Development and Validation of the Quality of Life Instrument for Chinese

ZHAO Li

A thesis submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy

Principal Supervisor: Professor Kelvin K.C. CHAN

Hong Kong Baptist University

March 2005
ABSTRACT

Background: Researchers are finding limitations of currently available health-related quality of life instrument tools for outcome studies in Chinese medicine and integrative medicine. Chinese medicine relies very much on asking subjective feelings of patients in the process of diagnosis and monitoring of treatment. For thousands of years, Chinese medicine practitioners have accumulated a good wealth of experiences in asking questions about health of their patients based on the health concept in Chinese medicine. In the present study, these experiences were then transformed into questions for a new health-related quality of life instrument. It is believed that the instrument can contribute to the existing Patient Report Outcome measures.

Research Aims: The purpose of this research is to develop and validate the Chinese Quality of Life Instrument (ChQOL), a new self-reported health-related quality of life instrument, based on a well established theory on health in Chinese medicine.

Methods: This research was carried out two according to major aspects:

The first part is to develop and validate the ChQOL (Putonghua version). The development of the ChQOL was based on the health concept in Chinese medicine with a theory driven approach. The first task was to explore the health concept in Chinese medicine and build the conceptual framework of the ChQOL. An expert panel was then invited to comment and give suggestions for improvement of the initial framework. According to their suggestions, the framework was refined and a set of initial items for the ChQOL. The refined framework, together with the key domains, facets and initial items of the ChQOL were then mailed to a sample of about 100 Chinese medicine practitioners throughout Mainland China for their comments and advice. A revised set of items were developed for linguistic testing, by using a convenient sample consisting of both healthy people and patients with chronic illness who attended Chinese medicine treatment. After that, an item pool was developed for field-testing. Field test was conducted in both north and south China on a convenient sample of healthy and patient subjects to determine the construct validity and psychometric properties of the ChQOL including reliability, validity and responsiveness.

The second part is to develop and validate the ChQOL (Hong Kong Cantonese version, ChQOL-HK). This is an extended part of the ChQOL studies following the successful development of the Putonghua version. A standard translation procedure was followed. Field test was carried out on a convenient sample of healthy subjects and patients with chronic illness to determine the psychometric properties of the ChQOL-HK in local Chinese medicine clinics of the university with the help of a final year student.

Results: Construct validity was established by using various methods, i.e. the internal consistency in all facets and domains were good; the correlation between facets to domain, and domains to overall ChQOL correlation were high; confirmation factor analysis showed that the structure fitness of all facet, domain and overall structure were
Chinese Medicine clinics for the ChQOL-HK.

I also want to express my gratefulness to Ms. Wong Codi (Queen Elizabeth Hospital) and Ms Lang Jian-ying (Guangzhou University of Traditional Chinese Medicine) for their tremendous help on some of the statistical analysis.

I would also like to express my thanks to all the staff at the Research and Development Division and postgraduate students in the School of Chinese Medicine for their kind assistances throughout my study.

I would like to acknowledge the Hong Kong Baptist University for financial support of the postgraduate studentship.

Finally and most importantly, I am indebted to my parents, my husband and my daughter, for their love, complete support, confidence, patience and care during the pursuit of this degree. I wish to dedicate this achievement to them.
# TABLE OF CONTENTS

DECLARATION...........................................................................................................i

ABSTRACT...............................................................................................................ii

ACKNOWLEDGEMENTS..........................................................................................iv

TABLE OF CONTENTS...............................................................................................vi

LIST OF TABLES.......................................................................................................xiii

LIST OF FIGURES.....................................................................................................xvii

LIST OF APPENDICES..............................................................................................xix

LIST OF ABBREVIATIONS.........................................................................................xxi

CHAPTER 1  INTRODUCTION....................................................................................1

1.1 Research Aims.....................................................................................................2
1.2 Study Design......................................................................................................3
1.3 Structure of the Thesis......................................................................................3

