

Appendix A

Consent to Participate in a Research Study

Health and Communication

You are being invited to take part in a research study about health and communication. If you take part in this study, you will be one of about 160 people to do so.

The person in charge of this study is Dr. Len Lecci of the University of North Carolina at Wilmington. UNCW graduate student, Alexis Scanlon will be gathering and analyzing the information for the study. There may be other people on the research team assisting at different times during the study.

By doing this study we hope to learn more about the relationship between health risks as well as doctor-patient communication styles.

The research procedures will be conducted at the University of North Carolina at Wilmington. You will need to come to the Social and Behavioral Sciences Building, room 116 once during the study. The visit will take about 1 hour. The total amount of time you will be asked to volunteer for this study is 1 hour.

There are three separate stages within this study. The first stage of this study involves a brief health exam including blood pressure, heart rate and enzyme screenings for susceptibility to meningitis. During the second stage of the study, you will be asked to participate in a computerized task in which you will have the opportunity to choose from different styles of communication that your doctor might use. Third, you will be asked to complete a few questionnaires that ask you about your views about health. To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

Although we have made every effort to minimize this, you may find some of the questions we ask (or some procedures we ask you to do) to be upsetting or stressful. If so, we can tell you about some people who may be able to help you with these feelings.

You will not get any personal benefit from taking part in this study.

If you decide to take part in the study, it should be because you really want to volunteer. There will be no penalty and you will not lose any benefits or rights you would normally have if you choose not to volunteer. You will not be treated differently by anyone if you choose not to participate in the study. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

There are no costs associated with taking part in this study.

You will receive one credit for a class for taking part in this study. If you should have to stop participating before the study is over, you will still receive the credit.

Your information will be combined with information from other people taking part in the study. When we write up the study to share it with other researchers, we will write about the combined information. You will not be identified in these written materials.

This study is anonymous. That means that no one, not even members of the research team, will know that the information you gave came from you.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information or what that information is. ID numbers will be assigned with lists linking names and ID numbers kept in a locked file cabinet.

However, there are some circumstances in which we may have to show your information to other people. We may be required to show information that identifies you to people who need to be sure that we have done the research correctly, such as the UNCW Institutional Review Board.

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. There will be no penalty and no loss of benefits or rights if you stop participating in the study. You will not be treated differently by anyone if you decide to stop participating in the study.

Before you decide whether or not to participate in the study, please ask any questions that come to mind now. Later, if you have questions about the study, you can contact the investigator, Dr. Lecci at 910-962-7262. If you have any questions about your rights as a research participant, contact Dr. Candace Gauthier, Chair of the UNCW Institutional Review Board, at 910-962-3558.

I understand that my participation in this research study is entirely voluntary. I may refuse to participate without penalty or loss of benefits. I may also stop participating at any time without penalty or loss of benefits. I have received a copy of this consent form to take home with me.

Signature of person consenting to take part in the study

Date

Printed name of person consenting to take part in the study

Name of person providing information to the participant

Date

Appendix C

What is Meningitis

Mayo Clinic staff

Overview

Meningitis is an infection and inflammation of the membranes (meninges) and cerebrospinal fluid surrounding your brain and spinal cord. Before current vaccines, most meningitis cases occurred in children younger than 5 years, but the incidence of the disease has increased among young people between the ages of 15 and 24. Older adults also tend to have a higher incidence of meningitis.

The seriousness of the infection and the best treatment depend on the cause of the infection:

Viruses. Most cases of meningitis are caused by viruses. This type of meningitis is called viral meningitis or aseptic meningitis. It usually causes signs and symptoms for up to 10 days before resolving on its own.

Bacteria. Bacterial meningitis is generally much more serious than viral meningitis. Most cases of bacterial meningitis occur when bacteria from an infection in another part of your body travel through your bloodstream to your brain and spinal cord. This type of meningitis can strike suddenly, usually with a high fever, severe headache and vomiting. As the disease progresses, the brain may swell and begin to bleed. This is a medical emergency that can result in disability or death. How well you recover depends on how quickly you receive treatment.

