

## The validity and reliability of the functional impairment checklist (FIC) in the evaluation of functional consequences of severe acute respiratory distress syndrome (SARS)

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Accepted in revised form 28 July 2005

### Abstract

Severe acute respiratory distress syndrome (SARS) contributed to significant mortality and morbidity worldwide. We aimed to establish the validity, reliability and responsiveness of the functional impairment checklist (FIC) as a measurement tool for physical dysfunction in SARS survivors. One hundred and sixteen (65 females and 51 males, mean age 45.6) patients who joined the SARS rehabilitation programme were analysed. The factor analysis yielded two latent factors. The mean FIC-symptom and FIC-disability score were 24.12 (SD  $\pm$  20.2) and 26.11 (SD  $\pm$  27.32), respectively. Based on the item-scale correlation coefficients, the Cronbach's alpha coefficients reflecting the internal consistency reliability of scale score were 0.75 for FIC-symptom and 0.86 for FIC-disability. Test-retest reliability in 23 patients showed no statistical significant difference in the FIC scores between tests with intraclass correlation coefficient (ICC) 0.49–0.57. The FIC scales correlated both with 6 minute walking test (6MWT) distance (–0.26 and –0.38) and handgrip strength (HGS) (–0.20 and –0.27). Moreover, the FIC scales correlated with St. George's respiratory questionnaire (SGRQ) (0.19 to 0.52) and short form 36 Hong Kong (SF-36) domains (–0.19 to –0.59). Both FIC scales correlated stronger with physical component summary (PCS) (–0.41 and –0.55) than with mental component summary (MCS) (–0.30 and –0.23). FIC reduced significantly at 6 months while the SF-36 PCS and MCS did not show any change. In conclusion, the study results indicate the FIC is reliable, valid and responsive to change in symptom and disability as a consequence of SARS, suggesting it may provide a means of assessing health related quality of life (HRQOL) outcomes in a longitudinal follow up.

**Key words:** Function impairment checklist, HRQOL, Physical dysfunction, SARS

**Abbreviations:** FIC – function impairment checklist; HRQOL – health related quality of life; ICC – intraclass correlation coefficients; MCS – SF-36 mental component summary; 6MWT – 6 minute walking test; PCS – SF-36 physical component summary; SARS – severe acute respiratory syndrome; SF-36 – short form 36 Hong Kong; SGRQ – St. George's respiratory questionnaire

### Introduction

Severe acute respiratory syndrome (SARS) was caused by a novel coronavirus (SARS Co-V) and hit the international community in 2003. The global cumulative total of probable cases was 8096 with

774 deaths reported from 29 countries [1]. SARS contributed to significant mortality and morbidity worldwide. SARS wrecked havoc in Hong Kong since it faced the largest outbreak outside Mainland China [2–4]. A total of 1755 people were infected by SARS, it caused death to 299 people, with a case

fatality rate of 17% [3]. Among the infected, 386 people (22%) were health care workers of hospitals, clinics and medical students [2].

Many patients in the recovery phase of SARS complained of limitations in physical function from general weakness to shortness of breath causing varying degree of limitations in their occupational, social and leisure activities or activities of daily living [5, 6]. At the height of the SARS crisis in May 2003, a panel of medical researchers and specialist clinicians joined the Secretary for Health, Welfare and Food to outline advances in treatment protocol and rehabilitation programme for SARS patients. The recommendation was that all those in need must receive comprehensive and standardized assessment, followed by rehabilitation services. The Hospital Authority Hong Kong introduced interdisciplinary rehabilitation programs tailor-made for recovered SARS patients. The Wong Tai Sin Hospital (WTSH) became the first to launch the program in May 2003 [7]. In order to provide effective rehabilitation programs for SARS patients, it was critical to develop a clinical tool or checklist to identify and quantify the morbidity among SARS survivors so as to evaluate the extent of impairment and disability [3, 6].

Health related quality of life (HRQOL) instruments had been widely applied in rehabilitation programmes of different diseases, which included both disease-specific and generic outcome measurement instruments [8–11]. However, because SARS was a novel disease, no existing HRQOL instrument was applicable for the necessary assessment. To fill the void, the Hospital Authority Hong Kong designed an instrument called functional impairment checklist (FIC) to make post-SARS evaluation. The FIC was a symptom and disability focused questionnaire adopted as a territory wide functional assessment tool in the Post-SARS clinics. In addition to evaluating post-SARS health related issues, the FIC also served as a clinical checklist for referral to the SARS rehabilitation programme. The FIC was complemented by two other existing HRQOL assessment tools to make disease-specific and generic quality of life assessment. The disease-specific tools used in the SARS rehabilitation program was a respiratory disease tool validated for chronic obstructive lung diseases and asthma, the St. George's respiratory questionnaire (SGRQ)

[12]. The generic quality-of-life measure, short form 36 Hong Kong (SF-36) (HK), was included as to measure the more global issues affecting the physical and psychological well being [13] for this novel disease with unknown sequelae.

The objectives of the present study were (1) to establish the validity, reliability and responsiveness of FIC as a measurement tool for physical dysfunction in SARS survivors; (2) to examine the correlation of FIC score in different constructs with physical and HRQOL measures and (3) to evaluate the functional profiles of patients recovered from SARS.