CHAPTER 2  OVERVIEW............................................................................................5

2.1 Quality of Life Studies......................................................................................5
  2.1.1 Definitions of Quality of Life and Health-related Quality of Life............7
  2.1.2 The Structure of Quality of Life.................................................................13
  2.1.3 Measurement of Quality of Life.................................................................15
    2.1.3.1 Instruments/Questionnaires.................................................................16
    2.1.3.2 Validity of Self-Reporting.................................................................16
2.1.3.3 Summing Domain Score to Form Overall Score…………..……………18
2.1.4 Cross-cultural Issues…………………………………………………………21
2.2 Chinese Medicine………………………………………………………………...24
  2.2.1 The Theory of Yin and Yang…………………………………………………24
  2.2.2 The Health Concept in Chinese Medicine…………………………………...28
  2.2.3 Seven Emotions………………………………………………………………….34
2.3 The Relationship between Chinese Medicine and Quality of Life……………….35
2.4 Significance in Applying Quality of Life Measurement in the Evaluation System
  of Chinese Medicine………………………………………………………………36
  2.4.1 The Need for Clinical Efficacy Assessment of Chinese Medicine………..36
  2.4.2 The Need for Standardization of Diagnosis and Research on the Essence of
    “Zheng” of Chinese Medicine……………………………………………………38
  2.4.3 The Need for Uniqueness/Character of Chinese Medicine…………………..40
  2.4.4 The Need for Internationalization of Chinese Medicine…………………….40
  2.4.5 The Need for a Bridge between Chinese Medicine and Western Medicine…41
2.5 Application……………………………………………………………………….42
  2.5.1 Develop and Select New Chinese Medicine Products………………………42
  2.5.2 Understand Sub-healthy Status, Develop and Select Health Products………43
  2.5.3 Select Different Therapy Measures………………………………………….44
2.6 Feasibility of Developing a New Instrument for Quality of Life Assessment Based
  on Chinese Medicine………………………………………………………………44

PART I
DEVELOPMENT AND VALIDATION OF THE CHINESE QUALITY OF LIFE
INSTRUMENT (PUTONGHUA VERSION)

CHAPTER 3 DEVELOPMENT A NEW QUALITY OF LIFE INSTRUMENT FOR
CHINESE (ChQOL) …………………………………………………………… 48

3.1 Instrument Development…………………………………………………………48
  3.1.1 Conceptualization of the ChQOL…………………………………………………49
  3.1.2 Building of the Theoretical Framework of the ChQOL…………………………50
  3.1.3 Item Generation…………………………………………………………………..56
3.1.4 Forming Scales.................................................................58
3.1.5 Linguistic testing..........................................................59
3.2 Instrument Testing............................................................63
3.2.1 Objective.................................................................63
3.2.2 Methods.................................................................63
  3.2.2.1 Study Design.........................................................63
  3.2.2.2 Sample..............................................................63
  3.2.2.3 Instruments........................................................64
  3.2.2.4 Training of Interviewers...........................................65
  3.2.2.5 Statistical Analysis................................................66
3.2.3 Results.................................................................67
  3.2.3.1 Sample Characteristics.............................................67
  3.2.3.2 Item-Facet Structure Fitness......................................69
  3.2.3.3 Facet-Domain/Sub-domain Structure Fitness...................75
  3.2.3.4 Domain-Overall ChQOL Structure Fitness.......................77
  3.2.3.5 Comparison of the Final Version of the ChQOL with the WHOQOL-100 and SF-36..................................................81
3.3 Discussion and Conclusion................................................85

CHAPTER 4  PSYCHOMETRIC PROPERTIES OF THE CHINESE QUALITY OF LIFE INSTRUMENT..................................................87

4.1 Missing Value.............................................................87
4.2 Scale Behavior.............................................................87
  4.2.1 Distribution of Item Scores...........................................87
  4.2.2 Distribution of Facet and Domain Scores...........................88
4.3 Reliability.................................................................91
  4.3.1 Internal Consistency....................................................91
  4.3.2 Test-retest Reliability..................................................92
4.4 Validity.................................................................93
  4.4.1 Concurrent Validity.....................................................93
    4.4.1.1 Self-reported Health Status.......................................94
    4.4.1.2 WHOQOL-100......................................................94
CHAPTER 5 RESPONSIVENESS IN PATIENTS WITH CONGESTIVE HEART FAILURE

