Research Article

Development of Smoking Cessation Health-Related Quality of Life Scale

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Abstract

The purpose of this methodological research was to develop a smoking cessation health-related quality of life scale and examine the validity and reliability of this measure. The research involved 3 steps: (1) scale development, (2) expert review of the scale, and (3) testing of the scale. A total of 431 current adult smokers and ex-smokers who visited the smoking cessation clinics in hospitals/ institutes and community pharmacies participated in the study. The initial scale was developed and based on a literature review and semi-structured interviews with smokers, ex-smokers, and healthcare professionals. A five-point Likert scale was used as an item response choice. For psychometric properties, exploratory factor analysis with item analysis was used to examine the construct validity and reliability of the scale. Known group validity was used to support the evidence of construct validity. Results indicated that the scale had content validity, construct validity, and high internal consistency reliability. The scale consisted of 36 items with an overall coefficient alpha 0.93. A four-factor structure was identified and interpreted as representing four subscales: (1) general well being (18 items), (2) satisfaction (8 items), (3) craving and self-control (4 items), and (4) psychological and emotional problems (6 items). The Mann-Whitney-U test revealed ex-smokers who had quit smoking for ≥ 3 months reported significantly higher quality of life scores than smokers on the four subscales ($P < 0.02$), demonstrating the construct validity of the scale. The findings provide preliminary evidence of scale validity and reliability.

***Key Words*:** Health-related quality of life; Validity; Reliability; Scale; Smoking cessation; Tobacco dependence

Introduction

Tobacco smoking is recognized as a contributing factor to a number of acute and chronic diseases (WHO, 2008). It is the chief preventable cause of morbidity and mortality, with enormous economic costs for the individual smoker and for society in general (CDC, 2005; WHO, 2008). This habit globally kills more than 5 million people annually and is estimated to be > 8 million deaths per year by 2030 (WHO, 2008). In the United States, cigarette smoking is responsible for approximately 438,000 deaths (1 of every 5 deaths) each year (CDC, 2005). Despite

numerous attempts to inform people about the dangers of smoking, the rates of tobacco use cessation remain very low. Many new smokers, especially young people, are added to the ranks of persistent smokers each day (CDC, 2005; Wongwiwatthananukit, 2003). Smokers who try to quit using willpower, i.e., "cold turkey," alone have about a 5-7% long-term success (Wongwiwatthananukit, 2003). If they use behavioral counseling and/or pharmacotherapy, the long-term quitting rates are approximately double or even triple the rates of successful quitting relative to placebo, which is generally less than 30% (Wongwiwatthananukit, 2003). Despite the benefits of pharmacotherapy, its major disadvantage is its associated high cost. This may affect the smoker's ability to afford therapy, resulting in underutilization of this therapy (Prochazka, 2000). Long-term abstinence remains difficult among smokers due to a high rate of relapse (Fiore et al., 2008; Prochazka, 2000). For example, among 19 million adult smokers who attempt to quit every year, only 4 to 7% permanently quit smoking (Fiore et al., 2008).

It is well known that smoking behavior is a complex interplay of psychological, socio-cultural, and nicotine factors (Fiore et al., 2008; Wongwiwatthananukit, 2003). From this perspective, smokers would experience nicotine withdrawal symptoms and psycho-social changes during the quitting process. These would adversely affect a person's functioning and sense of well-being and/or health-related quality of life (HRQOL) (Cramer and Spilker, 1998; Fayer and Machin, 2000; Lyons et al., 1994). Assessment of HRQOL is more than a measure of the number and severity of a smoker's nicotine withdrawal symptoms; it also quantifies changes in the perceived impact of smoking and smoking cessation on functioning and well-being. Research studies have shown that former and those who have never smoked report higher HRQOL scores than do smokers (Cummings et al., 1985; Erickson et al., 2004; Lyons, 1994; Mulder et al., 2001; Olufade et al., 1999; Shaw et al., 2001; Stewart et al., 1995; Strandberg at al., 2008; Tillmann and Silcock, 1997; Wilson et al., 1999; Zillich et al., 2002). However, most studies are cross-sectional, using a generic measure or a combination of a generic (i.e., Medical Outcome Study 36-item; SF-36) and a cessation-specific (i.e., 15 cessation-targeted items) scale, have a small sample size, and utilize no control group. There is only one study which has examined the HRQOL during smoking cessation process on a longitudinal basis (i.e., 2-6 weeks after screening visit) (Shaw et al., 2001).

Although there is currently a measure available to assess changes in HRQOL associated with smoking cessation (Olufade et al., 1999), its disadvantages are its length (i.e., 51 items) to complete in clinical and community settings. In addition, it contains questions that are more-or-less repeated in a different format and cannot be adapted for practical use with different cultural and ethnic backgrounds, e.g., Thais or other Asians. For example, Thai people are often characterized as being inhibited, obedient, more hesitant in their emotional expression, and less forthcoming to strangers about sensitive and/or embarrassing topics e.g., sex, vitality, mental health. This perhaps affects their response to some items of the scale. Missing data would be expected when sensitive areas are addressed in the scale. However, there is no established cross-culturally scale in existence to measure the impact of smoking cessation on HRQOL for Thais.

