Application for ethical approval at DTU Compute's Institutional Review Board

Project title:

Analysis of emotions using physiological signals: a pilot study

Principal investigator:

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Date: September 19, 2022

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1 Project background, objectives and hypotheses

1.1 Background

The body's response to stress is controlled by the autonomic nervous system (ANS), which has two interacting parts: the sympathetic and the parasympathetic nervous system. The sympathetic nervous system prepares the body to deal with threat by increasing respiration, heart rate, blood pressure, and sweat secretion - characteristics of high arousal. The parasympathetic nervous system has opposing effects, slowing breathing and lowering heart rate - characteristic of low arousal. The level of flexibility in switching between high and low arousal depends on how quickly the ANS can change heart rate and is the physiological basis of emotion regulation. Physiological measures such as pulse or heart rate and electrodermal activity capture arousal levels, where as heart rate variability is a measure of emotion regulation [1].

Previous studies have demonstrated that experimenter induced stress leads to increased electrodermal activity and heart rate compared with resting conditions [2] [3]. Increased heart rate and skin conductance level, response rate and response magnitude are also associated with negative emotions such as sadness and fear [4]. One study was able to discriminate between fear, sadness, anger, contentment, and amusement using skin conductance and heart rate patterns on dimensions of activation and approach/withdrawal [5].

1.2 Objective

The goal of this project is to study the relationships between measures of physiological arousal (electrodermal activity (EDA), blood volume pulse (BVP), accelerometer (ACC) and skin temperature) and stress and specific emotions.

In our NNF funded research project WristAngel, we will use (some of) these physiological measurements from the Empatica E4 wristband to detect distress and emotion in children with obsessive compulsive disorder (OCD). This pilot study aims to setup a baseline for pre- and post-processing of biosignals as stress and emotion indicators, which will enable us to write a more detailed statistical analysis plan for WristAngel.

Furthermore, the collected data will be meaningful to use in DTU's 02445 course, statistical evaluation of AI. Therefore, we intend to make a project in this course with a pseudo-anonymized version of the data.

1.3 Hypothesis

We hypothesize that changes in the acquired physiological signals, i.e., EDA, BVP, temperature and their derived features are correlated to the changes in the emotional state (e.g., experimenter induced frustration, self-reported emotion). The null-hypotheses include:

- 1. There is no difference in physiological signals among resting, stress and recovery conditions.
- 2. The physiological signals cannot discriminate among dimensions of emotions (activation and approach/withdrawal).
- 3. The physiological signals cannot discriminate among specific emotions.

2 Study methods

2.1 Experimental design, measurement and post-processing

Experimental design: Resting condition: Before and after the stress-inducing task participants will be asked to find a comfortable sitting position and sit quietly for 5 minutes.

Stress/frustration condition: Participants are divided in multiple teams of 2 and compete in a puzzle competition. Four teams will be competing in an alternating fashion while the remaining teams will be in either the post- or pre-task resting phase. The competition consists of 4 rounds and is in total 72 minutes. The task of the competition is to solve as many Tangram puzzles as possible in total during the 4 rounds. The task is designed to be difficult. A solved puzzle yields 1 point and the team with the most points at the end of the competition wins. A round consists of 1+3 phases: wristband calibration (1 minute), pre-task resting (5 minutes), task solving (5 minutes), post-task resting (5 minutes). 60 seconds at the end of the pre-task and task phases are reserved to answer the emotion evaluation questionnaire.

A team is handed a 7-piece tangram puzzle and a set of sketches of various puzzles. The participants of the teams have one role each: an instructor and a puzzle-solver. The puzzle-solver is the only one who is allowed to touch and assemble the puzzle pieces. The instructor is the only one who is allowed to look at the puzzle solutions. As a team you help each other to solve the puzzles. You may at any point skip a puzzle and choose another one to solve. You may switch your team roles throughout the competition.

The order of puzzle-sketches are the same before hand-out such that all teams has puzzle-sketches in the same order.

For each round, at the end of the pre-task and task phases, participants will be asked to rate their feelings of a variety of emotions and how difficult it was for them to solve the task using the following questionnaire:

- 1. On a scale from 0-10, where 0 is not frustrated at all and 10 is extremely frustrated, how frustrated are you feeling right now?
- 2. On a scale from 0-10, where 0 is not upset at all and 10 is extremely upset, how upset are you feeling right now?
- 3. On a scale from 0-10, where 0 is not hostile at all and 10 is extremely hostile, how hostile are you feeling right now?
- 4. On a scale from 0-10, where 0 is not alert at all and 10 is extremely alert, how alert are you feeling right now?
- 5. On a scale from 0-10, where 0 is not ashamed at all and 10 is extremely ashamed, how ashamed are you feeling right now?
- 6. On a scale from 0-10, where 0 is not inspired at all and 10 is extremely inspired, how inspired are you feeling right now?
- 7. On a scale from 0-10, where 0 is not nervous at all and 10 is extremely nervous, how nervous are you feeling right now?
- 8. On a scale from 0-10, where 0 is not determined at all and 10 is extremely determined, how determined are you feeling right now?

