

Framingham Heart Study

Manual of Procedures

MOP-version 1.0

August 22, 2018

Research Examination Center

Generation 3, Omni 2, NOS Cohorts Examination 3

Section #3 Tech Administered Questionnaires

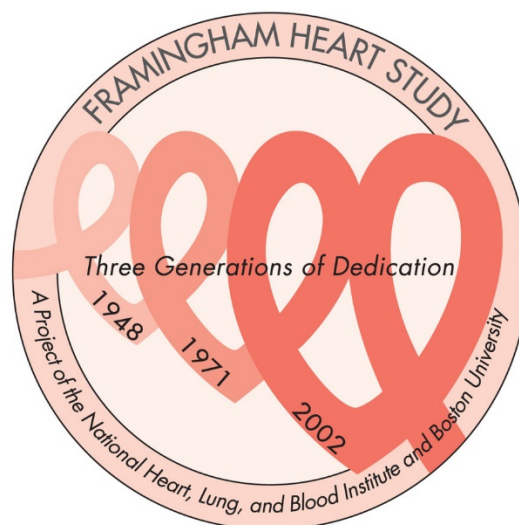


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1.0 CES-D Scale

A. Rationale and Background:

The Center for Epidemiologic Studies Depression Scale (CES-D) was developed for use in epidemiologic research of depressive symptomatology in the general population. It was designed as a screening instrument to elicit symptoms associated with depression. It is intended to document the presence and severity of depressive symptoms but is not intended to make clinical diagnosis. It assesses the current state of the subject by focusing on symptomatology in the past week.

Note: The depression questions used in the NHANES 1 survey were the 20-item set of the CES-D developed and validated by the Center for Epidemiologic Studies, National Institute of Mental Health (NIMH).

The scale is given at each exam. The scale is not given if the patient is: sedated, aphasic, non-English speaking, or uncooperative.

B. Procedure:

1. Each question is read to the participant who responds with one of four answers.
2. Response alternatives should be printed on paper which is placed in front of the participant for reference.
3. Each category of response should be explained to the participant prior to administering the scale.
4. If the participant is unable to read the response sheets, the interviewer should read each response as well as the question referring to their feelings in the past week.
5. Be sure the participant understands that the questions refer to his/her feelings only during the past week.

C. CES-D Scoring:

Each item has a range of four response options which indicated how often the survey examinee had felt that way during the past week:

Response Option

Rarely or none of the time (less than 1 day)

Some or a little of the time (1-2 days)

Occasionally or a moderate amount of the time (3-4 days)

Most or all of the time (5-7 days)

Questionnaire items 4, 8, 12, and 16 were worded in a positive (i.e., nondepressed) direction. The other 16 scale items were worded in a negative direction to elicit depressive symptomatology directly. To score the CES-D, the sense of the four positive questionnaire items was reversed by subtracting their coded value (indicating the response option selected) from 3. Then the coded values for all 20 items were summed into a total score. The range of possible scores was 0-60. The final score is calculated by the computer.

D. Methods:

The CES-D Questionnaire consists of 20 questions. Since it is a scale for depression, it must be completed using responses by the participant, not a proxy.

SCRIPT: *The questions below ask about your feelings. For each of the following statements, please say if you felt that way during the past week.*

1. Hand the response sheet to the participant and explain the response options. The following definitions should be given:

Code

Rarely or none of the time (< one full day)

Some or a little of the time (1 to 2 days in the past week)

Occasionally or moderate amount of time (3 to 4 days in the past week, or about 1/2 the time)

Most of the time (5 to 7 days in the past week)

If participant answers *YES* to a given statement, repeat the above responses to get a correct answer.

2. Read each item as it is written on the form. Preface statements 1, 6 & 11 with the statement *During the past week*, then continuing with the response categories. For example:

SCRIPT: *During the past week I was bothered by things that usually don't bother me. Did you feel that way rarely or none of the time, some or a little of the time, occasionally or moderate amount of time, or most or all of the time?*

Question 1: During the past week I was bothered by things that usually don't bother me.

Question 6: During the past week I felt depressed.

Question 11: During the past week my sleep was restless

****Note: Emphasize to the participant that it is only the past 7 days.****

3. Discontinue reading the responses when the participant provides a response before you are finished. On the next item, however, again begin to read the entire set of responses.
4. Code **9** = *Refused* or *Do not know* is used when:
 - a. The question was asked, but the participant chooses not to answer. For example, response was *I would rather not say*, or *Go on to the next question*.
 - b. The question was asked, but the participant does not know, does not remember, or does not understand the statement.

