

Development of cough assessing tools

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Tools for assessing outcomes of chronic cough

| Aspect to be assessed | Recommended tools | Strength of evidence |
|-----------------------|---|------------------------|
| ① Frequency | Acoustic cough counting | |
| ② Severity | VAS, NRS | Should be standardized |
| ③ Impact on life | QoL questionnaire □ Leicester Cough Questionnaire (LCQ) □ Cough Quality of Life Questionnaire (CQLQ) □ Chronic Cough Impact Questionnaire (CCIQ) | Validated and reliable |

④ Cough sensitivity **Tussigenic challenges** to understand mechanisms

- **QoL instrument** is recommended as **the choice of outcome measurement**
- Cough counting alone should not be used to establish validity of QoL questionnaires
- Tussigenic challenge is not recommended as primary outcome measures, but may be useful to investigate cough reflex hypersensitivity

Summary of strength of evidence and effect estimate for clinical research question

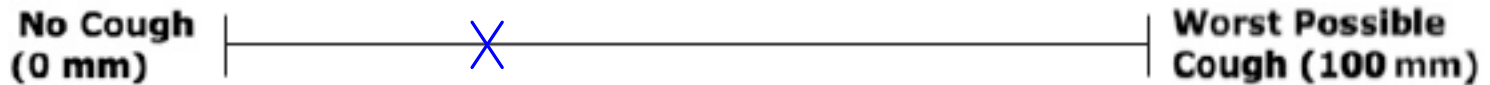
| Instrument (Dimension Assessed) | Validity (ie, Correlation With Other Measures of Cough) | Reliability | | Responsiveness |
|---|---|---|--|---|
| | | Internal Consistency (Cronbach α) | Repeatability | |
| LCQ (severity/QoL) | High SOE 17 studies; 1,191 subjects Range of $r = 0.93-0.93$ | High SOE 4 studies; 430 subjects Range of $r = 0.77-0.93$ | High SOE 2 studies; 256 subjects Range of $r = 0.86-0.92$ | High SOE 12 studies; 862 subjects Range of ES = 0.84-19.5 |
| CQLQ and ACOS ^a (severity/QoL) | High SOE 6 studies; 360 subjects Range of $r = 0.24-0.79$ | Low SOE 2 studies; 208 subjects Range of $r = 0.63-0.92$ | Low SOE 2 studies; 76 subjects Range of $r = 0.75-0.93$ | Moderate SOE 8 studies; 484 subjects Range of MID = 10.6-21.9 |
| PC-QOL (severity/QoL) | Moderate SOE 4 studies; 593 subjects Range of $r = 0.01-0.70$ | Moderate SOE 3 studies; 247 subjects Range of $r = 0.56-0.91$ | Insufficient SOE 1 study; 43 subjects Range of $r = 0.40-0.51$ | Moderate SOE 4 studies; 519 subjects Range of ES = 0.32-0.41 |
| Electronic recording devices (frequency) | High SOE 23 studies; 774 subjects Range of $r = 0.89-0.99$ | NA | Moderate SOE 6 studies; 239 subjects Range of $r = 0.8-1.0$ | <u>Low SOE</u> 2 studies; 129 subjects Detected change with treatment |
| Visual analog scales (severity/QoL) | Insufficient SOE 13 studies; 638 subjects No summary measure | NA | Insufficient SOE 1 study; 54 subjects Range of $r = 0.71-0.78$ | Moderate SOE 6 studies; 250 subjects Detected change with treatment |

SOE, strength of evidence; ES, effect size; MID, minimal important difference

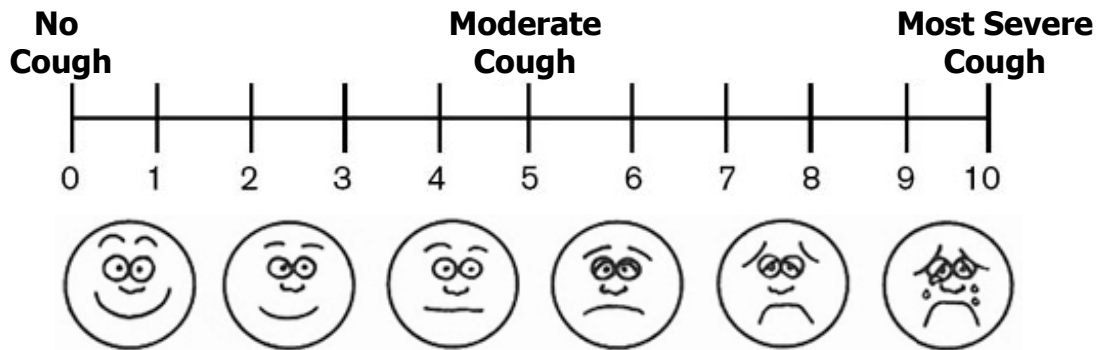
Areas for future research

7. Although QoL questionnaires provide important information in the research setting, **future research** should be directed to **transitioning the use of these questionnaires** in an **appropriate format for the clinical setting.**

