

Amendments: ER/NAAA21/2

<b>Project Title</b>	Improving the Sensitivity of the PHQ-4 as a Depression/Anxiety Measure in Subclinical Populations
<b>Status</b>	Conditional approval
<b>Email</b>	naaa21@sussex.ac.uk
<b>Phone No.</b>	07407270216
<b>Applicant Status</b>	UG
<b>Department</b>	Psychology
<b>Supervisor</b>	Makowski, Dominique
<b>Project Start Date</b>	02-Oct-2023
<b>Project End Date</b>	14-May-2024
<b>External Funding in place</b>	No
<b>External Collaborators</b>	No
<b>Funder/Project Title</b>	
<b>Name of Funder</b>	

## Ethical Review Application ER/NAAA21/1 (continued)

**Project Description**

This project aims at validating a modification of the PHQ-4 questionnaire (4 items; Lowe B. et al., 2010) for depression and anxiety. Specifically, the goal is to test the benefits of adding a new response option in the likert scale aimed at improving the questionnaire's sensitivity to mood fluctuations in the general (non-clinical) population.

This will be investigated by testing whether the correlation with established measures of depression and anxiety (BDI and STAI) is higher with the modified PHQ-4 as compared to the original version.

The survey, delivered online, will include the following parts:

- Read the study information sheet and agree to consent form. See ethical considerations section below.
- Standard demographic survey  
(age, gender, ethnicity, highest completed education level)  
(ethnicity collected just to fully describe the sample of participants)
- Mood antecedents: participants will be invited to tick from a list of mood disorders if they have been diagnosed with any of them and if they are currently undergoing medical treatment.
- Then participants will then be invited to answer all four questionnaires in random order:
- PHQ-4 (randomly assigned to the original or the modified version): The modified version simply adds a new response item - 'once or twice' - in between 'not at all' and 'several days' in the likert scale.
- BDI-II (Beck A. T. et al, 1996): self-report 21 item questionnaire with strong validity and reliability to measure depression.
- STAI-5 (Zsido, A. N., 2020): This 5-items questionnaires measures anxiety. Changes will be made in asking how participants feel right now to 'over the past 2 weeks' to keep it consistent with the instructions of the PHQ-4 and BDI-II.
- IAS (Murphy, J. et al. 2019): This questionnaire assesses interoceptive accuracy and is included as part of a larger protocol, but won't be analyzed in the present work.
- Finally, debriefing information will be provided.

The key ethical issues are the questionnaires used. The questionnaires used in the study ask people to reflect and acknowledge their feelings and state of mind. Some people might find completing these types of questionnaires to cause them distress and negative emotions. If participants find the questionnaires distressing, they are invited to stop the study at any time without giving a reason. If they find that completing the questionnaire raises any concerns for them about their current levels of anxiety or depression, they are suggested to make an appointment with their GP to discuss strategies to help them manage, as well as discussing further sources of support. If they are a student at the University of Sussex, they are also suggested to contact the student life centre for counselling services and advice via email:

studentcentre@sussex.ac.uk, phone: +441273075700 or via their website: <https://student.sussex.ac.uk/centre/>. Otherwise, they can also seek helpful information about depression and anxiety on the NHS choices website: <https://www.nhs.uk/mental-health/feelings-symptoms-behaviours/feelings-and-symptoms/>

Ethical Review Form Section A (ER/NAAA21/1)	
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?	Yes
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)? <a href="http://www.sussex.ac.uk/staff/research/governance/erp_overview/humantissue">http://www.sussex.ac.uk/staff/research/governance/erp_overview/humantissue</a>	No
>> Risk Assessment	

<p>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.</p>	<p>The study asks participants some personal questions about their feelings, personality and current state of mind. These questions relate to symptoms of anxiety and depression. Due to that, these questions might end up causing students to feel anxious, distressed and sad as in order to answer these questions they will be looking into and being fully aware of their current state and feelings, in which there may be some feelings they are trying not to focus on and avoid. Also, these questions may cause some worry of having a mental health problem, and even cause humiliation about the way they feel and</p>
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their current state.  
Therefore, we give the participants an opportunity to quit the questionnaire at any time, while still being able to read the debrief page. We also provide information about counselling and support services in both the study information sheet and the debrief sheet. Data will be entirely anonymous.

