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

1. SCOPE

The negative mood induction procedure has been used widely 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" this would usually result in the researcher completing a full CUREC 2 application. This Approved Procedure is intended to cover only studies in which participants have been screened to ensure an absence of currently significant depressive symptoms or suicidal ideation (as described below). Note this procedure does not cover studies in which deception is used during the induction of negative mood, such as occurs with failure tasks in which participants are asked to complete a difficult or impossible task and are then given feedback indicating that their performance was substandard.

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 perform a task designed to induce a lower mood such as listening to sad music, watching sad films, reading cards containing sad (Velten) statements (negative statements such as “There are things about me that I don’t like”) or focussing on difficulties they have experienced in their life (or some combination of these). The researcher should remain present in the room throughout the procedure.

If several cognitive tasks are to be administered following induction of sad mood, then mood boosters (i.e. further “doses” of the mood induction procedure) may be 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.

Participants should be asked to rate their mood (e.g. happiness and despondency) periodically on visual analogue scales or similar measures, 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 participants will vary depending on the study. In addition to the standard information included for all studies, those studies using mood induction procedures should include a description of the mood induction procedure itself, its intended outcome and a statement concerning the possibility of inducing a negative mood. An example of the description of the mood induction procedure that can be included in the Participant Information Sheet is included in section 6.2 below.

The Information Sheet should be 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.

5. CONSENT OF PARTICIPANTS

The specific details will vary depending on the study, but the consent form will always be on University headed paper and researchers should follow the guidance on informed consent, which can be found at:
http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/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 made aware of and given informed consent to participate in this aspect of the session. Participants should be screened for depressive symptoms or suicidal ideation. Researchers should simply ask ‘Are you currently depressed’ and ‘Do you have any thoughts of self-harm’. If researchers receive a positive response, then they need to clarify the response further. 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.

- 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?
- 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?
- Have you thought about suicide, or have you done anything to harm yourself?

Researchers should consult the IDREC Best Practice Guidance 08 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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