Ethical Review Application (ER/ASF25/4) Ana Ferreira Neves

Project Title Validation of a modification to the PHQ-4

StatusConditional approvalEmailasf25@sussex.ac.uk

Phone No.

Applicant StatusPG (Taught)DepartmentPsychology

Supervisor Makowski, Dominique

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External Funding in place No **External Collaborators** No

Funder/Project Title Name of Funder

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Ethical Review Application ER/ASF25/4 (continued)

Project Description

This project takes the form of an online survey containing various questionnaires present in random order. Its main objective is to validate a modification of the PHQ-4 depression and anxiety questionnaire (Lowe et al., 2010), by testing the benefits of adding a new response option in the Likert scale in 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 will also include questionnaires related to emotional and bodily awareness.

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

Study information and consent form. See ethical considerations section below.

Standard demographic questions (age, gender, education level, etc.)

Mood difficulties antecedents: participants will be invited (but it will be explicitly marked as non-required) to tick from a list of issues if they have been diagnosed with any of them and if they are currently undergoing medical treatment related to them.

Then participants will then be invited to answer all questionnaires in random order:

• PHQ-4 (randomly assigned to be either 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, et al., 1996): self-report 21 item questionnaire with strong validity and reliability to measure depression • STAI-5 (Zsido, 2020): This 5-items questionnaires measures anxiety. Changes will be made in the instructions from 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. • Interoceptive questionnaires (such as the IAS, Murphy et al., 2019) with items pertaining to bodily functions and activity.

Finally, debriefing information will be provided, and participants will be be given a final opportunity to withdraw their participation.

The key ethical issue is the nature of some of the questions that 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/

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Question	Response
>> Checklist	
A1. Will your study involve participants who are currently or potentially vulnerable or unable to give informed consent or	No
in a dependent position (e.g. people under 18, people with learning difficulties, over-researched groups or people in care	
facilities)?	
A2. Will participants be required to take part in the study without their consent or knowledge at the time (e.g. covert	No
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.	
A3. Unless specifically and clearly consented (e.g. a media release form), will it be possible, through a research output,	No
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).	
A4. Might the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative	No
consequences beyond the risks likely to be encountered in the everyday life of the participants?	
A5. Is there a risk that the research topic might lead to disclosures from the participant concerning their beliefs,	No
involvement in illegal actions or any other activities that may represent a threat to themselves or others?	
A6. Will the study involve collecting any personal special category information* in a form that could allow the participant/	No
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]	
A7. Will any drugs, placebos or other substances (such as food substances or vitamins) be administered as part of this	No
study and will any invasive or potentially harmful procedures of any kind will be used?	
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)?	No
http://www.sussex.ac.uk/staff/research/governance/erp_overview/humantissue	
>> 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.	

