Would you like to take part in a research study?

Participants needed for a study about detecting anxiety non-invasively

**GOAL OF RESEARCH**

We all regularly have to face situations that trigger various emotional responses. For certain people however, many situations and/or stimuli can trigger strong feelings of anxiety that greatly affect their quality of life. Moreover, anxiety management on a daily basis requires constant effort on the individual’s part. Questionnaires and anxiety scales can help with the diagnosis of anxiety disorders, but they are not practical in real life to monitor anxiety/stress levels throughout the day. There is therefore an advantage to build an affordable, automated, lightweight wearable device that uses physiological signals like heat rate and respiration, and that can monitor anxiety and stress levels in the clinic, and ultimately at home.

Studying anxiety in a lab setting can be challenging. One method used to study emotional responses in participants of all ages is to show videos that can cause stress/fear/anxiety. The purpose of this study is to investigate the feasibility of using ECG and respiration signals to effectively detect anxiety/stress and monitor its progress.

If you volunteer as a participant in this study, you will be asked to fill in two questionnaires, and watch different media (movie clips, audio, texts) that can cause certain levels of anxiety, fear, sadness or happiness while two non-invasive sensors are placed on your hands/arms and chest. Certain clips contain material that can be disturbing to certain viewers. The session will take up to 1 hour and you will be seated during the experiment. The final decision about participation is yours and you can withdraw at any time.

**PARTICIPATION CRITERIA**

We invite you to take part in this study if you:
- Are 19 years of age or older
- You speak English fluently
- Have not been diagnosed with hypertension
- Have not been diagnosed with arrhythmia
- Have no allergies, asthma, or other breathing problems

If you are interested in taking part in this study, please contact Dr Mohamed Elgendi in the Menrva Research Group by email at moe.elgendi@gmail.com or 604-600-4139 for more details.
Information and Consent Form  Menrva

**Study Title:** Detection of anxiety using non-invasive biosignals

**Conducted by:**
Carlo Menon, PhD, Professor (Principal Investigator)
Mohamed Elgendi, PhD, Postdoc (Project Lead)

**Purpose:**
We all regularly have to face situations that trigger various emotional responses. For certain people however, many situations and/or stimuli can trigger strong feelings of anxiety that greatly affect their quality of life. Moreover, anxiety management on a daily basis requires constant effort on the individual’s part. Questionnaires and anxiety scales can help with the diagnosis of anxiety disorders, but they are not practical in real life to monitor anxiety/stress levels throughout the day. There is therefore an advantage to build an affordable, automated, lightweight wearable device that uses physiological signals like heat rate and respiration, and that can monitor anxiety and stress levels in the clinic, and ultimately at home.

Studying anxiety in a lab setting can be challenging. One method used to study emotional responses in participants of all ages is to show videos that can cause stress/fear/anxiety. The purpose of this study is to investigate the feasibility of using ECG and respiration signals to effectively detect anxiety/stress and monitor its progress.

**Description of Protocol:**
If you volunteer as a participant in this study, you will be asked to fill in two questionnaires (Beck Anxiety Inventory and Hamilton Anxiety Rating Scale), and watch different media (movie clips, audio, texts) while two non-invasive sensors are placed on your hands/arms and chest. The media can induce certain levels of anxiety, fear, sadness or happiness, and certain movie clips contain material that can be disturbing to certain viewers. You will be able to stop the projection at any time during the data collection process if you find the content disturbing or feel uncomfortable watching. The session will take up to 1 hour and you will be seated during the experiment. The final decision about participation is yours and you can withdraw at any time.

**Video/Photograph of Experiment:**
As part of this experiment we may want to take videos or photographs of how you perform tasks. These videos/photographs will be used as a record of the session and will assist if the data shows anomalies. We will try not to capture your face in these videos/photographs. Only the principal investigator and those directly involved in the study will have access to the original videos/photographs. These files will be identified with a participant code to keep your identity anonymous and stored on a password protected computer hard-drives in the Menrva lab and on a secured server on the Simon Fraser University Faculty of Applied Science network. All coded video and photo data will be stored for a minimum of 5 years after completion of this study.

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Sometimes a certain sequence of video or a photograph clearly shows a particular feature or detail that would be helpful in teaching or when presenting the study results at a scientific presentation or in a publication. Regardless, the individuals who see the videos/photographs will not be told your name and any identifiable feature will be blocked or blurred before the video/photograph is presented. You can later decide not to let other people see the videos/photographs by telling one of the investigators and the videos/photographs will not be shown to anyone other than those individuals directly involved in the study. You can still participate in this study even if you choose to restrict viewing of the videos/photographs to only persons directly involved in this study.

Please read the following statements clearly and check one of the boxes in each case.