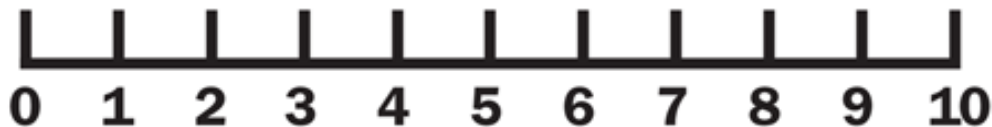
Self-reported cough severity



치료 후 기침이 좋아졌어요...



Numeric Rating Scale 0-10 (11-point scale)



Leicester Cough Questionnaire. © 2001.

This questionnaire is designed to assess the impact of cough on various aspects of your life. Read each question carefully and answer by CIRCLING the response that best applies to you. Please answer ALL questions, as honestly as you can.

1. In the last 2 weeks, have you had chest or stomach pains as a result of your cough?

| | | | | | | |
|-----------------|------------------|------------------------|------------------|----------------------|------------------------|------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | Hardly any of the time | None of the time |

2. In the last 2 weeks, have you been bothered by sputum (phlegm) production when you cough?

| | | | | | | |
|------------|------------|---------------|------------|--------------|--------|-------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Every time | Most times | Several times | Some times | Occasionally | Rarely | Never |

3. In the last 2 weeks, have you been tired because of your cough?

| | | | | | | |
|-----------------|------------------|------------------------|------------------|----------------------|------------------------|------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | Hardly any of the time | None of the time |

4. In the last 2 weeks, have you felt in control of your cough?

| | | | | | | |
|------------------|------------------------|----------------------|------------------|------------------------|------------------|-----------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| None of the time | Hardly any of the time | A little of the time | Some of the time | A good bit of the time | Most of the time | All of the time |

5. How often during the last 2 weeks have you coughed?

| | | | | | | |
|-----------------|------------------|------------------------|------------------|----------------------|------------------------|------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | Hardly any of the time | None of the time |

6. In the last 2 weeks, my cough has made it difficult to breathe

| | | | | | | |
|-----------------|------------------|------------------------|------------------|----------------------|------------------------|------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | Hardly any of the time | None of the time |

7. In the last 2 weeks, my cough has interfered with my job, or other daily tasks

| | | | | | | |
|-----------------|------------------|------------------------|------------------|----------------------|------------------------|------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | Hardly any of the time | None of the time |

8. In the last 2 weeks, I felt that my cough interfered with the overall enjoyment of my life

| | | | | | | |
|-----------------|------------------|------------------------|------------------|----------------------|------------------------|------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | Hardly any of the time | None of the time |

9. In the last 2 weeks, exposure to paints or fumes has made me cough

| | | | | | | |
|-----------------|------------------|------------------------|------------------|----------------------|------------------------|------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | Hardly any of the time | None of the time |

10. In the last 2 weeks, has your cough disturbed your sleep?

| | | | | | | |
|-----------------|------------------|------------------------|------------------|----------------------|------------------------|------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | Hardly any of the time | None of the time |

11. In the last 2 weeks, how many times a day have you had coughing bouts?

| | | | | | | |
|--------------------------------|---------------------------|------------------------------|---------------------------|------------------------------|--------|------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| All of the time (continuously) | Most times during the day | Several times during the day | Some times during the day | Occasionally through the day | Rarely | None |

19문항

Reliability and validity of a Korean version of the Leicester cough questionnaire

레스터 기침 설문 (Leicester cough questionnaire)

이 설문지는 당신 삶의 다양한 측면에 대한 기침의 영향을 평가하기 위한 것입니다. 각 질문을 주의 깊게 읽고 귀하께 가장 잘 해당되는 답을 표시하시기 바랍니다. 가능한 정직하게 모든 질문에 답해 주시기 바랍니다.