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Ethical Review Form Section B (ER/ASF25/4)	
Question	Response
>> Data Collection and Analysis (Please provide full details)	
B1. PARTICIPANTS: How many people do you envisage will	Given the correlation nature of the study, we hope to collect a
participate, who are they, and how will they be selected?	minimum of 50 participants per condition (100 in total).
B2. RECRUITMENT: How will participants be approached and	Participants will be recruited via convenience sampling (e.g., via
recruited?	social media), or via other recruitment platforms if available (e.g.,
	SONA, Prolific). The samples from different methods of
	recruitment will be collected separately in case they are different
	(the incentive type - e.g., student credits - and amount - or lack
	thereof - will thus be known to mitigate its potential effect). As we
	aim at recruiting a diverse sample, there are no exclusion criteria.
B3. METHOD: What research method(s) do you plan to use; e.g.	The study is composed of a series of questionnaires.
interview, questionnaire/self-completion questionnaire, field	
observation, audio/audio-visual recording?	
B4. LOCATION: Where will the project be carried out e.g. public	Participants will be able to partake in the study online. However,
place, in researcher's office, in private office at organisation?	we encourage participants to complete it in a quiet place with as
	little distraction as possible.
B5. PARTICIPANT WELLBEING: Will the study involve engaging	The study asks participants some personal questions about their
participants in the discussion of potentially distressing or sensitive	feelings, personality and current state of mind, which might trigger
topics? (e.g. sexual activity, drug use, ethnicity, political	negative feelings. Therefore, we give the participants an
behaviour, potentially illegal activities). If so, please set out how	opportunity to quit the questionnaire at any time throughout the
you will manage the well-being of participants.	experiment. We also provide information about counselling and
	support services in both the study information sheet and the
	debrief sheet. Participant's data anonymity will be entirely
	ensured.
>> Confidentiality and Anonymity	
B6. Will questionnaires be completed anonymously and returned	Yes
indirectly?	
B7. Will research data only be identifiable by a unique identifier	N/A
(e.g. code/pseudonym)? If Yes, please explain how this will be	
attributed in B11a below.	
B8. Will lists of identity numbers or pseudonyms linked to names	N/A
and/or addresses be stored securely and separately from the	
research data? If Yes, explain how this will occur in B11a below.	
B9. Will all place names and institutions which could lead to the	N/A
identification of individuals or organisations be changed unless	
this is consented to explicitly in the consent form?	
B10. Will all personal information gathered be treated in strict	Yes
confidence and never disclosed to any third parties?	
B11. Can you confirm that your research records will be held in	Yes
accordance with data protection regulations?	

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Ethical Review Form Section B (ER/ASF25/4) (cont.)

Data Di Li Li ANIVI I (C. L. L. L. V	T
B11a. Please explain how ANY identifiable personal and/or	There will be no identifiable information.
research data will be managed and securely stored ensuring that	
participants have given appropriate informed consent for this.	
D40 D 14 1 1 1	
B12. Do you intend to use the research data for any purpose	No
other than that for which consent is explicitly given? If so, please	
explain below	
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	V
B13. Will all respondents be given an Information Sheet and be	Yes
given adequate time to read it before being asked to agree to	
participate?	
B14. Will all participants taking part in an interview, focus group,	No
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.	
B15. Will all participants self-completing a questionnaire be asked	Yes
to show consent to participate by a specific and identifiable	163
action? (Give details in B17 below)	
B16. Will all participants be told that they can withdraw their	Yes
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?	
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	No
necessary for this project? If yes, please ensure you complete the	
next question.	
B19. Are any other ethical clearances or permissions (internal or	No
external) required? Please see the help text (i) for further details.	
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	No
UK?	
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	

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Ethical Review Form Section B (ER/ASF25/4) (cont.)

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	No
project which have not been covered above?	
B22a. If yes, please explain:	

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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 by closing the browser
 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.
- Please note that various checks will be performed to ensure the validity of the data. We
 reserve the right to withhold credit awards or reimbursement (if applicable) should we
 detect non-valid responses (e.g., random patterns of answers, instructions not read, ...).
- By participating, you agree to follow the instructions and provide honest answers. If you do
 not wish to participate, simply close your browser.

BDI - II

Instructions: 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. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. I have not experienced any change in my sleeping.
- 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

- o. 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

- o. 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

- o. 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

- o. 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

- o. 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.

Total Score:	
. o ta. 5 to. c.	

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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 pe	_	
Strongly	Disagree	Strongly	Agree
I	can always accurately perc	eive when I need to urinate	
Strongly	Disagree	Strongly	Agree
	I can always accurately pe	rceive when I am in pain	
Strongly	Disagree	Strongly	Agree
r	l can always accurately pero		
Strongly	Disagree	Strongly	Agree
	l can always accurately per		
Strongly	Disagree	Strongly	Agree
	l can always accurately perc tired/		
Strongly	Disagree	Strongly	Agree
	I can always accurately pe		
Strongly	Disagree	Strongly	Agree
	I can always accurately pe	rceive when I am hungry	
Strongly	Disagree	Strongly	Agree
	l can always accurately perc	-	
Strongly	Disagree	Strongly	Agree
	l can always accurately per	0 0	

