Ethical Review Application (ER/EB672/1) Emma Benn

Project Title	Exploring the link between Interoception and Primal World Beliefs
Status	Conditional approval
Email	eb672@sussex.ac.uk
Phone No.	
Applicant Status	UG
Department	Psychology
Supervisor	Makowski, Dominique
Project Start Date	25-Sep-2024
Project End Date	31-May-2025
External Funding in place	No
External Collaborators	No
Funder/Project Title	
Name of Funder	
Project Description	This is an amendment of the project with ethical review application ER/ASF25/2 to extend its end date. This study aims to investigate the link between Primal World Beliefs and Interoception. Participants will undertake, in one sitting, different tasks (resting and interoceptive tasks) as well as questionnaires. The interoception tasks, will provide objective measures of interoceptive abilities, which include the tapping task (TAP) and the heartbeat counting task (HCT; Schandry, 1981). The questionnaires will provide subjective measures of interoceptive abilities: the Interoceptive Accuracy Scale (IAS; Murphy et al., 2020), the Multidimensional Assessment of Interoceptive Awareness second version (MAIA-2, Mehling et al., 2018) and the Primal Inventory 99 (PI-99, Clifton et al., 2019). Firstly, participants will undergo a resting state where they will be instructed to close their eyes for 8-minutes, and then asked to fill a resting state assessment (Diaz et al., 2014). After completion of this task, participants will be divided into two groups. Those with odd-numbered IDs (1,3,5…) will begin with the objective measures of interoceptive ability - the TAP and HCT. These tasks will be followed by the IAS, MAIA-2, and PI-99 in random order. Participants with even-numbered IDs (2,4,6..) will start with the subjective measures of interoceptive ability, namely the IAS, MAIA-2, and the PI-99; followed by the TAP and HCT. This aims to minimise any potential impact of the questionnaires on the performance of the tasks, and vice versa; for example, participants that respond to the questionnaires first and self-rating as good detectors might perform differently on the subsequent heartbeat tasks. Therefore, the overall outcomes are better understood by observing the possible effect of controlling the task order.

Ethical Review Form Section A (ER/EB672/1)	
Question	**Response**
>> Checklist	
A1. Will your study involve participants who are currently or potentially vulnerable or unable to give informed consent or in a dependent position (e.g. people under 18, people with learning difficulties, over-researched groups or people in care facilities)?	No
A2. Will participants be required to take part in the study without their consent or knowledge at the time (e.g. covert observation of people in non-public places), and / or will deception of any sort be used? Please refer to the British Psychological Society Code of Ethics and Conduct (or similar guidelines) for further information.	No
A3. Unless specifically and clearly consented (e.g. a media release form), will it be possible, through a research output, to identify participants in any way? (This does not include taking email details for participant prize draws or identifying participants from signed consent forms or holding identity encryption spreadsheets that are stored securely separate from the research data).	No
A4. Might the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative consequences beyond the risks likely to be encountered in the everyday life of the participants?	No
A5. Is there a risk that the research topic might lead to disclosures from the participant concerning their beliefs, involvement in illegal actions or any other activities that may represent a threat to themselves or others?	No
A6. Will the study involve collecting any personal special category information* in a form that could allow the participant/ participants to be identified? [* identifiers relating to race, ethnic origin, politics, religion, trade union membership, philosophical beliefs, genetics, biometrics, health, sex life or sexual orientation]	No
A7. Will any drugs, placebos or other substances (such as food substances or vitamins) be administered as part of this study and will any invasive or potentially harmful procedures of any kind will be used?	No
A8. Will your project involve working with any substances and / or equipment which may be considered hazardous?	No
A9. Will your study involve the taking and/or storage of human tissue that falls under the Human Tissue Act (HTA)? http://www.sussex.ac.uk/staff/research/governance/erp_overview/humantissue	No
>> Risk Assessment	
A10. If you have answered Yes to ANY of the above questions, your application may be considered as HIGH risk. If, however you wish to make a case that your application should be considered as LOW risk please enter the reasons here. Researchers should note that SREOs or C-RECs may decide NOT to agree with the case that you have made.	

Ethical Review Form Section B (ER/EB672/1)	
Question	**Response**
>> Data Collection and Analysis (Please provide full details)	
B1. PARTICIPANTS: How many people do you envisage will participate, who are they, and how will they be selected?	We will attempt to recruit 100 participants. Participants will be adults from the student population.
B2. RECRUITMENT: How will participants be approached and recruited?	Recruitment of the following participants will be done through SONA.