About 700 Americans die of meningitis each year. If you suspect that you or someone in your family has signs or symptoms of meningitis, seek medical care right away. There's no way to tell what kind of meningitis you have without seeing your doctor

<http://www.mayoclinic.com/invoke.cfm?id=DS00118>

Debriefing

The purpose of the study which you have just participated is to investigate the role of illness fear activation in affecting the attentional biases of hypochondriacal and non-hypochondriacal individuals and apply this information to real life situations where patients are seen by doctors giving illness confirming or disconfirming information. Although we know much about the nature of how hypochondriacal and nonhypochondriacal individuals react to medical advice, we do not know which type of health feedback is most readily accepted by each group. We believe that more hypochondriacal people are less likely to desire feedback that does not confirm and illness and thus frequently seek second and third opinions causing a great amount of stress and a substantial cost to the health care system. Through this research we hope to gain a deeper understanding of how doctors and patients communicate with one another. With this invaluable information, the manner in which doctors provide health feedback to their patients who are more hypochondriacal can be modified to produce a more beneficial experience for both parties involved.

In order to make the setting as realistic as possible, we had to activate your illness fears. Depending on what group you were assigned to, you were told that the paper strip would test for an enzyme that could make you more or less susceptible for meningitis. **However, there is no such enzyme related to meningitis, nor any test that exists that would be able to tell if you were more or less susceptible to meningitis.** Your results were made up and had nothing to do with your present state of health. The paper strip that we gave you turned color only because of the glucose from the mouthwash in your saliva – not because of anything related to how susceptible you are to illness. Again, there is no relation to the results of your test and your current state of health. The purpose of the “enzyme test” was to get you thinking about your health so we could test which type of information you were more prone to look at in the following computer test. This provided a realistic situation much like a doctor’s office in which you were concerned about an illness and provided with feedback that would mimic what you might hear from a doctor.

We do ask that you keep the details and procedure related to this study as confidential as possible. To keep yours and all participants’ time and participation in this study valuable, please do not tell anyone what happened during the experiment. Thank you for your participation and cooperation. If you have any questions regarding the study, feel free to ask the research assistant.

Appendix E

Research Assistants' Protocol for Stressed Participants

The experiment you are conducting will most likely cause some participants to feel slightly uncomfortable as they will be receiving some undesirable feedback concerning their health.

Be alert to the participants behavior at all times, especially after giving the health feedback. In the case that a participant is experiencing moderate to severe anxiety at any time during the experiment, the following instructions should be followed in step-order.

1. Talk to the participant. If you feel that the participant is no longer able to continue (or no longer wishes to continue), stop the experiment. Ask them if they are okay and ask them what they are experiencing at the moment. Provide them with the debriefing form and explain that their results are inconsequential. Assure them that the test was not real and that they are not at any more risk than anyone else for meningitis. Ask if they have any questions. Be willing to stay with them long enough for them to calm down.
2. If the participant is still shaken or has questions about their health or the study that you are unqualified to answer, provide them with Dr. Lecci's office and telephone numbers provided below. If Dr. Lecci is in his office during the time you are running the subject, take the person directly to him. He will make the appropriate assessment and provide referrals if necessary.
3. Dr. Lecci will assess the participant, making appropriate referrals to the health center or counseling center when warranted.

Appendix F

STAI

DIRECTIONS: Read each statement and then answer how you FEEL RIGHT NOW. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer that seems to describe how you feel right now. Record your answers on the scantron.

A= almost never
B= sometimes
C=often
D=almost always

1. I feel pleasant.
2. I feel nervous and restless.
3. I feel satisfied with myself.
4. I wish I could be as happy as others seem to be.
5. I feel like a failure.
6. I feel rested.
7. I am "calm, cool and collected."
8. I feel that difficulties are piling up so that I can't overcome them.
9. I worry too much over something that really doesn't matter.
10. I am happy.
11. I have disturbing thoughts.
12. I lack self-confidence.
13. I feel secure.
14. I make decisions easily.
15. I feel inadequate.
16. I am content.
17. Some unimportant thought runs through my mind and bothers me.
18. I take disappointments so keenly that I can't put them out of my mind.
19. I am a steady person.
20. I get in a state of tension or turmoil as I think over my recent concerns and interests.

Please be sure to bubble in your birth date and gender on the scantron.

Appendix G

Whitely

Please answer the following questions using this 5 point scale. Record your answers on the scantron.

- A = not at all
- B = a little
- C = moderately
- D = quite a bit
- E = a great deal

1. Do you often worry about the possibility that you have got a serious illness?
2. Are you bothered by many pains and aches?
3. Do you find that you are often aware of various things happening in your body?
4. Do you worry a lot about your health?
5. Do you often have the symptoms of very serious illnesses?
6. If a disease is brought to your attention (through radio, television, newspapers or someone you know) do you worry about getting it yourself?
7. If you feel ill and someone tells you that you are looking better, do you become annoyed?
8. Do you find that you are bothered by many different symptoms?
9. Is it easy for you to forget about yourself, and think about all sorts of other things?
10. Is it hard for you to believe a doctor when he tells you there is nothing for you to worry about?
11. Do you get the feeling that people are not taking your illness seriously enough?
12. Do you think that you worry about your health more than most people?
13. Do you think there is something seriously wrong with your body?
14. Are you afraid of illness?

Appendix H

SAMPI

Please answer the next five questions using the following scale. Again, record your answers on the scantron.

- A = not at all
- B = a little
- C = moderately
- D = quite a bit
- E = extremely

1. I can't stand smoke, smog or pollutants in the air.
2. I am often aware of various things happening within my body.
3. When I bruise myself, it stays noticeable for a long time.
4. I sometimes can feel the blood flowing in my body.
5. Sudden loud noises really bother me.
6. I can sometimes hear my pulse or my heartbeat throbbing in my ear.
7. I hate to be too hot or too cold.
8. I am quick to sense the hunger contractions in my stomach.
9. Even something minor, like an insect bite or a splinter really bothers me.
10. I can't stand pain.

Appendix I

IC

Ever been diagnosed? Please indicate whether you or someone close to you has ever been diagnosed by a physician for any of the following conditions by recording your answers on the scantron. Use the following scale:

A- yes

B- no

1. heart disease
2. asthma
3. chronic pulmonary or lung disease
4. cancer
5. arthritis
6. hepatitis
7. hepatitis
8. jaundice
9. flu
10. allergies
11. meningitis
12. migraine headaches
13. diabetes
14. mononucleosis
15. strep throat
16. pneumonia

Research Assistant Directions

1) **Arrive at least 15 minutes before participant is scheduled.** Be sure that all materials in the lab are arranged (directions, forms, apparatus) ahead of time. Please wear the white lab coats and the stethoscope. Set up the computer screen and enter in the person's subject number where it asks for ID. Open up the windows for doctor A and doctor B, close the section that keeps track of the questions answered in each window, position the windows so that the question number is behind the index card paper taped to the screen, and position doctor A on the right hand side for all even numbered subjects (doctor A should be on the left for odd numbered trials – we'll switch this once we reach the 81st subject). Paper cups should be labeled cup 1 (marked with line) and cup 2 (not marked). Wait for participant to arrive, greet and bring into room 113 c.

2) **“Hi, my name is (_____), and I am conducting the research for Alexis Scanlon and Dr. Lecci today. Have you been in an experiment concerning meningitis this year?”**

If yes, terminate experiment. They'll have to sign up for something else to get credit.

3) **Give participant “Consent to Participate in Research Study” form.** Ask participant to carefully read the form and let you know when they are finished. Ask if they have any questions. If not, ask participant to sign and print their name on the second page of the consent form. Research assistant signs and dates last line.

4) **Give participant “Medical Information Release/ Request – UNCW students” form.** Ask participant to carefully read the form and let you know when they are finished. Be prepared to answer any questions about who will see what information. Have them fill out information and sign this form.

5) **Give the participant the IC Questionnaire form. Make sure to record their ID number at the top.** This form asks if they or anyone close to them (such as family or a close friend) has ever had meningitis. If they mark yes for meningitis (number 11), let them know that the study involves meningitis and ask them if that is okay. If not, let them go. If they still want to participate, ask them to elaborate on their experience with meningitis on the back of the questionnaire.

If the person decides to participate despite their meningitis experience, note that you will need to pay particular attention to the person's level of discomfort / anxiety at all times, especially if they are in the experimental condition. Refer to the attached protocol for specific procedures (“Protocol for Stressed Participants”) to follow in the case in which participant becomes overly distressed and can no longer participate in the study.

6) **“Okay, let’s begin. The first part of the study will involve a brief health screening and an enzyme test that assesses your susceptibility to meningitis. Now, I am going to take your blood pressure and heart rate. While I’m doing this, please read the following information about meningitis and the enzyme test you will be taking later in the study.”**

Give participant “What is meningitis” paper AND the appropriate “Enzyme PKR” paper to participant. (Take these papers back from them when they are done).