Our measurement goals and hypotheses were as follows. First, FIC could be used to evaluate the varying degree of physical dysfunction in SARS survivors, both cross-sectionally and longitudinally. Second, FIC had significant correlations with physical parameters: the higher the FIC score, the lower would be the physical function measurement. Third, FIC had significant correlations with HRQOL measures: the higher the FIC score, the lower would be the HRQOL measures. The correlation between the FIC score and the physical components of HRQOL should be stronger than that of mental components.

## Methods

### *Item generation*

We used five sources of information to develop the content of the FIC: (1) the literature of health outcomes in SARS (which was scarcely); (2) existing patient based measures of lung diseases (mainly for chronic lung diseases); (3) international pulmonary rehabilitation guidelines [14, 15]; (4) the expert opinions of key health professionals involved in SARS patient care (respiratory and rehabilitation physicians, respiratory and rehabilitation specialist nurses, physiotherapists, occupational therapists and expert in social science) about problems commonly reported by patients recovered from SARS and (5) interviews with 30 patients who had recovered from SARS.

On the basis of the information collected from the five sources, we developed a conceptual model to guide the development of the preliminary versions of the FIC. Initially, we envisioned the FIC

to contain two core content physical domains (9 items on symptom based impairment and disability) and one psychological domain (4 items). We had pre-tested preliminary versions of the FIC in May 2003 with 30 SARS convalescent patients to evaluate content validity, clarity and appropriateness of wording and questionnaire format. They found the questionnaire items representative of their problems and responded positively to the questionnaire items.

#### *Item reduction*

Clinicians and experts in the field of SARS management were asked to participate in the item reduction phase. The Hospital Authority of Hong Kong had convened a Working Group on Physical and Psychosocial rehabilitation that comprised respiratory physicians, rehabilitation physicians, physiotherapists, occupational therapists, clinical psychologists, social workers and community partners from all cluster territories in Hong Kong. Twenty-four experts in the Working Group convened a series of urgent meetings to review the transcripts, they analysed the qualitative information and decided on a set of standardized assessment tools. The team reduced the physical items to 8 and eliminated the psychological domain. The team determined that the psychological assessment would be better performed by the clinical psychologists using the Hospital Anxiety Depression Scale (HADS) [16] and the impact of event scale revised (IES-R) [17]. The FIC would serve as a symptom and disability checklist for the general or chest physicians and as a screening tool for physical rehabilitation specifically for SARS patients. Before the targeted launch of the FIC for clinical use in June 2003, Hospital Authority convened a meeting with 20 Respiratory Physicians to receive their comments.

The next step was to conduct focus group discussions with SARS patients to explore potentially relevant items and establish the content validity for the FIC. In June, WTSH conducted a series of four focus group discussions with 48 SARS patients. The disease severity of the patients interviewed varied from mild to severe, and included SARS patients who were in convalescence and those who had been discharged home. The results of the focus groups showed that the items on the FIC were

representative of the physical symptoms and the functional disability experienced by the SARS survivors.

The final version of the FIC consisted of eight items, each item was evaluated on four degrees of severity (0: nil, 1: mild, 2: moderate, 3: severe). The FIC could be administered through self-reporting or by interviewers (Appendix). The eight items assessed the functional limitations as a result of SARS. The first four questions focused on symptom-based impairment. This part examine the physical symptoms such as shortness of breath, general and muscle weakness, which was common in the early phase of recovery because the sequelae of SARS were diffuse and not limited to respiratory system. The latter four questions focused on disability, which was the limitation of activities as a result of physical or psychosocial effects of SARS. They examined the functional limitation in occupation, leisure and social activities and activities of daily living (basic and instrumental).

#### *Recruitment of patients and data collection*

Of the 467 SARS patients admitted to WTSH for convalescent stay, 459 of them were discharged alive between April and July 2003. We conducted an initial round of FIC survey by administering the questionnaire to a total of 265 patients through various means, including face-to-face interview and self-completion at the hospital and mail return from home [6]. All 459 discharged patients were invited to participate in the post-SARS rehabilitation programme at WTSH, but only 116 patients agreed to join the outcome assessment and rehabilitation programme.

During the clinic visit, clinical staff collected information on smoking status, pre-morbid state, pulmonary and general co-morbidities and respiratory profiles (SaO<sub>2</sub> at rest, respiratory rate and heart rate). Physical and HRQOL outcome measurements were performed at the same time. Irrespective of whether the patients had already responded to the FIC questionnaire in the initial survey round, they were uniformly interviewed by clinicians on the eight FIC items. Due to the availability of the other outcome measures, we determined to confine this study on validation of the FIC instrument to these 116 patients who

attended the post-SARS rehabilitation clinic at baseline, noting the likelihood of self-selection bias in this group.

Physical parameters measured include 6 minute walking test (6MWT) distance, and handgrip strength (HGS) of both dominant and non-dominant hands. The physiotherapists collected the 6MWT and HGS measurements. The SGRQ and SF-36 (HK) were self-administered but supervised by the interviewers.