**** If "unknown" is used more than 4 times on the questionnaire it is no longer considered valid for research. Do your best to have the participant give you an answer listed on the response key.****

5. Press on the response on the form in Redcap.
6. When the participant asks about the meaning of any item or tries to qualify a statement, simply repeat the statement. For example:

Participant: *What do you mean by bothered?*

Interviewer: *I was bothered by things that usually don't bother me. Did you feel that way rarely or none of the time, some or a little of the time,*

occasionally or moderate amount of time, or most or all of the time during the past week?

7. When the participant still asks about the meaning or says he/she does not understand, check **9** = refused or do not know. Do not try to interpret the statement for the participant.

1.1 Training and Certification of Staff

New Staff

- Given Protocol to read, understand, ask questions to Supervisor
- Protocol is demonstrated by Supervisor
- New Staff observes other Techs performing Protocol
- New Staff practices Protocol on staff and volunteers
- New Staff performs Protocol on participant with Supervisor or Certified Tech observing
- When Supervisor feels New Staff is proficient in Protocol, Supervisor will certify New Staff
- Certified New Staff will perform Protocol on own
- Certification date is noted in Certification Log

Recertification of Staff

- Occurs when there is a major deviation on Supervisor Observations or a new study with a new protocol is introduced into the exam
- Protocol is demonstrated by Supervisor
- Staff observes other Techs performing Protocol
- When Supervisor feels Staff is proficient in Protocol, Supervisor will recertify Staff
- Recertification date is noted in Certification Log

1.2 Supervisor Checklist

Date: _____

Tech ID# _____

Supervisor: _____

Participant _____

CES-D Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	CES-D
		SCRIPT: <i>The questions below ask about your feelings. For each of the following statements, please say if you felt that way <u>during the past week</u>.</i>
		Hand the response sheet to the participant and explain the response options. The following definitions should be given: <u>Code</u> Rarely or none of the time (< one full day) Some or a little of the time (1-2 days) Occasionally or moderate amount of time (3-4 days) Most of the time (5-7 days)
		Read each item as it is written on the form, prefacing questions 1, 6 and 11 with the statement <i>During the past week</i> , and then continuing with the response categories.
		Press the response on the form in Redcap
		When the participant asks about the meaning of any item or tries to qualify a statement, simply repeat the statement.
		If the participant is unable to read the response sheets, the interviewer should read each response as well as the question referring to their feelings in the past week.

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?
		Did the technician ask the questions exactly as written on the form?

		Did the technician correctly clarify any questions the participant had?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Signature:		
Date:		

1.3 Handout for CESD

Rarely or none of the time (Less than 1 day)

Some or a little of the time (1-2 days)

Occasionally or moderate amount of time (3-4 days)

Most or all of the time (5-7 days)

2.0 Physical Activity Questionnaire

Rest and Activity for a Typical Day (Tech 16)

1. Explain that the first section is Rest and Activity for a Typical Day (24 hours).
2. The day is broken up into different types of activities and a typical day is considered MOST days of the week.
3. Read through each activity and do NOT clarify.
 - **Sleep**
 - Example: napping during the day and actual night sleep.
 - **Sedentary**
 - Example: sitting in the car, eating meals, TV, computer, etc.
 - **Slight Activity**
 - Example: walking to the car, shopping, standing in line, etc.
 - **Moderate Activity**
 - **Heavy Activity**

Explain that a total number of hours for a typical day must equal 24 hours.

4. This should capture over the past year.
5. Make adjustments according to participant until the total number of hours equals 24.

Time Spent Actually Doing the Activity

Introductory Script:

Now I'll ask you about your Physical Activities. Only include time spent actually doing the activity. For Example, sitting by the pool does not count as time swimming; sitting in a chair lift does not count for skiing.

*First I'll ask about **Vigorous Activities**. Vigorous activities increase your heart rate, or make you sweat doing them, or make you breathe hard, or raise your body temperature. If you do an activity but not vigorously, please include it later when I ask you about other non-strenuous activities.*

In the past 12 months for at least one hour total time in any month did you do the following activities? (example: you may have done three 20 minute sessions in the month).