B3. METHOD: What research method(s) do you plan to use; e.g. interview, questionnaire/self-completion questionnaire, field observation, audio/audio-visual recording?	Firstly, participants will complete a resting state task for 8-minutes. Then depending on their ID number, they will either perform the self-completion questionnaires first and then the tasks, or vice versa. The TAP task will asks participants to tap the spacebar at different rhythms, this provides a measure of beat-to-tap consistency by matching each tap to the nearest heartbeat to calculate the time difference in between. The HCT task will ask participants to count the number of heartbeats that occur during a specific period, which will then be compared to participants actual number of heartbeats. Bayesian correlation tests will be conducted to analyse the relationship between each interoceptive features and primal beliefs. During the tasks, physiological data, including cardiac activity and EEG data. Cardiac activity will be collected through a BITalino device via ECG, with disposable electrodes (PluX biosignals brand, https://www.pluxbiosignals.com/collections/electrodes/products/gelled-self-adhesive-disposable-ag-agcl-electrodes-pack-of-200) placed on the collarbones and above the hipbone (or PPG a fingertip sensor if the former is impossible), which are non-invasive surface physiological measures. The researchers will receive the proper training to handle the equipment as well as ensure participants' comfort and safety during the setup and recording. Electroencephalography (EEG) will be conducted using the Muse 2 headset, a lightweight and non-intrusive device. The headset is designed to be worn comfortably behind the ears and on the forehead, utilizing four electrodes to capture electrical signals from the brain's temporal and frontal lobes. Specifically, the four channels (TP9, TP19, AF7, and AF8) will be recorded using dry electrodes placed at these sites.Although this headset is commercially available for meditation purposes, it will be used exclusively for research in our study. We will recomend participants to hear a headband to ensure unobstructed contact between the electrodes and their skin. EEG will be used to measure heartbeat evoked potentials. Participants will be instructed beforehand about the setup (the fact that electrodes will be placed on their collarbones and above the hip) and to wear loose and comfortable clothes. Upon placement of the first electrode, researchers will ask and look up for signs of potential allergic reaction (redness and discomfort), in which case the device will be removed, and alternative measures will be done (pulse via finger-tip PPG).

B4. LOCATION: Where will the project be carried out e.g. public place, in researcher's office, in private office at organisation?	Upon signing up for the study, participants will be invited to come to the Psychophysiology lab to complete the experiment.
B5. PARTICIPANT WELLBEING: Will the study involve engaging participants in the discussion of potentially distressing or sensitive topics? (e.g. sexual activity, drug use, ethnicity, political behaviour, potentially illegal activities). If so, please set out how you will manage the well-being of participants.	No
>> Confidentiality and Anonymity	
B6. Will questionnaires be completed anonymously and returned indirectly?	Yes
B7. Will research data only be identifiable by a unique identifier (e.g. code/pseudonym)? If Yes, please explain how this will be attributed in B11a below.	Yes
B8. Will lists of identity numbers or pseudonyms linked to names and/or addresses be stored securely and separately from the research data? If Yes, explain how this will occur in B11a below.	No
B9. Will all place names and institutions which could lead to the identification of individuals or organisations be changed unless this is consented to explicitly in the consent form?	Yes
B10. Will all personal information gathered be treated in strict confidence and never disclosed to any third parties?	Yes
B11. Can you confirm that your research records will be held in accordance with data protection regulations? (http://www.sussex.ac.uk/ogs/policies/information/dpa)	Yes
B11a. Please explain how ANY identifiable personal and/or research data will be managed and securely stored ensuring that participants have given appropriate informed consent for this.	All data will be used for nothing other than the explicit purpose of our study. Since participants need to enter their names to sign the information and consent form, the names and participant IDs we assigned will be stored in an Excel document protected by password, in case they want to withdraw their data. We will record behavioral data, 4 EEG channels (used for heartbeat evoked potentials), physiological measures (ECG, PPG, RSP) - used in the physiological tasks - and accelerometer data (used to identify noisy data segments).Raw data will be stored in a box folder accessible only to the PI and researchers.
B12. Do you intend to use the research data for any purpose other than that for which consent is explicitly given? If so, please explain below	No

B12a. If you answered NO to any of the above in this section (or think more information could be useful to the reviewer) please explain here:	The anonymized and unidentified data will be made available open-access on OpenNeuro after the experiment completion.
>> Informed Consent and Recruitment of Participants	
B13. Will all respondents be given an Information Sheet and be given adequate time to read it before being asked to agree to participate?	Yes
B14. Will all participants taking part in an interview, focus group, observation (or other activity which is not questionnaire based) be asked to sign a consent form? If you are obtaining consent another way (such as verbally), please explain under B17 below.	Yes
B15. Will all participants self-completing a questionnaire be asked to show consent to participate by a specific and identifiable action? (Give details in B17 below)	Yes
B16. Will all participants be told that they can withdraw their participation at any time during the research and can ask for their data to be destroyed and/or removed from the project until it is no longer practical to do so?	Yes
B17. If you answered NO to any of the above in this section (or think more information will be useful to the reviewer) please explain here:	
>> Context	
B18. Is DBS (Disclosure and Barring Service) clearance necessary for this project? If yes, please ensure you complete the next question.	No
B19. Are any other ethical clearances or permissions (internal or external) required? Please see the help text (i) for further details.	No
B19a. If yes, please give further details including the name and address of the organisation. If other ethical approval has already been received please attach evidence of approval, otherwise you will need to supply it when ready. (You do not need to provide evidence of a current DBS check at this point).	
B20. Does the research involve any fieldwork - Overseas or in the UK?	No
B20a. If yes, where will the fieldwork take place? If undertaken overseas you must attach an OTSSRA form. In the event that the Foreign and Commonwealth Office has specific travel warnings in place for the country (ies) to be visited you will also need to provide a detailed risk assessment. https://www.gov.uk/foreign-travel-advice	
B21. Will any researchers be in a lone working situation?	Yes

B21a. If yes, briefly describe the location, time of day and duration of the lone working. What precautionary measures will be taken to ensure safety of the researcher(s)?	The location of the experiment will be at Psychophysiology lab, during working university hours. The whole procedure should not take any longer than 1h30 minutes from start to finish. This is not antecipated to carry any risks.
>> Any further concerns	
B22. Are there any other ethical considerations relating to your project which have not been covered above?	No
B22a. If yes, please explain:	For this project, we will follow all manufacturer guidelines when using the Muse 2 headband. More can be found on the Muse.pdf.