5.1 Methods.........................................................................................108
5.1.1 Subjects..................................................................................108
5.1.2 Study Design..........................................................................108
5.1.3 Statistical Analysis.................................................................110
5.2 Results.........................................................................................112
5.2.1 Subject Characteristics..........................................................112
5.2.2 Responsiveness Using the Response to the Patient’s Global Rating of Change in Overall QOL as a Criterion of Change........................................112
5.2.3 Responsiveness Using the NYHA Functional Class Changes as a Criterion for Change.................................................................115
5.3 Discussion and Conclusion........................................................117

PART II
DEVELOPMENT AND VALIDATION OF THE CHINESE QUALITY OF LIFE INSTRUMENT – HONG KONG CANTONESE VERSION

CHAPTER 6 DEVELOPMENT AND VALIDATION OF THE HONG KONG CANTONESE VERSION OF THE CHINESE QUALITY OF LIFE INSTRUMENT (ChQOL-HK).................................................121
6.1 Introduction ............................................................................................................. 121
  6.1.1 The Need of Hong Kong Cantonese Version of the ChQOL ......................... 121
    6.1.1.1 The Modernization of Chinese Medicine in Hong Kong ...................... 121
    6.1.1.2 The Internationalization of Chinese Medicine .................................. 123
  6.1.2 Issues of Translation and Linguistics ............................................................... 123
    6.1.2.1 Translation ........................................................................................... 123
    6.1.2.2 Linguistics and Dialect ........................................................................... 125
6.2 Objective .................................................................................................................. 125
6.3 Methods ..................................................................................................................... 125
  6.3.1 Research Design ................................................................................................. 125
    6.3.1.1 Drafting of the Hong Kong Cantonese Version .................................... 126
    6.3.1.2 Field Test on the Hong Kong Cantonese Version ................................ 128
  6.3.2 Survey Design .................................................................................................... 129
    6.3.2.1 Sampling ................................................................................................ 129
    6.3.2.2 Instruments ............................................................................................ 129
    6.3.2.3 Statistical Analysis .................................................................................. 129
6.4 Results ....................................................................................................................... 130
  6.4.1 Subject Characteristics ....................................................................................... 130
  6.4.2 Scale Behavior ................................................................................................... 132
  6.4.3 Reliability ........................................................................................................... 135
    6.4.3.1 Internal Consistency .............................................................................. 135
    6.4.3.2 Test-retest Reliability ............................................................................ 136
  6.4.4 Validity ................................................................................................................. 137
    6.4.4.1 Concurrent Validity ................................................................................ 137
      6.4.4.1.1 Self-reported Health Status ............................................................... 137
      6.4.4.1.2 WHOQOL-BREF(HK) ................................................................. 137
    6.4.4.2 Convergent Validity ................................................................................ 138
    6.4.4.3 Known-Groups Validity .......................................................................... 142
      6.4.4.3.1 Known-Groups Validity for the ChQOL-HK between Healthy Subjects and Patients .......................................................... 142
      6.4.4.3.2 Known-Groups Validity for the ChQOL-HK among the Three Self-reported Health Status ............................................. 142
      6.4.4.3.3 Known-Groups Validity for the ChQOL-HK among the Three
APPENDIX B2  WHOQOL-100 Chinese Version.................................207

APPENDIX B3  WHOQOL-BREF Chinese Version..............................219

APPENDIX B4  WHOQOL-BREF Hong Kong Chinese Version
(WHOQOL-BREF(HK)).........................................................223

APPENDIX B5  Minnesota Living with Heart Failure Questionnaire (MLHF) Chinese
Version.................................................................227

APPENDIX C  PUBLICATIONS.....................................................228

GLOSSARY.................................................................255

LIST OF PUBLICATIONS....................................................258

CURRICULUM VITAE.......................................................261