- 9. On a scale from 0-10, where 0 is not attentive at all and 10 is extremely attentive, how attentive are you feeling right now?
- 10. On a scale from 0-10, where 0 is not afraid at all and 10 is extremely afraid, how afraid are you feeling right now?
- 11. On a scale from 0-10, where 0 is not active at all and 10 is extremely active, how active are you feeling right now?
- 12. (Only asked in the task phase) On a scale from 0-10, where 0 is not difficult at all and 10 is extremely difficult, how difficult did you find the task?

Measurement: The participants will be fitted with an Empatica E4 wristband on their non-dominant wrist. Each wristband will be associated with one participant and will be assigned a common ID.

The measurements will be extracted from the wristband via the E4 Manager application on a PC/Mac at the end of the experiment and stored on a secure drive.

Post-processing: Post experiment, a variety of features will be derived from the physiological signals (e.g. heart rate variability from BVP) using an appropriate software.

2.2 Tasks

The primary goal of the study is to design data processing pipelines to process physiological data collected with the Empatica E4 wristband and to test and develop models to detect the influence of frustration on the acquired physiological signals. The overall goal can be subdivided into the following tasks:

- 1. *Pre-processing:* This step involves the removal of acquisition- and sensor-noise removal from the biosignals, and evaluating the suitability of the obtained signals for further processing.
- 2. Influence of task-induced emotions on biosignals: How strong is the influence of changes in emotional state (if any) on the biosignals. Furthermore, we investigate the sensitivity of each biosignal to the emotional-state changes.
- 3. Tracking changes in the biosignals: Granular analysis of the biosignals to detect signal regions where signals deviate from resting (reference).
- 4. *Individual differences in biosignals:* Study the uniqueness of biosignals among individuals to gauge transferability and generalizability to unseen data and subjects.
- 5. Synchrony between pairs: Coherence of biosignals between team members.

2.3 Analysis

Signal processing: Filtering, peak-picking, normalization and outlier analysis will be employed to pre-process and clean the signals.

Statistical analysis: Time-domain, frequency-domain and non-linear features will be used to obtain descriptive statistics of the signals [6]. We will perform statistical tests on the 3 session-phases to investigate for significant differences in the physiological signals during the three stages of the task, with $\alpha=0.05$ as the significance level. The null-hypothesis is that the task-induced frustration does not have an influence on the physiological biosignals. The Benjamini-Hochberg False Discovery Rate (FDR) will be used to address false discoveries due to multiple hypothesis testing.

Classification, anomaly detection and transfer learning: Bayesian learning, clustering and transfer learning using conventional machine learning and deep-learning will be explored for the aforementioned tasks in detecting anomaly, tracking signal change-points, and studying the limits of generalizing the above methods to biosignals from unseen subjects.

Software packages: Python (version>= 3.9.7) and associated packages will be used for prepost-processing, analysis and learning.

3 Participant

We will recruit a maximum of 24 participants. Participants are invited by email.

3.1 Inclusion criteria

- 1. Age >= 18
- 2. Member of the section of Statistics & Data Analysis at DTU Compute
- 3. Affiliated with the WristAngel research project

3.2 Exclusion criteria

- 1. Known cardio vascular diseases
- 2. Use of heart medication or any other medication known to affect heart rate
- 3. Age < 18

3.3 Reimbursement

Each participant will be compensated with food and drinks for their participation in the study.

4 Ethical considerations

Written consent is obtained from the participant before the experiment begins. If a participant withdraws during the experiment, the data will be deleted. However, the data will not be deleted after the experiment has finished.

4.1 Ethical implications

The tangram puzzle task is designed such that it should be very difficult for the participants to solve and thereby elicit frustration and possibly other negative emotions and the competitive format of the experiment is chosen to further stress participants.

The experiment task and format are necessary for the purpose of the pilot study and the data collected comprise of signals reflecting on the emotional state of a participant. However, there is expected to be no negative impact on the participants.