1. Read through each **Vigorous Activity** question.
 - a. If answered NO, move to next question.
 - b. If answered YES, move below to answer,
 - i. How many months did you do this activity?
 - ii. How many times per month did you do this activity?
 - iii. How long did you do this activity on average each time? (# of Minute)
 - c. If answered UNKNOWN, Click on Unknown

****NOTE: If jogging is done on a treadmill, record under machine. Also, clarify with the participant that vigorous running is outside for question 1.****

Now, I'd like to ask you about more leisurely activities.

2. Read through each **Leisurely Activity** question and code the same as vigorous.
3. Leisurely Activity is less strenuous than Vigorous.
4. For ALL estimates, round up to the nearest whole number.

Now I'm going to ask you some questions about your physical activity during the past year at WORK ONLY

5. Define “do you work” as currently working as of the past year.
6. This does NOT include stay at home mothers, but DOES include paying jobs and volunteer work. Volunteer work should be prompted for if the participant does not offer the information.
7. If YES code the number of hours worked per week.

At work do you...Sit, Stand, or Walk.

8. Circle: **NEVER, SELDOM, SOMETIMES, OFTEN, or ALWAYS.**

My next question is about your Leisure time

In the past week, about how many hours per day did you sit and watch TV or videos?

In the past week, about how many hours per day did you use a computer or play computer games or play video games?

9. Responses: **none or <1 hour**

1 hour

2 hours

3 hours

4 hours

5 or more hours

2.1 Training and Certification of Staff

New Staff

- Given Protocol to read, understand, ask questions to Supervisor
- Protocol is demonstrated by Supervisor
- New Staff observes other Techs performing Protocol
- New Staff practices Protocol on staff and volunteers
- New Staff performs Protocol on participant with Supervisor or Certified Tech observing
- When Supervisor feels New Staff is proficient in Protocol, Supervisor will certify New Staff
- Certified New Staff will perform Protocol on own
- Certification date is noted in Certification Log

Recertification of Staff

- Occurs when there is a major deviation on Supervisor Observations or a new study with a new protocol is introduced into the exam
- Protocol is demonstrated by Supervisor
- Staff observes other Techs performing Protocol
- When Supervisor feels Staff is proficient in Protocol, Supervisor will recertify Staff
- Recertification date is noted in Certification Log

2.2 Supervisor Checklist

Date: _____

Tech ID# _____

Supervisor: _____

Participant _____

Physical Activity Supervisor Checklist

Yes	No	Physical Activity – Part One
		The tech explains that the first section is <u>Rest and Activity for a Typical Day over the past year</u> (24 hours).
		The tech explains that it has to be a whole number and it has to equal 24 hours.
		The tech reads through each activity. <ul style="list-style-type: none"> ▪ Sleep ▪ Sedentary ▪ Slight Activity ▪ Moderate Activity ▪ Heavy Activity
		Examples are given as needed
		Adjustments are made according to the participant until the total number of hours equals 24
		The tech does not coach them or help them fill in the numbers.

Yes	No	Physical Activities – Vigorous (parts 2 and 3)
		<p>SCRIPT: <i>Now I'll ask you about your Physical Activities. Only include the time spent <u>actually doing</u> the activity. For example, sitting by the pool does not count as time swimming; sitting in a chair lift does not count for skiing.</i></p> <p><i>First I'll ask about your vigorous activities. Vigorous activities increase your heart rate, or make you sweat doing them, or make you breathe hard, or raise your body temperature. If you do an activity but not vigorously, please include it later when I ask you about other non-strenuous activities.</i></p> <p><i>In the past 12 months for at least one hour total time in any month did you do the following</i></p>

		<i>activities? For example you may have done three 20 minute sessions in the month.</i>
		Read each item as it is written on the form. Clarify as necessary.
		Click on the response in the RedCap survey
		Physical Activities – non-strenuous (part 4)
		<i>SCRIPT: Now I'd like to ask you about more leisurely activities. In the past 12 months for at least one hour total time in any month did you...</i>
		Read each item as it is written on the form. Clarify as necessary.
		Click on the response in the RedCap survey
		SCRIPT: Now I'm going to ask you some questions about your physical activity during the past year at <u>WORK ONLY</u>
		Read the questions and code responses. Include volunteer work. Do not include stay at home moms.
		SCRIPT: My next question is about your leisure time.
		Read the questions and code responses. <u>Code</u> none or < 1 hour 1 hour 2 hours 3 hours 4 hours 5 or more hours Unknown

