

## **Attachment 1: CFS Patient Perspective Focus Group Guide**

### **Introduction**

Hi, my name is \_\_\_\_\_, and I work as a contractor for the Centers for Disease Control and Prevention (CDC). The CDC is interested in learning what people with chronic fatigue syndrome or CFS (which is also known as Myalgic Encephalomyelitis (ME) think about the symptoms that they have.

CDC wants to use this information to help develop new CFS educational materials and distribute these materials to improve communication between patients and healthcare professionals.

We are holding discussion groups and telephone interviews with CFS patients and want to talk to people who have been given a CFS diagnosis by a physician. You have been invited to take part in this discussion because you have been given a CFS diagnosis by a physician.

### **How focus group will work**

- Want to keep the discussion informal and relaxed
- Eat, use restroom as you like
- Observers are sitting in another room watching us
- Our discussion is being audio taped
- During the discussion, participants should feel free to ask me or each other questions if something is not clear
- There are no right or wrong answers. We are interested in your discussion of your experience and observations, and these may vary in the room.
- If you think differently with what someone else says, please say so or I'll think that you all agree
- Be careful not to talk all at once; I don't want to miss anything that is said
- My job is to make sure we hear from everyone. Some people talk more than others, and I'll be encouraging everyone to speak up.
- You do not have to answer any specific questions you do not want to answer.
- The discussion we'll have tonight is confidential and should not be discussed after you leave the focus group.

Public reporting burden of this collection of information is estimated to average 120 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D74, Atlanta, Georgia 30333; ATTN: PRA (0920-1026)

- Please turn off your cell phones or pagers or put them on vibrate.

## **Does anyone have any questions?**

## **Have participants introduce themselves**

To start off today, I'd like to ask you to say your first name and briefly to tell everyone a little bit about yourself.

Thanks. We invited you here today because you received a CFS diagnosis from a physician. I'd like to ask you about your CFS symptoms. While we would like to have the time to hear about each person's personal history with CFS, today we want to talk specifically about your symptoms. We just want to get an overall sense of your experience by asking some broad questions, and later we'll dive in more deeply to some of the specifics. We'll only spend about 15 minutes to go through these opening questions before getting more specific.

### 1. What are your CFS symptoms?

#### **Probe:**

- Sore throat
- Chronic pain: in joints, in muscles
- Severe headaches
- Forgetfulness/memory problems or problems with thinking or concentrating
- Unrefreshing sleep, insomnia
- Crash/collapse - fatigue or exhaustion following exertion
- Sensitivity to light, sound
- Severe fatigue, exhaustion, weakness, lack of energy
- Dizziness, losing balance, fainting, light-headedness
- Color changes on skin, hands or feet
- Intolerance of low-impact exercise

### 2. How do your CFS symptoms affect you?

### 3. When in your illness did your symptoms affect you the most?

#### **Probe:**

- Early in your illness (2 years or less)
- Later on in your illness (more than two years)
- Which symptoms

### 4. Have your CFS symptoms changed over time? If so, how?

#### **Probe:**

- Improved
- Worsened
- Developed new symptoms
- Some symptoms gone away

### 5. How would you describe your symptoms to a doctor?

#### **Probe:**

- Worst symptoms
- Why?

### 6. How would you describe your symptoms to a friend or family member?

## Patients' Experience with Cognitive Symptoms (30 minutes)

**MODERATOR TRANSITION:** OK, now let's talk about your experience of how CFS affects your cognition. By "cognition," I mean how symptoms of CFS affect how you concentrate or think about things.

7. What are some of the cognitive symptoms you feel from CFS?

**Probe:**

- Confusion
- Disorientation
- Can't focus
- Can't find right words
- Problems with decision making

8. How would you describe your cognitive symptoms to your doctor?

9. How would you describe your cognitive symptoms to your friends and family?

10. Have you become more forgetful or feel like you are in a fog? If yes, please describe.

11. How do the cognitive symptoms of CFS affect you?

**Probe:**

- Work/Occupation
- Housework (complete tasks under time constraints, etc.)
- Family
- Friends
- Social Life (following or participating in the conversation)
- Bathing
- Preparing food
- Getting dressed
- Housework
- Walking or driving ability

12. Have your cognitive symptoms changed over time? If so, how?

**Probe:**

- Improved
- Worsened
- Gone away
- New symptoms
- Duration
- "Come and go"

13. What are some of the things that make your cognitive symptoms feel better? Worse?

**Probe:**

- Medications
- Activity/exercise
- Sleep

- Alternative medicines
- Self-management

14. Have you seen a physician or other health care provider for your cognitive symptoms? If yes, what kind of health care provider?

**Probe:**

- Internist, family practice doctor
- Psychologist
- Specialist (what kind)
- Alternative medicine provider - chiropractor, acupuncturist
- Physical therapist
- Other

**Patient's Experience with Physical Symptoms**

**MODERATOR TRANSITION:** OK, now let's get more specific and focus on how CFS affects you physically. By physical, I mean how symptoms of CFS affect your physical functioning. You may have mentioned some of these already but it is OK to list them again.