Standardized protocols were followed in conducting the 6MWT [18]. Patients were required to walk with full speed during the 6 minute time frame with oximetry monitoring. The physiotherapists recorded the data of the 6MWT distance, SaO<sub>2</sub> and heart rate, the rate of perceived dyspnoea (RPD) and rate of perceived exertion (RPE) HGS (in kg) of hands was assessed by the Jamar hand dynamometer [19, 20].

The Chinese (Hong Kong) version of the SF-36 questionnaire is a generic measure that can be used in any particular age and disease group [21, 22]. SF-36 has been tested in many diseases, such as COAD and asthma and has been a reliable and certified instrument in differentiating the health benefits on different programmes [13]. The instrument consisted of 36 questions examining eight different domains of interests including physical function, role physical, bodily pain, general health, vitality, social function, and role emotional and mental health. In addition, physical component summary (PCS) and mental component summary (MCS) can be calculated [23].

SGRQ Chinese version is a 50-item respiratory specific questionnaire validated for chronic obstructive pulmonary diseases (COPD) and bronchiectasis patients [24, 25]. It measures HRQOL in three domains: symptoms (distress owing to respiratory symptoms), activity (the effects owing to impairment of mobility or physical activity) and impacts (the psychological impact of the disease). A summary score is also calculated. Each of the scores ranges from 0 (no reduction in HRQOL) to 100 (maximal reduction in HRQOL).

### *Statistical analyses*

Descriptive statistics (proportions, means and standard deviations) were compiled to describe the study population of 116 patients who joined the

rehabilitation programme at baseline. We also calculated the percentage of the study subjects achieving the highest (floor effect) and lowest (ceiling effect) possible FIC score. Chi-square tests were conducted to assess if there were any statistically significant differences in the age, sex and comorbidity profiles and the distribution of responses to each FIC item between this study group and the other group of 149 patients who only responded in the initial survey round but did not attend the clinic.

Principal component factor analysis was used to identify the number of latent factors underlying the correlations among sets of the FIC items, based on the minimum criterion of the eigenvalue of each individual factor  $> 1$ . The score of each scale being identified from the factor analysis was derived by weighting the raw scores of the items included in the scale with their respective factor loadings and then transforming the weighted product sum to a score ranging from 0 to 100.

The construct validity of the FIC scales was examined by the cross-sectional analysis on its correlations with physical parameters, SF-36 (HK) and SGRQ. The strength of correlation was assessed by Spearman rank correlation coefficients. *A priori*, we regarded a correlation coefficient  $> 0.6$  indicating a strong correlation,  $0.3 - < 0.6$  as moderate correlation and  $< 0.3$  as weak correlation [26, 27].

The discriminant validity of the FIC was examined by comparing the scale scores in study subgroups with different levels of SF-36 (PCS and MCS) and 6MWT performance. The test of significance between the sub-normal and relatively normal subgroups was performed by the two-sample *t*-test.

The reliability of the FIC scales was evaluated by means of item-internal consistency, testing the correlation between each item and its hypothesized scale with correction for overlap. We used a correlation coefficient of 0.40 [28] as the standard for supporting item-internal consistency. Item-discriminant validity is supported if the correlation between an item and its hypothesized scale is higher than its correlation with all other scales. Between-scale correlation was computed to determine whether each scale measured a distinct construct, which was supported when such correlation coefficient was less than its Cronbach's alpha coefficient [29].

**Table 1.** Demographic and baseline characteristics of SARS patients included in the study

		N	%
Sex	Female	65	56.0
	Male	51	44.0
Age	Mean 45.6 years		
	SD 15.1 years		
	Range 15–85 years		
Co-morbidity	Diabetes mellitus	10	8.6
	Tuberculosis	6	5.2
	Hypertension	5	4.3
	Ischaemic heart disease	3	2.6
	COPD	3	2.6
	Malignancy	2	1.7
	Asthma	2	1.7
	Preexisting lung fibrosis	2	1.7
	Cerebro-vascular disease	0	0.0
	Pre-morbid status	Independent	111
Independent with assistance or aids		4	3.4
Dependent with 1 assistant		1	0.9
Smoking status	Non-smoker	100	88.5
	Chronic smoker	5	4.4
	Social smoker	2	1.8
	Ex-smoker	6	5.3
<i>FIC items</i>			
Breathlessness at rest (Q1)	Nil	92	79.3
	Mild	20	17.2
	Moderate	4	3.4
	Severe	0	0.0
Breathlessness on exertion (Q2)	Nil	38	32.8
	Mild	47	40.5
	Moderate	26	22.4
	Severe	5	4.3
Generalized weakness (Q3)	Nil	45	38.8
	Mild	51	44.0
	Moderate	15	12.9
	Severe	5	4.3
Muscle weakness or wasting (Q4)	Nil	60	51.7
	Mild	40	34.5
	Moderate	12	10.3
	Severe	4	3.4
Limitations with previous occupational activities (Q5)	Nil	32	27.6
	Mild	50	43.1
	Moderate	22	19.0
	Severe	12	10.3
Limitation with social and leisure activities (Q6)	Nil	58	50.0
	Mild	27	23.3
	Moderate	19	16.4
	Severe	12	10.3
Limitation with basic activities of daily living (Q7)	Nil	87	75.0
	Mild	12	10.3
	Moderate	8	6.9
	Severe	9	7.8
Limitation with instrumental activities of daily living (Q8)	Nil	61	52.6
	Mild	29	25.0
	Moderate	16	13.8
	Severe	10	8.6

Test-retest reliability, measuring the ability of the FIC to produce consistent scores over a short period of time (i.e. within two weeks), was assessed by the intraclass correlation coefficient (ICC). According to a previous report [30], an ICC between 0.4 and 0.75 represents good reproducibility.

