL scores with adjustment of confounding effect of age

	Number of co-morbidities		
	3 vs 2†	4 vs 2†	>4 vs 2†
	coefficient (P-value)		
TBQ global score	-1.885 (0.636)	3.615 (0.382)	9.456 (0.018*)
EQ-5D-5L score	-0.019 (0.378)	-0.015 (0.489)	-0.083 (<0.001*)
EQ-5D VAS	-1.900 (0.455)	-3.528 (0.182)	-9.430 (<0.001*)
SF-6D score	-0.028 (0.265)	-0.066 (0.010*)	-0.123 (<0.001*)
WONCA COOP			
Physical fitness	0.402 (0.112)	0.353 (0.178)	0.632 (0.012*)
Feelings	0.372 (0.016*)	0.222 (0.163)	0.553 (<0.001*)
Daily activities	0.254 (0.109)	0.108 (0.506)	0.497 (0.002*)
Social activities	0.213 (0.165)	0.219 (0.167)	0.445 (0.004*)
Change in health	0.096 (0.587)	0.092 (0.615)	0.049 (0.780)
Overall health	0.301 (0.110)	0.348 (0.074)	0.547 (0.004*)
Global health rating	0.164 (0.357)	0.274 (0.137)	0.443 (0.013*)

SD = Standard Deviation; TBQ = Treatment Burden Questionnaire; VAS = Visual Analogue Scale; SF-6D = Short-Form 6-Dimensions

* P-value of <0.05 as statistical significant; † two co-morbidities as reference category in regression analysis

Table 5. Spearman correlation coefficients between TBQ, other HRQOL scores and multi-morbidities

	Spearman correlation coefficient											
	TBQ global score	EQ-5D-5L score	EQ-5D VAS	SF-6D score	WONCA COOP						Global health rating	Multi- comorbidit y
					Physical fitness	Feelings	Daily activities	Social activities	Change in health	Overall health		
TBQ global score	NA	-.280**	-.311**	-.303**	0.002	.205**	.212**	.290**	0.038	.200**	0.074	.150*
EQ-5D-5L score	-.280**	NA	.441**	.523**	-.402**	-.289**	-.392**	-.373**	-.143*	-.332**	-0.109	-.371**
EQ-5D VAS	-.311**	.441**	NA	.430**	-.259**	-.179*	-.330**	-.354**	-.175*	-.367**	0.021	-.282**
SF-6D score	-.303**	.523**	.430**	NA	-.450**	-.474**	-.490**	-.504**	-0.037	-.420**	0.039	-.402**
WONCA COOP												
Physical fitness	0.002	-.402**	-.259**	-.450**	NA	.255**	.360**	.353**	0.031	.284**	0.000	.207**
Feelings	.205**	-.289**	-.179*	-.474**	.255**	NA	.312**	.336**	0.003	0.053	-.148*	.149*
Daily activities	.212**	-.392**	-.330**	-.490**	.360**	.312**	NA	.547**	0.102	.256**	0.003	.172*
Social activities	.290**	-.373**	-.354**	-.504**	.353**	.336**	.547**	NA	0.044	.202**	-.158*	.150*
Change in health	0.038	-.143*	-.175*	-0.037	0.031	0.003	0.102	0.044	NA	.207**	0.021	0.019
Overall health	.200**	-.332**	-.367**	-.420**	.284**	0.053	.256**	.202**	.207**	NA	0.063	.275**
Global health rating	0.074	-0.109	0.021	0.039	0.0005	-.148*	0.003	-.158*	0.021	0.063	NA	0.114
Multi-morbidities	.150*	-.371**	-.282**	-.402**	.207**	.149*	.172*	.150*	0.019	.275**	0.114	NA

NA = not applicable; TBQ = The Burden of Treatment Questionnaire; VAS = Visual Analogue Scale; SF-6D = Short-Form 6-Dimensions

Notes:

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*Correlation is significant at the 0.05 level (2-tailed); **Correlation is significant at the 0.01 level (2-tailed)

For Peer Review

1
2 **Cultural Adaptation and Psychometric Properties of the Chinese Burden of Treatment**
3 **Questionnaire (C-TBQ) in Primary Care Patients with Multi-Morbidity**
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8 **Running head:** Validation of the Chinese Treatment of Burden Questionnaire
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11 **Article category:** Research methods
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Key Messages

- Multi-morbidity is associated with significant societal and personal burdens
- Treatment burden results from an excessive workload required to manage health
- Generic instruments to assess treatment burden in multi-morbidity are needed
- The Chinese Burden of Treatment Questionnaire (C-TBQ) is valid and reliable

Abstract word count 247

Manuscript word count 2781

For Peer Review

Abstract

Background

The Burden of Treatment Questionnaire (TBQ) assesses the impact of a patient's treatment workload on their quality of life

Objectives

The aim was to translate and validate the TBQ on Chinese primary care patients with multi-morbidity.

Methods

The English TBQ was translated and back-translated using professional translators. Cognitive debriefing interviews were performed on 15 patients. The resulting instrument was tested on 200 primary care patients with multi-morbidity (>1 chronic disease) to examine its psychometric performance including exploratory factor analysis, confirmatory factor analysis, internal consistency and reliability. EQ-5D-5L, SF-6D, WONCA COOP Charts and the Global Health Rating Scale were used to assess convergent and divergent validity.

Results

Median age of the respondents was 62 years (range 22-95 years) with a median of 4 conditions. The median TBQ total score was 16 (interquartile range 7.25-30). There was a significant floor effect (>15%) observed for all items. Spearman's correlations was >0.4 for all items demonstrated adequate internal construct validity. TBQ global score correlated with number of conditions ($p=0.034$), EQ-5D-5L ($p<0.001$), SF-6D ($p<0.001$), and the Feelings ($p=0.004$), Daily activities ($p=0.003$) and Social activities ($p<0.001$) domains of the WONCA COOP. There was no significant correlation between global health rating and TBQ global scores ($p=0.298$). Factor analysis demonstrated a three-factor structure. There was good internal consistency (Cronbach's alpha = 0.842) and good test-retest reliability (ICC = 0.830).

Conclusion

The newly translated Chinese version of the TBQ appears to be valid and reliable for use in Cantonese-speaking, adult primary care patients with multi-morbidity.

Keywords: Chronic Disease, Multi-morbidity, Primary Care, Psychometrics, Quality of Care, Quality of Life

Cultural Adaptation and Psychometric Properties of the Chinese Burden of Treatment Questionnaire (C-TBQ) in Primary Care Patients with Multi-Morbidity

Background

Multi-morbidity, often defined as having two or more chronic illnesses, is an important priority for health services research¹. With multi-morbidity now exceeding single morbidity², there are growing concerns that disease-centred healthcare models may result in over treatment and increased risks for adverse events in patients with multi-morbidity^{3,4}. The World Health Organization recognizes patients with multi-morbidity as being more vulnerable⁵. They have higher risks of polypharmacy, adverse drug events, medication nonadherence⁶ and more complex patterns of service use⁷. Patients are typically older, may have cognitive impairments or poorer health literacy⁸. Multi-morbidity is associated with greater psychological distress, depression, anxiety, and poorer health-related quality of life (HRQOL)^{9,10}.

Patient experience studies have revealed that patients with multi-morbidity often encounter burdens not only from their symptoms, but also from the activities needed to maintain health¹¹. Managing health requires time and effort, which if excessive, can result in unintentional consequences¹¹. 'Treatment burden' is an emerging concept which refers to the patient workload resulting from their treatments and disease-related self-care¹². 'Patient capacity' is the ability to cope with the illness and treatment burden¹³. Excessive treatment burden has been associated with reduced therapeutic adherence, increased hospitalization rates and mortality¹⁴.

There are currently several instruments that assess treatment burden for specific conditions, but burden can result from both individual diseases as well as from a combination of diseases, hence the need for instruments that can assess treatment burden generically^{15,16}. To date, there have been five instruments developed to measure treatment burden in patients with multi-morbidity^{15,17-20}. Each has its own merits and shortcomings including length, applicability, language and scope²⁰.

The Burden of Treatment Questionnaire (TBQ) developed by Tran, Ravaud et al is a patient-reported measure that assesses the consequences of medical interventions against the patient's self-perceived ability to cope. The original 13-item TBQ was developed in France, but its application was limited to patients within the French healthcare system. A more comprehensive 15-item English version was subsequently developed and validated for use in a broader range of settings¹⁷. The strength of the English TBQ is that it measures a number of aspects of treatment burden including the economic burdens. Its main weakness is it has only been validated on a relatively young, healthy and well-educated subject population^{17,20}. Hong Kong

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2 has a pluralistic healthcare system where patients use both public and private services with
3 80% of primary care delivered in the private sector and 80% of tertiary care in the public sector.
4 The English TBQ was selected for translation and adaptation due to its comprehensiveness in
5 assessing various aspects of treatment burden (including financial burdens) with relevant items
6 for Hong Kong's pluralistic health setting.
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11 Translating a pre-existing instrument into a different language, and evidence of its
12 psychometric properties are needed to support the validity and reliability of the instrument to
13 ensure that the attributes being measured are conceptually equivalent to the original. This
14 process enables cross-cultural comparisons. It is also important to ensure a translated
15 instrument is culturally relevant and acceptable to the target population.
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21 The aim of this study was to perform a translation and cultural adaptation of the TBQ from
22 English to Chinese for use in Hong Kong, and explore the psychometric properties in a sample
23 of Chinese primary care patients with multi-morbidity. The findings will provide evidence to
24 support future observational studies on treatment burden to inform medical education and
25 improve quality of care.
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30 **Methods**

31 *Translation and cultural adaptation of the TBQ*

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33 Procedures as recommended by the International Society for Pharmacoeconomics and
34 Outcomes Research (ISPOR) task force were followed²¹. Permission was obtained from the
35 TBQ authors and MAPI Trust (holders of the copyright). Two professional translators
36 performed the forward and backward translations. Two bilingual local primary care providers
37 reconciled discrepancies between the back translation and original English version.
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44 Cognitive debriefing interviews were conducted on 15 Cantonese Chinese speaking patients
45 with a balanced sampling of ages and genders to assess for clarity, relevance and
46 interpretation. Two bilingual authors reviewed the results and made final modifications to the
47 instrument.
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51 *Subject Sampling and Recruitment for Psychometric Testing of the C-TBQ*

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53 Subjects were recruited from a government-funded General Out-Patient Clinic (GOPC) of the
54 Hong Kong Hospital Authority (HA). The HA is a governmental body responsible for the
55 delivery of approximately 80% of chronic disease care in Hong Kong²². Eligible subjects
56 with multi-morbidity were identified using a screening checklist of 20 common chronic
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1 diseases²³. Exclusion criteria included aged <18 years; unable to understand Cantonese;
2 refusal to participate; or too ill to give consent.
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5 *Study Instruments*

6 *Chronic disease count* is a commonly used measure of multi-morbidity and was defined as
7 the simple unweighted enumeration of the number of diseases present²⁴. To assess the
8 number of diseases, subjects were asked to self-complete a checklist of 20 chronic conditions
9 (**Supplementary Material 1**) derived from the Hong Kong Primary Care Morbidity Survey
10 2007-2008²³. Those with two or more chronic diseases were identified as having multi-
11 morbidity.
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18 *Burden of Treatment Questionnaire (TBQ) English version* is a 15-item questionnaire that
19 assesses the patient's workload to maintain their health and its impact on quality of life¹⁷.
20 Each item is scored from 0-10 with total scores ranging from 0 (no burden) to 150 (high
21 burden). The instrument was validated for multi-setting use^{15,17}.
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26 *Short-form Six-dimension (SF-6D)* is a preference-based measure of health, with a six-
27 dimensional health state classification (physical health, role limitation, bodily pain, vitality,
28 mental health, and social functioning) that quantifies a patient's health for each dimension,
29 against a set of preference-based weights obtained from representative samples of general
30 population²⁵⁻²⁷. Values are between 0 (death) and 1 (full health). The SF-6D utility score was
31 calculated using the Hong Kong Chinese SF-6D value set²⁶. The minimum important
32 difference (MID) value of the SF-6D is 0.033²⁸.
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39 *EuroQol Five-dimension Five-level Questionnaire (EQ-5D-5L)* is a standardised instrument
40 with five items representing five dimensions (mobility, self-care, usual activities,
41 pain/discomfort, and anxiety/depression) and a visual analogue scale (VAS) from 0-100. It
42 provides a single index value for health status²⁹⁻³². The EQ-5D-5L utility score was
43 calculated based on the EQ-5D-5L value set for China³³. The MID value of the EQ-5D-5L
44 for the Chinese scoring algorithm is 0.058³⁴.
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50 *Global Health Rating Scale* is a single item scale that asks subjects to rate their current
51 general health status on a five-point scale **from Excellent to Poor**. This item was extracted
52 from the Chinese SF-12v2 that has been validated in Hong Kong³⁵.
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56 *WONCA/COOP Chart* is an instrument used to assess functional status in primary care^{36,37}. It
57 contains six charts relating to physical fitness, feelings, daily activities, social activities,
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1 change in health and overall health, rated on a five-point scale. The instrument has been
2 validated in Hong Kong³⁸.