1. 지난 2주 동안, 기침으로 인해 가슴통증이나 복통을 느낀 적이 있습니까?

1. 항상 2. 대부분 시간 3. 상당한 시간 4. 때때로 5. 약간 6. 거의 없음. 7. 전혀 없음.

2. 지난 2주 동안, 기침할 때 가래 때문에 불편했습니까?

1. 항상 2. 대부분 3. 여러 번 4. 때때로 5. 드물게 6. 거의 없음 7. 전혀 없음.

3. 지난 2주 동안, 기침 때문에 피곤을 느꼈습니까?

1. 항상 2. 대부분 시간 3. 상당한 시간 4. 때때로 5. 약간 6. 거의 없음. 7. 전혀 없음.

4. 지난 2주 동안, 당신이 기침을 조절할 수 있다고 느꼈습니까?

1. 전혀 안됨 2. 거의 안됨 3. 약간 조절 4. 때때로 조절 5. 상당히 조절 6. 대부분 조절 7. 항상 조절됨

The Cough Quality of Life Questionnaire (CQLQ)

This instrument (The Cough Quality of Life Questionnaire ©2000 by Richard S. Irwin, Cynthia T. French, and Kenneth E. Fletcher; all rights reserved) is protected by copyright.

Instructions for Respondents

Please indicate below how your cough bothers you. Circle the response option that best describes the degree of your agreement concerning each of the following 28 statements.

Please respond to every item

28문항

1. Family and or close friend
2. I have experienced prolonged absences from important activities such as work, school, or volunteer services.
3. I have been completely prevented from engaging in important activities such as work, school, or volunteer services.

Response Options

The response options are as follows: strongly disagree, 1; disagree, 2; agree, 3; strongly agree. 4.

Chronic Cough Impact Questionnaire

The questions below are about areas in your life that might be affected by cough. For each question, check the answer that best describe how your activities, relationships and feelings are being affected by cough in the past 2 weeks (1 = not at all ; 2 = a little ; 3 = enough ; 4 = much; 5 = very much)

20문항

In the past 2 weeks, has your cough affected the following activities?

Work

Physical activities

Spare time

Social life Night sleep

귀하의 만성폐쇄성폐질환 (COPD) 은 어떠십니까? 만성폐쇄성폐 질환 (COPD) 평가 검사 (CAT) 를 해주십시오.

다음 질문들은 귀하와 담당 의료진이 만성폐쇄성폐질환(COPD)이 귀하의 육체적, 정신적 건강 과 일상생활에 미치는 영향을 평가하기 위한 것입니다. 답안과 검사 점수는 만성폐쇄성폐질환 (COPD) 관리를 향상시키고 치료 효과를 최대화하는데 사용될 수 있습니다.

만약 이 질문지를 인쇄하여 종이에 작성하시려면, [여기를 클릭하여 인쇄하십시오.](#)

만약 아래의 각 질문들을 온라인상에서 작성하시려면, 현재 귀하의 건강상태를 가장 잘 표현한 칸을 클릭하여 (✓)표시를 해 주십시오.

예: 나는 매우 행복하다 0 2 3 4 5 나는 매우 슬프다

| | | | 점수 |
|------------------------------|-------------|------------------------------|----------------------|
| 나는 전혀 기침을 하지 않는다 | 0 1 2 3 4 5 | 나는 항상 기침을 한다 | <input type="text"/> |
| 나는 가슴에 전혀 가래가 없다 | 0 1 2 3 4 5 | 나는 가슴에 가래가 가득 차 있다 | <input type="text"/> |
| 나는 전혀 가슴이 답답함을 느끼지 않는다 | 0 1 2 3 4 5 | 나는 가슴이 아주 답답함을 느낀다 | <input type="text"/> |
| 나는 언덕이나 계단을 오를 때 전혀 숨이 차지 않다 | 0 1 2 3 4 5 | 나는 언덕이나 계단을 오를 때 아주 숨이 차다 | <input type="text"/> |
| 나는 집에서 활동하는데 전혀 제약을 받지 않는다 | 0 1 2 3 4 5 | 나는 집에서 활동하는데 많은 제약을 받는다 | <input type="text"/> |
| 폐질환에도 불구하고 나는 외출하는데 자신이 있다 | 0 1 2 3 4 5 | 폐질환으로 인하여 나는 외출하는데 전혀 자신이 없다 | <input type="text"/> |
| 나는 잠을 깊이 잔다 | 0 1 2 3 4 5 | 폐질환으로 인하여 나는 잠을 깊이 자지 못한다 | <input type="text"/> |
| 나는 기운이 왕성하다 | 0 1 2 3 4 5 | 나는 전혀 기운이 없다 | <input type="text"/> |