Strongly Agree

Strongly Disagree

I can always accurately perceive when I need to defecate Strongly Disagree Strongly Agree I can always accurately perceive when I am sexually Strongly Disagree Strongly Agree I can always accurately perceive when I am going to Strongly Disagree Strongly Agree I can always accurately perceive when someone is touching me affectionately rather than nonaffectionately Strongly Disagree Strongly Agree I can always accurately perceive when I am going to burp Strongly Disagree Strongly Agree I can always accurately perceive when I am going to cough 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 thirsty Strongly Disagree Strongly Agree I can always accurately perceive when I am hot/cold Strongly Disagree Strongly Agree I can always accurately perceive when something is going to be itchy

Strongly Disagree Strongly Agree

I can always accurately perceive when I am going to get
a bruise

Strongly Disagree Strongly Agree



Multidimensional Assessment of Interoceptive Awareness - Version 2 (MAIA-2)

Instructions:

Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life.

		Never	Very Rarely	Rarely	Occasionall y	Very Frequently	Always
1	When I am tense I notice where the tension is located in my body.	0	1	2	3	4	5
2	I notice when I am uncomfortable in my body.	0	1	2	3	4	5
3	I notice where in my body I am comfortable.	0	1	2	3	4	5
4	I notice changes in my breathing, such as whether it slows down or speeds up.	0	1	2	3	4	5
5	I ignore physical tension or discomfort until they become more severe.	5	4	3	2	1	0
6	I distract myself from sensations of discomfort.	5	4	3	2	1	0
7	When I feel pain or discomfort, I try to power through it.	5	4	3	2	1	0
8	I try to ignore pain.	5	4	3	2	1	0
9	I push feelings of discomfort away by focusing on something.	5	4	3	2	1	0
10	When I feel unpleasant body sensations, I occupy myself with something else so I don't have to feel	5	4	3	2	1	0
11	When I feel physical pain, I become upset.	5	4	3	2	1	0
12	I start to worry that something is wrong if I feel any discomfort.	5	4	3	2	1	0
13	I can notice an unpleasant body sensation without worrying about it.	0	1	2	3	4	5
14	I can stay calm and not worry when I have feelings of discomfort or pain.	0	1	2	3	4	5
15	When I am in discomfort or pain I can't get it out of my mind.	5	4	3	2	1	0
16	I can pay attention to my breath without being distracted by things happening around me.	0	1	2	3	4	5



		Never	Very Rarely	Rarely	Occasionall y	Very Frequent l y	Always
17	I can maintain awareness of my inner bodily sensations even when there is a lot going on around me.	0	1	2	3	4	5
18	When I am in conversation with someone, I can pay attention to my posture.	0	1	2	3	4	5
19	I can return awareness to my body if I am distracted.	0	1	2	3	4	5
20	I can refocus my attention from thinking to sensing my body.	0	1	2	3	4	5
21	I can maintain awareness of my whole body even when a part of me is in pain or discomfort.	0	1	2	3	4	5
22	I am able to consciously focus on my body as a whole.	0	1	2	3	4	5
23	I notice how my body changes when I am angry.	0	1	2	3	4	5
24	When something is wrong in my life I can feel it in my body.	0	1	2	3	4	5
25	I notice that my body feels different after a peaceful experience.	0	1	2	3	4	5
26	I notice that my breathing becomes free and easy when I feel comfortable.	0	1	2	3	4	5
27	I notice how my body changes when I feel happy / joyful.	0	1	2	3	4	5
28	When I feel overwhelmed I can find a calm place inside.	0	1	2	3	4	5
29	When I bring awareness to my body I feel a sense of calm.	0	1	2	3	4	5
30	I can use my breath to reduce tension.	0	1	2	3	4	5
31	When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	0	1	2	3	4	5
32	I listen for information from my body about my emotional state.	0	1	2	3	4	5
33	When I am upset, I take time to explore how my body feels.	0	1	2	3	4	5
34	I listen to my body to inform me about what to do.	0	1	2	3	4	5
35	I am at home in my body.	0	1	2	3	4	5
36	I feel my body is a safe place.	0	1	2	3	4	5