3 *Data Collection*

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5
6 A field worker approached patients in the waiting room and screened for multi-morbidity
7 using the checklist. Patients with \geq two conditions were invited to participate. The field
8 worker explained the study, obtained consent and administered the questionnaire. Subjects
9 were re-contacted two weeks later to collect data for test-retest reliability. The first interview
10 was face-to-face. The second interview was telephone-administered.

11 *Statistical Analysis*

12
13 Descriptive statistics (median, inter-quartile range, and percentage of floor and ceiling
14 effect), and the floor and ceiling of the C-TBQ item and global scores were determined. For
15 the C-TBQ, the floor is the *least* amount of burden whilst the ceiling is the *greatest* (a reverse
16 of most HRQOL instruments). The floor and ceiling effect is the proportion of patients who
17 achieved the worst or the best possible scores, with 15% used as the threshold for having a
18 significant effect³⁹.

19
20 Internal construct validity was assessed using item-total scale correlation with scores >0.4
21 demonstrating adequate correlation⁴⁰.

22
23 Convergent validity was assessed using Spearman's rho correlation to test against health
24 utility, WONCA/COOP and General Health Rating scores, and number of diseases. It was
25 hypothesised that patients with higher numbers of chronic diseases would have more
26 treatment burden, and an increase in treatment burden would be associated with poorer
27 HRQOL (reflected by lower SF-6D and EQ-5D-5L scores).

28
29 Sensitivity was determined by performing known-group comparisons of the C-TBQ total
30 score between subjects with different numbers of diseases using independent t-test or analysis
31 of variance, where appropriate. As older people are more likely to have more morbidity,
32 analyses were adjusted for confounding effects due to age. Regression coefficients and
33 corresponding p-values were used to measure the effect of the number of diseases (>4 , 4, 3
34 versus 2 as reference category) on the C-TBQ and HRQOL scores. It was hypothesised that a
35 higher number of diseases would be associated with increased burden, with and without
36 adjusting for age⁴¹.

37
38 Test-retest reliability was assessed by examining the intra-class correlation coefficient (ICC)
39 of the C-TBQ global score with an ICC >0.7 indicating good reproducibility⁴².

Exploratory factor analysis (EFA) utilizing a principal component method with varimax rotation was used to explore dimensionality and the underlying factor structure, and to compute factor Eigenvalues. Factors with Eigenvalues >1 were retained. Individual rotated factor loadings and the Cronbach's alpha if each individual item were removed were estimated. Goodness-of-fit of the factor structure derived by EFA were subsequently assessed using confirmatory factor analysis (CFA). Goodness-of-fit index (GFI)⁴³, adjusted goodness-of-fit index (AGFI)⁴³, root mean square error of approximation (RMSEA)⁴⁴, and comparative fit index (CFI) were used to assess the model goodness-of-fit, and were considered adequate if: 1) $RMSEA \leq 0.08$; 2) $GFI \geq 0.90$; 3) $AGFI \geq 0.80$; and 4) $CFI \geq 0.95$.

Internal consistency of the C-TBQ was assessed using Cronbach's alpha with cut-off scores ≥ 0.7 indicating adequate internal consistency⁴².

CFA was performed using LISREL 8.80 (Scientific Software International, Inc., Lincolnwood, IL, USA). Other statistical analyses were performed using STATA 13.0.

Results

Instrument translation and adaptation

Table 1 shows the characteristics of the cognitive debriefing participants. The C-TBQ took an average of 10.2 minutes to complete and was easy to comprehend. Modifications for use on Hong Kong Chinese patients are summarised in **Supplementary Material 2**.

Supplementary Material 3 outlines the iterative steps taken to reconcile the translation.

Supplementary Material 4 contains the final version of the C-TBQ and back-translated English TBQ (Hong Kong version) registered with Mapi Research Institute.

Psychometric testing of the C-TBQ

The median age of subjects ($N=200$) was 62 (range 22 to 95) years with a median of four conditions (**Table 1**). Subjects with no chronic disease were not sampled as it was thought that the TBQ would not be relevant. A significant floor effect was found for all items. All correlations between items and global scores scored >0.4 demonstrating adequate internal construct validity (**Table 2**).

Factor analysis. EFA using the principal component method with varimax rotation extracted three factors with eigenvalues ≥ 1.0 on which all 15 items loaded significantly (and exclusively), and explained 51.091% of the total variations (**Table 2**). The three-factor CFA model derived by EFA met the criteria for demonstrating adequate goodness-of-fit ($RMSEA=0.0747$; $GFI=0.89$; $AGFI=0.85$; $CFI=0.95$).

1
2 *Known group comparisons.* Analyses were conducted on patients with two, three, four and >
3 four conditions. There was a significant difference in mean C-TBQ global scores between
4 patients with different numbers of multi-morbidities ($p=0.049$). Further analyses were
5 conducted on patients with two or three (Mean=18.1, SD=16.5), four or five (Mean=23.6,
6 SD=20.7), and >five chronic conditions (Mean=27.2, SD=20.4). There was a significant
7 difference in mean C-TBQ global scores between groups indicating that patients with more
8 conditions had higher C-TBQ scores (**Table 3**). Using a MID value of 0.033 for SF-6D score,
9 the differences in SF-6D scores between groups were meaningful. However, using an MID
10 value 0.058, the differences in EQ-5D-5L scores between groups were not meaningful. **Table**
11 **4** shows the effect of the number of morbidities on the C-TBQ and other HRQOL scores
12 controlling for age. Patients with >four conditions had significantly higher C-TBQ global
13 scores, poorer EQ-5D-5L scores and EQ-5D VAS scores than those with only two.
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23 *Reliability.* The C-TBQ was internally consistent (Cronbach's alpha =0.842), and reliable
24 (ICC=0.830) demonstrating good test-retest reliability.
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26
27 *Convergent validity.* **Table 5** summarizes the correlations between the C-TBQ, health utility
28 scores, WONCA/COOP scores, General Health Rating scores, and multi-morbidities. C-TBQ
29 global scores negatively correlated with the EQ-5D-5L ($r= -0.280$, $p <0.01$), EQ-5D VAS ($r=$
30 -0.311 , $p <0.01$), and SF-6D ($r= -0.303$, $p <0.01$), but positively correlated with
31 WONCA/COOP feelings ($r= 0.205$, $p <0.01$), daily activities ($r= 0.212$, $p <0.01$), social
32 activities ($r= 0.290$, $p <0.01$), overall health ($r= 0.200$, $p <0.01$), and the number of diseases
33 ($r= 0.150$, $p <0.05$). A weak correlation ($r= 0.074$, $p >0.05$) was observed between global
34 health rating and C-TBQ global score.
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41 **Discussion**

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44 Our study found that Chinese patients with multi-morbidity aged from 25 to 83 years could
45 understand, correctly interpret and respond to all the items of the C-TBQ, however, an
46 introductory sentence explaining 'treatment burden' was needed it was an unfamiliar concept.
47 Treatment burden is a relatively novel Western concept and our Chinese patients had never
48 thought of health care as work. Once explained, they easily understood the analogy. Most
49 subjects completed the questionnaire in less than 10 minutes with the exception of an 83-
50 year-old respondent, indicating that more time might be needed when administering the
51 instrument on elderly patients. For some items, exemplars were added to enhance reliability.
52 For example, we added 'such as eating less sugar and eating more vegetables' to Item 5 to
53 promote the understanding of 'dietary modification'.
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1 Similar to other treatment burden questionnaires, there was a significant floor effect²⁰. This
2 may have been due to the sample frame. Participants were primary care patients with
3 relatively milder diseases, receiving government-subsidised care. Many were elderly,
4 unemployed or retired, and hence may not have experienced the burden of 'taking time off
5 work to attend medical visits'. Further studies on different patient populations, particularly
6 those with greater complexity or those who are encumbered with significant out-of-pocket
7 costs may reveal a different pattern of scores. A lack of a ceiling effect indicates that the C-
8 TBQ may be better for monitoring burden deterioration.

16 As hypothesised, the C-TBQ global score strongly correlated with disease number, all health
17 utility scores and most of the WONCA/COOP domain scores. A recent review found
18 treatment burden was associated with the cumulative effect of an increased workload
19 resulting from a higher number of conditions¹¹. Similarly, recent study which found a 3.4-
20 unit reduction in the EQ-VAS score for each additional condition⁴¹. Conversely, there was
21 only a weak correlation between C-TBQ scores the Global Health Rating scale. This suggests
22 that the C-TBQ correlates better with measures that capture the impact of illness on daily
23 functioning than those assessing the patient's perception of their health.

30 Although the English TBQ was found to be uni-dimensional, factor analysis of the C-TBQ
31 demonstrated a three-factor structure. This may have potential implications for instrument
32 scoring. The structure of the C-TBQ suggested three domains of treatment burden. Factor 1
33 related to the direct burdens of receiving health care such as drug treatments, investigations
34 and medical visits. Item TBQ7 (inconveniencing friends and family) also loaded on this
35 factor, possibly because much of this burden may be related to transportation issues to attend
36 medical appointments. Factor 2 related to administrative and financial burdens, whilst Factor
37 3 was lifestyle-related including item TBQ8 on being a 'reminded that they had health
38 problems'.

46 The internal consistency and test-retest reliability of the C-TBQ were comparable to the
47 French and English versions^{15,17}.

51 *Strengths and Limitations*

53 A key strength of this study was our subject sampling. We used a representative sample of
54 primary care patients with multi-morbidity including a large proportion of elderly patients,
55 with a median of four conditions.

59 There were also limitations. Subjects were recruited by convenience sampling from a single
60 site where health care was delivered by specialist family physicians in a government-

1 subsidized health care setting. Selection bias may impact the floor and ceiling effect
2 measurements in this study and the pattern of burden observed. A future larger scale study
3 with subjects across a broader age range, from both public and private settings are
4 recommended to examine the prevalence, risk factors, mediators, and moderators of
5 treatment burden.
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10 This instrument focussed specifically on treatment burdens related to chronic disease care in
11 Western medicine health care settings and further modifications to the C-TBQ may be needed
12 to include aspects of treatment burden resulting from Chinese Medicine. Further testing is
13 recommended to assess the instrument's performance in other Chinese-speaking health care
14 populations such as in China or Taiwan, or in secondary and tertiary settings.
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20 **Conclusions**

21 In settings such as Asia, where patients may be less likely to verbally disagree with their
22 doctors, admit to non-compliance, or disclose that they cannot cope, a treatment burden
23 questionnaire can potentially be useful for identifying at-risk patients, and help facilitate better
24 patient-centred doctor-patient interactions. Treatment burden scores can be used to promote or
25 evaluate shared decision-making interventions. Our study found that the Chinese TBQ is valid,
26 reliable and sensitive, and provides evidence to support its use in larger scale epidemiological
27 studies and health services research.
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39 Thi Tran for giving us permission to translate and adapt their Burden of Treatment
40 Questionnaire. The questionnaire is copyrighted to Phillippe Ravaud, and administered by the
41 Mapi Research Trust.
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48 **Compliance with ethical standards**

49 All authors declare that they have no competing interests.
50
51

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57

58 **Ethical approval**

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For Peer Review

Table 1. Subject characteristics for the cognitive debriefing interviews and psychometric testing of the Chinese Burden of Treatment Questionnaire (TBQ)

Cognitive debriefing subjects (n=15)				
	Participant no.	Age (years)	Gender	Completion Time (mins)
Chinese Instrument -Version 1	1	34	M	36
	2	54	F	72
	3	55	M	47
	4	56	F	41
	5	25	M	13
Chinese Instrument -Version 2	6	46	F	6
	7	78	F	15
	8	78	M	13
	9	75	M	13
	10	76	M	12
Chinese Instrument -Version 3 (final)	11	83	M	18
	12	37	F	9
	13	52	M	10
	14	54	F	9
	15	64	M	5
		57.8		21.3
Psychometric testing subject characteristics (N=200)				
Demographic, % (n)		Total (N = 200)		
Age, median (Interquartile range)		62 (56-67) years		
Gender				
Female		55.0 % (110)		
Male		45.0 % (90)		
Number of chronic conditions				
1		0.0 % (0)		
2		17.5 % (35)		
3		27.5 % (55)		
4		22.5 % (45)		
>4		32.5 % (65)		
Median (Interquartile range)		4 (3-5)		