15. What are some of the physical symptoms you feel from CFS?

16. How would you describe your physical symptoms to your doctor?

17. How would you describe your physical symptoms to your friends and family?

18. Have you had to cut down on your physical activity? If so, how?

19. How do the physical symptoms of CFS affect you?

**Probe:**

- Work/Occupation
- Housework
- Family
- Friends
- Social life
- Bathing, showering, getting dressed
- Preparing food, meals
- Walking or driving ability

20. Have any of your physical symptoms changed over time? If so, how?

**Probe:**

- Improved
- Worsened
- Gone away
- New symptoms
- "Come and go"
- Duration

21. What are some of the things that make your physical symptoms feel better? Worse?

**Probe:**

- Medications
- Activity/exercise
- Sleep
- Alternative medicine
- Self-management

22. Have you seen a physician or other health care provider for your physical symptoms? If yes, what kind of health care provider?

**Probe:**

- Internist, family practice doctor
- Specialist (what kind)
- Alternative medicine provider - chiropractor, acupuncturist
- Physical therapist
- Personal trainer
- Other

### **Patients' Experience with Post-Exertional Malaise**

**MODERATOR TRANSITION:** I'd now like to ask you about your experience with how you feel after doing either physical or mental activities.

#### **Scenario 1**

Now I am going to read a scenario and ask you to comment on it.

You have gone to the grocery store to shop for groceries and household goods. After you pay for everything you roll the cart to your car and start to unload the bags. As you climb into the driver's seat, you suddenly "crash" and can barely lift up your arm to insert the keys in the ignition.

23. Have you ever had a similar experience in which your body just "crashes" after doing something physical? If so, can you please describe?

**Probe:**

- Body
- Mind
- Emotions

24. What are some words you would use to describe this feeling of "crashing?"

**Probe:**

- Intolerance
- collapse

25. How do your symptoms from "crashing" affect you for the rest of the day?

**Probe:**

- Length of time – hours, days

26. What strategies do you use to help yourself feel better?

## Scenario 2

Now I am going to read a second scenario and ask you to comment on it.

Your friend has come over to help plan another's friends birthday lunch. As you sit and talk about the guest list and menu, your head starts to hurt and you suddenly feel wiped out. You have trouble following the conversation and feel like you are in a fog.

27. Have you ever had a similar experience in which you "crash" after doing something that takes mental concentration? If so, can you please describe?

### Probe:

- Body
- Mind
- Emotions

28. What are some words you would use to describe this feeling of "being in a fog?"

29. How do your symptoms from "being in a fog" affect you for the rest of the day?

30. What strategies do you use to help yourself feel better?

## Patients' Expectations

**MODERATOR TRANSITION:** We have just a few more questions. I'd like you to now tell me what you expect in terms of CFS treatment and management.

1. When a healthcare provider evaluates you for your CFS, what would you like him or her to ask you? Why?

- If I were to give you a questionnaire today that asks about CFS, what would be most important to ask you?

### Probe:

- Physical
- Cognitive – thinking, concentrating
- PEM – crashing
- Medications

- If I were to give you a questionnaire 6 months from today that asks about CFS, what would be most important to ask you?

### Probe:

- Physical
- Cognitive – thinking, concentrating

- PEM – crashing
- Medications

## **Conclusion**

Do you have any questions for me?

Before you leave, I'd like to ask you to fill out a brief form with information about you.

\*\* Hand out data sheets.

**Thank you for your time and contribution. When you leave, the hostess will give you a copy of your consent form and your token of appreciation.**

# **INFORMED CONSENT FORM FOR CHRONIC FATIGUE SYNDROME INDIVIDUALS IN FOCUS GROUPS**

## Chronic Fatigue Syndrome: Symptoms from the Patient Perspective

### **Introduction**

You are being invited to take part in a focus group. A focus group is a small group discussion among seven to ten people. You have been asked to participate in a one and one-half hour focus group because you have been given a diagnosis of chronic fatigue syndrome (CFS) (also known as Myalgic Encephalomyelitis (ME) by a physician. You are being asked to sign a consent form to participate in the focus group.

This focus group is called *Chronic Fatigue Syndrome: Symptoms from the Patient Perspective*. Each focus group will have up to 10 participants and one moderator, and there will be a total of four focus groups. The Centers for Disease Control and Prevention (CDC) is sponsoring all of the focus groups. Aspen Government Information Solutions, a research company headquartered in Torrance, California, is CDC's contractor to conduct the focus groups.

### **Purpose**

Educators want to learn how CFS patients think about their symptoms and learn how doctors could ask CFS patients about the symptoms they are experiencing. The information will help develop new educational materials for healthcare professionals and guide them in communicating with CFS patients.

### **Procedures**

If you choose to participate, you will be asked to join other people who have CFS in a discussion. A moderator from Aspen will facilitate the group. The discussion will last one and one-half hours.