| | |
|--|--|
| Name of questionnaire | COPD Assessment Test (CAT) |
| Type of questionnaire-description | Patient-completed questionnaire assessing globally the impact of COPD (cough, sputum, dysnea, chest tightness) on health status |
| Number of items | 8 (one question assessing impact on sleep) |
| Scaling of items | 1 to 5 |
| Scoring | Range of CAT scores from 0–40. Higher scores denote a more severe impact of COPD on a patient’s life. The difference between stable and exacerbation patients was five units. No target score represents the best achievable outcome. |
| Test-retest reproducibility | Reported, <u>intra-class correlation coefficient=0.8</u> (P.W. Jones, G. Harding, P. Berry, I. Wiklund, W-H. Chen and N. Kline Leidy. Development and first validation of the COPD Assessment Test. Eur Respir J 2009, 34: 648–654). |
| Internal consistency | Reported Cronbach’s $\alpha=0.88$ (P.W. Jones, G. Harding, P. Berry, I. Wiklund, W-H. Chen and N. Kline Leidy. Development and first validation of the COPD Assessment Test. Eur Respir J 2009, 34: 648–654) |
| Validity | <u>High correlation with SGRQ (r=0.84)</u> across 7 European countries (Jones PW, Brusselle G, Dal Negro RW, Ferrer M, Kardos P, Levy ML, et al. Properties of the COPD assessment test in a cross-sectional European study. European Respiratory Journal. 2011 July 1, 2011;38(1):29-35.) and r=0.8 in US. (P.W. Jones, G. Harding, P. Berry, I. Wiklund, W-H. Chen and N. Kline Leidy. Development and first validation of the COPD Assessment Test. Eur Respir J 2009, 34: 648–654) |
| Minimally important difference | <u>Not determined.</u> Mapping against SGRQ suggests MCID at a group level is 1.6. Experts also suggest that scores <10 have a low impact, 10-20 medium, 21-30 high and >30 very high impact, requiring gradually more interventions (Click Here). |
| Limitations | Clinically important minimal difference remains to be rigorously studied |

COugh Assessment Test, COAT

- 기침 상태 평가를 위한 1차원 도구
- 최소(5~6) 문항의 자기 기입식 간편설문지
- 기침 상태에 대한 점수화된 지표
- 기침 상태의 객관화, 빠르고 정확한 소통





Development and first validation of the COPD Assessment Test

P.W. Jones*, G. Harding[#], P. Berry[†], I. Wiklund[†], W-H. Chen[#] and N. Kline Leidy[#]

ABSTRACT: There is need for a validated short, simple instrument to quantify chronic obstructive pulmonary disease (COPD) impact in routine practice to aid health status assessment and communication between patient and physician. Current health-related quality of life questionnaires provide valid assessment of COPD, but are complex, which limits routine use.

The aim of the present study was to develop a short validated patient-completed questionnaire, the COPD Assessment Test (CAT), assessing the impact of COPD on health status.

21 candidate items identified through qualitative research with COPD patients were used in three prospective international studies (Europe and the USA, n=1,503). Psychometric and Rasch analyses identified eight items fitting a unidimensional model to form the CAT. Items were tested for differential functioning between countries. Internal consistency was excellent: Cronbach's $\alpha=0.88$. Test re-test in stable patients (n=53) was very good (intra-class correlation coefficient 0.8). In the sample from the USA, the correlation with the COPD-specific version of the St George's Respiratory Questionnaire was $r=0.80$. The difference between stable (n=229) and exacerbation patients (n=67) was five units of the 40-point scale (12%; $p<0.0001$).

The CAT is a short, simple questionnaire for assessing and monitoring COPD. It has good measurement properties, is sensitive to differences in state and should provide a valid, reliable and standardised measure of COPD health status with worldwide relevance.

COAT 개발 순서

■ COAT 설문 항목 취합과 선택

■ COAT의 reliability 검증

Test-retest reproducibility (repeatability)

- Intra-class correlation coefficient, paired t-test, Pearson correlation?