Table 2. Descriptive statistics and exploratory factor analysis of each TBQ item

Item number	Item description	Median (IQR)	Floor (%)	Ceiling (%)	Spearman's rho correlation	Rotated factor loading			Cronbach's alpha (if item deleted)
						Factor 1	Factor 2	Factor 3	
TBQ_1a	The problems related to the discomfort caused by your medications (tablets, inhalers, eye drops, injections) such as: pain, taste, shape, size, and bruising.	0 (0-2)	65.0	0.5	.592**	0.681	0.020	0.108	0.833
TBQ_1b	The problems caused by how many times a day you need to take your medications (for example: once per day, twice per day, three times per day).	0 (0-2)	66.0	0.5	.626**	0.782	0.103	0.014	0.831
TBQ_1c	The problems caused by the effort you need to make to remember to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...).	0 (0-0)	76.5	1.0	.552**	0.724	0.122	0.101	0.833
TBQ_1d	The problems caused by the precautions you need to take when taking your medications (for example: taking them at specific times of the day or with meals, not being able to do certain things after taking medications, such as driving or lying down...).	0 (0-1)	69.5	0.5	.596**	0.746	0.170	0.246	0.826
TBQ_2a	The problems related to having to go for regular lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated inconveniences.	0 (0-3.75)	53.0	2.5	.674**	0.650	0.248	0.272	0.823
TBQ_2b	The problems related to self-monitoring (for example: taking your blood pressure or checking your blood sugar): frequency, time spent and associated inconveniences.	0 (0-2)	67.5	0.5	.582**	0.488	0.162	0.356	0.831

TBQ_2c	The problems related to doctor or allied health visits: frequency and time spent for these visits, or difficulties in finding the healthcare centres.	0 (0-4)	47.0	1.5	.649**	0.443	0.420	0.289	0.825
TBQ_2d	The problems related to your relationships with your doctors, nurses and other allied health professionals (for example: feeling not listened to enough or not taken seriously).	0 (0-0)	81.5	1.0	.484**	0.484	0.314	0.033	0.837
TBQ_2e	The problems related to arranging medical appointments (for example: doctor's visits, lab tests and other exams), and reorganizing your schedule around these appointments.	0 (0-2)	61.0	1.5	.664**	0.149	0.584	0.477	0.828
TBQ_3	The problems related to the administrative burden associated with your healthcare (for example: the time and effort you take to fill in forms for hospitalizations, insurance claims, reimbursements and/or obtaining social services)?	0 (0-3)	60.0	2.5	.549**	0.057	0.802	0.060	0.838
TBQ_4	The problems related to the financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?	0.5 (0-5)	50.0	1.5	.680**	0.252	0.737	0.122	0.830
TBQ_5	The problems related to having to modify your diet, reduce your alcohol intake or stop smoking as recommended by your doctor (for example: avoiding certain foods, eating less sugar, eating more vegetables...)?	0 (0-3)	49.5	0.5	.562**	0.259	0.087	0.716	0.832
TBQ_6	The problems related to needing to exercise more as recommended by your doctor (for example: walking, jogging, swimming...)?	0 (0-4)	50.5	1.0	.542**	0.143	0.141	0.764	0.835
TBQ_7	The things you need to do to look after your health may sometimes cause your family, friends and co-workers inconvenience (for example: needing help from family to administer injections at home, needing help from friends to get to and from doctors' appointments, needing co-workers to cover for you so that you can go to your doctors'	0 (0-0)	83.0	1.0	.426**	0.401	0.363	0.039	0.837

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appointments...), how much does it impact your relationships with them?

TBQ_8	'The need for medical healthcare on a regular basis reminds me of my health problems'	0 (0-3.75)	63.5	5.0	.419**	0.012	0.049	0.509	0.854
	TBQ Global score	16 (7.25-30)	11.0	0.5		Factor 1	Factor 2	Factor 3	Total
					Eigenvalue	3.586	2.107	1.971	7.664
					% of variance explained	23.906	14.046	13.139	51.091

Notes:

IQR = Interquartile range; TBQ = The Burden of Treatment Questionnaire

*Correlation is significant at the 0.05 level (2-tailed).

**Correlation is significant at the 0.01 level (2-tailed).

For Peer Review

Table 3. Known group comparisons of TBQ global score and HRQOL scores between groups

	Number of Chronic Conditions (N = 200)					P-value	Number of Chronic Conditions (N = 200)			
	1	2	3	4	>4		2-3	4-5	>5	P-value
	(n = 0)	(n = 35)	(n = 55)	(n = 45)	(n = 65)		(n = 90)	(n = 73)	(n = 37)	
mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD	mean ± SD		
TBQ global score	NA	20.5±18.6	16.6±14.9	22.7±19.7	26.2±21.2	0.049*	18.1±16.5	23.6±20.7	27.2±20.4	0.031*
EQ-5D-5L score	NA	0.95±0.12	0.94±0.08	0.94±0.07	0.88±0.11	<0.001*	0.94±0.10	0.93±0.08	0.85±0.12	<0.001*
EQ-5D VAS	NA	82.7±10.4	81.5±10.4	79.7±10.2	74.6±14.2	0.002*	82.0±10.3	80.0±10.5	70.0±14.7	<0.001*
SF-6D score	NA	0.87±0.10	0.84±0.12	0.80±0.10	0.75±0.12	<0.001*	0.85±0.11	0.79±0.11	0.74±0.12	<0.001*
WONCA COOP										
Physical fitness	NA	1.9±1.1	2.4±1.2	2.3±1.0	2.7±1.3	0.028*	2.2±1.2	2.4±1.1	2.8±1.3	0.027*
Feelings	NA	1.2±0.5	1.5±0.7	1.4±0.6	1.6±0.9	0.039*	1.4±0.7	1.5±0.8	1.6±0.7	0.423
Daily activities	NA	1.1±0.4	1.3±0.7	1.2±0.4	1.5±1.0	0.011*	1.2±0.6	1.3±0.7	1.6±1.1	0.018*
Social activities	NA	1.1±0.2	1.2±0.7	1.2±0.7	1.4±0.9	0.106	1.2±0.5	1.3±0.7	1.5±1.0	0.037*
Change in health	NA	2.9±0.6	3.0±0.8	3.0±0.8	2.9±0.9	0.935	2.9±0.7	2.9±0.8	3.0±1.0	0.936
Overall health	NA	2.7±0.7	3.0±0.8	3.1±0.9	3.3±0.9	0.006*	2.9±0.8	3.0±0.9	3.6±0.8	<0.001*
Global health rating	NA	3.0±0.6	2.9±0.7	3.0±0.7	3.2±0.7	0.182	2.9±0.6	3.0±0.7	3.2±0.7	0.111

SD = Standard Deviation; TBQ = The Burden of Treatment Questionnaire; VAS = Visual Analogue Scale; SF-6D = Short-Form 6-Dimensions;

*significant difference at the 0.05 level (2-tailed) by independent t-test or analysis of variance test, where appropriate

Table 4. Effect of the number of co-morbidities on TBQ and HRQOL scores with adjustment of confounding effect of age

	Number of co-morbidities		
	3 vs 2†	4 vs 2†	>4 vs 2†
	coefficient (P-value)		
TBQ global score	-1.885 (0.636)	3.615 (0.382)	9.456 (0.018*)
EQ-5D-5L score	-0.019 (0.378)	-0.015 (0.489)	-0.083 (<0.001*)
EQ-5D VAS	-1.900 (0.455)	-3.528 (0.182)	-9.430 (<0.001*)
SF-6D score	-0.028 (0.265)	-0.066 (0.010*)	-0.123 (<0.001*)
WONCA COOP			
Physical fitness	0.402 (0.112)	0.353 (0.178)	0.632 (0.012*)
Feelings	0.372 (0.016*)	0.222 (0.163)	0.553 (<0.001*)
Daily activities	0.254 (0.109)	0.108 (0.506)	0.497 (0.002*)
Social activities	0.213 (0.165)	0.219 (0.167)	0.445 (0.004*)
Change in health	0.096 (0.587)	0.092 (0.615)	0.049 (0.780)
Overall health	0.301 (0.110)	0.348 (0.074)	0.547 (0.004*)
Global health rating	0.164 (0.357)	0.274 (0.137)	0.443 (0.013*)

SD = Standard Deviation; TBQ = Treatment Burden Questionnaire; VAS = Visual Analogue Scale; SF-6D = Short-Form 6-Dimensions

* P-value of <0.05 as statistical significant; † two co-morbidities as reference category in regression analysis

Table 5. Spearman correlation coefficients between TBQ, other HRQOL scores and multi-morbidities

	Spearman correlation coefficient												
	WONCA COOP											Global health rating	Multi-comorbidity
	TBQ global score	EQ-5D-5L score	EQ-5D VAS	SF-6D score	Physical fitness	Feelings	Daily activities	Social activities	Change in health	Overall health			
TBQ global score	NA	-.280**	-.311**	-.303**	0.002	.205**	.212**	.290**	0.038	.200**	0.074	.150*	
EQ-5D-5L score	-.280**	NA	.441**	.523**	-.402**	-.289**	-.392**	-.373**	-.143*	-.332**	-0.109	-.371**	
EQ-5D VAS	-.311**	.441**	NA	.430**	-.259**	-.179*	-.330**	-.354**	-.175*	-.367**	0.021	-.282**	
SF-6D score	-.303**	.523**	.430**	NA	-.450**	-.474**	-.490**	-.504**	-0.037	-.420**	0.039	-.402**	
WONCA COOP													
Physical fitness	0.002	-.402**	-.259**	-.450**	NA	.255**	.360**	.353**	0.031	.284**	0.000	.207**	
Feelings	.205**	-.289**	-.179*	-.474**	.255**	NA	.312**	.336**	0.003	0.053	-.148*	.149*	
Daily activities	.212**	-.392**	-.330**	-.490**	.360**	.312**	NA	.547**	0.102	.256**	0.003	.172*	
Social activities	.290**	-.373**	-.354**	-.504**	.353**	.336**	.547**	NA	0.044	.202**	-.158*	.150*	
Change in health	0.038	-.143*	-.175*	-0.037	0.031	0.003	0.102	0.044	NA	.207**	0.021	0.019	
Overall health	.200**	-.332**	-.367**	-.420**	.284**	0.053	.256**	.202**	.207**	NA	0.063	.275**	
Global health rating	0.074	-0.109	0.021	0.039	0.0005	-.148*	0.003	-.158*	0.021	0.063	NA	0.114	
Multi-morbidities	.150*	-.371**	-.282**	-.402**	.207**	.149*	.172*	.150*	0.019	.275**	0.114	NA	

NA = not applicable; TBQ = The Burden of Treatment Questionnaire; VAS = Visual Analogue Scale; SF-6D = Short-Form 6-Dimensions

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*Correlation is significant at the 0.05 level (2-tailed); **Correlation is significant at the 0.01 level (2-tailed)

For Peer Review

Supplementary Material 1.

Disease list

For Peer Review

Supplementary 1

Disease list

1.	Hypertension
2.	Diabetes
3.	Lipid disorder
4.	Dermatitis
5.	Allergic rhinitis
6.	Dyspepsia
7.	Asthma
8.	Anxiety
9.	Osteoarthritis
10.	Gout
11.	Cerebrovascular disease
12.	Depression
13.	Low back pain
14.	Ischaemic heart disease
15.	Benign prostatic hypertrophy
16.	Bursitis/ tendinitis/synovitis
17.	Hypothyroidism
18.	Haemorrhoids
19.	Osteoporosis
20.	Chronic obstructive pulmonary disease

Derived from the HK primary care morbidity survey list of top 80% of health problems

http://www.hkcfp.org.hk/Upload/HK_Practitioner/2010/hkp2010vol32mar/original_article_2.html

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3 Supplementary Material 2.
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5 Cultural Adaptation of the TBQ
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For Peer Review

Procedures in the Translation and Cultural Adaptation of the TBQ

1. Expert panel review

Content validation of the English TBQ performed by expert local panel review. Panel consisted of two primary care doctors, one research nurse experienced in instrument development of patient reported outcomes, one health-related quality of life researcher and one primary care patient

2. Forward translation from English to Chinese

Two independent TBQ Chinese forward translations were performed by professional translators (language@languageventure.com)

3. Reconciliation

A reconciled TBQ Chinese draft 1 (Chi T1) was developed based on the two professional forward translations by a research assistant and the principal researcher who were both native speakers of the target language: Traditional Chinese/ Cantonese.

