Development and effectiveness validation of the ICF-COVID combination scale

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ABSTRACT

Objective: To develop an ICF-COVID scale and evaluate its reliability and validity. By establishing such a scale, we hope to provide clinical advices for the rehabilitation of suspected patients with new covavirus pneumonia.

Design: Firstly, literature review and expert group-discussion were applied to determine the initial items of the ICF-COVID scale. Secondly, the ICF-COVID scale was applied in 155 suspected patients with new coronary pneumonia by online survey. Finally, the reliability and validity of the scale were evaluated.

Setting: A face-to-face offline research but in an electronic survey manner.

Perticipants: 155 suspected patients with new coronary pneumonia from ten hospitals.

Interventions: Not applicable.

Main Outcome Measures: Cronbach α coefficient, Spearman-Brown half-reliability coefficient, KMO value, S-CVI value and I-CVI value.

Results: The ICF-COVID scale contains five items. The Cronbach α coefficient of the scale was 0.861. Spearman-Brown half-reliability coefficient was 0.814. KMO value was 0.854. S-CVI value was 0.813, and I-CVI value was between 0.846 and 1.000.

Conclusion: The ICF-COVID scale had a good reliability and validity. It can evaluate the health and function status of patients with new coronary pneumonia.

Key words: new coronary pneumonia; ICF; ICF generic set; functional evaluation; reliability; validity

Abbreviations: International Classification of Functioning, Disability and Health (ICF); International Classification of Functioning, Disability and Health for patients with new coronary pneumonia (ICF-COVID).

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INTRODUCTION

The new corona virus pneumonia (referred to new coronary pneumonia) was officially named corona virus disease 2019 (COVID-19) [1] by the World Health Organization. Nowadays, COVID-19 has become a universal epidemic outbreak all over the world. The most common symptoms of COVID-19 are fever, cough and dyspepsia, myalgia, fatigue, anorexia, diarrhea, etc.[2, 3]. The severity of the disease varies a lot. Most patients show mild symptoms. However, nearly 20% of the patients progress to a more serious disease. The elderly or those with underlying diseases are more likely to suffer from severe disease[4]. About 33% of patients are accompanied by acute respiratory distress syndrome (ARDS), acute respiratory tract injury, septic shock and other complications [2, 3]. Previous studies have shown that such diseases are also likely to cause lung function, physical and mental damage, leading

to a decline in quality of life in terms of physical function, physical pain, overall health and vitality [5]. According to the Chinese Official Document Diagnosis and Treatment Program of COVID-19 [6], the criteria the standard of release and discharge of patients is only to show that the patient's signs of infection are eliminated but not equal to functional recovery. Moreover, Chinese authors highlighted that the COVID-19 epidemic has underscored potential gaps in mental health services during emergencies [7], which noted an increase of psychological problems during this epidemic, including anxiety, depression, and stress [8]. Not surprisingly, the UK media are already reporting a substantial psychological impact of both the outbreak and the response. Residents have been comparing the situation to "the end of the world" and "Epidemic Panic" is a common psychological problem [9]. Facing the serious situation, patients and frontline healthcare workers are vulnerable to the emotional impact of COVID-19 [10]. Therefore, helping the patients with COVID-19 to recover their physical and mental function, quality of life and rebuild social participation in a comprehensive way is an urgent problem. In order to do well in the rehabilitation work of patients with COVID-19, the Chinese Association of Rehabilitation Medicine issued the "Comprehensive Guidance on the Prevention and Control of Rehabilitation Hospitals during the COVID-19 Outbreak (First Edition)". It is recommended that appropriate rehabilitation treatment techniques should be standardized under the premise of safety prevention and control to meet the rehabilitation needs of patients as far as possible. However, there is currently no effective assessment tool to evaluate the physical, psychological and social functions of isolated patients due to the impact of the epidemic. ICF (International Classification of Functioning, Disability and Health, ICF) is a functional classification system promulgated by the World Health Organization. Its core theory is to describe the three dimensions of dysfunction using a bio-psycho-social model: tissue and organ dimensions (body structure and function), individual dimension (activity), and social dimension (participation). This system provides a comprehensive assessment of patient health and function at an overall level [11]. It is expected to provide a theoretical basis for developing the evaluation tools for the functional status and rehabilitation needs of patients with COVID-19.