Internal consistency: Cronbach's α

계층적 처리를 통한 항목 추리기 작업: age and sex bias, % missing response, floor and ceiling effect, item to total correlation, test of redundancy (inter-item correlation)

■ COAT의 validity, responsiveness 검증

비교지표: Cough NRS, Korean-LCQ

대상환자: 중규모; N=200 (Interim analysis, N=100)

정상 CXR, ACE inhibitor 복용자 제외, 8주 이상의 기침으로 천식, 상기도기침 증후군, 위-식도역류기침, 원인 미상 기침 (idiopathic cough). 다른 질환은 제외. Cough NRS 1-3, 4-6, 7-10 군에 해당하는 환자들을 20%-50%-30% 비율 정해서 (?) 포함시킴 (CAT 개발 중 GOLD stage I~IV 대상자 15%-35%-35%-15% 포함)

■ COAT 개발 완료 후 연구 계획

대규모 환자 대상 validation, MID of COAT 결정 연구

Big data cough registry를 통한 유효한 치료법 발굴

기침 설문(LCQ, CQLQ, CCIQ)에서 다루어지는 설문 항목들

기침연구회 운영위원 병원의 호흡기 의사들로부터 COAT에서 다룰 설문 항목에 대한 의견을 취합하는 이메일 발송시 응답률을 높이기 위한 제시어들

| | |
|--|---|
| <p>I. 신체적 문제 (Physical)</p> <ul style="list-style-type: none">- 기침 때문에 구역, 구토- 신물, 속쓰림- 식욕 감퇴- 두통- 요실금- 대변 실금- 진땀이 난다- 가슴이 아프다- 목소리 변성- 어지러움- 호흡곤란- 피곤함, 지침- (야간) 수면 장애- 기침(cough bout)의 빈도- 가래 | <p>II. 정신적 문제 (Psychological)</p> <ul style="list-style-type: none">- 큰 병일까 걱정됨: 폐결핵, 폐암 등- 건강에 대한 염려- 곤란함, 당황스러움- 불쾌함, 지긋지긋함- 좌절감- 무엇인가에 집중하기 어려움 <p>III. 사회적 문제 (Social)</p> <ul style="list-style-type: none">- 다른 사람들이 기침하는 나를 이상하게 생각할까?- 친구/동료/가족이 불편해함- 사회생활에(직장, 학교 등) 지장 있음- 여가 생활에 지장 있음- 대화, 전화하는데 지장이 있음- (교회에서) 노래하기 불편함 |
|--|---|

COAT 구성 질문 선정

COAT 질문 항목의 조건

- ① 기침 환자에게 흔한 증상이어야 한다.
- ② 남녀노소 모두에게 보편적인 증상이어야 한다.
- ③ 치료에 따른 기침 상태 변화를 반영할 수 있는 질문이어야 한다.

6. 흉통 외 동반 증상
7. 주변 환경에 대한 민감도
8. 대화 장애
9. 건강에 대한 염려

COAT 항목 조건에 의하여 선정된 6개의 카테고리

1. 기침의 빈도
2. 일상 생활 (사회 생활)
3. 수면 장애
4. 기침과 동반된 흉부 통증
5. 체력 저하
6. 주변 환경에 대한 민감도

기침이 얼마나 심하십니까? 기침 평가 검사(COAT)를 해주십시오.

다음 질문들은 기침이 얼마나 심한지 귀하의 육체적, 정신적 건강 상태와, 기침으로 인한 일상생활에 미치는 영향을 평가하기 위한 것입니다. 답안과 검사 점수는 기침 정도 및 상태 변화 평가를 객관화하여 치료효과를 향상시키고자 고안되었습니다. 아래의 각 항목마다 최근 **5일** 간의 귀하의 상태에 해당하는 점수에 체크 표시(**V**)를 해주십시오.