To address this deficiency and increased feasibility of the scale, this methodological research (Polit and Hungler, 1999; Wongwiwatthananukit et al., 2002) aimed to conceptualize and develop a reliable and valid smoking cessation health-related quality of life (SCHRQOL) scale. It was designed to assess the HRQOL of smokers and ex-smokers in addition to clinical outcome (i.e., abstinence) in clinical and community settings. This would allow healthcare professionals to develop interventions to address identified HRQOL deficits and provide programmatic

assessment data to evaluate the effectiveness of tobacco cessation programs.

Methods

The methodological research was implemented through three major steps: (1) scale development, (2) expert review of the scale, (3) testing of the scale (i.e., pretest and pilot test of the scale). The study was approved by the Research Ethics Committee, Faculty of Pharmaceutical Sciences, Chulalongkorn University.

Step 1: Scale Development

The purpose of this step was to define SCHRQOL (Smoking Cessation Health-Related Quality of Life), identify scale subscales, generate items, and design the scale format. SCHRQOL was defined as a total well-being of person who smokes or quits smoking including his/her physical, psychological, and social health status/function. Tentative subscales and an item pool for each subscale of the content domain were based extensively on the literature review (Cummings et al., 1985; Erickson et al., 2004; Lyons, 1994; Mulder et al., 2001; Olufade et al., 1999; Shaw et al., 2001; Stewart et al., 1995; Strandberg at al., 2008; Tillmann and Silcock, 1997; Wilson et al., 1999; Zillich et al., 2002), the SF-36 (Juniper et al., 1996; Lermankul, 2000; Lermankul and Meetam, 2000; Ware and Sherbourne, 1992), and semi-structured interviews with 16 smokers, 8 ex-smokers, and 5 healthcare professionals involved with smoking cessation programs. The information was analyzed and scale items that assessed the aspect/domain of HRQOL were extracted, pooled, and generated. The scale was designed to use as a condition-specific, self-assessment scale by smokers ≥ 20 years old and using any method of smoking cessation. It was intended to assess the HRQOL within the past week.

The format and design of the scale, including selection of response choices, were based on the five-point Likert scale. The scale was administered to smokers and ex-smokers who would be requested to judge the perceived HRQOL during smoking cessation on two rating scales (i.e., a frequency scale: 1=none of the time, 2=a little of the time, 3=some of the time, 4=most of the time, and 5=all of the time; an evaluation scale: 1=not at all, 2=slightly, 3=moderately, 4=quite a bit, and 5=extremely). Summated rating scales (Spector, 1992) was used to calculate the item scores of the scale and subscales (i.e., positive statements: 1 = 0 points, 2 = 25 points, 3 = 50 points, 4 = 75 points, 5 = 100 points and negative statements: 1 = 100 points, 2 = 75 points, 3 = 50 points, 4 = 25 points, 5 = 0 points). The scores were calculated by adding the raw scores on each subscales/all items on all subscales and then dividing it by the total number of items for that subscales/all subscales. The scores ranged from 0 (i.e., worst HRQOL) to 100 (i.e., best HRQOL). A demographic form was also created during this step.

Step 2: Expert Review of the Scale

The purpose of this step was to secure content validity of the scale items and ensure their relevancy and representativeness to each subscale's domain by an expert panel. Three pharmacy practice faculty and another six healthcare professionals working in smoking cessation clinics and were content experts with respect to smoking cessation reviewed the initial pool items. They were asked to rate each item's relevance in measuring the HRQOL during smoking cessation using a content validity index (CVI) (Lynn, 1986). The CVI was a four-point ordinal scale: 1 = not relevant, 2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant, 3 = relevant, but needing minor alteration, and 4 = very relevant. A CVI was then calculated for each item. The CVI for each item is the proportion of experts who rated the item as content valid, i.e., a rating of three or four. For the nine experts used in this study, the proportion whose endorsement was required to establish content validity beyond the 0.05 level of significance was 0.78 (Lynn, 1986). In other words, seven experts out of nine had to rate the item either a three or a four before it would be judged to have content validity.

Each item was reviewed for content, grammatical correctness, organization, readability, and clarity. The expert panel was also asked to share/ suggest any additional items that were related to the subscales and/or germane to the HRQOL expected during smoking cessation that should be considered for inclusion in the scale, but were unintentionally omitted. The revised items were then formatted and used in the testing step of the study. Each item was also randomly placed in the scale so that there would be no effect of item order on the perceived HRQOL.

Step 3: Testing of the Scale

3.1 Pretest The purpose was to identify and solve any potential problems with the items e.g., answering, ambiguity, time to complete.

Participants and Settings

A convenience sample of 13 adult current smokers and 7 ex-smokers was recruited from the smoking cessation clinic at Thanyarak Institute, Pathumtani, Thailand during October 2004.

Measures

A healthcare professional coordinator administered the scales to the participants and conducted a discussion feedback of the scale items. Participants were debriefed regarding the pretest process and informed to review and provide feedback for the written instruction, readability, organization, comprehensiveness, redundancy, clarity of wording or difficulty phrasing of the items and responses, and any concerns regarding the scale. They were also informed that the returned responses to the scale were treated anonymously and would have no bearing on their treatment or services. The revised items were then formatted and used in the pilot testing step. Each item was also randomly placed in the scale so there would be no effect of item order on the perceived HRQOL.