Therefore, developing a scale to evaluate the functional status and psychological health is emergent and necessary. The aim of this research is to develop an ICF-COVID scale based on the ICF framework and validate its reliability and validity. By developing this scale, we hope to make a comprehensive functional assessment of patients with COVID-19 at an overall level and provide guidance for the development of rehabilitation programs for patients with COVID-19.

METHODS

The schematic research diagram of this study is showed in figure 1.

Participants

By convenience sampling method, 155 suspected patients with COVID-19 were selected from the isolation ward of ten designated hospitals. The participating hospitals contain Shenzhen Hospital, Southern Medical University, The Third People's Hospital of Shenzhen, The Second
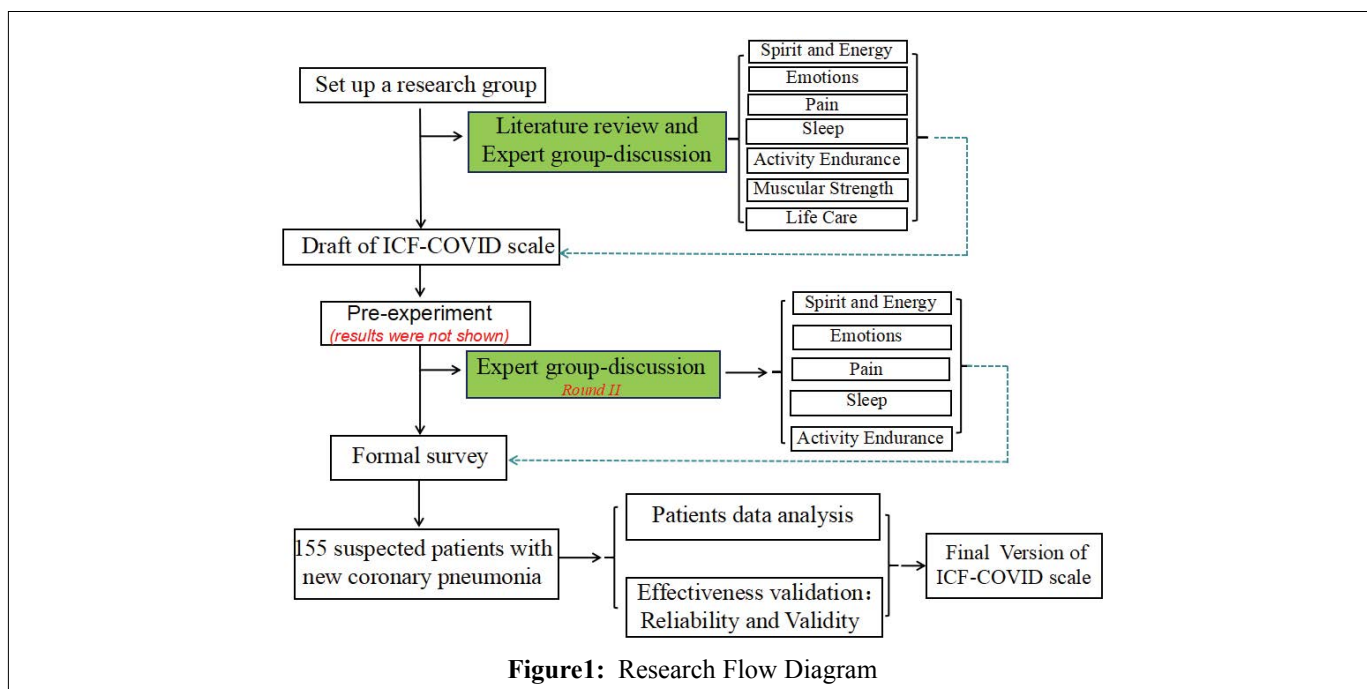