4. Cognitive debriefing (I)

Cognitive debriefing interviews were conducted on Chi T1 using 5 conveniently sampled participants who were all native-Cantonese speakers (3 males, 2 females; age range: 25-56 years).

5. Backward translation from Chinese Chi T1 to English

Backward translation of the Chi T1 to English was performed by a bilingual research assistant and principal researcher, and was compared with the original English TBQ. Differences from the original version were mainly due to the attempts to enhance clarity and inclusivity, to improve translational equivalence, and to match the responses to the questions.

6. TBQ Chinese translation version 2

Chi T1 was revised to create TBQ Chinese draft 2 (Chi T2) in response to the findings of the initial set of cognitive debriefing interviews.

7. Cognitive debriefing (II)

A second set of cognitive debriefing interviews were conducted on Chi T2 using 5 primary care patients (3 males, 2 females; age range: 46-78 years).

8. Backward translation from Chinese Chi T2 to English

Backward translation of the Chi T2 to English was performed by a bilingual research assistant and principal researcher, and was compared with the original English TBQ. Differences from the original version were mainly due to the attempts to enhance clarity and inclusivity, to improve translational equivalence, and to match the responses to the questions.

9. TBQ Chinese translation version 3

Minor revisions were made to Chi T2 in response to the findings of the second set of

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3 cognitive debriefing interviews to create TBQ Chinese draft 3 (Chi T3).
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6 **10. Cognitive debriefing (III)**

7 Cognitive debriefing interviews on the Chi T3 were conducted on a further 5 primary care
8 patients (3 males, 2 females; age range: 37 -83 years) with no further revisions to the
9 Chinese questionnaire. Chi T3 = final TBQ Chinese (HK version)
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12 **11. Backward translation from Chinese Chi T3 to English (final)**

13 Backward translation of the Chi T3 to English was performed by a bilingual research assistant
14 and principal researcher, and validated by a research nurse creating the final version of the
15 TBQ English (HK version).
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Supplementary Material 3.
Translation of the TBQ

For Peer Review

Question no.	Original English	Forward Chinese Translation A	Forward Chinese Translation B	Reconciliated Chinese version 1	Cognitive debriefing I Findings
					Did not understand/ only partially understood the question. Suggestions: - 請就以下每個有關藥物的負擔或問題作出評價 - 請閣下就下列健康問題作答 (由程度1-10中選擇) - 為了照顧健康, 請花點時間, 想想你需要做的每件事。請就以下每個問題作出評價。
1	How would you rate the problems related to :	您會如何評價以下各項所相關的問題	您如何評價與下列相關的問題	您會如何評價以下各項所相關的問題	Understood the instruction Suggestions: - 對以下問題選擇適合答案 - 你會如何評價各項問題
1A	The taste, shape or size of your tablets and/or the annoyances caused by your injections (for example: pain, bleeding, bruising or scars)?	藥物的味道、形狀或大小及 / 或注射的麻煩不適 (例如: 痛楚、流血或疤痕)?	藥片味道、形狀或尺寸和/或注射帶來的煩惱 (例如: 疼痛、出血、瘀傷或疤痕)	藥物的味道、形狀或大小及 / 或注射的困擾不適 (例如: 痛楚、流血或疤痕)	Did not understand the question; incorrect interpretation e.g. thought the item was asking about what aspects of the medication annoyed them the most, hence participants thought the response options did not match the question Suggestions: - 藥物的味道、形狀或大小及 / 或注射的麻煩不適, 對您做成的問題有多少 - 注射藥物時引起的不適 - 或注射的煩擾不適
1B	The number of times you should take your medication daily?	您每天須服藥幾次?	您每天服藥多少次?	您每天須服藥幾多次?	Wrongly interpreted the question, participants tended to answer the actual number of times they took medication instead of answering how the number of times of taking medication would affect them, hence response options did not match the question Suggestions: - 每天須服藥多少次 - 服藥次數對你的影響程度
1C	The efforts you make not to forget to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...)	為了緊記服藥您所作的努力 (例如: 安排離家在外時的治療、預備及使用藥盒.....)	您為了不忘記服藥而做的事情 (例如: 管理離家期間的治療藥物, 準備和使用藥盒...)	您為了不忘記服藥而做的努力 (例如: 安排離家在外時的療程、準備及使用藥盒.....)	Wrongly interpreted the question, participants tended to answer things they did to remember to take their medications instead, hence response options did not match the question. Suggestions: - 為了記得服藥對你付出的努力有否做成不便 - 為按時服藥所作的相關安排引致的額外負擔情況 - ...預備藥盒
1D	The necessary precautions when taking your medication (for example: taking them at specific times of the day or meals, not being able to do certain things after taking medications such as driving or lying down...)	服藥時必須注意的事項 (例如: 在每天特定時間或配合餐膳服藥、服藥後不能做某些事情, 如駕駛或躺下.....)	服藥時必要的注意事項 (例如: 在一天當中的特定時間或者就餐時用藥, 服用藥物後不能做某些事情, 如駕駛車輛或躺下...)	服藥時必須注意的事項 (例如: 在每天特定時間或用餐時服藥、服藥後不能做某些事情, 如駕駛或躺下.....)	Wrongly interpreted the question, participants tended to answer things they needed to pay attention to when taking medications, hence response options did not match the question Suggestions: - 服藥前/後需注意事項時有否引致閣下不便? 如有... - 或進食前/後服藥
2	Regarding your medical follow-up, how would you rate the problems related to :	就您的醫療跟進而言, 您會如何評價以下各項所相關的問題	關於您的醫學隨訪, 您如何評價以下相關問題	就您的醫療跟進而言, 您會如何評價以下各項所相關的問題	Understood the instruction Suggestions: - 就下述各項醫療跟進治療作出評價 - 評價以下相關問題
2A	Lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated nuisances or inconveniences	化驗及其他檢驗 (例如: 驗血或放射檢查): 頻率、花費時間, 以及相關的不適或不便	化驗和其他檢查 (例如: 驗血或放射診斷): 頻率、花費的時間和相關的滋擾或不便	化驗及其他檢驗 (例如: 驗血或放射檢查): 頻率、花費時間, 以及相關的不適或不便	Understood the question, response options matched the question Suggestions: - 化驗及相關檢驗 (例如: 驗血或放射檢查): 次數, 費用, 時間, 期間的不適或不便;

2B	Self-monitoring (for example: taking your blood pressure or checking your blood sugar) : frequency, time spent and associated nuisances or inconveniences	自我監察 (例如：自行測量血壓或檢查血糖)：頻率、花費時間，以及相關的不適或不便	自我監控 (例如：測量您的血壓或檢查您的血糖)：頻率、花費的時間和相關的不適或不便	自我監察 (例如：自行測量血壓或檢查血糖)：頻率、花費時間，以及相關的不適或不便	Understood the question, but 1 participant was not sure how to answer it
2C	Doctor visits and other appointments: frequency and time spent for these visits and difficulties finding healthcare providers	醫生覆診及其他預約 ：此類覆診或預約的頻率及花費時間，以及尋找保健服務供應商的困難	看醫生和其他預約 ：這些就診的頻率和花費的時間，以及尋找醫療服務供應者的困難	看醫生及其他預約 ：此類就診或預約的頻率及花費時間，以及尋找保健服務供應者的困難	Some participants did not understand the question; response options did not match the question
2D	The difficulties you could have in your relationships with healthcare providers (for example: feeling not listened to enough or not taken seriously)	您可能遇到與 保健服務供應商相處 上的難題 (例如：感到未獲細心聆聽或認真對待)	您與 醫療服務提供者之間關係 上的難處 (例如：感覺對方沒有仔細聽您講話或者不重視您)	您可能遇到與 保健服務提供者相處 上的難題 (例如：感到未獲細心聆聽或認真對待)	Some participants did not understand the question; should have provided more details e.g. clinics instead of only saying healthcare providers
2E	Arranging medical appointments (doctors visits, lab tests and other exams) and reorganizing your schedule around these appointments	安排預約醫療服務 (到醫生處覆診、接受化驗及其他檢驗)及 重新安排您的日程 以配合此等預約	安排預約就診 (醫生處就診、化驗和其他檢查)以及因就診預約而需要 重新安排您的日程	安排預約醫療服務 (看醫生、做化驗和其他檢查)及 重新安排您的日程 以配合此等預約	Understood the question, but some participants thought the response options did not match the question, mainly because they did not understand the purpose of the questionnaire
	How would you rate	您會如何評價	您如何評價	您會如何評價	
3	The administrative burden related to healthcare (for example: all you have to do for hospitalizations, reimbursements and/or obtaining social services)	與保健相關的 行政負擔 (例如：您須住院、報銷費用及 / 或申領社會服務做的事)	與醫療相關的 行政負擔 (例如：您為了住院、報銷和/或獲取社會服務而不得不做的事情)	與保健相關的 行政負擔 (例如：您須住院、報銷費用及 / 或申領社會服務做的事)	Understood the question, but the examples given were too similar to things related to financial burden
4	The financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?	與您的保健相關的 財政負擔 (例如：實付支出或保險保障範圍外的支出) ?	與醫療相關的 財政負擔 (例如：自付費用或者沒有承保的開支)	與您的保健相關的 財政負擔 (例如：實付支出或保險保障範圍外的支出)	Understood the question; response options matched the question Suggestions: - 受訪者就是次引致的直接財政付擔 (例如：實付支出或保險保障範圍外的支出)
5	The burden related to dietary changes (for example: avoiding certain foods or alcohol, having to quit smoking...)?	與 膳食改變 相關的負擔 (例如：須避免食用某些食物或避免喝酒、須戒煙.....)	與 飲食改變 相關的負擔 (例如：不能吃某些食物或飲酒、必須戒煙...)	與 飲食改變 相關的負擔 (例如：須避免吃某些食物或避免喝酒、須戒煙...)	Understood the question; response options matched the question, but the wordings should be changed for easier understanding Suggestions: - 改變飲食習慣帶來的不便或負擔 (例如：須避免食用某些食物或避免喝酒、須戒煙.....)
6	The burden related to doctors' recommendations to practice physical activity (for example: walking, jogging, swimming...)?	與 醫生建議鍛煉體能 相關的負擔 (例如：散步、緩步跑、游泳.....)	與 醫生建議進行運動 相關的負擔 (例如：步行、慢跑、游泳...)	與 醫生建議做運動 相關的負擔 (例如：步行、慢跑、游泳...)	1 participant did not understand the question and thought the response options did not match the question mainly because she did not understand the main purpose of this questionnaire. Others understood the question but suggested that the wordings should be changed for easier understanding
7	How does your healthcare impact your relationships with others (for example: needing assistance in everyday life, being ashamed to take your medication...)?	您的保健如何影響 您與他人的關係 (例如：日常生活需要協助、服藥時感到不好意思.....) ?	您的醫療對 您與他人的關係 有何影響 (例如：在日常生活中需要幫助，對服藥感到難為情...)	您的保健如何影響 您與他人的關係 (例如：日常生活需要協助、服藥時感到不好意思.....)	Did not understand / partially understood the question, wordings should be changed to make it clear that the item was asking 'how things you need to do to take care of your health are impacting your relationships with others'. Suggestions: - 你是否需要協助日常生活, 包括服藥, 對你做成的問題有多少 - 因醫療需要引至家人照顧的額外負擔;
Response options for the above items	Does not apply Not a problem 0 1 2 3 4 5 6 7 8 9 10 Big problem	不適用 不是問題 0 1 2 3 4 5 6 7 8 9 10 問題很大	不適用 不是問題 0 1 2 3 4 5 6 7 8 9 10 問題很大	不適用 不是問題 0 1 2 3 4 5 6 7 8 9 10 問題很大	
8	'The need for medical healthcare on a regular basis reminds me of my health problems '	「定期接受醫療服務 讓我覺得我有健康問題 」	「定期就診 提醒我健康有問題 」	定期接受醫療服務會提醒我自己健康上的問題	1 participant did not understand the question and wrongly interpreted it: 定期檢查/ 接受醫療服務可減低患病風險/ 提高健康警覺
Response options for item 8	Not at all 0 1 2 3 4 5 6 7 8 9 10 All the time	完全沒有 0 1 2 3 4 5 6 7 8 9 10 時時刻刻	完全不會 0 1 2 3 4 5 6 7 8 9 10 總是這樣	完全不會 0 1 2 3 4 5 6 7 8 9 10 總是這樣	

