STUDIES USING A NEGATIVE MOOD INDUCTION PROCEDURE WITH BOTH HEALTHY INDIVIDUALS AND INDIVIDUALS WITH A HISTORY OF DEPRESSION

1. SCOPE

The musical mood induction procedure has been used for more than 15 years to examine the effects of mood change on cognitive processing. This approved procedure is designed to cover the use of a negative mood induction procedure in studies of both healthy individuals and individuals with a history of depression. Because a negative mood induction might occasionally “induce anxiety, stress or another harmful psychological state in participants that might persist beyond the duration of the test/interview” (Checklist Section D) this procedure would usually result in the researcher ticking a grey box on the CUREC application form and completing a full application. This approved procedure is intended to cover only studies in which participants have been screened to ensure an absence of depressive symptoms or suicidal ideation in the preceding 8 weeks (as described below).

In a typical study, participants are informed that the purpose of the mood induction procedure is to induce a sad mood and that in order to do this they will be asked to listen to some sad music and to read cards containing sad (Velten) statements (negative statements such as “There are things about me that I don’t like”) The mood induction music (for example ‘Russia under the Mongolian Yoke’ by Prokofiev, re-mastered at half-speed) is played to the participant through loud-speakers for 8 minutes. During this time participants are asked to read through the Velten Statements and to identify those that are most helpful to them in inducing a sad mood whilst trying to evoke the thoughts and feelings described by the cards. The researcher remains present in the room throughout the procedure but does not interact with the participant in any way, unless addressed directly by the participant.

If several cognitive tasks are to be administered following induction of sad mood, then mood boosters are given between tasks. These are necessary because induced mood is transient and mood induction boosters are needed to sustain the mood during completion of the post-induction cognitive tasks. In each booster, the volume of the music is increased for a period of two minutes and participants are asked to focus once again on the Velten Statements, which they have selected to be the most effective in helping them to induce a sad mood.

Participants are asked to rate their mood (usually happiness and despondency) periodically on visual analogue scales, prior to, during and following the mood induction procedure enabling interviewers to detect individuals whose mood changes as a result of the mood induction and whose sad mood is persisting at the end of the study session.

2. TRAINING OF RESEARCH STAFF

All researchers should be trained in the use of the mood induction procedure.
Researchers need to be sensitive to Mental Health issues, and avoid working in situations that could leave them exposed to accusations of abuse. They must follow the guidance set out in the University’s ‘Safeguarding Code of Practice’, including completing the online training course ‘An introduction to Safeguarding’, as well as undertaking risk assessments of the proposed research. Any risk assessment should also include details of how research participants can report concerns about any member of the University with whom they will be interacting.

Researchers should also take responsibility for complying with safeguarding regulations and research practices which relate to the setting(s) (country, institution) of their research. As well as such compliance, researchers should consult guidance from the relevant professional associations.

3. METHODS FOR RECRUITING PARTICIPANTS
This approved procedure is intended to cover studies in which participants are recruited from the community (for example through the distribution of posters in local community buildings) and from student populations. It does not cover studies in which participants are recruited through NHS settings or as a consequence of their use of an NHS service.

4. INFORMATION PROVIDED TO PARTICIPANTS
The specific details provided to parents will vary depending on the study, but will always include:

- the name of the study
- the name(s) and status(es) (e.g. doctoral student) of the researchers carrying out the study and how to contact them
- a brief rationale of the study, including its purpose and value
- why potential participants are being invited to take part in the research
- an explanation of what the potential participant would do, including estimated duration of the test session and where it would take place
- that potential participants can ask questions about the study before they decide whether to participate
- that potential participants can choose whether they participate and, if they agree, they may withdraw from the study without penalty at any time by advising the researchers of this decision
- information about any additional personal information that would be obtained
- information about who would have access to the data, how it will be stored and what will happen to the data at the end of the study
- statement that the data would be anonymised
- what benefits (direct or indirect) may accrue to the participants in the study
- what risks are involved in the study
- that the project has received ethics clearance through the University of Oxford’s ethical approval process for research involving human participants.
- where applicable, a note to explain that the research will be written up as a student’s thesis and how the personal data included in that thesis will be published and stored
- the procedure for raising a concern or making a complaint
The Information Sheet is written in simple but non-patronising language. Most word-processing packages provide readability statistics for a document, and one should aim for a 12-year-old (Year 7) reading level for adults.

Please refer to the Information Sheet associated with this Approved Procedure.