The responsiveness of the FIC was determined by examining the difference between baseline and 6-month results using the paired sample *t*-test. Effect size of the change was calculated and values of 0.2, 0.5, 0.8 were suggested to indicate small, medium and large effects, respectively [31].

The data analysis was carried out using Statistical Analysis System (SAS) Version 8.2 software. A two-sided *p*-value of less than 0.05 was considered to indicate statistical significance for all test statistics.

## Results

### Study population

The analysis included 116 patients (65 females and 51 males) who joined the SARS rehabilitation programme at baseline. The mean age of patients

was 45.6 (range 15–85) and mean time of assessment was 60 days (SD  $\pm$  23.9 days) from the disease onset. The demographic and baseline characteristics of SARS patients included in the study and their responses to individual FIC items were summarized in Table 1 and their other physical and HRQOL measures in Table 2. No statistical significant differences were found when comparing their age, sex and comorbidity profiles and responses to each of the eight FIC items against those of the other 149 patients who only responded to the FIC questionnaire but did not join the rehabilitation programme at baseline.

### Validity

Table 3 summarized the results output from the factor analysis with varimax rotation on two factors. The eigenvalue of the first factor was 4.22 which explained 53% of the total measured variance while the second factor's was 1.04 which explained 13% of the variance. The last four items associated with functional disability were loaded on the first factor with factor loadings of 0.65–0.92. The first four items representing symptoms formed the second factor, with factor loadings of 0.53–0.83. We decided to adopt a two-factor

**Table 2.** Clinical characteristics of SARS patients included in the study: SF-36 (HK), SGRQ and physical function parameters

	N	Mean	SD	Minimum	Maximum
Assessment from onset of disease (days)	116	60.59	23.94	13	102
<i>SF-36 domains</i>					
Physical function	112	61.61	27.11	0	100
Role physical	112	20.76	34.53	0	100
Bodily pain	112	62.42	26.52	10	100
General health	112	47.55	19.26	10	95
Vitality	112	50.67	20.51	0	95
Social function	110	55.23	29.44	0	100
Role emotion	112	37.50	40.30	0	100
Mental health	112	64.68	21.36	0	100
<i>SGRQ domains</i>					
SGRQ symptom	116	24.71	22.30	0	85.1
SGRQ activity	116	46.11	26.59	0	100.0
SGRQ impact	116	27.97	19.80	0	96.1
SGRQ total	116	33.34	19.25	0	90.8
<i>Physical function parameters</i>					
6MWT (m)	116	415.5	168.9	0	170.5
Dominant handgrip (kg)	113	21.27	10.44	2.5	12
Non-dominant handgrip (kg)	99	20.71	10.21	1.5	12

Abbreviations: SF-36 (Short Form 36 Hong Kong version), SGRQ (St. George's Respiratory Questionnaire), 6MWT (6 minute walking test).

**Table 3.** Factor analysis on FIC items

	Factor loading	
	Factor 1	Factor 2
Breathlessness at rest (Q1)	0.228	<b>0.529</b>
Breathlessness on exertion (Q2)	0.269	<b>0.821</b>
Generalized weakness (Q3)	0.121	<b>0.833</b>
Muscle weakness (Q4)	0.338	<b>0.653</b>
Limitations with previous occupational activities (Q5)	<b>0.654</b>	0.487
Limitation with social and leisure activities (Q6)	<b>0.730</b>	0.360
Limitation with basic activities of daily living (Q7)	<b>0.922</b>	0.094
Limitation with instrumental activities of daily living (Q8)	<b>0.805</b>	0.316
Eigenvalue	4.22	1.04
Cumulative proportion of total sample variance explained	53%	66%

model to represent the two constructs of functional limitations in SARS patients – symptom and disability.

The FIC scores for these two scales were derived by the transformation of weighted scores of the items hypothesized on each scale according to the factor loadings (Table 3). The mean FIC symptom score in the studied sample were 24.12 (SD ± 20.2) with an observed range of 0–88, as compared to the corresponding values for FIC disability score: mean 26.11; SD ± 27.32 and observed range 0–100. For FIC symptom score, the percentage of

data at ceiling (nil dysfunction) was 20.7% while no subject was at floor (maximal dysfunction). For FIC disability score, 17.2% of data was at ceiling whereas 5.2% at floor.