Ethical Review Form Section B (ER/NAAA21/1)	
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?	The goal is to recruit at least 30 participants, but given the correlation nature of the study and of the recruitment procedure, a higher number is hoped for.
B2. RECRUITMENT: How will participants be approached and recruited?	a questionnaire will be sent out to participants in social media platforms and completed online.
B3. METHOD: What research method(s) do you plan to use; e.g. interview, questionnaire/self-completion questionnaire, field observation, audio/audio-visual recording?	questionnaires
B4. LOCATION: Where will the project be carried out e.g. public place, in researcher's office, in private office at organisation?	The study is online and can be completed anywhere, but we encourage participants to do it in a quiet place with as little distraction as possible.
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.	As the study does involve filling out questionnaires about feelings and state of mind, we will direct all participants to sources of support should any of their responses to questionnaires concern them in any way or cause them to feel any type of way.
>> 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.	N/A
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.	N/A
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?	N/A
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? ( <a href="http://www.sussex.ac.uk/ogs/policies/information/dpa">http://www.sussex.ac.uk/ogs/policies/information/dpa</a> )	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.	
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:	
>> 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.	N/A
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. <a href="https://www.gov.uk/foreign-travel-advice">https://www.gov.uk/foreign-travel-advice</a>	
B21. Will any researchers be in a lone working situation?	No
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)?	
>> 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:	

# Thank you for participating

It means a lot to us. Don't hesitate to share the study by sending this link:

<https://dominiquemakowski.github.io/PHQ4R/study2/experiment/experimenter1.html>

## Information

The purpose of this study was for us to understand how mood fluctuations and mood disorder symptoms (or absence thereof) are expressed and what difficulties they can generate. Your participation in this study will be kept completely confidential.

If you have any questions about the project, please contact D.Makowski@sussex.ac.uk.

**You can safely close the tab now.**

End



# Informed Consent

## Invitation to Take Part

You are being invited to take part in a research study to further our understanding of Human psychology.

Thank you for carefully reading this information sheet.

This study is being conducted by Dr Dominique Makowski from the School of Psychology, University of Sussex, who is happy to be contacted (D.Makowski@sussex.ac.uk) if you have any questions.

## Why have I been invited and what will I do?

We are surveying adults to understand how mood fluctuations and mood disorders symptoms (or absence thereof) are expressed and what difficulties they can generate. This study contains various questionnaires about your personality, feelings and current state of mind. The whole experiment will take you **about 10 min** to complete. Please make you sure that you are in a quiet environment, and that you have time to complete it in one go.

## What will happen to the results and my personal information?

The results of this research may be written into a scientific publication. Your anonymity will be ensured in the way described in the consent information below. Please read this information carefully and then, if you wish to take part, please acknowledge that you have fully understood this sheet, and that you consent to take part in the study as it is described here.

## Consent

- I understand that by signing below I am agreeing to take part in the University of Sussex research described here, and that I have read and understood this information sheet
- I understand that my participation is entirely voluntary, that I can choose not to participate in part or all of the study, and that I can withdraw at any stage without having to give a reason and without being penalised in any way (e.g., if I am a student, my decision whether or not to take part will not affect my grades).
- I understand that since the study is anonymous, it will be impossible to withdraw my data once I have completed and submitted the test/questionnaire.
- I understand that my personal data will be used for the purposes of this research study and will be handled in accordance with Data Protection legislation. I understand that the University's Privacy Notice provides further information on how the University uses personal data in its research.
- I understand that my collected data will be stored in a de-identified way. De-identified data may be made publically available through secured scientific online data repositories.

For further information about this research, or if you have any concerns, please contact

Dr Dominique Makowski (D.Makowski@sussex.ac.uk). This research has been approved

(ER/NAAA21/1) by the ethics board of the School of Psychology, The University of

Sussex has insurance in place to cover its legal liabilities in respect of this study.

I will post this link in social media platforms and send it to my friends and family to complete:

Hi, as part of my third-year research dissertation i am collecting primary data to understand how mood fluctuations and mood disorder symptoms are expressed and what difficulties they can generate. Some questions may be sensitive. I would be grateful if you participate in my study by following the link below (will take approximately 7-10 minutes):

<https://dominiquemakowski.github.io/PHQ4R/study2/experiment/experimenter1.html>

Thank you for anyone who takes the time to complete it

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the number at the end of the statement that indicates how you have been feeling **during the past two weeks**. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

**I feel that difficulties are piling up so that I cannot overcome them**

☐ ☐ ☐ ☐

Not at all      Somewhat      Moderately so      Very much so

**I worry too much over something that really doesn't matter**

☐ ☐ ☐ ☐

Not at all      Somewhat      Moderately so      Very much so

**Some unimportant thoughts run through my mind and bothers me**

☐ ☐ ☐ ☐

Not at all      Somewhat      Moderately so      Very much so

**I take disappointments so keenly that I can't put them out of my mind**

☐ ☐ ☐ ☐

Not at all      Somewhat      Moderately so      Very much so

**I get in a state of tension or turmoil as I think over my recent concerns and interests**

☐ ☐ ☐ ☐

Not at all      Somewhat      Moderately so      Very much so

Continue

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully. And then pick out the one statement in each group that best describes the way you have been feeling **during the past two weeks**, including today. If several statements in the group seem to apply equally well, circle the highest number for that group.