Figure1: Research Flow Diagram

People's Hospital of Shenzhen, Longgang Central Hospital of Shenzhen, Fuyong People's Hospital of Shenzhen, Longzhu Hospital of Shenzhen, Xinhua Hospital of Hubei Province, and Huangshi Traditional Chinese Medicine Hospital of Hubei Province. Tongji Hospital, Tongji Medical College, Huazhong University of Science & Technology (Main-Hospital district and Sino-French Eco-City district). The research time start from February 2020 to May 2020. Inclusion criteria: ① those aged 18 to 80 years old; ② those with normal ability of listening, reading, writing, and speaking mandarin; ③ those who are willing to participate in this study and can give active cooperation. Exclusion criteria: ① those with mental illness or cognitive impairment; ② those with severe complications.

Before conducting the questionnaire, research stuffs were trained uniformly. Stuffs must be familiar with the precautions during the testing process, make sure that patients are not interrupted and forbade giving any suggestive or obstructive behavior. All patients in this research signed an informed consent form, and patients have the right to drop out of the research at any moment.

Initial items formation

An in-depth literature retrieval and review was conducted on the theme of "ICF Generic Set" and "ICF Rehabilitation Set". Databases such as PubMed, Web of Science, ScienceDirect, SpringerLink, Wiley Online Library and Google Scholar were conducted. The retrieval time of literature starts from the time of database establishment. As a result, the measuring tools related to the ICF Generic Set and ICF Rehabilitation Set were retrieved detailedly [12-17]. We selected and marked the items which highlight the characteristics of the ICF Generic Set and offer guidance on building the ICF-COVID item pool. Based on the selected items, the draft was designed for the ICF-COVID Generic Set Scale. Finally, five items including Spirit and energy, Emotion, Algesia, Sleep, and Activity Endurance were entered into the scale. We used the Numeric Rating Scale (NRS) to assess the degree of item damage based on the ICF-COVID scale. The digital score changes from 0 to 10, where 0 represents no problem and 10 represents complete disorder. This numeric rating method has been demonstrated useful for the assessment of functioning in routine clinical practice and across a variety of hospital departments and health conditions in our former research [18]. The contents of ICF-COVID Scale are shown in Table 1.

Data collection

In order to ensure the health safety of researchers and reduce the COVID-19 cross-infection caused by the contact of paper documents, our study used the online QR Code to distribute the questionnaire. The precautions during the test are clearly informed and ensure that the patient understands the purpose and interests of the study. The researcher is obliged to answer the questions or items when patients have some questions.

Table 1: Category description of ICF-COVID Scale

code	Category	Concise, intuitive, and precise description
b130	Spirit and energy	Physical and subjective initiative to achieve general goals and meet special needs
		Leading question: Have you been energetic in the past week?
		Key scoring points: energy, complexion, appetite, degree of doing things.
b152	emotions	The ability to generate appropriate emotions and manage various emotions
		Leading question: How about your emotion since you came to the hospital?
		Key scoring points: emotions, self-control.
b134	sleep	Can sleep selectively and maintain appropriate time and quality to meet daily needs.
		Leading question: How about your sleep since you came to the hospital?
		Key scoring points: Sleep quality includes sleep time, ability to fall asleep again after waking up, energy state after waking up, fatigue state and whether to use medication.
b280	pain	Feeling uncomfortable somewhere in the body due to potential or actual damage
		Leading question: Did you have any discomfort or pain since you came to the hospital?
		Key scoring points: pain, drugs.
b455	Activity endurance	With the ability to continue to exercise for a certain amount of time and intensity
		Leading question: How tired were you after daily activities in the last week?
		Key scoring points: Ability to complete daily activities (fully normal, lightly laborious, relatively laborious, very laborious, completely unable to do daily activities); fatigue state (no fatigue, slight fatigue, obvious fatigue, very fatigue, complete fatigue); heart rate after moderate exercise (according to 3min stairs climbing test classification, 6min walking experiment classification).