Question no.	Amended Chinese version 2	Cognitive debriefing II Findings
	請花點時間，想想你為了照顧健康所做的每件事。請就以下每個項目所相關的負擔或問題作出評價。	Understood the instructions, but needed further explanations on the word "burden". Suggestions: 請花點時間，想想你為了照顧健康所做的每一件事。請就以下每一個項目所相關的負擔或問題作出評價。
1	以下各項目對你來說有多大問題? (0 為“沒有問題”; 10 為“很大問題”)	Understood the instructions
1A	因為你的藥物 (藥丸, 吸入器, 眼藥水, 打針) 而引致的不適 (例如: 痛楚, 味道, 形狀, 腫脹), 對你來說有多大問題?	Understood the question; response options matched the question
1B	你每天的服藥次數 (例如每天一次, 二次, 三次), 對你來說有多大問題?	Understood the question; response options matched the question
1C	為了記得服藥你所做的事情 (例如: 安排離家在外時的療程、預備及使用藥盒....), 對你來說有多大問題?	Understood the question; response options matched the question
1D	你服藥時需要注意的事項 (例如: 需在每天特定的時間或用餐時服藥、服藥後不能做某些事情, 例如駕駛或躺下.....), 對你來說有多大問題?	Understood the question; response options matched the question
2	就你的醫療跟進而言, 評價以下各項問題:	Understood the instructions
2A	需要定期去進行化驗及其他檢驗 (例如: 驗血或放射檢查); 其次數, 所花的時間, 及相關的不便, 對你來說有多大問題?	Understood the question; response options matched the question
2B	自我監察 (例如: 自行測量血壓或檢查血糖); 其次數, 所花的時間, 及相關的不便, 對你來說有多大問題?	Understood the question; response options matched the question
2C	看醫生或其他專科: 其次數與所花的時間, 或尋找醫療中心的困難, 對你來說有多大問題?	Understood the question; response options matched the question
2D	你與你的醫生, 護士, 與其他的專科醫生相處上所遇到的問題 (例如: 感覺對方沒有細心聆聽你講話或者不重視你), 對你來說有多大問題?	Understood the question; response options matched the question
2E	安排預約醫療服務 (例如: 看醫生、做化驗及其他檢驗) 及重新安排你的日程以配合這些預約, 對你來說有多大問題?	Understood the question; response options matched the question
	以下各項對你來說有多大問題?	Understood the instructions
3	與你的保健相關的行政負擔 (例如: 你需花時間就住院填寫表格, 保險索償, 報銷費用及 / 或申領社會服務), 對你來說有多大問題?	Understood the question; response options matched the question
4	與你的保健相關的財政負擔 (例如: 實際支出或保險保障範圍外的支出), 對你來說有多大問題?	Understood the question; response options matched the question
5	因醫生的建議而需要改變你的飲食習慣, 減少飲酒或戒煙 (例如: 避免吃某種食物, 減少吸收糖分, 多吃蔬菜...), 對你來說有多大問題?	Understood the question; response options matched the question
6	因醫生的建議而需要多做運動 (例如: 散步、緩步跑、游泳.....), 對你來說有多大問題?	Understood the question; response options matched the question
7	因為需要照顧自己的健康要做的事情 (例如: 在家打針時需要家人的協助, 去看醫生及離開時需要朋友的協助, 去看醫生時需要同事工作上的支援...), 這些事對你與你的家人, 朋友及同事之間的關係有多大影響?	Understood the question; response options matched the question Suggestions: ...會麻煩到家人, 朋友, 同同事, 這對你來說有多大影響?
Response options for the above items	不適用 沒有 0 1 2 3 4 5 6 7 8 9 10 很大	Response options matched the question
8	a. 「定期接受醫療服務提醒我自己健康上有問題。」 b. 這對你來說有多大問題?	Understood the question; one of the participants interpreted it as a positive thing (which makes sense as well)
Response options for item 8	a. 十分不同意 0 1 2 3 4 5 十分同意 b. 沒有 0 1 2 3 4 5 很大	Response options matched the question

Question no.	Amended Chinese version 3	Back translated English version 2
	請花點時間，想想你為了照顧健康所做的每一件事。請就以下每一個項目所相關的負擔或問題作出評價。	Take a moment and consider everything you have to do to take care of your health. Please rate the burden or problem associated with each of the following items.
1	以下各項目對你來說有多大問題? (0 為“沒有問題”; 10 為“很大問題”)	How big a problem are the following to you (0 means “Not a problem” while 10 means “Very big problem”):
1A	因為你的藥物 (藥丸, 吸入器, 眼藥水, 打針) 而引致的不適 (例如: 痛楚, 味道, 形狀, 腫脹), 對你來說有多大問題?	The problems related to the discomfort caused by your medications (tablets, inhalers, eye drops, injections) such as: pain, taste, shape, size, bruising.
1B	你每天的服藥次數 (例如每天一次, 二次, 三次), 對你來說有多大問題?	The problems caused by how many times a day you need to take your medications (for example: once per day, twice per day, three times per day).
1C	為了記得服藥你所做的事情 (例如: 安排離家在外時的療程、預備及使用藥盒....), 對你來說有多大問題?	The problems caused by the effort you need to make to remember to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...).
1D	你服藥時需要注意的事項 (例如: 需在每天特定的時間或用餐時服藥、服藥後不能做某些事情, 例如駕駛或躺下.....), 對你來說有多大問題?	The problems caused by the precautions you need to take when taking your medications (for example: taking them at specific times of the day or with meals, not being able to do certain things after taking medications, such as driving or lying down...).
2	就你的醫療跟進而言, 評價以下各項問題:	Regarding your medical follow-up, how would you rate the following problems:
2A	需要定期去進行化驗及其他檢驗 (例如: 驗血或放射檢查): 其次數, 所花的時間, 及相關的不便, 對你來說有多大問題?	The problems related to having to go for regular lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated inconveniences.
2B	自我監察 (例如: 自行測量血壓或檢查血糖): 其次數, 所花的時間, 及相關的不便, 對你來說有多大問題?	The problems related to self-monitoring (for example: taking your blood pressure or checking your blood sugar): frequency, time spent and associated inconveniences
2C	看醫生或其他專科: 其次數與所花的時間, 或尋找醫療中心的困難, 對你來說有多大問題?	The problems related to doctor or allied health visits: frequency and time spent for these visits, or difficulties in finding the healthcare centers.
2D	你與你的醫生, 護士, 與其他的專科醫生相處上所遇到的問題 (例如: 感覺對方沒有細心聆聽你講話或者不重視你), 對你來說有多大問題?	The problems related to your relationships with your doctors, nurses and other allied health professionals (for example: feeling not listened to enough or not taken seriously).
2E	安排預約醫療服務 (例如: 看醫生、做化驗及其他檢驗) 及重新安排你的日程以配合這些預約, 對你來說有多大問題?	The problems related to arranging medical appointments (for example: doctor's visits, lab tests and other exams), and reorganizing your schedule around these appointments
	以下各項對你來說有多大問題?	How big a problem are the following to you
3	與你的醫療相關的行政負擔 (例如: 你需花時間就住院填寫表格, 保險索償, 報銷費用及 / 或申領社會服務), 對你來說有多大問題?	The problems related to the administrative burden associated with your healthcare (for example: the time and effort you take to fill in forms for hospitalizations, insurance claims, reimbursements and/or obtaining social services)?
4	與你的醫療相關的財政負擔 (例如: 實際支出或保險保障範圍外的支出), 對你來說有多大問題?	The problems related to the financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?
5	因醫生的建議而需要改變你的飲食習慣, 減少飲酒或戒煙 (例如: 避免吃某種食物, 減少吸收糖分, 多吃蔬菜...), 對你來說有多大問題?	The problems related to having to modify your diet, reduce your alcohol intake or stop smoking as recommended by your doctor (for example: avoiding certain foods, eating less sugar, eating more vegetables...)?
6	因醫生的建議而需要多做運動 (例如: 散步、緩步跑、游泳.....), 對你來說有多大問題?	The problems related to needing to exercise more as recommended by your doctor (for example: walking, jogging, swimming...)?
7	因為需要照顧自己的健康要做的事情, 有時會麻煩到你的家人, 朋友, 跟同事 (例如: 在家打針時需要家人的協助, 去看醫生及離開時需要朋友的協助, 去看醫生時需要同事工作上的支援...), 這對你與他們之間的關係有多大影響?	The things you need to do to look after your health may sometimes cause your family, friends and co-workers inconvenience (for example: needing help from family to administer injections at home, needing help from friends to get to and from doctors' appointments, needing co-workers to cover for you so that you can go to your doctors' appointments...), how much does it impact your relationships with them ?
Response options for the above items	不適用 沒有 0 1 2 3 4 5 6 7 8 9 10 很大	Does not apply None 0 1 2 3 4 5 6 7 8 9 10 Very big
8	a. 「定期接受醫療服務提醒我自己健康上有問題。」 b. 這對你來說有多大問題?	a. “The need for medical healthcare on a regular basis reminds me of my health problems.” b. How big a problem is this to you?
Response options for item 8	a. 十分不同意 0 1 2 3 4 5 十分同意 b. 沒有 0 1 2 3 4 5 很大	a. Strongly disagree 0 1 2 3 4 5 Strongly agree b. None 0 1 2 3 4 5 Very big

Question no.	Original English TBQ	Back translated English TBQ version 2	Rationale for amendments
	Take a moment and consider everything you have to do to take care of your health. Please rate the burden or problem associated with each of the following items.	Take a moment and consider everything you have to do to take care of your health. Please rate the burden or problem associated with each of the following items.	No change
1	How would you rate the problems related to :	How big a problem are the following to you (0 means "Not a problem" while 10 means "Very big problem"):	To enhance clarity
1A	The taste, shape or size of your tablets and/or the annoyances caused by your injections (for example: pain, bleeding, bruising or scars)?	The problems related to the discomfort caused by your medications (tablets, inhalers, eye drops, injections) such as: pain, taste, shape, size, bruising.	To enhance clarity and improve translational equivalence of "annoyances" i.e. discomfort To enhance inclusivity of "tablets" i.e. medications
1B	The number of times you should take your medication daily?	The problems caused by how many times a day you need to take your medications (for example: once per day, twice per day, three times per day).	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item
1C	The efforts you make not to forget to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...)	The problems caused by the effort you need to make to remember to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...).	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item To improve translational equivalence
1D	The necessary precautions when taking your medication (for example: taking them at specific times of the day or meals, not being able to do certain things after taking medications such as driving or lying down...)	The problems caused by the precautions you need to take when taking your medications (for example: taking them at specific times of the day or with meals, not being able to do certain things after taking medications, such as driving or lying down...).	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item
2	Regarding your medical follow-up, how would you rate the problems related to :	Regarding your medical follow-up, how would you rate the following problems:	No change
2A	Lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated nuisances or inconveniences	The problems related to having to go for regular lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated inconveniences.	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item To improve translational equivalence
2B	Self-monitoring (for example: taking your blood pressure or checking your blood sugar) : frequency, time spent and associated nuisances or inconveniences	The problems related to self-monitoring (for example: taking your blood pressure or checking your blood sugar): frequency, time spent and associated inconveniences	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item
2C	Doctor visits and other appointments: frequency and time spent for these visits and difficulties finding healthcare providers	The problems related to doctor or allied health visits: frequency and time spent for these visits, or difficulties in finding the healthcare centers.	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item To improve translational equivalence
2D	The difficulties you could have in your relationships with healthcare providers (for example: feeling not listened to enough or not taken seriously)	The problems related to your relationships with your doctors, nurses and other allied health professionals (for example: feeling not listened to enough or not taken seriously).	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item To improve translational equivalence of "healthcare providers"
2E	Arranging medical appointments (doctors visits, lab tests and other exams) and reorganizing your schedule around these appointments	The problems related to arranging medical appointments (for example: doctor's visits, lab tests and other exams), and reorganizing your schedule around these appointments	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item
	How would you rate	How big a problem are the following to you	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item To improve translational equivalence
3	The administrative burden related to healthcare (for example: all you have to do for hospitalizations, reimbursements and/or obtaining social services)	The problems related to the administrative burden associated with your healthcare (for example: the time and effort you take to fill in forms for hospitalizations, insurance claims, reimbursements and/or obtaining social services)?	To enhance clarity of "administrative burden" i.e. adding more related examples To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item To improve translational equivalence
4	The financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?	The problems related to the financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item
5	The burden related to dietary changes (for example: avoiding certain foods or alcohol, having to quit smoking...)?	The problems related to having to modify your diet, reduce your alcohol intake or stop smoking as recommended by your doctor (for example: avoiding certain foods, eating less sugar, eating more vegetables...)?	To enhance clarity: to emphasize that what we are asking here is "the problem" caused by the item To enhance clarity of "dietary changes" i.e. modify your diets etc. Two domains included in one item: diet and smoking
6	The burden related to doctors' recommendations to practice physical activity (for example: walking, jogging, swimming...)?	The problems related to needing to exercise more as recommended by your doctor (for example: walking, jogging, swimming...)?	To enhance clarity of "physical activity" i.e. exercise more To improve translational equivalence
7	How does your healthcare impact your relationships with others (for example: needing assistance in everyday life, being ashamed to take your medication...)?	The things you need to do to look after your health may sometimes cause your family, friends and co-workers inconvenience (for example: needing help from family to administer injections at home, needing help from friends to get to and from doctors' appointments, needing co-workers to cover for you so that you can go to your doctors' appointments...), how much does it impact your relationships with them ?	To enhance clarity of "others" i.e. family, friends, and co-workers
Response options for the above items	Does not apply Not a problem 0 1 2 3 4 5 6 7 8 9 10 Big problem	Does not apply None 0 1 2 3 4 5 6 7 8 9 10 Very big	To match the response to the question To improve translational equivalence as no proper chinese words could be decided for the term 'problem'
8	'The need for medical healthcare on a regular basis reminds me of my health problems '	Has been divided into 2 questions (8a and 8b) as below	To improve clarity as 1.: not everyone may be reminded his/ her health problems when visiting a doctor; and 2.: some participants did not perceive being reminded of their health problems as a negative thing, but positive, as they could then do something to improve their health condition
8a	N/A	"The need for medical healthcare on a regular basis reminds me of my health problems."	
8b	N/A	How big a problem is this to you?	
Response options for item 8	Not at all 0 1 2 3 4 5 6 7 8 9 10 All the time	a. Strongly disagree 0 1 2 3 4 5 Strongly agree b. None 0 1 2 3 4 5 Very big	To match the response to the question To improve translational equivalence