I agree to allow videos/photographs to be taken of my participation in this experiment for study purposes as described above with the understanding that my facial and/or other identifiable features will be blocked:

Yes ☐  No ☐

I agree to allow videos/photographs in which I appear to be used in teaching, scientific presentations and/or publications with the understanding that I will not be identified by name and that my facial and/or other identifiable features will be blocked:

Yes ☐  No ☐

**Benefits:**

There are no direct benefits to you by participating in this study. However, the information collected may assist with the design of a portable, automated stress and anxiety detection tool.

**Participant Risk:**

The sensors used to collect the two biosignals are non-invasive. The ECG sensor will be placed on the hands or arms, while the respiration sensor will placed above your clothing on the chest.

The research team is not in a position to diagnose anxiety disorders. There is a risk that some individuals prone to anxiety may feel certain levels of anxiety in response to the stimuli during the session. If you feel like you cannot continue with the protocol, the experimenter will terminate the session without prejudice or consequences to you.

In the unlikely event of an anxiety attack, the protocol will be terminated and the experimenter will ensure your safety. You will be allowed to remain in the testing area for as long as you need. Should the attack escalate or persist for more than 10 minutes, Campus
Security will be called to provide proper care.

Incidental Findings
We are not in a position to diagnose any heart conditions. Should the ECG detect abnormal heart rate activity, you will be informed and we will suggest that you consult your physician if you are concerned.

Data Security:
To maintain your confidentiality, a participant code will be affiliated with your data. The name/code relationship will only be known and available to the principal investigator and those directly involved in the study and will be stored in a secured cabinet separate from other data. Experimental data will be stored on password protected computer hard-drives in the Menrva lab and on a secured server on the Simon Fraser University Faculty of Applied Science network. All experimental data will be stored for a minimum of 5 years after the completion of this study. Anonymized data may be uploaded to an online repository after the completion of the study. This means that other researchers might have access to the data for future use. Your confidentiality will be maintained.

Time Commitment
Your participation in this study will require a time commitment of up to 1 hour.

Remuneration
You will NOT receive payment or compensation for your participation.

Do I Have to Be Part of this Study?
It is up to you to decide if you want to be part of this study. You are under no obligation to be part of this study. You should take time to review the information presented to you before deciding whether you wish to participate. If you are a student, your decision on whether to participate will not influence your grades in any coursework.

Who Should Not Be Part Of This Study?
You should not be part of this study if one or more of the following applies. You
- Are less than 19 years of age (participants need to be legally considered adults)
- Do not speak English fluently (participants need to understand consent form and instructions to participate)
- Are diagnosed with hypertension (this can affect baseline recordings of signals and skew results)
- Are diagnosed with arrhythmia (this can affect baseline recordings of signals and skew results)
- Have allergies, asthma, or other breathing problems (this can affect baseline recordings of signals and skew results)
- Have been diagnosed with a severe anxiety disorder with regular panic attacks (we do not want to exacerbate a known serious condition that could impact the health of the participant)
Withdrawal from this Study:
You may withdraw from the study at any time, without prejudice, and if you are a student, without adverse effect on your grades in any coursework, by notifying one of the investigators conducting the experiment of your decision. You do not need to give a reason for withdrawing from the study. If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be destroyed.

Dissemination of results:
The results of this study may be published in journal articles and presented at research conferences. For the purpose of publication, some journals require the data to be uploaded to a designated server. You agree that anonymized information collected during this study could be made available in that capacity.

Permission to re-contact:
It is possible that you may be eligible to participate in other studies within the Menrva laboratory. If you would like to give the team permission to re-contact you for future studies, please check the appropriate box:

Yes ☐  No ☐

If you check yes, the team will keep your contact information for that purpose. This information will be secured and kept separate from the data collected during the study.

Contact About My Involvement in the Study:
This study has been reviewed by, and has received clearance through, the Office of Research Ethics. In the event that you have any comments or concerns resulting from your participation in this study, please contact the Director, Office of Research Ethics, Dr. Jeffrey Toward at jtoward@sfu.ca or 778-782-6593. For questions and/or results pertaining to the study, you may contact Dr. Carlo Menon at cmenon@sfu.ca or 778-782-6860.

Consent of Participant:
I have read the information presented above regarding the procedures, commitments and risks involved in volunteering for this study and have received satisfactory answers to any related questions I had. The specific details of this experiment have been explained. I may withdraw from the study at any time, without consequences by notifying the investigators of my decision. With full knowledge of all foregoing, I agree, of my own free will to be a participant in this study.

_________________________________________  ___________________________
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Participant Name (Print)  

______________________________  
Signature of Participant  

______________________________  
Date  

--- Anonymized information: the information is irrevocably stripped of direct identifiers and risk of re-identification of individuals is low or very low. ---