Statistical analysis

SPSS17.0 software was used for data statistical analysis. The Cronbach α coefficient, Split-half Reliability, Structural Validity, and Content Validity were used to evaluate the reliability and validity of the ICF-COVID scale.

Item analysis

According to the data collected by the Questionnaire Star Platform, the contents of the questionnaires are numbered in chronological order, input data, and statistically analyzed. Item analysis is used to measure the validity and suitability of questionnaire scale items. The principle is to sum the analysis items first, and then divide them into high and low score groups (bounded by 27% and 73% quantile). T test is used to compare the difference between high and low score groups. If there is a difference, it indicates that the scale item is properly designed. Otherwise, it means that the scale item cannot distinguish the information, and the design is unreasonable and should be deleted.

RELIABILITY AND VALIDITY VALIDATION

Reliability evaluation

The Cronbach's α coefficient and the Split-half Reliability was used to evaluate the Scale internal consistency reliability.

Validity evaluation

Content validity and exploratory factor analysis were used for validity testing.

(1) Item-level content validity index (I-CVI) is the ratio of the total number of 4 or 5 scores given by participating experts to the total number of all scores. Scale-level content validity index (S-CVI) is the percentage of items that are rated as 4 to 5 by all experts among all items.

(2) The exploratory factor analysis method is used to determine whether the questionnaire is suitable for factor analysis by Kaiser-Meyer-Olkin (KMO) statistics and the Bartlett Spherical Test. During the factor analysis, the "feature root > l" is taken as the extraction criteria of the common factor, and the factor load of each common factor is obtained by mutating the maximum orthogonal rotation, and the item of the factor load > 0.4 is extracted into the common factor.

RESULTS

Formation of the preliminary scale

After three rounds of expert group discussions, our research team removed d230 (performing daily tasks), d450 (walking) and d850 (paid employment) on the basis of the ICF Generic Set [8, 9]. Two categories of b134 (sleep) and b455 (activity endurance function) were added in the ICF Rehabilitation Set[14, 15].

Questionnaire results

A total of 155 questionnaires were distributed using the Questionnaire Star Platform, and 155 valid questionnaires were received, with an effective recovery rate of 100%.

The results showed that there were 83 male patients (53.55%) and 72 female patients (46.45%). The age of the patients ranged from 19 to 78 (47.85 ± 18.068) years old (Table 2).

Table 2: General information of the research object (n = 73)

Item	Category	Sample (N)	Percentage (%)
Gender	Male	83	53.55
	Female	72	46.45
Age	18~35	45	29.68
	36~60	62	40.00
	>61	47	30.32
Hometown	Hubei province	67	43.23
	other Provinces	88	56.77
Days of hospitalization	0~3	38	24.52
	4~10	43	27.74
	11~20	34	21.94
	>21	40	25.80
Underlying disease (multiple choice)	None	98	63.23
	Hypertension	36	23.23
	Diabetes	20	12.90
	Tumor	3	1.94
	Chronic respiratory diseases	5	3.23
	Others (chronic pharyngitis, gastritis, etc.)	26	16.77
Hospital	Shenzhen Hospital, Southern Medical University	38	24.52
	Xinhua Hospital of Hubei Province	20	12.9
	The Third People's Hospital of Shenzhen	36	23.23
	Tongji Hospital of Wuhan (2 districts)	31	20.00
	Other Hospitals	30	19.35

Item analysis of ICF-COVID Scale

The item analysis used the extreme group method to test the discrimination degree of the items: (1) According to the total score of the scale, the first 27% and the last 27% of the subjects were divided into high score group and low score group respectively; (2) The critical ratio or decision value of each item was obtained by independent sample T-test (critical ratio, CR); (3) The t values of other items in the scale were ranged from -20.062 to -9.806, and all other items reached statistically significant ($P < 0.001$). The item analysis results of the ICF-COVID scale are shown in Table 3.