The construct validity of the FIC could also be reflected from the cross-sectional correlations with other measures in Table 4. The correlation between FIC disability scale score and the physical measure of 6MWT distance (–0.38), moderate in magnitude, was stronger than its respective correlations with both dominant and non-dominant HGS (–0.27 and –0.26). This set of correlation

**Table 4.** Correlations of FIC symptom and disability scores, with physical functional parameters, SF-36 (HK) and SGRQ scores

<i>Physical and functional parameters</i>	N	FIC symptom	FIC disability
6MWT distance	116	–0.263**	–0.383***
HGS dominant hand	113	–0.203*	–0.273**
HGS non-dominant hand	99	–0.194	–0.260**
<i>SF-36 (HK) domains</i>			
Physical function (PF)	112	–0.359***	–0.516***
Role physical (RP)	112	–0.397***	–0.347***
Bodily pain (BP)	112	–0.389***	–0.385***
General Health (GH)	112	–0.318***	–0.384***
Vitality (VT)	112	–0.402***	–0.337**
Social function (SF)	110	–0.441***	–0.590***
Role emotion (RE)	112	–0.225*	–0.189*
Mental health (MH)	112	–0.294**	–0.259**
Physical component Score (PCS)	110	–0.405***	–0.548***
Mental Component Score (MCS)	110	–0.297**	–0.228*
<i>SGRQ domains</i>			
SGRQ symptom	116	0.239**	0.191*
SGRQ activity	116	0.513***	0.521***
SGRQ impact	116	0.439***	0.428***
SGRQ total	116	0.516***	0.480***

\*  $p$ -value < 0.05, \*\* $p$ -value < 0.01, & \*\*\* $p$ -value < 0.001 (Based on Spearman rank correlation).

Abbreviations: SGRQ (St. George's respiratory questionnaire), 6MWT(6 minute walking test).

coefficients associated with FIC disability scale was consistently higher than the corresponding set associated with FIC symptom scale ( $-0.26$ ,  $-0.20$ ,  $-0.19$ ).

For both FIC symptom and disability scales, they correlated weakly with SF-36 mental health and emotion function ( $-0.19$  to  $-0.29$ ). The strength of correlations between FIC symptom scale score and the other six SF-36 domains were moderate ( $-0.32$  to  $-0.44$ ), being strongest with SF-36 social function ( $-0.44$ ). FIC disability scale score also correlated moderately with the other six SF-36 domains ( $-0.34$  to  $-0.59$ ), being strongest with social function ( $-0.59$ ) and physical function ( $-0.52$ ). Consistently, FIC symptom scale score had a stronger correlation with SF-36 PCS component ( $-0.41$ ) than MCS component ( $-0.30$ ); likewise for the corresponding correlations with FIC disability scale score ( $-0.55$  vs.  $-0.23$ ).

Both FIC scale scores showed a similar moderate degree of correlation with SGRQ activity (around  $0.52$ ) and SGRQ impact (around  $0.43$ ), but weakly with SGRQ symptom ( $0.24$  with FIC symptom and  $0.19$  with FIC disability).

Both FIC symptom and disability scale scores, reflecting degree of physical dysfunction, were significantly ( $p$ -value  $< 0.01$ ) higher in patients with significantly impaired quality of life in terms of PCS SF-36 HK  $< 40$  than those  $\geq 40$  (Table 5). But for the counterpart measure comparing MCS  $< 40$  with MCS  $\geq 40$  groups, such difference ( $p$ -value =  $0.02$ ) only existed in FIC symptom

score. Subjects with lower levels of HRQOL scored higher FIC scores on both constructs and than subjects with higher levels of HRQOL. Such discriminant validity of the FIC was also manifested from the significant difference in the two FIC scale scores between subjects with subnormal 6MWT performance and normal performance.

### Reliability

The item-internal consistency was above the standard of  $0.4$  for all individual items, which ranged  $0.43$ – $0.67$  for symptom-related items and  $0.58$ – $0.65$  for disability-related items (Table 6). The correlation of each of the eight items with its hypothesized scale was greater than its correlation with the other scale. This led to a scaling success rate of  $100\%$  (8 out of 8 pairwise comparisons). For both scales, their Cronbach's alpha coefficients ( $0.75$  for symptom and  $0.86$  for disability) were well above the minimum  $0.7$  level for reliability establishment. These two reliability coefficients were also higher than the correlation between the symptom and disability scale scores ( $0.55$ ).

Test-retest reliability was measured in a subgroup of 23 patients two weeks apart. There was no significant difference in the two scale scores between the two tests: FIC-symptom  $12.44 \pm 12.19$  (test  $\pm$  SD) vs.  $15.04 \pm 11.17$  (retest  $\pm$  SD),  $p$ -value =  $0.30$ ; FIC-disability  $9.67 \pm 9.38$  (test  $\pm$  SD) vs.  $10.45 \pm 10.44$  (retest  $\pm$  SD),  $p$ -value =  $0.69$ . The ICC were  $0.49$  for FIC symptom and  $0.57$

**Table 5.** Discriminant validity of FIC

		N	FIC symptom	FIC disability
PCS SF-36 (HK) <sup>a</sup>	< 40	80	27.17 $\pm$ 18.11	28.54 $\pm$ 26.28
	40 or above	30	12.44 $\pm$ 16.06	12.01 $\pm$ 15.74
	$p$ -value		$< 0.001^{***}$	$< 0.001^{***}$
MCS SF-36 (HK) <sup>a</sup>	< 40	37	29.63 $\pm$ 21.63	28.18 $\pm$ 24.99
	40 or above	73	19.87 $\pm$ 16.22	21.93 $\pm$ 24.80
	$p$ -value		$0.019^*$	$0.216$
6MWT <sup>b</sup>	Normal	30	18.91 $\pm$ 18.09	16.50 $\pm$ 14.95
	Sub-normal	86	25.93 $\pm$ 20.68	22.47 $\pm$ 29.82
	$p$ -value		$0.101$	$0.003^{**}$

\*  $p$ -value  $< 0.05$ , \*\*  $p$ -value  $< 0.01$ , & \*\*\* $p$ -value  $< 0.001$  (based on two-sample  $t$ -tests).