4.2 Data protection and handling

Before the experiment, the participant will sign a consent form and fill a general questionnaire with questions on age and gender. The recorded physiological measurements, questionnaire answers and the participant information will be anonymized by generating a random ID for each participant, and the randomly generated key will be deleted. The data and the general information will be stored on the secure storage at DTU and anonymization of the data will be ensured by storing the consent with the identifying information and data separately without the possibility of tracing back to the individual IDs from the data.

4.3 Data sharing and dissemination of results

An anonymized version of the resulting dataset(s) will comprise of physiological measurements questionnaire answers only, (i.e. not of gender and age), and will be used for further educational purposes at DTU.

The findings from the study will be submitted for publication in a peer-reviewed journal and we anticipate at least one scientific paper resulting from the study. All publications will be performed such that the identity of the participants is protected.

References

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- [2] S. Ollander, C. Godin, A. Campagne, and S. Charbonnier, "A comparison of wearable and stationary sensors for stress detection," in 2016 IEEE International Conference on Systems, Man, and Cybernetics (SMC), pp. 004362–004366, IEEE, 2016.
- [3] R. Goel, M. An, H. Alayrangues, A. Koneshloo, E. T. Lincoln, and P. E. Paredes, "Stress tracker—detecting acute stress from a trackpad: Controlled study," *Journal of Medical Internet Research*, vol. 22, no. 10, p. e22743, 2020.
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- [6] D. Makowski, T. Pham, Z. J. Lau, J. C. Brammer, F. Lespinasse, H. Pham, C. Schölzel, and S. H. A. Chen, "NeuroKit2: A python toolbox for neurophysiological signal processing," *Behavior Research Methods*, vol. 53, pp. 1689–1696, feb 2021.





Appendix I: Informationsbrev

Informationsbrev til deltageren (DK)

Kære deltager,

I dette brev oplyser vi dig om eksperimentets formål og fremgangsmåde. Det er vigtigt at du læser brevet omhyggeligt. Hvis du har nogle spørgsmål, skal du ikke tøve med at kontakte os (Line H. Clemmensen, lkhc@dtu.dk) for præciseringer.

Dine rettigheder som deltager

Din deltagelse i dette eksperiment er frivillig. Det betyder at du til enhver tid kan forlade eksperimentet uden at det har nogle konsekvenser for dig, uden at du behøver at give en begrundelse. Data, der er behandlet i forskningsprojektet inden du trækker dit samtykke tilbage, vil ikke blive slettet. Hvis du trækker dit samtykke tilbage midt i forsøget, vil vi slette dine data, og de kan dermed ikke behandles i forsknignsprojektet. Vi vil bede dig om en erklæring om informeret samtykke til at deltage, efter at du er blevet informeret om eksperimentet.

Formålet med forskningsprojektet

I dette forsøg undersøger vi fysiologiske signaler som måles under en stressfremmende øvelse. Vi er især interesseret i at undersøge sammenhængen mellem de fysiologiske signaler og forskellige følelser som opleves under øvelsen. Forskningsresultaterne skal etablere metoder til at pre- og post-pocessere det indsamlede data, hvilket bl.a. kan bruges til at udvikle digitale assistenter til børn med psykiske lidelser som fx OCD (obsessive compulsive disorder).

Lagring og håndtering af data

Alt registreret forskningsdata (fysiologiske signaler og besvarelser af følelses-spørgeskemaet) vil blive opbevaret anonymiseret, det vil sige at det ikke vil have nogen forbindelse til dit navn, din adresse, dit CPR-nummer eller andre oplysninger, der gør det muligt at identificere dig. For at imødekomme dette opbevares din data unde en nøglekode, som kun forskerne er bekendt med og som vil blive slettet, når den ikke er nødvendig længere (efter dataanalysen). Personlige oplysninger som dit navn vil ikke blive opbevaret. En del af forskningsdataen, fx BVP (blood volume pulse), vil blive gjort tilgængelig via DTUs datalager i anonymiseret form med en tilfældig nøglekode, som ikke er gemt eller kendt af forskerne. Selv om identifikationsoplysninger er slettet er det muligt at nogen vil være i stand til at identificere dig i de offentliggjorte forskningsdata.

Detektering af forskelle mellem opgave udført under stress og målinger umiddelbart før og efter opgave

1 September 2021



Vi vil benytte os af electrodermal activity (EDA), blood volume pulse (BVP), accelerometer (ACC) og hud temperatur signaler målt under en stressfremmende opgave til at designe en data processerings pipelines, baseret på de forskelle vi observerer pre-opgaven, under opgaven og post-opgaven. De fysiologiske signaler bliver målt med et Empatica E4 armbånd, hvilket er en sikker og ikke-invasiv metode. I forsøget bliver du bedt om, af flere omgange, at være med i en konkurrence, hvor man skal løse puslespil på tid. Du vil endvidere blive bedt om at besvare et spørgeskema omkring de følelser du registrerede under udførelsen af denne opgave.