Reliability analysis

The reliability of the ICF-COVID scale was validated with Cronbach's α coefficient and Split-half reliability. The total Cronbach's α coefficient of the ICF-COVID scale is 0.861, the Split-half reliability Spearman-Brown coefficient is 0.814, and the Cronbach's α coefficient and the Split-half reliability Spearman-Brown coefficient are both exceed 0.8, indicating that the scale has a high degree of internal consistency and has high stability and reliability of results [19].

Validity Analysis

(1) Content validity

The scale was evaluated by 5 experts with advanced medical titles and professor titles of higher education. The results showed that the S-CVI value was 0.813, the I-CVI value was between 0.846 and 1.000. According to the previous information, S-CVI > 0.80 and I-CVI > 0.78 suggested that the content validity is effective and reliable[20, 21].

(2) Exploratory factor analysis

The results showed that the KMO value was 0.854 and the test value of the Bartlett spherical test was 344.164 (df = 10, P < 0.001), which indicates that it is suitable for factor analysis. By using the principal component analysis, one common factor with an eigenvalue above 1 was extracted and the cumulative contribution rate was 64.502%. The load factor of each item is shown in Table 4. The final questionnaire factor scree plot is shown in Figure 2.

DISCUSSIONS

In this study, with the aim of dealing better with the urgent psychological problems of people involved in the COVID-19 epidemic, we developed a ICF-COVID scale for the functional assessment of patients with COVID-19 based on literature review and expert consensus, and provided a theoretical framework for patients' rehabilitation intervention and follow-up. By utilizing this scale, we can know the exact functional status of COVID-19 patients and give proofs for doctors to make a comprehensive intervention therapy plan.
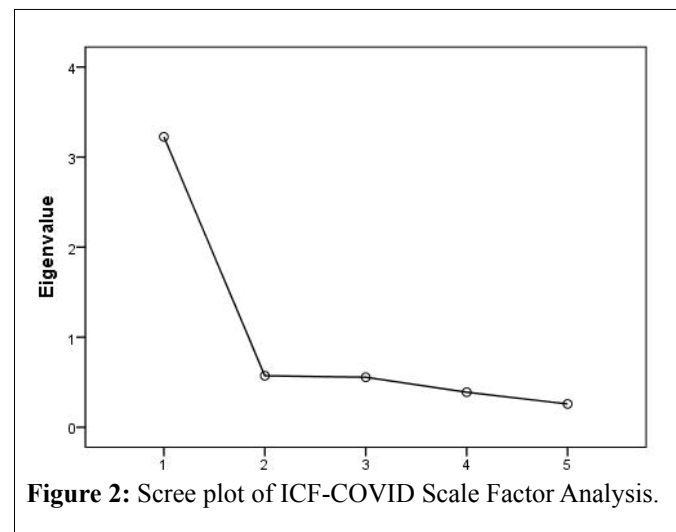

Figure 2: Scree plot of ICF-COVID Scale Factor Analysis.

ICF provides a theoretical framework for describing and evaluating health at the individual and social levels, describing individual health status in terms of physical function, physical structure, activity and participation. Meanwhile, the scale takes into consideration the health effects of background factors such as the environmental factors, personal factors and other background factors on health, and can be used as a guiding framework for prognosis assessment and intervention [22], which is the most important clinical outcome index in addition to morbidity and mortality. The ICF core scale can be used for functional evaluation in a specific period, and it has been widely used in the world, especially in clinical evaluation, quality control, medical insurance payment standards, and economic benefit analysis.

