

Cover Page for Study Protocol Document

Official Study Title: What makes people better at retrieving difficult words?

NCT05066750

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Protection of Human Subjects

1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design: This experiment will involve young and older adult participants. All participants will be prohibited from making hand gestures, a constraint shown to increase the difficulty of word retrieval. Then participants will be given a brief mindfulness exercise or control procedure, following which they will be given a definition-naming task. Participants' responses, including tip-of-the-tongue (TOT) experiences, will be recorded while they name the words that fit definitions. Approximately 100 young and 100 older participants (50 from each age group in each study condition) will be tested to obtain the desired power after eliminating unusable data (due to equipment malfunctions, participant drop-out, failure to pass the cognitive screen, etc.).

b. Study Procedures, Materials, and Potential Risks: This experiment will employ gesture restriction procedures prior to administering the mindfulness exercise. We will measure physiological indices (heart rate and skin conductance). Electrodes will be placed on participants' palms, and participants will be told to hold still so as not to dislodge them. This procedure will increase the difficulty of the subsequent naming task. Participants assigned to the mindfulness intervention condition will listen to a 10-minute guided meditation presentation. The presentation instructs participants to engage in breathing exercises, and includes music intended to be calming, with binaural beats. Participants in the control condition will be deceived by the experimenter that equipment has been left elsewhere and told the experimenter must go retrieve it. The experimenter will leave the participant in the room for 10 minutes, the same time required for the mindfulness exercise. This control condition leaves the participant to wonder what is happening and engage in naturalistic mind wandering. After the delay, the experimenter will return and say the equipment could not be located. The word retrieval task will consist of definitions for 60 low-frequency target words selected to have induced high rates of TOTs in my previous research. Participants will type the answer they retrieve, the letter T when they have a TOT, or D when they do not know the answer. Percent of trials with correct responses and TOTs will be collected. There are minimal risks involved in participation. Some people may find the tasks difficult and may experience frustration or concern. The experiment involves slight deception in that participants will not be told that they are in a control condition when they are left alone in the room, and also not told the true purpose of having them not gesture. These deceptions will be thoroughly addressed in the debriefing. Healthy older adults do not constitute a vulnerable population, and are at no greater risk due to this minimal deception than younger adults.

2. Adequacy of Protection Against Risks

a. Informed Consent and Assent: Young participants will see a description of the study on the SONA system, and older participants will be contacted over email or by phone and told that the study is about how people produce words aloud and requires 1 hour to complete. If they agree, they will come to the testing site and be given a consent form to read and sign.

b. Protections Against Risk: If a participant becomes upset or concerned regarding his or her naming performance, reassurance will be given that the task is designed to be difficult.

Participants will be reminded that they have the right to discontinue participation without penalty if they feel uncomfortable. Participants will also be told that they may decline having their data included in the final report if they so choose. The consent form will let participants know that hard copy data will be kept in a file cabinet in a locked office and electronic data files will be kept on password-protected computers. Any information obtained in this study that can be connected to participants will remain confidential and will be disclosed only with the participant's written permission or as required by law. Participant information will be kept separately from data, in a secure location. Participant information and data will be linked only by a meaningless participant identification code. Only Dr. James and her research assistants will have access to raw or coded data.

3. Potential Benefits of the Proposed Research to Research Participants and Others: All participants will be given information on the normal cognitive changes to be expected in older adulthood, particularly regarding the increased difficulty of word retrieval. They will also learn about how anxiety and mindfulness may affect cognitive processes. There are no other direct benefits available to subjects. The minimal risks encountered by participants are outweighed by these benefits.

4. Importance of the Knowledge to be Gained: The proposed research will lead to increased understanding of the cognitive changes that accompany healthy aging. The studies address word retrieval, a topic about which older adults have expressed great concern. Further, the mindfulness manipulation may suggest practical strategies for improving word retrieval in young and older adulthood.