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?
		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly use the answer key?
		Did the technician correctly clarify any questions the participant had?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Initials:		
Date:		

3.0 Rosow-Breslau Questionnaire

A. Rationale & Background

Respondents' self-assessments of health may raise questions about the validity of such judgments. However, we are not interested in the literal details of people's medical condition as much as in the behavioral consequences, their physical capacity for role fulfillment and social participation. We are primarily concerned with the *functional* health which old people report, i.e., the degree to which they claim they can manage adequately or are restricted in their activities because of their physical condition or capacity. *Breslau, M, Rosow, I: A Guttman Health Scale for the Aged. 556-559*

B. Methods

The method of assessing physical functioning is **self-report**. The questions assess the degree of difficulty that a person has performing a specific activity. This form has several important purposes:

1. This data will enable us to assess the level of independence and function in the study population.
2. It is hypothesized that impairments of physical function may be a risk factor for cardiovascular end points and progression of disease.
3. It will measure loss of physical functioning as a consequence of cardiovascular disease.

C. Procedures

Questions:

Coding

No, unable to do
Yes, independent
Does not do
Unknown

1. *Are you able to do heavy work around the house, like shovel snow or wash windows, walls, or floors without help? (Scrub floors, wash windows, rake leaves, and mow lawn).*
2. *Are you able to walk half a mile without help? (Walk one half mile or 4-6 blocks without stopping for more than 5 minutes).*
3. *Are you able to walk up and down one flight of stairs without help?*

3.1 Training and Certification of Staff

New Staff

- Given Protocol to read, understand, ask questions to Supervisor
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3.2 Supervisor Checklist

Date: _____

Tech ID# _____

Supervisor: _____

Participant _____

Rosow-Breslau Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	Rosow-Breslau Questions
		Are you able to do heavy work around the house, like shovel snow or wash windows, walls, or floors without help? (Scrub floors, wash windows, rake leaves, mow lawn).
		Are you able to walk half a mile without help? (Walk one half mile or 4-6 blocks without stopping for more than 5 minutes).
		Are you able to walk up and down one flight of stairs without help?

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?
		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly clarify any questions the participant had?
		Did the technician correctly use the answer key?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		

Supervisor Signature:
Date:

4.0 Respiratory Questionnaire

Confidential

Page 2 of 2

If asthma started since your last exam, at what age did it start?

(Age in years, 888 = If asthma started before last exam, 999 = Unknown)

If you no longer have asthma, at what age did it stop?

(Age in years, 888 = Still have it, 999 = Unknown)

Have you received medical treatment for this in the past 12 months?

- No
- Yes
- Unknown

Have you EVER had any of the following conditions diagnosed by a doctor or other health care professional? Chronic Bronchitis

- No
- Yes
- Unknown

Emphysema

- No
- Yes
- Unknown

COPD (Chronic Obstructive Pulmonary Disease)

- No
- Yes
- Unknown

Sleep Apnea

- No
- Yes
- Unknown

Pulmonary Fibrosis

- No
- Yes
- Unknown

Additional Comments

Respiratory Disease

T08 - Respiratory Disease Q

FHS_IDTYPE_ID _____

Name: [lastname], [firstname]

DOB: [dob]

Age: [age] **Last Exam:** [lastexamdate]

Sex: [sex] **Last Medical Health Update:** [lastmhudate]

Respiratory Disease

Age at last exam _____

Form is intentionally left blank

Reason why form was left blank _____

Technician Number

- 19 -
- 556 -
- 701 -
- 718 -
- 725 -
- 778 -
- 788 -
- 794 -
- 857 -
- 865 -
- 866 -
- 867 -
- 868 -
- 869 -
- 870 -
- 871 -
-

Respiratory Diagnoses

Since your last exam ([lastexamdate]), . . .

Have you had asthma?

- No
- Yes
- Unknown

If "Yes"

Do you still have asthma?

- No
- Yes
- Unknown

Was the asthma diagnosed by a doctor or other health care professional?

- No
- Yes
- Unknown

4.1 Supervisor Checklist

Date: _____

Tech ID# _____

Supervisor: _____

Participant _____

Respiratory Questionnaire Supervisor Checklist

Yes	No	Respiratory Questionnaire Questions
		Respiratory questionnaire is administered. Questions are asked exactly as they are listed on the page.

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?
		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly clarify any questions the participant had?
		Did the technician correctly use the answer key?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Signature:		Date: