Information about Being in a Research Study
Clemson University

A Virtual Experimenter as a Means to Overcome Biases in Psychosomatic Research

Description of the Study and Your Part in It
Drs. Eric Muth and Bjoern Horing are inviting you to take part in a research study. Dr. Muth is a Professor of Psychology at Clemson University. Dr. Horing is a post-doctoral student at Clemson University, running this study with the help of Dr. Muth. The purpose of this research is to examine if a virtual experimenter (a computer generated version of a human experimenter) can be used to standardize the delivery of treatments and instructions in clinical trials.

Your part in the study will be to:
1) Complete a series of questionnaires describing yourself and asking about your mood, personality, attitudes and experiences.
2) Have your heart rate monitored by placing patches near your collar bone and on the right and left sides of your chest.
3) Have your blood pressure taken by placing an inflatable cuff around your arm.
4) Complete a hot water pain test in which you are asked to put your hand into a hot water bath that is similar in temperature to the hottest water that comes out of your tap at home. If at any time the heat is too painful, you may withdraw your hand from the water. You will complete two familiarization trials where you simply put your hand in and out of the water. Then you will be asked to place your hand in the water bath for a maximum of 1 min, out for 30 seconds, back in for 1 min, etc., for a maximum time in the water of 5 minutes. If at any time you feel you cannot continue with the next cycle of putting your hand in the hot water, you are free to stop the hot water test.
5) Continually rate your pain experience during the hot water test.
6) Interact with a virtual experimenter (a computer generated version of an experimenter) who will deliver the treatment to you. This interaction will be video recorded to monitor your responses.
7) Take either a proven pain medication (acetaminophen, an analgesic found in Tylenol, which is an over-the-counter medication) or a placebo (an inactive substance).
8) Complete the hot water test a second time after receiving the treatment.
9) Complete a post experiment interview.

It will take you about 2 hours to be in this study.

Risks and Discomforts
There is a small risk that you may develop a skin irritation due to the abrasive gel used during preparation for heart rate recordings, the gel in the patches or the patches themselves. We reduce this risk by giving you an alcohol pad to clean your skin after the study.

There is a risk of experiencing injury during the hot water pain test. We reduce this risk by keeping the water temperature below the temperature of the hot water that typically comes from
a household tap. We further reduce this risk by limiting your exposure to the hot water and instructing you to remove your hand if the heat becomes too painful. Finally, we reduce this risk by asking you not to participate if you have had previous injuries or surgeries to the hand you will immerse in water or if you have arthritis in that hand or have a circulatory problem or diabetes.

The drug usually have no side effects in the dosage employed in this experiment. However, in rare cases, the following side effects can occur:

- upset stomach, mild heartburn or stomach pain
- skin itching or rash.

In very rare cases, an allergic reaction can occur, possibly including

- rash
- itching/swelling (especially of the face/tongue/throat)
- severe dizziness
- trouble breathing.

We will monitor any of these effects throughout the experiment and will remind you to indicate if you notice any unusual reaction.

**Possible Benefits**

There are no direct benefits to you for participating in this study. However, the results from this study may benefit the design of future clinical studies. Tests of new treatments are difficult because they involve multiple clinical sites and investigators. These sites and investigators can inadvertently influence the results, e.g., a doctor or hospital with a good reputation might produce better results than a doctor or hospital with a bad reputation. A virtual experimenter has the potential to standardize the delivery of instructions in clinical trials in order to improve the testing of future treatments by making the test independent of experimenter and test site characteristics.

**Incentives**

You may be compensated with extra credit in one of your psychology classes and/or $20 for participating.

In the case of the extra credit in your psychology classes, instructors of psychology classes may allow you to participate in research conducted by psychology faculty and students. In some classes (particularly PSYCH 201), you can use participation in the subject pool as one of several possible ways to complete a “Research Experience” requirement for the class, or as one of several possible ways to receive extra credit for the class. In other classes that do not require a research experience, you may still sign up to participate in research as one of several possible ways to obtain extra credit in the classes.

**Protection of Privacy and Confidentiality**

We will do everything we can to protect your privacy and confidentiality. We will not tell anyone outside of the research team that you were in this study or what information we collected about you in particular. The video recorded during the interaction with the virtual experimenter...
will be deleted after transcription and analysis. Visual or audio recording will not be used in any other way, either in full or as an excerpt.

We might be required to share the information we collect from you with the Clemson University Office of Research Compliance and the federal Office for Human Research Protections. If this happens, the information would only be used to find out if we ran this study properly and protected your rights in the study.

**Choosing to Be in the Study**
You do not have to be in this study. You may choose not to take part and you may choose to stop taking part at any time. You will not be punished in any way if you decide not to be in the study or to stop taking part in the study. If you decide not to take part or to stop taking part in this study, it will not affect your grade in any way.

If you choose to stop taking part in this study, the information you have already provided will be used in a confidential manner or destroyed upon your request.

**Contact Information**
If you have any questions or concerns about this study or if any problems arise, please contact Dr. Eric Muth at Clemson University at 864-656-6741.

If you have any questions or concerns about your rights in this research study, please contact the Clemson University Office of Research Compliance (ORC) at 864-656-6460 or irb@clemson.edu. If you are outside of the Upstate South Carolina area, please use the ORC’s toll-free number, 866-297-3071.

**Consent**

I have read this form and have been allowed to ask any questions I might have. I agree to take part in this study. Further I give my permission for the investigators to make the online screening questionnaires, completed as part of my entry to this study, a permanent part of my data set to be analyzed along with the data collected from me today.

Participant’s signature: ___________________________ Date: ___________________________

A copy of this form will be given to you.