3.2 Pilot Test of the Scale The objectives were to explore the subscale/factor structure of the item developed scale, further reduce the number of items, and test the known group validity.

Participants and Settings

Participants consisted of a convenience sample of 500 smokers and ex-smokers (Guadagnoli and Velicer, 1988; Hatcher, 1994; Tinsley and Tinsley, 1987) in 14 smoking cessation clinics of hospitals/ institutes and community pharmacies in Thailand. Excluded from this phase of the research were those with a history of psychiatric disorders, alcohol or drug abuse in the past year, and use of other forms of tobacco products other than cigarettes. They participated in the cross-sectional study from November 2004 to May 2005.

Measures

A healthcare professional coordinator at each data collection sites received and administered the scale and a demographic form to participating participants. Participants were informed that the returned responses to the scales would be treated anonymously, used solely for research purposes, and would have no bearing on their treatments or services.

Analysis

Data were analyzed and managed using the Statistical Package for Social Science (SPSS version 15) software system. Exclude case listwise was performed when data were analyzed. Descriptive statistics of demographic variables were computed. The level of significance for any statistical tests was established at $\alpha = 0.05$. Exploratory factor analysis (EFA) (i.e., PROC FACTOR) was used to explore the tentative subscales within the group of items (Hatcher, 1994; Tinsley and Tinsley, 1987). In this portion of the study, the term "factor"was used interchangeably with "subscale". To determine factorability of the data (i.e., the appropriateness of factor analysis), correlation matrices [i.e., observed, partial (anti-image)], the Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMOMSA) for all of items and each item, and squared multiple correlation were determined.

A principal factor analysis was used as the method of factor extraction with an oblique (i.e., Promax)

rotation. The squared multiple correlations (SMC) were used as an initial communality estimate. An eigenvalue (Kaiser's criterion) cutoff of one, the Cattell's scree test, the proportion of the common variance accounted for a factor and the factor solution, and residual correlation matrix were used to determine the number of factors to be retained (Guadagnoli and Velicer, 1988; Hatcher 1994; Tinsley and Tinsley, 1987; Wongwiwatthananukit et al., 2002). An item was retained on a given factor/subscale if the factor loading was ≥ 0.50 for that factor. The simple structure, interpretability criteria, and at least three to four items per factor were used to interpret a factor solution. Item analysis (i.e., Cronbach's coefficient *alpha*, corrected item-subscale correlation) was also performed after the factor analysis procedure (Nunnally and Bernstein, 1994). For known group validation (Fayer and Machin, 2000), the authors hypothesized ex-smokers who had quit for ≥ 3 months would demonstrate higher HRQOL scores than smokers on each subscale of the scale. The Mann-Whitney U-test or Independence samples t-test was used to examine known group validation, as appropriate.

Results

Step 1: Scale Development

Based on the literature review and semi-structured interviews, the initial 71-item scale was created and intended to represent five subscales: (1) physical subscale (i.e., fitness, sleep, appetite), (2) psychological subscale (i.e., emotional, anxiety, mental health, vitality, role-emotional, cognitive functioning, self-esteem, bodily-image), (3) social subscale (i.e., social interaction, social functioning), (4) health perception subscale (i.e., general health perception, satisfaction), and (5) cessation-related symptoms subscale (i.e., craving, subjective complaints).

Step 2: Expert Review of the Scale

This step pared down the original 71-item scale to 61 items. There were some minor suggestions made by the reviewers to improve the clarity of the remaining 61 items (i.e., wording changes, grammatical corrections). Sixty-one items were revised accordingly and seven new items were included in the scale. This resulted in a 68-item scale. The 68 items were then formatted, randomly placed, and used in the testing step.

Step 3: Testing of the Scale

3.1 Pretest of the Scale

Sixty-eight items were revised accordingly and four new items were included in the scale. This resulted in a 72-item scale. The 72 items were then formatted and used in the pilot testing step. Each item was randomly placed within the scale so there would be no effect of item order on the perceived HRQOL ratings. The mean ± SD time to complete the scale was 18.5 ± 6.8 minutes.

3.2 Pilot Testing of the Scale

Four hundred and thirty-one smokers (*n* =155, 36%) and ex-smokers (*n* =276, 64%) participated and responded to the scale. Overall, the majority of participants were male, 92.8% (*n* =400) and 7.2% female (*n* =31). The mean ± SD age of participants was 39.5±13.0. Most of the participants graduated from high schools (*n* =112, 26%), college baccalaureate programs (*n* =105, 24.4%), and elementary schools (*n* =67, 15.5%). Participants had smoked for 1 to 60 years with the overall mean ± SD of 18.6±12.1 years. The majority of participants smoked 11-20 cigarettes per day (45%), 35% smoked < 10 cigarettes per day, and 22% smoked 21-30 cigarettes per day. The overall mean ± SD score on the Fagerström Test for Nicotine Dependence (FTND) was 5.4 ± 1.6 out of a possible total score of 10.