**1. Sadness\***

- ☐ 0. I do not feel sad
- ☐ 1. I feel sad much of the time
- ☐ 2. I am sad all the time
- ☐ 3. I am so sad or unhappy that I can't stand it

**2. Pessimism\***

- ☐ 0. I am not discouraged about my future
- ☐ 1. I feel more discouraged about my future than I used to
- ☐ 2. I do not expect things to work out for me
- ☐ 3. I feel my future is hopeless and will only get worse

**3. Past Failure\***

- ☐ 0. I do not feel like a failure
- ☐ 1. I have failed more than I should have
- ☐ 2. As I look back, I see a lot of failures
- ☐ 3. I feel I am a total failure as a person

**4. Loss of Pleasure\***

- ☐ 0. I get as much pleasure as I ever did from the things I enjoy
- ☐ 1. I don't enjoy things as much as I used to
- ☐ 2. I get very little pleasure from the things I used to enjoy
- ☐ 3. I can't get any pleasure from the things I used to enjoy

**5. Guilty Feelings\***

- ☐ 0. I don't feel particularly guilty
- ☐ 1. I feel guilty over many things I have done or should have done
- ☐ 2. I feel quite guilty most of the time
- ☐ 3. I feel guilty all of the time



#### 6. Punishment Feelings\*

- ☐ 0. I don't feel I am being punished
- ☐ 1. I feel I may be punished
- ☐ 2. I expect to be punished
- ☐ 3. I feel I am being punished

#### 7. Self-Dislike\*

- ☐ 0. I feel the same about myself as ever
- ☐ 1. I have lost confidence in myself
- ☐ 2. I am disappointed in myself
- ☐ 3. I dislike myself

#### 8. Self-Criticalness\*

- ☐ 0. I don't criticize or blame myself more than usual
- ☐ 1. I am more critical of myself than I used to be
- ☐ 2. I criticize myself for all of my faults
- ☐ 3. I blame myself for everything bad that happens

#### 9. Suicidal Thoughts or Wishes\*

- ☐ 0. I don't have any thoughts of killing myself
- ☐ 1. I have thoughts of killing myself, but I would not carry them out
- ☐ 2. I would like to kill myself
- ☐ 3. I would kill myself if I had the chance

#### 10. Crying\*

- ☐ 0. I don't cry anymore than I used to
- ☐ 1. I cry more than I used to
- ☐ 2. I cry over every little thing
- ☐ 3. I feel like crying, but I can't

#### 11. Agitation\*

- ☐ 0. I am no more restless or wound up than usual
- ☐ 1. I feel more restless or wound up than usual
- ☐ 2. I am so restless or agitated, it's hard to stay still
- ☐ 3. I am so restless or agitated that I have to keep moving or doing something

#### 12. Loss of Interest\*

- ☐ 0. I have not lost interest in other people or activities
- ☐ 1. I am less interested in other people or things than before
- ☐ 2. I have lost most of my interest in other people or things
- ☐ 3. It's hard to get interested in anything

**13. Indecisiveness\***

- ☐ 0. I make decisions about as well as ever
- ☐ 1. I find it more difficult to make decisions than usual
- ☐ 2. I have much greater difficulty in making decisions than I used to
- ☐ 3. I have trouble making any decisions

**14. Worthlessness\***

- ☐ 0. I do not feel I am worthless
- ☐ 1. I don't consider myself as worthwhile and useful as I used to
- ☐ 2. I feel more worthless as compared to others
- ☐ 3. I feel utterly worthless

**15. Loss of Energy\***

- ☐ 0. I have as much energy as ever
- ☐ 1. I have less energy than I used to have
- ☐ 2. I don't have enough energy to do very much
- ☐ 3. I don't have enough energy to do anything

**16. Changes in Sleeping Pattern\***

- ☐ 0. I have not experienced any change in my sleeping pattern
- ☐ 1a. I sleep somewhat more than usual
- ☐ 1b. I sleep somewhat less than usual
- ☐ 2a. I sleep a lot more than usual
- ☐ 2b. I sleep a lot less than usual
- ☐ 3a. I sleep most of the day
- ☐ 3b. I wake up 1-2 hours early and can't get back to sleep