Item analysis

The selection of scale items should follow the principles of great importance, high sensitivity, strong independence, good representative and certainty, as well as good maneuverability and acceptability [19]. The difficulty coefficient method and critical ratio method are used to analyze the scale items. In this study, the t-test method was used to select items from the perspective of discriminating ability, and to examine the individual ability of distinguishing items between high and low score groups. In this study, the p values of both high and low score groups is below 0.05, indicating that the 5 items in the ICF-COVID scale are well distinguishable and there is no need to delete the analysis items.

VALIDATION OF RELIABILITY AND VALIDITY

Till now, several ICF core scale have emerged, such as the ICF core scale for stroke, the ICF test table in spinal cord injury and elderly patients with chronic psychological failure, and the ICF breast cancer core scale, etc., which all have certain reliability and clinical practical value [16].

For any evaluation tool to be recognized, it must pass the reliability and validity test. This study evaluates the reliability, structural validity and content validity of the ICF-COVID scale through internal consistency and split-half reliability.

Reliability mainly expresses the constancy, consistency, reproducibility and stability of the test results, that is, whether the test results reflect the real characteristics of the stability and consistency of patients true. The Cronbach α coefficient is a method commonly used to test internal consistency in recent years. Generally, a coefficient above 0.7 means that the internal consistency of the scale is good, and the Spearman-Brown split-half reliability coefficient above 0.7 can indicate the measurement achieves sufficient reliability [19, 23]. In this study, the Cronbach α coefficient is 0.861 and the Spearman-Brown Split-half reliability coefficient is 0.814, which fully indicates that the ICF-COVID scale has a high quality level of reliability and good stability and consistency.

Validity refers to the consistency of the test score and the characteristics you want to measure. In other words, whether the test score can really reflect the characteristics it wants to measure is mainly to check the correctness or reliability of the research results. The factor analysis is used to test the structure validity, and comprehensive analysis is carried out through indicators such as KMO value, commonness, and factor load coefficient value. As a scholar, Kaiser designates that the measure of KMO above 0.9 is marvelous for factor analysis; while KMO below 0.5 is not credible and suitable for factor analysis. S-CVI above 0.78 proves that the item has good content validity [24]. In this study, the exploratory factor analysis KMO value is 0.854, the total S-CVI value is 0.813, and the I-CVI value is between 0.846 and 1.000, indicating the ICF-COVID set has good representativeness, reasonable design structure and good content validity.

FEASIBILITY VALIDATION

The feasibility of the scale refers to the difficulty of the scale in the implementation process, which is generally determined by the actual time and efficiency of the scale [25]. The completion time of the scale generally ranges from 5 to 20 minutes. The results of this study show that the completion rate of the ICF-COVID set is 100%, and the average completion time is 5.27 ± 6.55 minutes, much lower than that reported in the literature [26]. Therefore, it is indicated that the questionnaire is easy to understand, highly operable, and can be used as an evaluation tool for the function of isolated patients with COVID-19.

STUDY LIMITATION

At this stage, only preliminary investigations are conducted on suspected isolated patients. The sample size in our research is still too small. However, aiming to evaluate the functional status and psychological health of COVID-19 patient in this universal epidemic period, this scale should be utilized by more scientists as soon as quickly and the next step is to expand the scope of questionnaires and increase the sample size. Secondly, this study is only a cross-sectional study on a certain period. However, a longitudinal score comparison at different time points will be more meaningful. The last but not the least, the ICF-COVID scale does not include intervention content and clinical application evaluation. Therefore, the next step should be to develop a targeted nursing intervention and rehabilitation plan based on the ICF-COVID scale results, so as to build rehabilitation treatment and nursing based on the COVID-19 Model and thus to improve the quality of life and compliance of patients.

CONCLUSION

It is noteworthy that the ICF-COVID scale has good reliability, validity, feasibility and clinical guidance, and can be used as an evaluation tool for the functional status and psychological health of the isolated patients with COVID-19. In the future research, optimizing the constituent elements and a bigger sample test is needed to evaluate and validate the effectiveness of ICF-COVID scale.

AUTHOR DECLARATION

We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. We confirm that we have followed the regulations of our institutions concerning intellectual property.

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