<sup>a</sup> The classification of SF-36 Hong Kong: SF-36 (HK) PCS below 40 represents value below 1 SD from the Hong Kong population norm.

<sup>b</sup> The normality of the 6MWT distance was defined according to the local references values from the Physiotherapy Coordinating Committee, Hospital Authority Hong Kong.



**Table 6.** Item-internal consistency and item-discriminant validity of FIC

<i>FIC symptom</i>	N	Item-internal consistency <sup>a</sup>	Item-discriminant validity	Cronbach's alpha coefficient	Correlation between FIC symptom and disability
Breathlessness at rest	116	0.431***	0.388***	0.746	0.549
Breathlessness on exertion	116	0.674***	0.484***		
Generalized weakness	116	0.569***	0.403***		
Muscle weakness or wasting	116	0.535***	0.430***		
<i>FIC disability</i>					
Limitations with previous occupational activities	116	0.596***	0.543***	0.861	0.549
Limitation with social and leisure activities	116	0.580***	0.433***		
Limitation with basic activities of daily living	116	0.646***	0.299*		
Limitation with instrumental activities of daily living	116	0.578***	0.497***		

\*  $p$ -value < 0.05, \*\*  $p$ -value < 0.01, & \*\*\*  $p$ -value < 0.001 (By Spearman rank correlation test).

<sup>a</sup> Correlation between items and FIC symptom and disability scores corrected for overlap.

for FIC disability, meeting the reproducibility criterion.

### *Responsiveness*

The responsiveness of FIC was examined by comparing the changes in the FIC and the other outcome measures at baseline and 6 months after rehabilitation ( $n = 81$ ). A significant reduction from the baseline value to 6 months' was noted in the FIC symptom score (mean  $\pm$  SD: 25.4  $\pm$  20.7 vs. 9.3  $\pm$  12.8,  $p$ -value < 0.001) and in the FIC disability score (mean  $\pm$  SD: 27.0  $\pm$  27.8 vs. 12.5  $\pm$  18.8,  $p$ -value < 0.0001). There was also significant improvement in the physical capacity at 6 months as measured by the 6MWT distance (467.7  $\pm$  110.9 m to 576.5  $\pm$  95.8,  $p$ -value < 0.001) and HGS (21.4  $\pm$  10.9 kg vs. 29.1  $\pm$  10.2,  $p$ -value < 0.001). In terms of the effect size of the difference between the two time points, FIC symptom score (0.78), FIC disability score (0.52) and HGS (0.71) were considered as medium in size, while the effect size of 6MWT distance was large (0.98).

We have also examined the responsiveness of the SF-36 and the SGRQ. Significant differences were found in SGRQ symptom 26.7  $\pm$  22.4 vs. 15.2  $\pm$  22.2  $p$ -value < 0.001; SGRQ activity 45.3  $\pm$  27.6 vs. 29.8  $\pm$  22.5,  $p$ -value < 0.001; SGRQ impact 28.8  $\pm$  20.7 vs. 22.6  $\pm$  19.8

$p$ -value = 0.003; SGRQ total 22.7  $\pm$  20.3 vs. 24.2  $\pm$  19.3,  $p$ -value < 0.003. The effect size for SGRQ domains was between 0.29 and 0.5. However, there was no significant difference in both SF-36 summary scores at baseline vs. 6 months (PCS 32.1  $\pm$  13.6 vs. 34.3  $\pm$  13.0,  $p$ -value = 0.14; MCS 44.4  $\pm$  11.8 vs. 43.3  $\pm$  11.4,  $p$ -value = 0.44). There was improvement in the physical function (63.2  $\pm$  28.4 vs. 69.9  $\pm$  23.3,  $p = 0.04$ ), physical role (18.7  $\pm$  33.9 vs. 32.7  $\pm$  40.5,  $p = 0.004$ ) and social function (53.5  $\pm$  29.2 vs. 65.5  $\pm$  28.0  $p = 0.001$ ) with effect sizes 0.24 for physical function and 0.41 for the latter two domains. However, deterioration was noted in the body pain (61.1  $\pm$  26.9 vs. 53.2  $\pm$  26.1,  $p = 0.021$ ) and general health (46.4  $\pm$  19.7 vs. 40.4  $\pm$  23.6,  $p = 0.16$ ). There was no significant difference in other SF-36 domains.

### **Discussion**

SARS contributed to significant mortality and morbidity in Hong Kong. The sequelae and the HRQOL status of SARS survivors were of interest and importance given the impact of the novel disease was largely unknown. The purpose of developing an effective standardized assessment was to help us make comprehensive assessment, identify the needs of rehabilitation and evaluate

the long term consequences of the diseases for the SARS survivors.