Question no.	Amended Chinese version 3	Backward translation English version 3	Rationale for amendments
	<p>以下是有關「治療負擔」的問題，意指因你的醫療保健所引致的痛苦或不便。請花點時間，想想你為了照顧健康所做的每一件事。請就以下每一個項目所相關的負擔或問題作出評價。</p>	<p>The following questions ask about 'treatment burden', it refers to the suffering or inconvenience caused by your healthcare. Take a moment and consider everything you have to do to take care of your health. Please rate the burden or problem associated with each of the following items.</p>	<p>To enhance clarity: to explain the term "treatment burden"</p>
1	<p>以下各項目對你來說有多大問題? (0 為“沒有問題”; 10 為“很大問題”)</p>	<p>How big a problem are the following to you (0 means "Not a problem" while 10 means "Very big problem"):</p>	<p>No change</p>
1A	<p>因為你的藥物 (藥丸，吸入器，眼藥水，打針) 而引致的不適 (例如：痛楚，味道，形狀，瘀傷)，對你來說有多大問題?</p>	<p>The problems related to the discomfort caused by your medications (tablets, inhalers, eye drops, injections) such as: pain, taste, shape, size, bruising.</p>	<p>To enhance translational equivalence of the term "brusing"</p>
1B	<p>你每天的服藥次數 (例如每天一次，二次，三次)，對你來說有多大問題?</p>	<p>The problems caused by how many times a day you need to take your medications (for example: once per day, twice per day, three times per day).</p>	<p>No change</p>
1C	<p>為了記得服藥你所做的事情 (例如：安排離家在外時的療程、預備及使用藥盒....)，對你來說有多大問題?</p>	<p>The problems caused by the effort you need to make to remember to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...).</p>	<p>No change</p>
1D	<p>你服藥時需要注意的事項 (例如：需在每天特定的時間或用餐時服藥、服藥後不能做某些事情，例如駕駛或躺下.....)，對你來說有多大問題?</p>	<p>The problems caused by the precautions you need to take when taking your medications (for example: taking them at specific times of the day or with meals, not being able to do certain things after taking medications, such as driving or lying down...).</p>	<p>No change</p>
2	<p>就你的醫療跟進而言，評價以下各項問題：</p>	<p>Regarding your medical follow-up, how would you rate the following problems:</p>	<p>No change</p>
2A	<p>需要定期去進行化驗及其他檢驗 (例如：驗血或放射檢查)：其次數，所花的時間，及相關的不便，對你來說有多大問題?</p>	<p>The problems related to having to go for regular lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated inconveniences.</p>	<p>No change</p>
2B	<p>自我監察 (例如：自行測量血壓或檢查血糖)：其次數，所花的時間，及相關的不便，對你來說有多大問題?</p>	<p>The problems related to self-monitoring (for example: taking your blood pressure or checking your blood sugar): frequency, time spent and associated inconveniences</p>	<p>No change</p>
2C	<p>看醫生或其他專職醫療：其次數與所花的時間，或尋找醫療中心的困難，對你來說有多大問題?</p>	<p>The problems related to doctor or allied health visits: frequency and time spent for these visits, or difficulties in finding the healthcare centers.</p>	<p>To enhance translational equivalence of the term "allied health"</p>
2D	<p>你與你的醫生，護士，與其他的專職醫療人員相處上所遇到的問題 (例如：感覺對方沒有細心聆聽你講話或者不重視你)，對你來說有多大問題?</p>	<p>The problems related to your relationships with your doctors, nurses and other allied health professionals (for example: feeling not listened to enough or not taken seriously).</p>	<p>To enhance translational equivalence of the term "allied health professionals"</p>

2E	安排預約醫療服務（例如：看醫生、做化驗及其他檢驗）及重新安排你的日程以配合這些預約，對你來說有多大問題？	The problems related to arranging medical appointments (for example: doctor's visits, lab tests and other exams), and reorganizing your schedule around these appointments	No change
	以下各項對你來說有多大問題？	How big a problem are the following to you	No change
3	與你的醫療相關的 行政負擔 （例如：你需花時間就住院填寫表格，保險索償，報銷費用及 / 或申領社會服務），對你來說有多大問題？	The problems related to the administrative burden associated with your healthcare (for example: the time and effort you take to fill in forms for hospitalizations, insurance claims, reimbursements and/or obtaining social services)?	No change
4	與你的醫療相關的 財政負擔 （例如：實際支出或保險保障範圍外的支出），對你來說有多大問題？	The problems related to the financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?	No change
5	因醫生的建議而需要 改變你的飲食習慣，減少飲酒或戒煙 （例如：避免吃某種食物，減少吸收糖分，多吃蔬菜...），對你來說有多大問題？	The problems related to having to modify your diet, reduce your alcohol intake or stop smoking as recommended by your doctor (for example: avoiding certain foods, eating less sugar, eating more vegetables...)?	No change
6	因醫生的建議而需要 多做運動 （例如：散步、緩步跑、游泳.....），對你來說有多大問題？	The problems related to needing to exercise more as recommended by your doctor (for example: walking, jogging, swimming...)?	No change
7	因為需要照顧自己的健康要做的事情，有時會麻煩到你的家人，朋友，跟同事（例如：在家打針時需要家人的協助，去看醫生及離開時需要朋友的協助，去看醫生時需要同事工作上的支援...），這對你與他們之間的關係有多大影響？	The things you need to do to look after your health may sometimes cause your family, friends and co-workers inconvenience (for example: needing help from family to administer injections at home, needing help from friends to get to and from doctors' appointments, needing co-workers to cover for you so that you can go to your doctors' appointments...), how much does it impact your relationships with them ?	No change
Response options for the above items	不適用 沒有 0 1 2 3 4 5 6 7 8 9 10 很大	Does not apply None 0 1 2 3 4 5 6 7 8 9 10 Very big	No change
8	a. 「定期接受醫療服務提醒我自己健康上有問題。」 b. 這對你來說有多大問題？	“The need for medical healthcare on a regular basis reminds me of my health problems.” How big a problem is this to you?	No change No change
Response options for item 8	a. 十分不同意 0 1 2 3 4 5 十分同意 b. 沒有 0 1 2 3 4 5 很大	a. Strongly disagree 0 1 2 3 4 5 Strongly agree b. None 0 1 2 3 4 5 Very big	No change

Question no.	Original English TBQ	Backward translation English version 3
	<p>Take a moment and consider everything you have to do to take care of your health. Please rate the burden or problem associated with each of the following items.</p>	<p>The following questions ask about ‘treatment burden’, it refers to the suffering or inconvenience caused by your healthcare. Take a moment and consider everything you have to do to take care of your health. Please rate the burden or problem associated with each of the following items.</p>
1	How would you rate the problems related to :	How big a problem are the following to you (0 means “Not a problem” while 10 means “Very big problem”):
1A	<p>The taste, shape or size of your tablets and/or the annoyances caused by your injections (for example: pain, bleeding, bruising or scars)?</p>	<p>The problems related to the discomfort caused by your medications (tablets, inhalers, eye drops, injections) such as: pain, taste, shape, size, bruising.</p>
1B	<p>The number of times you should take your medication daily?</p>	<p>The problems caused by how many times a day you need to take your medications (for example: once per day, twice per day, three times per day).</p>
1C	<p>The efforts you make not to forget to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...)</p>	<p>The problems caused by the effort you need to make to remember to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...).</p>
1D	<p>The necessary precautions when taking your medication (for example: taking them at specific times of the day or meals, not being able to do certain things after taking medications such as driving or lying down...)</p>	<p>The problems caused by the precautions you need to take when taking your medications (for example: taking them at specific times of the day or with meals, not being able to do certain things after taking medications, such as driving or lying down...).</p>
2	Regarding your medical follow-up, how would you rate the problems related to :	Regarding your medical follow-up, how would you rate the following problems:
2A	<p>Lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated nuisances or inconveniences</p>	<p>The problems related to having to go for regular lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated inconveniences.</p>

2B	<p>Self-monitoring (for example: taking your blood pressure or checking your blood sugar) : frequency, time spent and associated nuisances or inconveniences</p>	<p>The problems related to self-monitoring (for example: taking your blood pressure or checking your blood sugar): frequency, time spent and associated inconveniences</p>
2C	<p>Doctor visits and other appointments: frequency and time spent for these visits and difficulties finding healthcare providers</p>	<p>The problems related to doctor or allied health visits: frequency and time spent for these visits, or difficulties in finding the healthcare centers.</p>
2D	<p>The difficulties you could have in your relationships with healthcare providers (for example: feeling not listened to enough or not taken seriously)</p>	<p>The problems related to your relationships with your doctors, nurses and other allied health professionals (for example: feeling not listened to enough or not taken seriously).</p>
2E	<p>Arranging medical appointments (doctors visits, lab tests and other exams) and reorganizing your schedule around these appointments</p>	<p>The problems related to arranging medical appointments (for example: doctor’s visits, lab tests and other exams), and reorganizing your schedule around these appointments</p>
	<p>How would you rate</p>	<p>How big a problem are the following to you</p>
3	<p>The administrative burden related to healthcare (for example: all you have to do for hospitalizations, reimbursements and/or obtaining social services)</p>	<p>The problems related to the administrative burden associated with your healthcare (for example: the time and effort you take to fill in forms for hospitalizations, insurance claims, reimbursements and/or obtaining social services)?</p>
4	<p>The financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?</p>	<p>The problems related to the financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?</p>
5	<p>The burden related to dietary changes (for example: avoiding certain foods or alcohol, having to quit smoking...)?</p>	<p>The problems related to having to modify your diet, reduce your alcohol intake or stop smoking as recommended by your doctor (for example: avoiding certain foods, eating less sugar, eating more vegetables...)?</p>

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6	The burden related to doctors’ recommendations to practice physical activity (for example: walking, jogging, swimming...)?	The problems related to needing to exercise more as recommended by your doctor (for example: walking, jogging, swimming...)?
7	How does your healthcare impact your relationships with others (for example: needing assistance in everyday life, being ashamed to take your medication...)?	The things you need to do to look after your health may sometimes cause your family, friends and co-workers inconvenience (for example: needing help from family to administer injections at home, needing help from friends to get to and from doctors’ appointments, needing co-workers to cover for you so that you can go to your doctors’ appointments...), how much does it impact your relationships with them ?
Response options for the above items	Does not apply Not a problem 0 1 2 3 4 5 6 7 8 9 10 Big problem	Does not apply None 0 1 2 3 4 5 6 7 8 9 10 Very big
8	‘The need for medical healthcare on a regular basis reminds me of my health problems ’	N/A
8a	N/A	“The need for medical healthcare on a regular basis reminds me of my health problems.”
8b	N/A	How big a problem is this to you?
Response options for item 8	Not at all 0 1 2 3 4 5 6 7 8 9 10 All the time	a. Strongly disagree 0 1 2 3 4 5 Strongly agree b. None 0 1 2 3 4 5 Very big