**17. Irritability\***

- ☐ 0. I am not more irritable than usual
- ☐ 1. I am more irritable than usual
- ☐ 2. I am much more irritable than usual
- ☐ 3. I am irritable all the time

**18. Changes in Appetite\***

- ☐ 0. I have not experienced any change in my appetite
- ☐ 1a. My appetite is somewhat less than usual
- ☐ 1b. My appetite is somewhat greater than usual
- ☐ 2a. My appetite is much less than before
- ☐ 2b. My appetite is much greater than usual
- ☐ 3a. I have no appetite at all
- ☐ 3b. I crave food all the time

pattern

- ☐ 1a. I sleep somewhat more than usual
- ☐ 1b. I sleep somewhat less than usual
- ☐ 2a. I sleep a lot more than usual
- ☐ 2b. I sleep a lot less than usual
- ☐ 3a. I sleep most of the day
- ☐ 3b. I wake up 1-2 hours early and can't get back to sleep

**17. Irritability\***

- ☐ 0. I am not more irritable than usual
- ☐ 1. I am more irritable than usual
- ☐ 2. I am much more irritable than usual
- ☐ 3. I am irritable all the time

**18. Changes in Appetite\***

- ☐ 0. I have not experienced any change in my appetite
- ☐ 1a. My appetite is somewhat less than usual
- ☐ 1b. My appetite is somewhat greater than usual
- ☐ 2a. My appetite is much less than before
- ☐ 2b. My appetite is much greater than usual
- ☐ 3a. I have no appetite at all
- ☐ 3b. I crave food all the time

**19. Concentration Difficulty\***

- ☐ 0. I can concentrate as well as ever
- ☐ 1. I can't concentrate as well as usual
- ☐ 2. It's hard to keep my mind on anything for very long
- ☐ 3. I find I can't concentrate on anything

**20. Tiredness or Fatigue\***

- ☐ 0. I am no more tired or fatigued than usual
- ☐ 1. I get more tired or fatigued more easily than usual
- ☐ 2. I am too tired or fatigued to do a lot of the things I used to do
- ☐ 3. I am too tired or fatigued to do most of the things I used to do

**21. Loss of Interest in Sex\***

- ☐ 0. I have not noticed any recent change in my interest in sex
- ☐ 1. I am less interested in sex than I used to be
- ☐ 2. I am much less interested in sex now
- ☐ 3. I have lost interest in sex completely





### About your emotions...

Over the **last 2 weeks**, how often have you been bothered by the following problems?

#### Feeling nervous, anxious or on edge



#### Not being able to stop or control worrying



#### Feeling down, depressed, or hopeless



#### Little interest or pleasure in doing things



Continue

### About your body sensations...

Below are several statements regarding how accurately you can perceive specific bodily sensations. Please rate on the scale how well you believe you can perceive each specific signal.

For example, if you often feel you need to urinate and then realise you do not need to when you go to the toilet, you would rate your accuracy perceiving this bodily signal as low.

Please only rate how well you can perceive these signals without using external cues. For example, if you can only perceive how fast your heart is beating when you measure it by taking your pulse, this would *not* count as accurate internal perception.

**I can always accurately perceive when I am breathing fast**

Strongly Disagree  Strongly Agree

**I can always accurately perceive when I am hungry**

Strongly Disagree  Strongly Agree

**I can always accurately perceive when my heart is beating fast**

Strongly Disagree  Strongly Agree

**I can always accurately perceive when I am going to sneeze**

Strongly Disagree  Strongly Agree

**I can always accurately perceive when I need to urinate**

Strongly Disagree  Strongly Agree

**I can always accurately perceive when my blood sugar is low**

Strongly Disagree  Strongly Agree

**I can always accurately perceive when something is going to be ticklish**

Strongly Disagree  Strongly Agree

**I can always accurately perceive when I am thirsty**

Strongly Disagree  Strongly Agree

Strongly Disagree  Strongly Agree

Strongly Disagree  Strongly Agree

Strongly Disagree  Strongly Agree

Strongly Disagree Strongly Agree

Strongly Disagree  Strongly Agree

Strongly Disagree  Strongly Agree

Strongly Disagree  Strongly Agree

Strongly Disagree  Strongly Agree

Strongly Disagree 0 Strongly Agree

Strongly Disagree Strongly Agree

Strongly Disagree  Strongly Agree

Continue