This study showed that the FIC was an internally consistent and reliable tool for the assessment of physical symptoms and disability in patients recovered from SARS. The FIC showed a high degree of construct validity. The FIC scores correlated well with the physical function measurement, SF-36 (HK) and SGRQ. There was good discriminant ability and the FIC was able to differentiate patients with different levels of quality of life and physical performance. The FIC scores were significantly higher in patients with impaired SF-36 (HK) and 6MWT measurement, suggesting the internal validity of the FIC. The test and retest reliability also demonstrated the reliability in the paired tests. In addition, there was a significant reduction in FIC scores at 6 months after rehabilitation as compared with baseline, and similar improvement was observed in other physical function parameters despite a slight difference in the relative magnitude. This suggested that FIC could be used as an evaluative tool to assess the functional profile of SARS patients longitudinally.

The cross-sectional construct validity of FIC was supported by its correlations with physical function and HRQOL measures. FIC-symptom and disability scales correlated negatively with the physical measures, with a stronger correlation with 6MWT distance ( $-0.26$  and  $-0.38$ ) than the HGS measurement ( $-0.20$  and  $-0.27$ ). The correlations between FIC scales and SF-36 domains were mostly moderate. The moderate correlation of FIC with SF-36 PCS and MCS suggested that the physical dysfunction after SARS contributed significantly to an impaired quality of life. As the FIC focused more on the physical aspects, its correlation with PCS was higher than that of MCS. In addition to the physical factors contributing to subnormal MCS, emotional or mental factors such as a relative lack of satisfaction towards the available social support, financial difficulties, relationship, family problems, personal perception and coping skills relative to the diseases might explain the outcome [32].

In SARS cases, a tri-phasic course of disease was proposed and corticosteroids, antiviral agents and immune modulation therapies had been used in Hong Kong [33]. SARS was primarily an

infectious disease with major insults on the lungs but systemic damage of different organs was noted from pathological reports [34, 35]. Although there were studies on the short-term outcome and risk factors for adverse clinical outcomes, there was limited knowledge about the functional consequences of SARS [36, 37]. Clinical follow-up of people recovered from SARS demonstrated radiological, functional and psychological abnormalities of varying degrees in the recovery period [5]. Lung function abnormalities were common, with the defect mainly restrictive with or without impairment of DLCO [38]. However, a Singapore study had described the pulmonary function impairment observed 3 months after discharge was mostly mild, which could not explain the reduced exercise capacity [39]. Non-ventilatory limitation during exercise was noted in the majority of our rehabilitation group and very few subjects had desaturation during the 6MWT. The muscle weakness and myopathy, cardiopulmonary deconditioning, cognitive impairment, psychosocial disturbance [32] and the side effects of medications (e.g. corticosteroids) might contribute to the overall dysfunction and perceived HRQOL. A study suggested that morbidity following SARS may be viewed as a sum of physical disability, cognitive and/or psychological impairment [39].

FIC was developed to provide a standardized assessment tool to evaluate the long-term consequences pursuant to the recommendations of the SARS Expert Committee that composed of 11 international experts reviewing the clinical management of the SARS in Hong Kong [3]. The evaluation of SARS patients should be comprehensive with FIC a disease specific questionnaire focusing on the physical aspects together with the information obtained from other measurements.

The FIC correlated moderately with the SGRQ scales, except weakly with the SGRQ-symptom. The weak correlation between FIC and SGRQ-symptom scores suggested that the physical problems after SARS were quite different from the chronic lung diseases. Moreover, SGRQ and other respiratory specific tools are mostly applied in the population of chronic lung diseases with features of airflow limitations. Clinicians experienced in SARS management commented some of the

questions were not applicable in the SARS population. For example, the questions on sputum production and wheezing episodes are irrelevant in the SARS population. It would be difficult to decide on the rehabilitation referral and assess the rehabilitation outcome based solely on the SGRQ results. The value of SGRQ as a disease specific tool in the SARS population has not been established.

The results of paired *t*-test demonstrated that FIC was more responsive to change than SF-36 and the change was consistent with that of 6MWT performance. Both the FIC and physical measurement showed improvement at the 6 months assessment but the SF-36 showed improvement only in physical function, role physical and social function domains and with smaller effect sizes. There was no significant change of the SF-36 PCS and MCS between baseline and 6 months. One possible explanation for the observation was that SARS might contribute to a sustained effect on health status. The recovery period can be prolonged even in patients with normal lung function results. Complications such as post-traumatic disorders [32, 40], avascular necrosis of bones might have a detrimental effect on the health status. The use of generic measure may detect some aspects of QOL that would not be detected by a disease-specific score and provide a more global individual assessment.

FIC had a distinct role in clinical decision making. FIC was a valid and appropriate disease-specific assessment tool for the evaluation of symptom and disability in the post-SARS follow up. A zero FIC scale score represents no limitation in functional activities while a FIC scale score above zero represents functional disability of varying degree may be present in patients who recovered from SARS. Abnormal FIC scale scores suggest possible dysfunction and are strong indication that further evaluation and more detailed assessment should follow to provide early intervention, if necessary. We advocate the use of both generic and disease specific tools in the rehabilitation assessment, as recommended by major rehabilitation guidelines [10, 14, 15]. The HRQOL measure would be complimentary to each other in providing detailed clinical information at different levels and was supported by the moderate correlation among the FIC, SF-36 and SGRQ.