For Peer Review

Question no.	Amended Chinese version 3	Cognitive debriefing III Findings
	<p>以下是有關「治療負擔」的問題，意指因你的醫療保健所引致的痛苦或不便。請花點時間，想想你為了照顧健康所做的每一件事。請就以下每一個項目所相關的負擔或問題作出評價。</p>	Understood the instructions
1	<p>以下各項目對你來說有多大問題? (0 為“沒有問題”; 10 為“很大問題”)</p>	Understood the instructions
1A	<p>因為你的藥物 (藥丸, 吸入器, 眼藥水, 打針) 而引致的不適 (例如: 痛楚, 味道, 形狀, 瘀傷), 對你來說有多大問題?</p>	Understood the question; Response options matched the question
1B	<p>你每天的服藥次數 (例如每天一次, 二次, 三次), 對你來說有多大問題?</p>	Understood the question; Response options matched the question
1C	<p>為了記得服藥你所做的事情 (例如: 安排離家在外時的療程、預備及使用藥盒....), 對你來說有多大問題?</p>	<p>Understood the question; Response options matched the question</p> <p>Some participants only focused on "using the pillbox" but understood it's not only about the pillbox after further explanations</p> <p>Participants' interpretations: - 使用藥盒對你來說有幾麻煩? - 要做D 咩令你記得食藥? - 要用藥盒有無問題? - 為左記得食藥要做D咩去幫助你 - 你為了服藥所做的事有無問題?</p>
1D	<p>你服藥時需要注意的事項 (例如: 需在每天特定的時間或用餐時服藥、服藥後不能做某些事情, 例如駕駛或躺下.....), 對你來說有多大問題?</p>	Understood the question; Response options matched the question
2	<p>就你的醫療跟進而言, 評價以下各項問題:</p>	Understood the instructions

1 2 3 4 5 6 7 8 9	2A	需要定期去進行化驗及其他檢驗 (例如: 驗血或放射檢查): 其次數, 所花的時間, 及相關的不便, 對你來說有多大問題?	Understood the question; Response options matched the question
10 11 12 13 14 15 16	2B	自我監察 (例如: 自行測量血壓或檢查血糖) : 其次數, 所花的時間, 及相關的不便, 對你來說有多大問題?	Understood the question; Response options matched the question
17 18 19 20 21 22	2C	看醫生或其他專職醫療: 其次數與所花的時間 , 或尋找醫療中心的困難, 對你來說有多大問題?	Understood the question; Response options matched the question
23 24 25 26 27 28 29 30 31	2D	你與你的醫生, 護士, 與其他的專職醫療人員 相處上所遇到的問題 (例如: 感覺對方沒有細心 聆聽你講話或者不重視你), 對你來說有多大問題?	Understood the question; Response options matched the question Participants' interpretations: - 與醫生交流上所遇到的問題
32 33 34 35 36 37 38	2E	安排預約醫療服務 (例如: 看醫生、做化驗及 其他檢驗) 及重新安排你的日程以配合這些預 約, 對你來說有多大問題?	Understood the question; Response options matched the question
39 40 41 42 43 44 45 46 47		以下各項對你來說有多大問題?	Understood the instructions 1 participant needed somemore explanations to understand the question, thought it's about financial burden (Q4).
48 49 50 51 52 53 54 55 56 57	3	與你的醫療相關的行政負擔 (例如: 你需花時 間就住院填寫表格, 保險索償, 報銷費用及 / 或 申領社會服務), 對你來說有多大問題?	Understood the question; Response options matched the question Suggestions: 行政手續
58 59 60	4	與你的醫療相關的財政負擔 (例如: 實際支出 或保險保障範圍外的支出), 對你來說有多大問題?	Understood the question; Response options matched the question Participants' interpretations: - 財政方面的問題
	5	因醫生的建議而需要改變你的飲食習慣, 減少 飲酒或戒煙 (例如: 避免吃某種食物, 減少吸收糖分, 多吃 蔬菜...), 對你來說有多大問題?	Understood the question; Response options matched the question

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6	<p>因醫生的建議而需要多做運動（例如：散步、緩步跑、游泳.....），對你來說有多大問題？</p>	<p>Understood the question; Response options matched the question</p>
7	<p>因為需要照顧自己的健康要做的事情，有時會麻煩到你的家人，朋友，跟同事（例如：在家打針時需要家人的協助，去看醫生及離開時需要朋友的協助，去看醫生時需要同事工作上的支援...），這對你與他們之間的關係有多大影響？</p>	<p>Understood the question; Response options matched the question</p>
Response options for the above items	<p>不適用 沒有 0 1 2 3 4 5 6 7 8 9 10 很大</p>	<p>Response options matched the question</p>
8	<p>a. 「定期接受醫療服務提醒我自己健康上有問題。」</p>	<p>1 participant needed more explanations to understand the question</p> <p>Understood the question; Response options matched the question</p> <p>Participants' interpretations: - 定期接受醫療服務提醒我有咩唔舒服 - 你認唔認同定期接受醫療服務提醒我有問題 - 定期睇醫生提醒自己健康ge問題 - 定期接受醫療服務是否有問題 (Wrong interpretation) - 接受定期醫療服務提醒我ge健康ge問題</p> <p>Suggestions: - 你認為定期接受醫療服務會提醒自己健康有問題嗎?</p>
Response options for item 8	<p>a. 十分不同意 0 1 2 3 4 5 十分同意</p> <p>b. 沒有 0 1 2 3 4 5 很大</p>	<p>Response options matched the question</p>

Question no.	Amended Chinese version 4	English version 4
	<p>以下是有關「治療負擔」的問題，意指因你的醫療保健所引致的痛苦或不便。請花點時間，想想你為了照顧健康所做的每一件事。請就以下每一個項目所相關的負擔或問題作出評價。</p>	<p>The following questions ask about ‘treatment burden’, it refers to the suffering or inconvenience caused by your healthcare. Take a moment and consider everything you have to do to take care of your health. Please rate the burden or problem associated with each of the following items.</p>
1	<p>以下各項目對你來說有多大問題? (0 為“沒有問題”; 10 為“很大問題”)</p>	<p>How big a problem are the following to you (0 means “Not a problem” while 10 means “Very big problem”):</p>
1A	<p>因為你的藥物 (藥丸, 吸入器, 眼藥水, 打針) 而引致的不適 (例如: 痛楚, 味道, 形狀, 瘀傷), 對你來說有多大問題?</p>	<p>The problems related to the discomfort caused by your medications (tablets, inhalers, eye drops, injections) such as: pain, taste, shape, size, bruising.</p>
1B	<p>你每天的服藥次數 (例如每天一次, 二次, 三次), 對你來說有多大問題?</p>	<p>The problems caused by how many times a day you need to take your medications (for example: once per day, twice per day, three times per day).</p>
1C	<p>為了記得服藥你所做的事情 (例如: 安排離家在外時的療程、預備及使用藥盒....), 對你來說有多大問題?</p>	<p>The problems caused by the effort you need to make to remember to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...).</p>
1D	<p>你服藥時需要注意的事項 (例如: 需在每天特定的時間或用餐時服藥、服藥後不能做某些事情, 例如駕駛或躺下.....), 對你來說有多大問題?</p>	<p>The problems caused by the precautions you need to take when taking your medications (for example: taking them at specific times of the day or with meals, not being able to do certain things after taking medications, such as driving or lying down...).</p>
2	<p>就你的醫療跟進而言, 評價以下各項問題:</p>	<p>Regarding your medical follow-up, how would you rate the following problems:</p>
2A	<p>需要定期去進行化驗及其他檢驗 (例如: 驗血或放射檢查): 其次數, 所花的時間, 及相關的不便, 對你來說有多大問題?</p>	<p>The problems related to having to go for regular lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated inconveniences.</p>
2B	<p>自我監察 (例如: 自行測量血壓或檢查血糖): 其次數, 所花的時間, 及相關的不便, 對你來說有多大問題?</p>	<p>The problems related to self-monitoring (for example: taking your blood pressure or checking your blood sugar): frequency, time spent and associated inconveniences</p>

2C	看醫生或其他專職醫療：其次數與所花的時間，或尋找醫療中心的困難，對你來說有多大問題？	The problems related to doctor or allied health visits : frequency and time spent for these visits, or difficulties in finding the healthcare centers.
2D	你與你的醫生，護士，與其他的專職醫療人員相處上所遇到的問題（例如：感覺對方沒有細心聆聽你講話或者不重視你），對你來說有多大問題？	The problems related to your relationships with your doctors, nurses and other allied health professionals (for example: feeling not listened to enough or not taken seriously).
2E	安排預約醫療服務（例如：看醫生、做化驗及其他檢驗）及重新安排你的日程以配合這些預約，對你來說有多大問題？	The problems related to arranging medical appointments (for example: doctor's visits, lab tests and other exams), and reorganizing your schedule around these appointments
	以下各項對你來說有多大問題？	How big a problem are the following to you
3	與你的醫療相關的 行政負擔 （例如：你需花時間就住院填寫表格，保險索償，報銷費用及 / 或申領社會服務），對你來說有多大問題？	The problems related to the administrative burden associated with your healthcare (for example: the time and effort you take to fill in forms for hospitalizations, insurance claims, reimbursements and/or obtaining social services)?
4	與你的醫療相關的 財政負擔 （例如：實際支出或保險保障範圍外的支出），對你來說有多大問題？	The problems related to the financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?
5	因醫生的建議而需要 改變你的飲食習慣，減少飲酒或戒煙 （例如：避免吃某種食物，減少吸收糖分，多吃蔬菜...），對你來說有多大問題？	The problems related to having to modify your diet, reduce your alcohol intake or stop smoking as recommended by your doctor (for example: avoiding certain foods, eating less sugar, eating more vegetables...)?
6	因醫生的建議而需要 多做運動 （例如：散步、緩步跑、游泳.....），對你來說有多大問題？	The problems related to needing to exercise more as recommended by your doctor (for example: walking, jogging, swimming...)?

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Response options for the above items
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Response options for item 8

因為需要照顧自己的健康要做的事情，有時會麻煩到你的家人，朋友，跟同事（例如：在家打針時需要家人的協助，去看醫生及離開時需要朋友的協助，去看醫生時需要同事工作上的支援...），這對你與他們之間的關係有多大影響？

不適用
沒有
0 1 2 3 4 5 6 7 8 9 10
很大

你在什麼程度同意以下的句子？

「定期接受醫療服務提醒我自己健康上有問題。」

完全沒有
0 1 2 3 4 5 6 7 8 9 10
時時刻刻

The things you need to do to look after your health may sometimes cause your **family, friends and co-workers** inconvenience (for example: needing help from family to administer injections at home, needing help from friends to get to and from doctors' appointments, needing co-workers to cover for you so that you can go to your doctors' appointments...), how much does it impact **your relationships with them** ?

Does not apply
None
0 1 2 3 4 5 6 7 8 9 10
Very big

To what extent do you agree with the following statement?

“The need for medical healthcare on a regular basis reminds me of my health problems.”

Not at all
0 1 2 3 4 5 6 7 8 9 10
All the time

Question no.	Original English TBQ	English Backward translation of the Chiense TBQ version 4
	<p>Take a moment and consider everything you have to do to take care of your health. Please rate the burden or problem associated with each of the following items.</p>	<p>The following questions ask about ‘treatment burden’, it refers to the suffering or inconvenience caused by your healthcare. Take a moment and consider everything you have to do to take care of your health. Please rate the burden or problem associated with each of the following items.</p>
1	How would you rate the problems related to :	How big a problem are the following to you (0 means “Not a problem” while 10 means “Very big problem”):
1A	<p>The taste, shape or size of your tablets and/or the annoyances caused by your injections (for example: pain, bleeding, bruising or scars)?</p>	<p>The problems related to the discomfort caused by your medications (tablets, inhalers, eye drops, injections) such as: pain, taste, shape, size, bruising.</p>
1B	<p>The number of times you should take your medication daily?</p>	<p>The problems caused by how many times a day you need to take your medications (for example: once per day, twice per day, three times per day).</p>
1C	<p>The efforts you make not to forget to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...)</p>	<p>The problems caused by the effort you need to make to remember to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...).</p>
1D	<p>The necessary precautions when taking your medication (for example: taking them at specific times of the day or meals, not being able to do certain things after taking medications such as driving or lying down...)</p>	<p>The problems caused by the precautions you need to take when taking your medications (for example: taking them at specific times of the day or with meals, not being able to do certain things after taking medications, such as driving or lying down...).</p>
2	Regarding your medical follow-up, how would you rate the problems related to :	Regarding your medical follow-up, how would you rate the following problems:

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2A	Lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated nuisances or inconveniences	The problems related to having to go for regular lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated inconveniences.
2B	Self-monitoring (for example: taking your blood pressure or checking your blood sugar) : frequency, time spent and associated nuisances or inconveniences	The problems related to self-monitoring (for example: taking your blood pressure or checking your blood sugar): frequency, time spent and associated inconveniences
2C	Doctor visits and other appointments: frequency and time spent for these visits and difficulties finding healthcare providers	The problems related to doctor or allied health visits: frequency and time spent for these visits, or difficulties in finding the healthcare centers.
2D	The difficulties you could have in your relationships with healthcare providers (for example: feeling not listened to enough or not taken seriously)	The problems related to your relationships with your doctors, nurses and other allied health professionals (for example: feeling not listened to enough or not taken seriously).
2E	Arranging medical appointments (doctors visits, lab tests and other exams) and reorganizing your schedule around these appointments	The problems related to arranging medical appointments (for example: doctor’s visits, lab tests and other exams), and reorganizing your schedule around these appointments
	How would you rate	How big a problem are the following to you
3	The administrative burden related to healthcare (for example: all you have to do for hospitalizations, reimbursements and/or obtaining social services)	The problems related to the administrative burden associated with your healthcare (for example: the time and effort you take to fill in forms for hospitalizations, insurance claims, reimbursements and/or obtaining social services)?
4	The financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?	The problems related to the financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?