Der vil være instruktioner og en forsøgsansvarlig til at hjælpe dig gennem forsøget.

Skulle du have spørgsmål til eksperimentet, de anvendte metoder eller din egen sikkerhed samt dine rettigheder, så tøv ikke med at kontakte os per e-mail (lkhc@dtu.dk) eller telefonisk (+45 45 25 37 64).
Med venlig hilsen, Line H. Clemmensen, Lektor

DTU privacy rules:

https://www.dtu.dk/english/About/strategy-policy/Policies/Privacy-policy https://www.dtu.dk/Om-DTU/strategi_aarsrapporter_mv/Politikker/Privatlivspolitik

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Appendix II: Informeret samtykke

Erklæring om informeret samtykke (DK)

 ${\it Eksperiment:} \ {\it Tangram Puzzling on time for WristAngel}$

Forskere: Line K. H. Clemmensen, Lektor, Sneha Das, Post doc, Nicklas Leander Lund, Forskningsassistent

Erklæring om informeret samtykke

1 September 2021 LKHC

Jeg bekræfter at:

- Jeg er blevet tilfredsstillende informeret om det pågældende forsøg, både mundtligt og skriftligt i form af informationsbrevet.
- Jeg har haft muligheden for at fremlægge spørgsmål vedrørende forsøget og at disse spørgsmål er blevet besvaret på tilfredsstillende vis.
- Jeg har overvejet min deltagelse i eksperimentet omhyggeligt.
- Jeg deltager af min egen fri vilje.

Jeg er enig i at:

- Mine data vil blive indsamlet og opbevaret til videnskabelige formål som nævnt i informationsbrevet i anonymiseret tilstand, dvs. med en nøglekode som forskerne ikke er bekendt med.
- Mine data må blive delt i en offentlig forskningsdatabase i anonymiseret tilstand, med en tilfældig nøglekode, der ikke er gemt af forskerne. Dette inkluderer f.eks. BVP (blood volume pulse) samt labels med den følelse jeg har vurderet bedst, beskrev min tilstand under forsøget. Navn, alder og køn er IKKE inkluderet.

Jeg forstår at:

- Min deltagelse er frivillig og jeg har ret til at trække mig fra eksperimentet til enhver tid uden at give en begrundelse.
- Hvis jeg tilbagekalder min deltagelse i forsøget, må mine forskningsdata stadigvæk anvendes til forskningsformål.
- Mit privatliv er beskyttet i henhold til dansk lovgivning og europæiske retningslinjer (GDPR; EU 2016/679).
- Der er en risiko for, at nogen muligvis kan identificere mig i offentligt delte forskningsdata.



Jeg giver mit samtykke til at deltage i dette	eksperiment
Fulde navn Fødselsdato	
	_
Dato, Place Signature	

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Appendix III: Instructions

INSTRUCTIONS

- 1) You will be given a copy of the consent form. Please read it carefully and let us know if you disagree with any of the terms.
- 2) If you agree with it, kindly sign the consent (add your name below your signature).
- 3) The competition lasts 72 min and is divided in 4 rounds of 1+3 phases: calibration (1 min), pre-task resting (5 min), task (5 min), post-task resting (5 min). For each round 2 min are reserved for rating of feelings of emotions.
- 4) Before the competition begins, you will be given an Empatica E4 wristband to wear in the entire duration of the competition. Please read the included instructions to understand how to operate the wristband.
- 5) In the calibration phase, turn on the wristband. At the end of the calibration phase press the button to mark the end of the phase.
- 6) At the end of the pre-task and task phases press the button to mark the end of the phase and use ~60 seconds to rate your level of emotions according to the provided questionnaire. After having answered the questionnaire press the button to mark the beginning of the following phase.
- 7) At the end of the post-task phase turn off the wristband.
- 8) Step 5), 6) and 7) are repeated for each round.
- 9) Your teammate and you are handed a 7-piece tangram puzzle and a set of sketches various puzzles. The task is to solve as many puzzles as possible in total of the 4 rounds. One of you, the puzzle-solver, is the only one who are allowed to touch and assemble the puzzle pieces. The other one of you, the instructor, is the only one who are allowed to look at the puzzle sketch. As a team you help each other to solve the puzzles. You may at any point skip a puzzle and choose another one to solve. You may switch your team roles throughout the competition.
- 10) Feel free to ask in case of any questions.