| | | | |
|-----------|--|--------|----|
| 예: 매우 기쁘다 | ① <input checked="" type="radio"/> ② ③ ④ ⑤ | 매우 슬프다 | 점수 |
|-----------|--|--------|----|

| | | | |
|------------------------------------|-----------|--------------------------------------|--|
| 기침이 없다 | ① ② ③ ④ ⑤ | 기침을 하루 종일 한다 | |
| 기침이 없어서 일상생활에 지장이 없다 | ① ② ③ ④ ⑤ | 기침 때문에 일상생활을 할 수 없다 | |
| 기침이 없어서 편하게 잘 수 있다 | ① ② ③ ④ ⑤ | 기침 때문에 잠자기 힘들다 | |
| 기침이 없어서 가슴이 아프지 않다 | ① ② ③ ④ ⑤ | 기침 때문에 가슴이 심하게 아프다 | |
| 기침이 없어서 피곤하지 않다 | ① ② ③ ④ ⑤ | 기침 때문에 많이 피곤하다 | |
| 찬 공기, 먼지 많을 때, 자극성 냄새 나는 곳에서도 편안하다 | ① ② ③ ④ ⑤ | 찬 공기, 먼지 많을 때, 자극성 냄새 나는 곳에서 기침이 심하다 | |

COAT,v1

Test-retest reproducibility (repeatability)

- Chronic cougher
- N=75 (male 44, female 31)
- Age 52.4 ± 17.2 years
- No therapeutic intervention between test and retest

| | ICCC* | Pearson's correlation | Paired t-test |
|-------------------------|----------------|-----------------------|---------------|
| Sum total | 0.939, p<0.001 | r=0.880, p<0.001 | 0.001 |
| Frequency | 0.834, p<0.001 | | |
| Activity | 0.869, p<0.001 | | |
| Sleep | 0.866, p<0.001 | | |
| Pain | 0.904, p<0.001 | | |
| Fatigue | 0.849, p<0.001 | | |
| Hypersensitivity | 0.875, p<0.001 | | |

*Intra-class correlation coefficient; <0.40, poor; 0.40~0.59, fair; .60~0.74, good; 0.75~1.00, excellent

COAT,v1

Item to total correlation of test-1

- Chronic cougher
- N=75 (male 44, female 31)
- Age 52.4 ± 17.2 years

| | Correlation, R |
|-------------------------|-----------------------|
| Frequency | 0.749, p<0.001 |
| Activity | 0.870, p<0.001 |
| Sleep | 0.790, p<0.001 |
| Pain | 0.706, p<0.001 |
| Fatigue | 0.792, p<0.001 |
| Hypersensitivity | 0.679, p<0.001 |

COAT,v1

Inter-item correlation of test-1

- Chronic cougher
- N=75 (male 44, female 31)
- Age 52.4 ± 17.2 years

| | Correlation, R | | Correlation, R |
|---------------------|----------------|-----------------------|----------------|
| Freq-Act | 0.674 | Sleep-Pain | 0.423 |
| Freq-Sleep | 0.602 | Sleep-Fatigue | 0.632 |
| Freq-Pain | 0.387 | Sleep-HySens | 0.389 |
| Freq-Fatigue | 0.404 | Pain-Fatigue | 0.598 |
| Freq-HySens | 0.443 | Pain-HySens | 0.320 |
| Act-Sleep | 0.706 | Fatigue-HySens | 0.463 |
| Act-Pain | 0.574 | | |
| Act-Fatigue | 0.634 | | |
| Act-HySens | 0.449 | | |

If **inter-item correlation** ≥ 0.7 , indicating that the items are similar (**potentially redundant**)

기침이 얼마나 심하십니까? 기침 평가 검사(COAT)를 해주십시오.

다음 질문들은 기침이 얼마나 심한지 귀하의 육체적, 정신적 건강 상태와, 기침으로 인한 일상생활에 미치는 영향을 평가하기 위한 것입니다. 아래의 각 항목마다 최근 **3일** 간의 귀하의 상태에 해당하는 점수에 체크 표시(**V**)를 해주십시오.

| | 없음 | 약함 | 보통 | 심함 | 매우 심함 |
|---------------------------------------|----|----|----|----|----------|
| 기침을 얼마나 자주 하나요? | ① | ② | ③ | ④ | ⑤ |
| 기침 때문에 일상생활에 지장이 있나요? | ① | ② | ③ | ④ | ⑤ |
| 기침 때문에 잠자기 힘든가요? | ① | ② | ③ | ④ | ⑤ |
| 기침 때문에 가슴이 아픈가요? | ① | ② | ③ | ④ | ⑤ |
| 기침 때문에 피곤한가요? | ① | ② | ③ | ④ | ⑤ |
| 먼지 많을 때, 자극성 냄새, 찬공기를 마실 때 기침이 심해지나요? | ① | ② | ③ | ④ | ⑤ |
| 총점 | | | | | 점 |