Although FIC had proven to be an effective assessment tools for post-SARS health assessment, the objective environment surrounding its development created several limitations. The development of FIC was to an extent limited by the practical and pragmatic considerations during the SARS epidemic. The urgent need of symptom and disability evaluation and rehabilitation provision for recovered SARS patients affected the extent of detailedness and comprehensiveness we could afford in item generation, reduction and design of the FIC. The FIC had been used by clinicians in the Post-SARS Clinics as a clinical checklist and for rehabilitation referral before a thorough evaluation on the instrument could be performed. Given the timing constraint, we were inhibited from planning any recruitment of control group(s) in the study. Moreover, in order to demonstrate its validity, one would prefer to test it against a larger sample size. However, resource implications and the crisis within the healthcare system cause by this novel corona virus presented tremendous limitations in conducting physical function and HRQOL tests in more centers.

Although one may question the findings of this validation study because of the likely self-selection bias by covering only those 116 patients willing to attend the post SARS rehabilitation programme, there was no statistically significant differences when comparing the participants' demographic profiles and FIC responses pattern with the other 149 patients who did not attend the programme. The validity of FIC had been assured as it requires the complement of the well validated SF-12 [41] or SF-36 for comprehensive assessment in the SARS follow up. One may also criticize FIC as imbalanced as it solely focuses on the physical function construct and omits the psychological status. We removed the psychological items from the original FIC design because there exist separate psychological assessment such as HADS, Impact of Event Scale (ILS-R) that would be used by clinical psychologists [16, 17, 32] in the SARS rehabilitation programme.

To further examine the validity of FIC in the assessment of physical symptoms and disability of SARS or in other diseases, the best practice would suggest that we establish control arms to compare the FIC profiles of SARS patients with the healthy population, as well as subjects who recovered from

acute infective diseases of the lungs or who have chronic lung diseases. The physical function and quality of life measures are to be collected concurrently with the FIC measurement in different disease groups.

## Conclusions

HRQOL instruments applied in SARS rehabilitation program were being examined in this study. We developed the FIC to meet the clinical need of evaluating symptoms and disability in a cohort of SARS survivors. The study results indicate the FIC is reliable, valid and responsive to change in symptom and disability as a consequence of SARS, suggesting it may provide a means of assessing HRQOL outcomes in a longitudinal follow up.

## Acknowledgements

We thank staff of TWGHs Wong Tai Sin Hospital and Kwong Wah Hospital for their participation and assistance in the SARS rehabilitation programme, Dr Wilson Yee, Mr Lawrence Fung, Dr Vivian Wong, Dr Jane Chan, Dr Daisy Dai and the SARS Rehabilitation working group, Hospital Authority Hong Kong for their support and the staff of Statistics and Research Unit of Hospital Authority Head Office for their statistical assistance.

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**Appendix: Functional Impairment Checklist****Functional Impairment Checklist**

**Hospital Authority  
Questionnaire of the physical  
functions of SARS patients**

**Gum Label**

Date of Assessment : \_\_\_\_\_ Time from disease onset (days): \_\_\_\_\_

Hereunder are statements describing different symptoms, feelings and situations. Please read the following and circle the answer best describing your current condition.

(0=not at all · 3=intensely)

	Nil	Mild	Moderate	Severe
1. Breathlessness at rest.	0	1	2	3
2. Breathlessness on exertion.	0	1	2	3
3. Generalized weakness.	0	1	2	3
4. Muscle weakness or wasting.	0	1	2	3
5. Limitations with previous occupational activities.	0	1	2	3
6. Limitations with social/ leisure activities <i>e.g. chatting with friends, gatherings, going to parks or movies</i>	0	1	2	3
7. Limitations with basic activities of daily living <i>e.g. toileting, shower/ bathing, dressing</i>	0	1	2	3
8. Limitations with instrumental activities of daily living <i>e.g. house cleaning, cooking or laundry</i>	0	1	2	3

## Functional Impairment Checklist

**Hospital Authority**  
嚴重急性呼吸系統綜合症病人功能問卷

*Gum Label*

評估日期：\_\_\_\_\_ 病發距離現在(多少天): \_\_\_\_\_

以下是一些用來形容不同病狀,感受和情況的句子。

請閱讀下列各項，並圈出最適合你情況的答案，以形容你現時<sup>□</sup>的狀況。

(0=完全沒有感到，3=極之感到)

	完全沒有	略為	頗為	極度
1. 我休息時有出現氣喘。	0	1	2	3
2. 我發力時有出現氣喘。	0	1	2	3
3. 我有感到全身乏力。	0	1	2	3
4. 我有肌肉無力或萎縮。	0	1	2	3
5. 我的工作能力受到影響。	0	1	2	3
6. 我的社交 / 休閒活動受到影響。 <i>如：和朋友交談、聚會、行公園、睇戲</i>	0	1	2	3
7. 我的日常自我照顧能力受到影響。 <i>如：如廁、洗澡、穿衣</i>	0	1	2	3
8. 我的家居生活操作能力受到影響。 <i>如：家居清潔、煮食、洗衣</i>	0	1	2	3