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5	The burden related to dietary changes (for example: avoiding certain foods or alcohol, having to quit smoking...)?	The problems related to having to modify your diet, reduce your alcohol intake or stop smoking as recommended by your doctor (for example: avoiding certain foods, eating less sugar, eating more vegetables...)?
6	The burden related to doctors' recommendations to practice physical activity (for example: walking, jogging, swimming...)?	The problems related to needing to exercise more as recommended by your doctor (for example: walking, jogging, swimming...)?
7	How does your healthcare impact your relationships with others (for example: needing assistance in everyday life, being ashamed to take your medication...)?	The things you need to do to look after your health may sometimes cause your family, friends and co-workers inconvenience (for example: needing help from family to administer injections at home, needing help from friends to get to and from doctors' appointments, needing co-workers to cover for you so that you can go to your doctors' appointments...), how much does it impact your relationships with them ?
Response options for the above items	Does not apply Not a problem 0 1 2 3 4 5 6 7 8 9 10 Big problem	Does not apply None 0 1 2 3 4 5 6 7 8 9 10 Very big
To what extent do you agree with the following statement?		
8	'The need for medical healthcare on a regular basis reminds me of my health problems '	"The need for medical healthcare on a regular basis reminds me of my health problems."
Response options for item 8	Not at all 0 1 2 3 4 5 6 7 8 9 10 All the time	Not at all 0 1 2 3 4 5 6 7 8 9 10 All the time

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Supplementary Material 4.

TBQ HK English and Chinese Versions

For Peer Review

治療負擔問卷 (香港中文版)

以下是有關「治療負擔」的問題，意指因你的醫療保健所引致的痛苦或不便。
請花點時間，想想你為了照顧健康所做的每件事。請就以下每個項目所相關的負擔或問題作出評價。

1. 以下各項目對你來說有多大問題? (0 為 “沒有問題” ; 10 為 “很大問題”)

A. 因為你的藥物 (藥丸, 吸入器, 眼藥水, 打針) 而引致的不適 (例如: 痛楚, 味道, 形狀, 瘀傷), 對你來說有多大問題?

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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B. 你每天的服藥次數 (例如每天一次, 二次, 三次), 對你來說有多大問題?

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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C. 為了記得服藥你所做的事情 (例如: 安排離家在外時的療程、預備及使用藥盒…), 對你來說有多大問題?

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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D. 你服藥時需要注意的事項 (例如: 需在每天特定的時間或用餐時服藥、服藥後不能做某些事情, 例如駕駛或躺下…), 對你來說有多大問題?

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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Treatment of Burden Questionnaire (Hong Kong Chinese and English)

2. 就你的醫療跟進而言，評價以下各項問題：

A. 需要定期去進行化驗及其他檢驗 (例如：驗血或放射檢查)：其次數，所花的時間，及相關的不便，對你來說有多大問題？

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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B. 自我監察 (例如：自行測量血壓或檢查血糖)：其次數，所花的時間，及相關的不便，對你來說有多大問題？

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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C. 看醫生或其他專職醫療：其次數與所花的時間，或尋找醫療中心的困難，對你來說有多大問題？

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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D. 你與你的醫生，護士，與其他的專職醫療人員相處上所遇到的問題 (例如：感覺對方沒有細心聆聽你講話或者不重視你)，對你來說有多大問題？

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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E. 安排預約醫療服務 (例如：看醫生、做化驗及其他檢驗) 及重新安排你的日程以配合這些預約，對你來說有多大問題？

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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Treatment of Burden Questionnaire (Hong Kong Chinese and English)

以下各項對你來說有多大問題？

3. 與你的醫療相關的**行政負擔**（例如：你需花時間就住院填寫表格，保險索償，報銷費用及／或申領社會服務），對你來說有多大問題？

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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4. 與你的醫療相關的**財政負擔**（例如：實際支出或保險保障範圍外的支出），對你來說有多大問題？

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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5. 因醫生的建議而需要**改變你的飲食習慣，減少飲酒或戒煙**（例如：避免吃某種食物，減少吸收糖分，多吃蔬菜…），對你來說有多大問題？

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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6. 因**醫生**的建議而需要**多做運動**（例如：散步、緩步跑、游泳……），對你來說有多大問題？

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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7. 因為需要照顧自己的健康要做的事情（例如：在家打針時需要家人的協助，去看醫生及離開時需要朋友的協助，去看醫生時需要同事工作上的支援…），這些事對你與你的家人，朋友及同事之間的關係有多大影響？

不適用 <input type="checkbox"/>	沒有 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	很大 10 <input type="checkbox"/>
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Treatment of Burden Questionnaire (Hong Kong Chinese and English)

你在什麼程度同意以下的句子?

8. 「定期接受醫療服務提醒我自己健康上有問題。」

完全沒有											時時刻刻
0	1	2	3	4	5	6	7	8	9	10	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

For Peer Review

Treatment Burden Questionnaire (Hong Kong) English

The following questions ask about ‘treatment burden’, it refers to the suffering or inconvenience caused by your healthcare. Take a moment and consider everything you have to do to take care of your health. Please rate the burden or problem associated with each of the following items.

1. **How big a problem are the following to you** (0 means “Not a problem” while 10 means “Very big problem”):

A. The problems related to the discomfort caused by your medications (tablets, inhalers, eye drops, injections) such as: pain, taste, shape, size, and bruising.

Does not apply	None	1	2	3	4	5	6	7	8	9	Very big
<input type="checkbox"/>	0										10
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B. The problems caused by how many times a day you need to take your medications (for example: once per day, twice per day, three times per day).

Does not apply	None	1	2	3	4	5	6	7	8	9	Very big
<input type="checkbox"/>	0										10
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C. The problems caused by the effort you need to make to remember to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...).

Does not apply	None	1	2	3	4	5	6	7	8	9	Very big
<input type="checkbox"/>	0										10
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

D. The problems caused by the precautions you need to take when taking your medications (for example: taking them at specific times of the day or with meals, not being able to do certain things after taking medications, such as driving or lying down...).

Does not apply	None	1	2	3	4	5	6	7	8	9	Very big
<input type="checkbox"/>	0										10
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Treatment of Burden Questionnaire (Hong Kong Chinese and English)

2. Regarding your medical follow-up, how would you rate the following problems:

A. The problems related to having to go for **regular lab tests and other exams** (for example: blood tests or radiology): frequency, time spent and associated inconveniences.

Does not apply <input type="checkbox"/>	None 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	Very big 10 <input type="checkbox"/>
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B. The problems related to **self-monitoring** (for example: taking your blood pressure or checking your blood sugar): frequency, time spent and associated inconveniences.

Does not apply <input type="checkbox"/>	None 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	Very big 10 <input type="checkbox"/>
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C. The problems related to **doctor or allied health visits**: frequency and time spent for these visits, or difficulties in finding the healthcare centers.

Does not apply <input type="checkbox"/>	None 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	Very big 10 <input type="checkbox"/>
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D. The problems related to your **relationships with your doctors, nurses and other allied health professionals** (for example: feeling not listened to enough or not taken seriously).

Does not apply <input type="checkbox"/>	None 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	Very big 10 <input type="checkbox"/>
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E. The problems related to **arranging medical appointments** (for example: doctor's visits, lab tests and other exams), and **reorganizing your schedule** around these appointments.

Does not apply <input type="checkbox"/>	None 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	Very big 10 <input type="checkbox"/>
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Treatment of Burden Questionnaire (Hong Kong Chinese and English)

How big a problem are the following to you:

3. The problems related to the **administrative burden** associated with your healthcare (for example: the time and effort you take to fill in forms for hospitalizations, insurance claims, reimbursements and/or obtaining social services)?

Does not apply <input type="checkbox"/>	None 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	Very big 10 <input type="checkbox"/>
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4. The problems related to the **financial burden** associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance)?

Does not apply <input type="checkbox"/>	None 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	Very big 10 <input type="checkbox"/>
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5. The problems related to having to **modify your diet, reduce your alcohol intake or stop smoking** as recommended by your doctor (for example: avoiding certain foods, eating less sugar, eating more vegetables...)?

Does not apply <input type="checkbox"/>	None 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	Very big 10 <input type="checkbox"/>
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6. The problems related to **needing to exercise more** as recommended by your **doctor** (for example: walking, jogging, swimming...)?

Does not apply <input type="checkbox"/>	None 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	Very big 10 <input type="checkbox"/>
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7. The things you need to do to look after your health may sometimes cause **your family, friends and co-workers** inconvenience (for example: needing help from family to administer injections at home, needing help from friends to get to and from doctors' appointments, needing co-workers to cover for you so that you can go to your doctors' appointments...), how much does it impact **your relationships with them**?

Does not apply <input type="checkbox"/>	None 0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	7 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>	Very big 10 <input type="checkbox"/>
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Treatment of Burden Questionnaire (Hong Kong Chinese and English)

To what extent do you agree with the following statement?

8. “The need for medical healthcare on a regular basis **reminds me of my health problems.**”

Not at all											All the time
0	1	2	3	4	5	6	7	8	9	10	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

For Peer Review

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) September 15, 2015

Text Section and Item Name	Section or Item Description	
Title and Abstract		
1. Title	Indicate that the manuscript concerns an <u>initiative</u> to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	Page 1
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local <u>problem</u> , methods, interventions, results, conclusions	Page 3
Introduction	<i>Why did you start?</i>	
3. <u>Problem Description</u>	Nature and significance of the local <u>problem</u>	Page 4
4. Available knowledge	Summary of what is currently known about the <u>problem</u> , including relevant previous studies	Page 4
5. <u>Rationale</u>	Informal or formal frameworks, models, concepts, and/or <u>theories</u> used to explain the <u>problem</u> , any reasons or <u>assumptions</u> that were used to develop the	Page 4-5
6. Specific aims	Purpose of the project and of this report	Page 5
Methods	What did you do?	Page 5-8
7. <u>Context</u>	Contextual elements considered important at the outset of introducing the <u>intervention(s)</u>	Page 5
8. <u>Intervention</u>	a. Description of the <u>intervention(s)</u> in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	Page 5

1 2 3 4 5	9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the <u>intervention(s)</u> b. Approach used to establish whether the observed outcomes were due to the	NA
6 7 8		a. Measures chosen for studying <u>processes</u> and outcomes of the <u>intervention(s)</u> , including rationale for choosing them, their operational	Page 6-7
9 10	11. Analysis	a. Qualitative and quantitative methods used to draw <u>inferences</u> from the data b. Methods for understanding variation within the data, including the effects of	Page 7-8
11 12 13	12. Ethical Considerations	<u>Ethical aspects</u> of implementing and studying the <u>intervention(s)</u> and how they were addressed, including, but not limited to, formal ethics review and	Page 12
14 15	Results	What did you find?	Page 8-9
16 17 18	13. Results	a. Initial steps of the <u>intervention(s)</u> and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the	Page 8-9
19 20	Discussion	What does it mean?	Page 9-11
21 22 23	14. Summary	a. Key findings, including relevance to the <u>rationale</u> and specific aims b. Particular strengths of the project	Page 9-11
24 25 26	15. Interpretation	a. Nature of the association between the <u>intervention(s)</u> and the outcomes b. Comparison of results with findings from other publications	Page 9-11
27 28 29	16. Limitations	a. Limits to the <u>generalizability</u> of the work b. Factors that might have limited <u>internal validity</u> such as confounding, bias, or	Page 11
30 31		a. Usefulness of the work b. Sustainability	
32 33 34	Other information		
35 36 37	18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	Page 12