5. CONSENT OF PARTICIPANTS

The specific details will vary depending on the study, but will always be on University headed paper and will always include:

- the name of the study;
- the name and status (e.g. doctoral student) of the researcher collecting the information and how to contact him/her;
- the purpose of the study;
- declarations that the participant:
  - has read the participant information sheet;
  - has had the opportunity to ask questions about the study and has received satisfactory answers to questions, and any additional details requested;
  - understands that s/he may withdraw from the study without penalty at any time by advising the researchers of this decision;
  - understands that this project has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee;
  - understands who will have access to personal data provided, how the data will be stored; and what will happen to the data at the end of the project;
  - where the research will be written up as a student’s thesis, understands how personal data included in that thesis will be published and stored (see the ORA website);
  - agrees to participate in this study;
  - understands how to raise a concern and make a complaint (see complaints procedure)

Participants will sign, print and date their names and the researchers who secure the consent will also sign, print and date their names.

Please refer to the Consent Form associated with this Approved Procedure.

Guidance on the informed consent process can be found at: http://www.admin.ox.ac.uk/curec/resources/informed-consent/

6. POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/OTHERS AND WHAT WILL BE DONE TO MINIMISE

6.1. Risks to participants

The negative mood induction procedure results in a transient increase in sad mood. Individuals who are experiencing current psychological distress or suicidal ideation should not complete the sad mood induction procedure, so adequate screening must be in place.

Occasionally sad mood may still be present to some degree at the end of the formal study session.

6.2. Safeguards
Participants should be provided with information about the mood induction in the information sheet. The fact that the mood induction procedure is under participants’ own control should be emphasised - participants have to actively engage in the induction procedure in order for it to have an effect. Participants who feel uncomfortable and do not want to get into a sad mood are unlikely to do so. For instance, the information sheet could be worded as follows:

“In order to assess the effect that your mood has on your thinking, at some point during the session you will be asked to bring to mind some sad thoughts while listening to music for a few minutes. To help you get into a sad mood you will also be asked to read some cards that contain statements describing the kinds of thoughts and feelings people have when in a sad mood. This procedure is called ‘mood induction’ and would be under your own control the whole time.”

The procedure should be discussed so that all participants have been aware of and given informed consent to participate in this aspect of the session.

Participants should be screened using a clinical interview to ensure that they have not experienced depressive symptoms or suicidal ideation in the eight weeks prior to participation in the mood induction. Researchers can select their own screening questions depending on the precise needs of the study and the clinical interviews available to their research team, but these should always encompass questions about depressive symptoms or suicidal ideation. For instance, a positive response to the second parts of questions 1 or 2, or a positive response to question 3 would be grounds for exclusion.

- **In the past two months has there been a period of time when you felt depressed or down, most of the day, nearly every day?** If YES, did that last as long as one week, was it nearly every day?
- **In the past two months has it been difficult for you to enjoy doing things you would normally enjoy?** (For example watching TV, seeing friends, reading a book, other hobbies and activities?). If YES, did that last as long as one week, was it nearly every day?
- **In the past two months have you thought about suicide, or have you done anything to harm yourself?**

Researchers should consult the IDREC guidelines [https://www.admin.ox.ac.uk/media/global/wwwadmingold/localsites/curec/documents/1-1PsychDistress.pdf](https://www.admin.ox.ac.uk/media/global/wwwadmingold/localsites/curec/documents/1-1PsychDistress.pdf) on how to respond if screening identifies participants in significant distress.

In the rare circumstances in which an individual shows signs of excessive sadness or distress during the mood induction the researcher should respond by immediately terminating the mood induction procedure.

Researchers should explicitly ask participants if their mood has returned to normal following completion of any study tasks and should fully debrief participants. During debriefing participants should be given an opportunity to discuss their experiences. This procedure, in itself, almost always has the effect of eradicating any persisting sad mood since it allows participants to step back from their experience of the mood induction and view it objectively.

If any sad mood persists participants can be given a positive mood induction (positive Velten statements and positive music). In practice this is very rarely, if ever, necessary.

Any adverse reactions to the mood induction procedure (e.g. if a participant becomes distressed) should be reported to the senior investigator.

7. **MONITORING AND REPORTING OF ADVERSE OR UNFORSEEN EVENTS**

In the rare circumstances in which an individual shows signs of excessive sadness or distress during the mood induction the researcher should respond by immediately terminating the mood induction procedure.
Any adverse reactions to the mood induction procedure (e.g. if a participant becomes distressed) should be reported to the senior investigator.

8. CHANGE HISTORY

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