The EFA was performed on 409 participants' raw data to explore possible subscales within the 72 items. Factor extraction results demonstrated 17 factors with eigenvalues greater than one, accounting for 66.8% of the total variance. An examination of the Cattell's scree test was inconclusive and suggested factor solutions ranging from three to five factors. Therefore, three to five factors were retained and

considered for oblique rotations. A four-factor solution appeared to be the best approximate simple structure and conceptual meaning of the factor underlying a set of 36 items. The proportion of the common variance which accounted for four factors still accounted for 40.2% of the total variance. Factors one, two, three, and four accounted for 25.5%, 7.4%, 3.7%, and 3.6% of the total variance, respectively. The coefficients of the residual correlation matrix demonstrated small and negative values, which supported the four-factor solution fit the data. When interpreting the rotated four-factor pattern matrix and removing ineffective items from the original 72 items, an item was retained on a given factor if the factor loading was ≥ 0.50 for that factor. Using this criterion, the revised scale consisted of 36 items.

All factor loading values ranged from 0.508 to 0.907 (Table 1). Eighteen of these items were found to load onto factor one. This was interpreted as representing the general well being subscale. Eight items loaded onto factor two, which was interpreted as representing the satisfaction subscale. Four items loaded onto factor three and was interpreted as representing the craving and self-control subscale. Six items loaded onto factor four, which was interpreted as representing the psychological and emotional problem subscale. Communality values which demonstrated how well the items' variance was explained by the four-factor solution ranged from 0.249 to 0.752. The correlations between each subscale ranged from 0.332 to 0.624. This indicated the subscales were separated, but correlated and using the oblique rotation was appropriate for the purpose of this study.

The overall coefficient *alpha* of the 36-item scale was 0.933 (Table 2). Subscale one (18 items), two (8 items), three (4 items), and four (6 items) had coefficient *alphas* of 0.9187, 0.8764, 0.8737, and 0.0.8299, respectively. The coefficient *alpha* did not increase with the deletion of any item for each subscale. All items on the four subscales had the corrected item-subscale correlation coefficients ≥ 0.30 (Nunnally and Bernstein, 1994). To complete the scale revision, the 36 items were randomly ordered and formatted again to ensure that there was no anchoring influence by any item order. For known group validity of the scale (Table 3), the Mann-Whitney-U test revealed that ex-smokers who had quit smoking for ≥ 3 months reported significantly higher HRQOL scores than smokers on all four subscales ($P < 0.02$), demonstrating evidence for the construct validity of the scale (Erickson et al., 2004; Olufade et al., 1999; Shaw et al., 2001; Stewart et al., 1995; Zillich et al., 2002).

Discussion

In the first step of this study, evidence was carefully obtained by first defining the content domain of HRQOL during smoking cessation according to scale development and validation process (Fayer and Machin, 2000; Juniper et al., 1996). Then, identification of scale subscales and generation of items were comprehensively based on the literature review and semi-structure interview. Because the scale was designed for use by smokers or ex-smokers as a self-assessment tool, five biases or response sets might have affected participants' responses (Smith and Glass, 1987): (1) acquiescence, (2) extremity, (3) evasiveness, (4) carelessness, and (5) social desirability. However, prior to the testing step, all items were randomly placed and formatted so there would be no effect of item order related to acquiescence, extremity, and evasiveness. Carelessness was minimized by providing instruction to the healthcare professional coordinator at each data collection site when administering the scale as well as instruction on the top of the scale directed to participants which encouraged them to respond candidly and honestly when completing the scale. Social desirability bias was also minimized by assuring participants of anonymity and confidentiality when conducting the testing step. The authors believe this step was thoroughly conducted and

Table 1 Factor loadings of smoking cessation health-related quality of life instrument (n = 409)

Items	*Factor 1*	*Factor 2*	*Factor 3*	*Factor 4*
Factor 1 General well being				
20. I feel sad.[a *]	**0.802**	0.065	-0.105	-0.144
29. I have a lack of energy [a *]	**0.793**	0.057	-0.036	-0.045
21. I feel stressful.[a *]	**0.749**	-0.032	0.023	-0.051
30. I feel so down.[a *]	**0.740**	0.074	0.020	-0.106
28. I feel bored.[a *]	**0.706**	0.136	0.098	-0.136
23. I feel downhearted and depressed (blue).[a *]	**0.660**	0.064	0.067	-0.027
16. I feel easily angry.[a *]	**0.621**	-0.090	0.049	0.132
2. I feel tired when doing vigorous activities such as lifting heavy objects, participating in strenuous sports.[a *]	**0.619**	-0.184	-0.590	0.015
44. I feel exhaustive.[a *]	**0.603**	-0.021	0.083	0.038
15. I feel more irritable toward those around me.[a *]	**0.598**	-0.071	0.114	0.106
4. I feel tired when climbing several flights of stairs.[a *]	**0.588**	-0.136	-0.088	-0.023
12. I have a lack of appetite.[a *]	**0.571**	-0.004	-0.078	-0.117
17. I feel restless, unsettled, and changeable.[a *]	**0.569**	-0.104	0.095	0.189
43. I feel dizzy or headaches.[a *]	**0.565**	-0.015	0.161	-0.046
34. I like to isolate myself from people around me [a *]	**0.539**	0.090	-0.057	-0.015
3. I feel tired when doing moderate activities such as moving a table, watering plants, washing clothes by hand 8-10 pieces.[a *]	**0.531**	-0.076	-0.087	0.104
36. I avoid social activities like visiting friends, party, relatives etc.[a *]	**0.517**	0.028	-0.054	0.015
5. I have trouble falling asleep.[a *]	**0.508**	0.007	-0.029	-0.049
Factor 2 Satisfaction				
57. I am proud of myself.[b #]	-0.075	**0.832**	0.071	-0.112
59. I feel respectful myself.[b #]	-0.141	**0.790**	0.072	-0.054
60. I have self-confidence.[b #]	-0.122	**0.778**	0.018	0.034
56. I feel valuable to family. [b #]	-0.082	**0.767**	-0.093	-0.021
63. I am satisfied with how I am coping with my family members [b #]	0.131	**0.666**	-0.192	0.115
64. I am satisfied with how I am coping with my friends .[b #]	0.068	**0.614**	-0.148	0.130
27. I feel full of life and a lot of energy.[a #]	0.023	**0.524**	0.207	-0.057
25. I have been a happy person.[a #]	0.158	**0.519**	0.099	-0.063
Factor 3 Craving and self-control				
41. I feel suffering from the urge to smoke.[a *]	-0.018	-0.007	**0.907**	-0.063
39. I feel craving toward smoking cigarettes.[a *]	0.026	-0.021	**0.866**	-0.079
40. I am obsessed by thoughts of smoking.[a *]	-0.016	0.027	**0.782**	0.024
52. I am worried that I might not successfully stop smoking.[b *]	-0.101	-0.041	**0.649**	0.189