		Never	Very Rarely	Rarely	Occasionall y	Very Frequently	Always
37	I trust my body sensations.	0	1	2	3	4	5

Developer Reference:

Mehling WE, Acree M, Stewart A, Silas J, Jones A (2018) The Multidimensional Assessment of Interoceptive Awareness, Version 2 (MAIA-2). PLoS ONE 13(12): e0208034. https://doi.org/10.1371/journal.pone.0208034

Administer Now

PHQ-4: THE FOUR-ITEM PATIENT HEALTH QUESTIONNAIRE FOR ANXIETY AND DEPRESSION

Over the last two weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3
Little interest or pleasure in doing things	0	1	2	3
TOTALS				

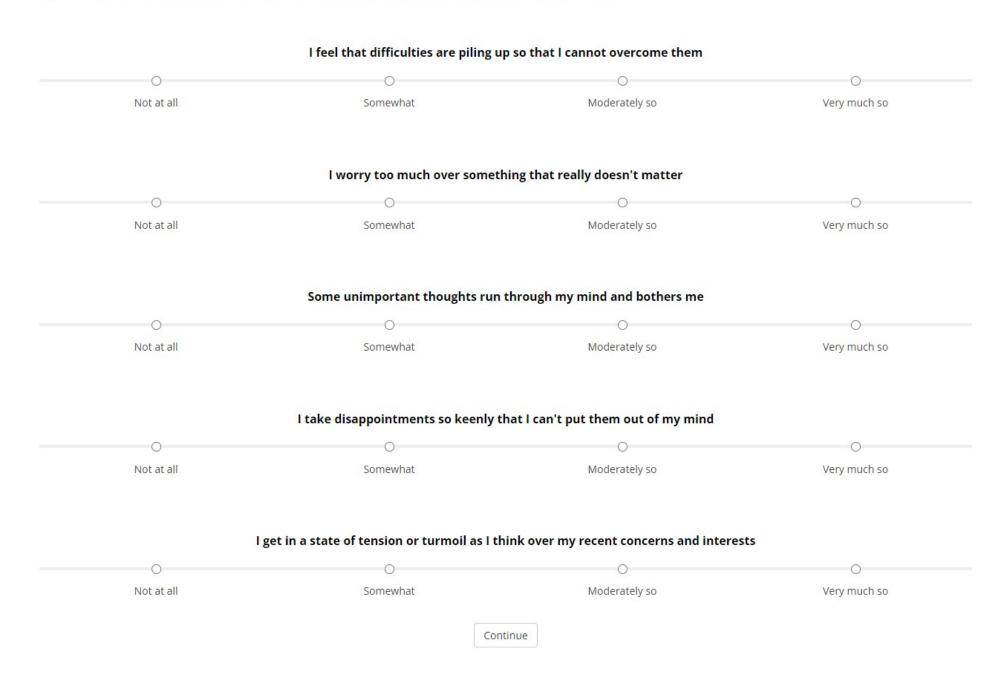
Total score is determined by adding together the scores of each of the 4 items. Scores are rated as normal (0-2), mild (3-5), moderate (6-8), and severe (9-12).

Total score \geq 3 for first 2 questions suggests anxiety.

Total score ≥3 for last 2 questions suggests depression.

Reprinted with permission from Kroenke K, Spitzer RL, Williams JB, Löwe B. An ultra-brief screening scale for anxiety and depression: the PHQ-4. Psychosomatics. 2009;50(6):613-21. From Principles of Neuropathic Pain Assessment and Management, November 2011.

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.



Thank you for participating

It means a lot to us. We know participating in scientific experiments can be long and not always the most fun, so we really do appreciate your help in helping us understand how the Human brain works.

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*, and check-out the **Reality Bending Lab** for more information about our research team.