Note: You will be told ahead of time which condition your participant is in. “Enzyme PKR information” is labeled on the top left corner H-1 for health protection condition and H-2 for the illness fear induction condition. It is very important that you give the correct paper according to the condition.

7) **Record blood pressure and heart rate.** DO NOT OFFER ANY POSITIVE OR NEGATIVE FEEDBACK to participant about results of bp and heart rate. If they ask what it is or if it’s okay, just say “fine.” **Don’t say that it’s “good” or “bad”.**

8) **“Next you will be self-administering the enzyme test. Do you have any questions about the directions that you have just read?”**

Answer any questions about the procedure by referring directly to the sheet that they have been given. Only repeat what has already been written. If asked other questions about it that you are unsure how to answer, just tell them that you are a research assistant and not affiliated with what the study means.

9) **Give the participant the materials that they will need.** Administer two cups, marked cup 1 and cup 2 ahead of time. Also give them the bottle of mouthwash, but not the testing strip just yet. Have them fill cup 1 with mouthwash up to the dark line. They will rinse with the mouthwash and spit it back into the cup and dispose of it immediately. Next, they will spit into cup 2.

10) You will **give them the enzyme testing strip and they will put it into cup 2.** You will wait one minute, or until the strip turns yellow-green. (It will always turn yellow-green). They throw all of their cups / strips out.

11) **“The strip has turned yellow-green. As indicated by your information sheet, this indicates that....”**

*Now, according to what condition they are in, read ONE of the following:

H-1: “...your test results are positive for the presence of the enzyme PKR. You are therefore less susceptible to meningitis than others who do not have the enzyme present in their body.”

Or...

H-2: “...your test results are positive for the presence of the enzyme PKR. You are therefore more susceptible to meningitis than others who do not have the enzyme present in their body.”

*Again, give them NO further feedback besides this. You are a research assistant and unable to provide them with any more information than has been provided to you. **The exception would be of course if they ask whether or not this means they have meningitis, in which case your answer would be a firm “no”!** We do not want to have people thinking that they actually have meningitis. This would be the time to pay particular attention to people’s reactions and refer to the “Protocol for Stressed Participants” protocol in the case that they show signs of being overly upset.*

12) Record their information on the *Health Overview* sheet and give it to them.

13) **“We will now proceed to the next part of our experiment. We are interested in styles of communicating with one’s doctor. In the following computer task you will have the opportunity to choose from different styles of communication that your doctor might use.”** Have them take a seat next to you at the computer screen (already turned on and ready)

See Directions for Computer task.

14) **“You will be presented with information from two doctors during this computer task, doctor A and doctor B. Click on the appropriate doctor to view that doctor’s information. For the first four trials, you will view information from only (Doctor A / Doctor B depending on condition) and rate that doctor’s information. There are two ratings – please make sure to do both and then save your answer.**

(Show them where the two ratings are on the screen and where they save their answer on the bottom).

For the second four trials you will view information from only (Doctor A / Doctor B depending on condition) and rate and save that information. I will tell you when to stop.

15) **Now, you may chose information from either doctor. I will let you know when the task has ended. Let me know when you are finished. This task is not timed. Go ahead and begin.”**

16) Sit unobtrusively until the participant tells you they are done. Perhaps get questionnaire packet and scantron ready to go. Keep count of their questions as you will have to tell them when they have selected a total of 28 items (i.e., 20 more after the initial 8 - 4 from each doctor). Be sure to click on the finish key when the subject has completed all 20 items.

- 17) **“That part of the experiment is now over. For the third and last part of this experiment, I will be asking you to fill out a few questionnaires that ask you about your views about health. Also included are some questions about the study. Let me know when you have finished.”**
- 18) **Fill out a credit slip** for the person while they are doing the questionnaire. Make sure the information on the computer has been saved.
- 19) (When they have finished)... **Thank them for taking part of the experiment. Give them a debriefing form** and ask that they read over it thoroughly, but not take it with them. Ask if they have any questions about the study (if there are any that you can't answer, direct them to the contact numbers at the bottom). Provide them with course credit slip. Reiterate the importance of their not telling anyone about the study. Thank them again.