Table 1 Factor loadings of smoking cessation health-related quality of life instrument (n = 409) (continued)

Items	*Factor 1*	*Factor 2*	*Factor 3*	*Factor 4*
Factor 4 Psychological and emotional problems				
55. I am worried that increased appetite after stop smoking would do harm to my health.[b *]	-0.185	-0.062	-0.026	**0.721**
54. I am worried about gaining weight after stop smoking.[b *]	-0.154	-0.078	-0.009	**0.671**
61. Mental and emotional problems have interfered with my normal activities with family.[b *]	0.097	0.046	0.028	**0.634**
62. Mental and emotional problems have interfered with my normal activities with friends.[b *]	0.146	0.046	0.028	**0.620**
49. Mental and emotional problems have interfered with my normal activities with family.[a *]	0.157	0.161	0.026	**0.561**
50. Mental and emotional problems have interfered with my normal activities with friends.[a *]	0.192	0.111	0.059	**0.520**

[a] = Frequency Response Choices: 1=None of the time, 2=A little of the time, 3=Some of the time, 4=Most of the time, and 5=All of the time

[b] = Evaluation Response Choices: 1=Not at all, 2=Slightly, 3=Moderately, 4=Quite a bit, and 5=Extremely

Item Scores of the Instrument: [#] Positive statements: 1 = 0 points, 2 = 25 points, 3 = 50 points, 4 = 75 points, 5 = 100 points. [*] Negative statements: 1 = 100 points, 2 = 75 points, 3 = 50 points, 4 = 25 points, 5 = 0 points.

Table 2 The overall coefficient alpha of the 36 items, corrected item-subscale correlation coefficients, and the coefficient alpha if the item was deleted from each subscale

Items	*Cronbach coefficient alpha*	*Corrected Item-Total correlation*	*Alpha if Item deleted*	*n*
Overall coefficient *alpha* (36 items) = 0.9331				423
Subscale 1 General well being	0.9187			429
20. I feel sad.[a *]		0.6454	0.9108	
29. I have a lack of energy [a *]		0.7232	0.9089	
21. I feel stressful.[a *]		0.6833	0.9098	
30. I feel so down.[a *]		0.6686	0.9102	
28. I feel bored.[a *]		0.6762	0.9098	
23. I feel downhearted and depressed (blue).[a *]		0.6646	0.9102	
16. I feel easily angry.[a *]		0.6776	0.9009	
2. I feel tired when doing vigorous activities such as lifting heavy objects, participating in strenuous sports.[a *]		0.5282	0.9138	
44. I feel exhaustive.[a *]		0.6366	0.9109	
15. I feel more irritable toward those around me.[a *]		0.6851	0.9098	
4. I feel tired when climbing several flights of stairs.[a *]		0.4674	0.9156	
12. I have a lack of appetite.[a *]		0.4285	0.9159	
17. I feel restless, unsettled, and changeable.[a *]		0.6740	0.9098	
43. I feel dizzy or headaches.[a *]		0.6033	0.9118	
34. I like to isolate myself from people around me [a *]		0.5039	0.9146	
3. I feel tired when doing moderate activities such as moving a table, watering plants, washing clothes by hand 8 -10 pieces.[a *]		0.5024	0.9143	
36. I avoid social activities like visiting friends, party, relatives etc.[a *]		0.4798	0.9152	
5. I have trouble falling asleep.[a *]		0.4435	0.9167	
Subscale 2 Satisfaction	0.8764			426
57. I am proud of myself.[b #]		0.7257	0.8511	
59. I feel respectful myself.[b #]		0.6928	0.8546	
60. I have self-confidence.[b #]		0.6993	0.8543	
56. I feel valuable to family. [b #]		0.6404	0.8604	
63. I am satisfied with how I am coping with my family members [b #]		0.6282	0.8616	
64. I am satisfied with how I am coping with my friends.[b #]		0.5863	0.8659	
27. I feel full of life and a lot of energy.[a #]		0.5560	0.8679	
25. I have been a happy person.[a #]		0.5546	0.8698	
Subscale 3 Craving and self-control	0.8737			429
41. I feel suffering from the urge to smoke.[a *]		0.7866	0.8017	