The focus group will be audiotaped so that we have accurate documentation of your responses. Researchers will use the recordings to describe the experiences of people in the group. A representative from CDC may be in a nearby room observing the discussion via video and audio feeds. The discussion will be confidential. The findings from the discussion will be shared with personnel from CDC so that they can learn about how people with CFS view their symptoms. Your name will not be associated with any comments you make. You may refuse to take part in this focus group. Your refusal will not affect any of your rights or benefits. If you decide to take part in this focus group, you may choose not to answer any question that you don't feel comfortable answering. This will not affect your participation in the group or your rights and benefits.

### **Risks of Taking Part in the Focus Groups**

There are no anticipated physical risks to participants. Focus group members will be asked to keep the information provided in the groups confidential. The researchers will also do everything allowable by law to assure that your privacy is protected. You may feel uncomfortable about some of the questions you are asked. You may choose not to answer any question that you do not want to answer.



## **Costs and Financial Risks**

There are no costs for participating in the focus group.

## **Possible Benefits of Participating in This Focus Groups**

There may not be any direct benefit to you in joining the focus group. However, you may benefit from hearing what others think about CFS.

## **Token of Appreciation for Participation**

You will receive \$50 to help cover travel expenses and parking. You will receive this amount at the end of the focus group session. If you decide to leave the group before the end of the session, you will still receive \$50.

## **Confidentiality**

CDC will treat data in a secure manner and will not disclose, unless otherwise compelled by law. The focus group audio files will be labeled with a study code, not your name. The files will be kept in a locked file in a locked office at the Aspen Group in Torrance, California. The audio files will be transcribed, and Aspen researchers will remove any information that can be linked to an individual. The comments made during the focus group will be used in reports to the government in summary form only. No names will be included in the report.

Personnel from CDC may be present at your focus group session. They will observe the discussion through a one-way glass window. To protect your identity, we will address you by your first name or another name that you prefer. We will also let you know when these observers are present. These observers will not be able to connect your full name to your information without your consent.

## **Participation is Voluntary**

It is up to you to decide about participation in the focus group. If you decide not to participate, you may still take part in other CDC programs and research. If you decide not to participate, you will not be penalized or lose any benefits or rights to which you would otherwise be entitled. Even if you agree to participate, you are not required to answer all the questions you are asked.

## **Questions**

You may phone the Focus Group Co-Director Dana Brimmer, Ph.D., a contractor with the Aspen Group, at (310) 294-9601 to have your questions answered. If you have any questions about your rights as a focus group participant you may call the CDC Human Research Protection Office at (800) 584-8814. You may also call the CDC Principal Investigator, Sally Lin, Ph.D., at (404) 639-1646. Calls to Dr. Brimmer or Dr. Lin may be toll calls.

You may mail a letter to:

Dana Brimmer  
Aspen Government Information Solutions  
24586 Hawthorne Blvd. # 108  
Torrance, CA 90505

## **Statement by Person Agreeing to Participate in This Focus Group**

I have been told about the focus group. I have been allowed to ask questions. I have had all my questions answered fully, and I would like to voluntarily participate in the focus group. By signing this form, I agree to be in the focus group. I have been given a copy of this consent form.

\_\_\_\_\_

Participant Name

\_\_\_\_\_

Participant Signature

\_\_\_\_\_

Date

Month of Birth: \_\_\_\_\_ Year of Birth \_\_\_\_\_

Please indicate your sex.

- Male
- Female

Please indicate your ethnicity.

- Hispanic or Latino
- Non Hispanic or Latino

Please indicate your race.

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

What best describes your marital status?

- Single
- Not Married
- Married
- Living with partner
- Separated
- Divorced
- Widowed

What best describes your employment status?

- Employed full-time
- Employed part-time
- Not employed, but looking for work
- Not employed and not looking for work
- Retired
- Student
- Homemaker

What best describes your level of education?

- Some high school
- High school graduate or equivalent
- Some college
- Bachelor's degree
- Graduate or professional degree

Which one of the following ranges includes your total yearly household income before taxes?

- Under \$20,000
- \$20,000 - \$29,999
- \$30,000 - \$39,999
- \$40,000 - \$49,999
- \$50,000 - \$69,999
- \$70,000 - \$99,999
- \$100,000 - \$149,999

\$150,000 or more

Do you currently receiving unemployment benefits

Yes

No

Do you currently have health insurance?

Yes

No

When were you diagnosed with CFS?

Month \_\_\_\_\_ Year \_\_\_\_\_

When did this illness that you are currently experiencing first begin? (If you cannot remember specific dates, please estimate to the best of your ability)

Month \_\_\_\_\_ Year \_\_\_\_\_

When this illness began, would you say that it came on all of a sudden or slowly over time?

All of sudden

Slowly over time

Not applicable

Don't know

Did your illness start after you experienced any of the following?

(Check one or more and please specify)

An infection illness

An accident

A trip or vacation

An immunization

Surgery

Severe stress

Other

In terms of your health today, would you describe today as a good day (reasonable physical functioning) or a bad day (worsening functioning)?

Good day

Bad day

How quickly would you say your health status changes from good to bad? Please circle.

1-2 days    3-5 days    one week    two weeks    one month    more than a month