Table 2 The overall coefficient alpha of the 36 items, corrected item-subscale correlation coefficients, and the coefficient alpha if the item was deleted from each subscale (continued)

Items	*Cronbach coefficient alpha*	*Corrected Item-Total correlation*	*Alpha if Item deleted*	*n*
39. I feel craving toward smoking cigarettes.[a *]		0.7706	0.8102	
40. I am obsessed by thoughts of smoking.[a *]		0.7359	0.8245	
52. I am worried that I might not successfully stop smoking.[b *]		0.6096	0.8842	
Subscale 4 Psychological and emotional problems	0.8299			430
55. I am worried that increased appetite after stop smoking would do harm to my health.[b *]		0.5097	0.8149	
54. I am worried about gaining weight after stop smoking.[b *]		0.4784	0.8227	
61. Mental and emotional problems have interfered with my normal activities with family.[b *]		0.6459	0.7844	
62. Mental and emotional problems have interfered with my normal activities with friends.[b *]		0.6681	0.7807	
49. Mental and emotional problems have interfered with my normal activities with family.[a *]		0.6558	0.7847	
50. Mental and emotional problems have interfered with my normal activities with friends.[a *]		0.6311	0.7898	

[a] = Frequency Response Choices: 1=None of the time, 2=A little of the time, 3=Some of the time, 4=Most of the time, and 5=All of the time

[b] = Evaluation Response Choices: 1=Not at all, 2=Slightly, 3=Moderately, 4=Quite a bit, and 5=Extremely

Item Scores of the Instrument: [#] Positive statements: 1 = 0 points, 2 = 25 points, 3 = 50 points, 4 = 75 points, 5 = 100 points. [*] Negative statements: 1 = 100 points, 2 = 75 points, 3 = 50 points, 4 = 25 points, 5 = 0 points.

Table 3 Comparative quality of life scores of smoking cessation health-related quality of life instrument be tween smokers and former smokers who had quit smoking > 3 months. (n = 266)

Subscale	*Smoking status*	*Descriptive statistics*			*Mann-Whitney U-test: test statistics*	
		mean±SD	**median**	**mode**	**Mann-Whitney U**	***P* Value**
General well being[α]	Former smoker (*n* = 111)	69.12 ± 15.88	73.61	73.61	6314.50	<0.001*
	Smoker (*n* = 155)	61.45 ± 17.48	61.11	51.39 75.00		
Satisfaction[β]	Former smoker (*n* = 111)	79.41 ± 17.72	84.38	100.00	5641.50	<0.001*
	Smoker (*n* = 155)	69.61 ± 17.53	71.88	68.75		
Craving and self-control[ϕ]	Former smoker (*n* = 111)	81.98 ± 22.04	93.75	100.00	2741.00	<0.001*
	Smoker (*n* = 155)	51.98 ± 21.17	50.00	50.00		
Psychological and emotional problems[δ]	Former smoker (*n* = 111)	74.14 ±19.82	79.17	100.00	7058.50	0.012*
	Smoker (*n* = 155)	67.74 ± 20.57	66.67	66.67		

* Significance at $p < 0.05$; [α] items 2,3,4,5,12,15,16,17,20,21,23,28,29,30,34,36,43,44; [β] items 25,27,56,57,59,60, 63,64; [ϕ] items 39,40,41,52; [δ] items 49,50,54,55,61,62

logically described. The initial scale appeared to have some evidence of validity based on its content.

For the second step of the study, the evidence of content validity was strengthened by an expert panel using CVI (Lynn, 1986). Based on the panel's suggestions, some items were deleted, revised, or left as is. This resulted in item improvement of content and relevance to the developed scale. The authors believe this step has provided adequate, empirical evidence of validity based on content for the developed scale. Construct underrepresentation and construct irrelevance were also addressed and considered by an expert review panel.

Pretesting of the scale with smokers and ex-smokers was helpful as a means to review the scale for content, grammatical correctness, organization, readability, and clarity. This process provided important information about whether participants understood the scale items, the layout, and the flow of the items. Evidence based on subscale structure (i.e., construct validity) and internal consistency reliability of the scale was obtained by conducting an EFA and performing an item analysis, respectively. Results of the EFA indicated there were four subscales and the accounted proportion of the common variance for the four subscales (36 items) was 40.2% of the total item variance. This value indicated that the four-subscale solutions explained most of the total variance quite well. The coefficient *alpha* of the 36-item scale, subscales one, two, three, and four ranged from 0.80-0.90. The values of the coefficient *alpha* were well above the desired criterion of 0.70 (Nunnally and Bernstein, 1994). This indicated strong support and good internal consistency reliabilities of the scale and each of its four subscales. The unidimensionality of the subscales were also confirmed from a high internal consistency and corrected item-subscale correlations. The authors were convinced that evidence based on the internal (subscale) structure was successfully obtained and confirmed by item analysis.

Items in general well being subscale were emerged from the combination of the initial items intended to represent three subscales in the first step of the study: (1) physical subscale (i.e., fitness, sleep, appetite), (2) psychological subscale (i.e., emotional, nervous, role-emotional), and (3) social subscale (i.e., social functioning). This result may be related to the unidimensionality of these three subscales specifically designed to assess the HRQOL of smoker and ex-smokers. This finding differs from the generic measure SF-36, which clearly separates each subscale when designed and administered to assess QOL in general population. Low correlation among subscales in healthy persons is likely the explanation of the separated scales. Additionally, smokers and ex-smokers would normally experience physical and psycho-social changes during the quitting process as a single component. The changes would adversely affect a person's functioning and sense of well-being and/or HRQOL (Cramer and Spilker, 1998; Fayer and Machin, 2000; Lyons et al., 1994). The adverse effect may still persist after quitting for a period of time. However, ex-smokers who were able to quit for a longer period of time would probably demonstrate a lower correlation among subscales over time. Thus, the subscales may reveal clearly separated subscales similar to those seen in general healthy population. Items in satisfaction subscale were emerged from the initial items in health perception and psychological subscales (i.e., satisfaction, vitality, self-esteem) from the first step. Craving and self-control subscale was consistent with the initial cessation-related symptoms subscale (i.e., craving, subjective complaints). Items belonged to psychological and emotional problems subscale were derived from the initial physical subscale (i.e., appetite), psychological subscale (i.e., emotional, anxiety, mental health, role-emotional), and social subscale (i.e., social interaction).

Known group validity was also supported for construct validity and indicated this scale can differentiate HRQOL between ex-smokers and

smokers on all four subscales. This result was also corroborated data from previous studies (Erickson et al., 2004; Olufade et al., 1999; Shaw et al., 2001; Stewart et al., 1995; Zillich et al., 2002). Particularly, HRQOL scores between ex-smokers and smokers on craving and self-control subscale were significantly different and similar to the studies by Olufade et al and Zillich et al. In addition, Shaw et al also found that self-control subscale was the most responsive to duration of smoking abstinence. The authors believe the developed scale can be considered appropriate for evaluating HRQOL during smoking cessation in addition to the previous scale (Olufade et al., 1999) (i.e., 51 items) for the following reasons: (1) testing with a larger sample size to achieve a good factor solution and specific to Thais; (2) possessing high internal consistency reliability; (3) reducing respondent burden, more feasible to use in practice (5-7 minutes to complete) and not too lengthy (i.e., 36 items); (4) using EFA to explore the true subscale structure within the groups of all possible items, rather than separating the subscales of the SF-36; and (4) containing high factor loadings.

Scale development is an ongoing, evolutionary process. Although this study has shown promising results, it does have several limitations that should be addressed. One such limitation involved the content domains of the scale. The content domains did not include all possible areas of HRQOL during smoking cessation, e.g., provider intervention, provider trust, relationships with healthcare professionals. Thus, the scale has limited generalizability to the four content subscales only. Another limitation involved the representativeness of the Thai and Asian smokers and ex-smokers. Participants who participated in this study were volunteers and a nonrandom sample. They were ≥ 20 years old and quit smoking ≤ 2 years. Although this may limit the generalizability of the use of the scales, future cross-validation of the scales with new, representative, independent samples are warranted.

This study demonstrated initial reliability and validity of scales which could be used to assess the HRQOL for Thais during smoking cessation. The scale could serve as a foundation for the advancement of research in the tobacco cessation area. Future research could be directed toward scale refinement, validation, and hypothesis testing. First, this scale should be tested further for its reliability (e.g., test-retest reliability) with an independent, representative sample to enhance its generalizability. Further establishment of construct validities e.g., responsiveness of the scale, convergent and discriminant validity with the use of a multitrate-multimethod (MTMM) approach, confirmatory factor analysis, should be conducted. A second direction could be using the scale to assess the effect of tobacco cessation methods on the improvement of the HRQOL. The scale could be further used for investigation to determine what interventions should be developed and used within or throughout the tobacco cessation programs/services with other Asian population to improve the patients' HRQOL.

Conclusion

This study created and evaluated a SCHRQOL scale (i.e., 36 items with 4 subscales). The results indicated this scale had built-in content validity, demonstrated high internal consistency reliability, a factor/subscale structure, and known group validity. Further refinement and testing of the scale would provide more comprehensive evidence for its construct validity when assessing the impact of smoking cessation on smokers and ex-smokers HRQOL. Ultimately, this would allow healthcare professionals to use and strengthen their tobacco cessation services/ programs to help improve a patient's HRQOL.

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References

Centers for Disease Control and Prevention. (2005) Annual smoking-attributable mortality, years of potential life lost, and economic costs-United States, 1997-2001. *MMWR Morbidity and Mortality Weekly Report* 54(25): 625-628.

Cramer, J. A. and Spilker, B. (1998) *Quality of life and pharmacoeconomics: An introduction*, Lippincott Raven, Philadelphia.

Cummings, K. M., Giovino, G., Jaen, C. R., and Emrich, L. J. (1985) Report of smoking withdrawal symptoms over a 21 day period of abstinence. *Addictive Behaviors* 10(4): 373-381.

Erickson, S. R., Thomas, L. A., Blitz, S. G., and Pontius, L. R. (2004) Smoking cessation: A pilot study of the effects on health-related quality of life and perceived work performance one week into the attempt. *Annals of Pharmacotherapy* 38(11): 1805-1810.

Fayer, P. M. and Machin, D. (2000) *Quality of life: assessment, analysis and interpretation*, John Wiley & Sons, Great Britain.

Fiore, M. C., Jaen, C. R,, Baker T. B., Bailey, W. C., Benowitz, N. L., Curry, S. J., Dorfman, S. F., Froelicher, E. S., Goldstein, M. G., Healton, C. G., and Henderson, P. N. (2008) *Treating tobacco use and dependence: 2008 update. clinical practice guideline*. U.S. Department of Health and Human Services, Rockville, MD.

Guadagnoli, E. and Velicer, W. F. (1988) Relation of sample size to the stability of component patterns. *Psychological Bulletin* 103(2): 265-275.

Hatcher, L. (1994) *A step-by-step approach to using the SAS system for factor analysis and structural equation modeling*, SAS Institute Inc., Cary, NC.

Juniper, E. F, Guyatt, G. H., and Jaeschke, R. (1996) How to develop and validate a new health-related quality of life instrument. In *Quality of life and pharmacoeconomics in clinical trial*. (Spilker, B., ed.), pp. 49-56. Lippincott Raven, Philadelphia.

Lermankul, W. (2000) Development of the health-related quality of life questionnaires. *Thai Journal of Pharmaceutical Sciences* 24(1-2): 71-85.

Lermankul, W. and Meetam, P. (2000) Development of Thai quality of life (SF-36) questionnaires. *Thai Journal of Pharmaceutical Sciences* 24(1-2): 92-111.

Lynn, M. R. (1986) Determination and quantification of content validity. *Nursing Research* 35(6): 382-385.

Lyons, R. A., Lo, S. V., and Littlepage, B. N. C. (1994) Perception of health amongst ever-smokers and never-smokers: a comparison using the SF-36 Health Survey Questionnaire. *Tobacco Control* 3(3): 213-215.

Mulder, I., Tijhuis, M., Smith, H. A., and Kromhout, D. (2001) Smoking cessation and quality of life:The effect of amount of smoking and time since quitting. *Preventive Medicine* 33(6): 653-660.

Nunnally, J. C. and Bernstein, I. H. (1994). *Psychometrics theory*. 3rd ed., McGraw-Hill, New York.

Olufade, A. O., Shaw, J. W., Foster, S. A., Leischow, S. J., Hays, R. D., and Coons, S. J. (1999) Development of the smoking cessation quality of life questionnaire. *Clinical Therapeutics* 21(12): 2113-2130.

Polit, D. E. and Hungler, B. P. (1999) *Nursing research: principles and method*, 6th ed. Lippincott Williams & Wilkins, Philadelphia.

Prochazka, A. V. (2000) New developments in smoking cessation. *Chest* 117 (4 suppl): 169S-75S.

Shaw, J. W., Coons, S. J., Foster, S. A., Leischow, S. J., and Hays, R. D. (2001) Responsiveness of the smoking cessation quality of life questionnaire. *Clinical Therapeutics* 23(6): 957-969.

Smith, M. L. and Glass, G. V. (1987) *Research and evaluation in education and the social science s*. Prentice-Hall, Englewood Cliffs, NJ.

Spector, P. E. (1992). *Summated rating scale construction: An introduction*. Sage, Newbury Park, CA.

Stewart, A. L., King, A. C., Killen, J. D., and Ritter, P. (1995) Does smoking cessation improve health-related quality-of-life. *Annals of Behavioral Medicine* 17(4): 331-338.

Strandberg, A. Y., Strandberg, T. E., Pitkala, K., Salomaa, V., Tilvis, R. S., and Miettinen, T. A. (2008) The effect of smoking in midlife on health-related quality of life in old age. *Archives of Internal Medicine* 168(18): 1968-1974.

Tillmann, M. and Silcock, J. A. (1997) A comparison of smokers' and ex-smokers' health-related quality of life. *Journal of Public Health Medicine* 19(3): 268-273.

Tinsley, H. E. and Tinsley, D. J. (1987) Uses of factor analysis in counseling psychology research. *Journal of Counseling Psychology* 34(4): 414-24.

Ware, J. E. and Sherbourne, C. D. (1992) The MOS 36-item short-form health survey (SF-36): I. conceptual framework and item selection. *Medical Care* 30(6): 473-483.

Wilson, D., Parsons, J., and Wakefield, M. (1999) The health-related quality-of-life of never smokers, ex-smokers, and light, moderate, and heavy smokers. *Preventive Medicine* 29(3): 139-144.

Wongwiwatthananukit, S. (2003) Role of pharmacists in smoking cessation program. In *Ambulatory pharmaceutical care* (Jindavijag, B. ed.), pp. 153-174. Thai Hospital Pharmacist Association, Bangkok.

Wongwiwatthananukit, S., Newton, G. D., and Popovich, N. G. (2002) Development and validation of an instrument to assess the self-confidence of students enrolled in the advanced pharmacy practice experiences. *American Journal of Pharmaceutical Education* 66(1): 5-19.

World Health Organization. (2008) *WHO report on the global tobacco epidemic 2008: the MPOWER Package*. WHO, Geneva, Switzerland.

Zillich, A. J., Ryan, M., Adams, A., Yeager, B., and Farris, K. (2002) Effectiveness of pharmacist-based smoking-cessation program and its im pact on quality of life. *Pharmacotherapy* 22(6): 759-765.