Cover Page for Study Protocol Document

Official Study Title: What makes people better at retrieving proper names?

NCT05550779

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Research Summary and Participant Information

Research purpose/significance

Provide a brief background and describe the major research question/s of the proposed study in language that can be understood by an individual outside your discipline.

This study tests the relationship between proper name retrieval, age, and a brief mindful breathing exercise intervention. Older adults demonstrate more tip-of-the-tongue (TOT) states compared to younger adults. Mindful breathing exercises are suggested to reduce anxiety and increase attentional functioning; therefore, improve cognitive performance. Overall, I expect that older adults will report more TOT states compared to the younger adults. Additionally, both old and younger adults in the mindful breathing exercise condition (compared to the control condition) should have a decrease in TOT states. This study will test the age effect on TOT rate as well as the magnitude of improvement following a mindful breathing exercise between old and younger adults.

Does this study only involve existing data and no living participants?

No

Methodology

Describe, in narrative format, the research design (descriptions of methods) and list procedures to be used.

The study will test 120 participants, 60 younger adults (ages 18-35) and 60 older adults (ages 60-80). All participants will be treated following the ethical guidelines of the American Psychological Association, and the first step will be providing informed consent to participate. Participants in the mindful breathing exercise 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, which have been found to provide a benefit beyond other mindfulness components. Participants in the control condition will listen to a 10-minute clip of a narration of a story about a scientist's experience on a planet who attempts to communicate with an extraterrestrial being. A mindfulness self-report rating will be asked after the clip.

Then participants will participate in a name retrieval task in which they will be shown 83 images of celebrities. They will be asked to either retrieve the name the celebrity in the image, say they don't know who the person is, or say the name is on the tip of their tongue. Once all images are shown, the mindfulness self-report rating will be administered once again. After, the participants will be shown the images in which they said they were experiencing a TOT state and asked if the name of the person they were thinking of is the actual name of the person. Then participants will be shown all the images again with the celebrity's name underneath and will be given a familiarity rating of the celebrity in which they rate how familiar they are with the celebrity in the photograph.

For the younger adult participants, after the familiarity rating is completed, the researcher will post in the Zoom chat a Qualtrics link to complete the second part of the study. The researcher will end the Zoom videoconference call and the participants will complete the second part of the study on their own. The second part of the study includes a demographics form, trait mindfulness scale (MAAS), post-study questionnaire (including questions regarding the purpose of the study and meditation habits), and a debriefing of the study.

However, for the older adult participants, after the familiarity rating is completed, the researcher will administer the Mini-Mental State Exam (MMSE; Folstein et al., 1975). Once the MMSE is complete, the older adult participants will receive the Qualtrics link via the Zoom chat, the researcher will end the Zoom videoconference call, and the participants will complete the second part of the study on their own. Data from anyone scoring fewer than 26 out of the maximum score of 30 on the MMSE will be excluded from the analyses with the resulting sample characterized as non-demented elderly.

Do you plan on conducting this research project in person (face to face) with participants?

No

Additional Interaction Information

Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject?

Yes

Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation?

No

Does this protocol involve the use of medical equipment (i.e. X-rays, PET scans, MRI, etc.) on participants? This would include any methods that add energy into the body or that could possibly increase risk or harm.

No

Does the research involve ANY of the following populations?

Research involves NONE of the populations listed

Participant Recruitment

Describe how participants will be *selected* and *rationale* for the selection criteria.

Because this study compares performance for young and older adults, people 18-35 or 60-80 years of age can participate. They must be native, fluent speakers of American English because the project tests aspects of language production that differ for speakers of different languages. They also must have resided in the United States (US) for at least 5 years so they are familiar with the celebrities shown in the name retrieval task.

Describe from where the participant population will be drawn. Include when, where, and how the potential participants will be recruited.

Young adults will be recruited utilizing the UCCS Psychology Department SONA System, and older adults will be recruited utilizing UCCS's community research volunteer list that includes many adults ages 60-80 (contacted via phone or email). If necessary, additional recruitment will occur via flyers or other advertisements (those materials will be submitted to the IRB before posting, if needed).

Participant Enrollment Detailed Information

Participant Enrollment Information

Participant Age Range	Estimated Total Number of Participants	Estimated Number of Male Participants	Estimated Number of Female Participants	Estimated Number of Non-Binary or Non-Categorizing Participants
Adults 18-65 years	60	No answer provided.	No answer provided.	No answer provided.
Adults over 65 years	60	No answer provided.	No answer provided.	No answer provided.

Describe how coercion or perceived coercion of research participants will be avoided for all research populations (i.e., provide detail regarding subjects who are students of, or supervised by, the investigator).

All participation is voluntary and individuals will be given the option to opt- out at any point during recruitment or during the study without any negative consequences. Compensation for this study is not large enough to be coercive, but adequately compensates participants for their time. Individuals known to the PI will not be targeted for recruitment.

Describe where the data will be stored, who will have access to the data, and measures taken to secure the data. Include procedures for maintaining participant confidentiality. For any hardcopy data, CD, tapes, specimens, etc., describe any physical safeguards that will be in place; for example, locked cabinet/office, data de-identified, encryption, approved cloud storage (Dropbox is not permitted).

Data will be downloaded from Qualtrics and video recordings will be downloaded from Zoom onto the PI's password-protected computer. Only the PI and faculty advisor, Dr. Lori James, will have access to the data.

Describe how the privacy of the participants and the confidentiality of the data will be maintained (i.e., participants will be assigned an ID number to protect identity).

Video recordings from Zoom will be used for data scoring verification. Therefore, the recordings are identifiable. However, the name of the participant will be changed in the Zoom videoconference to arbitrary ID numbers to track participant data.

Are you accessing a database/data set that requires a privacy, confidentiality, or any other type of signed agreement in order to be granted access?

No

Describe the plans for the final disposition or de-identification of data that are identifiable in any way (directly or indirectly via codes) once the study has ended. If the data will be kept indefinitely, describe the format of the data and purpose of retention. If data will be destroyed, describe the timeline and method.

Once the data is verified using the video recordings, the video recordings will be permanently deleted. The data file (which includes no identifiable participant information) will be retained until 5 years following any publication that results from the research.

Name those who will identify, document, and report adverse or unanticipated events.

Hannah Levitt

Risk and Benefit Analysis

Describe all benefits of the research (benefits to individual participants, society, and/or science). If none, state "none" in the space provided and in the informed consent document.

The study will give researchers a better understanding of how individuals' personal traits relate to their ability to produce proper names. There are no direct benefits to participants.

Describe all risks and potential risks (e.g. physical, mental, emotional, and/or legal) to the participants. All studies entail at least some risk (e.g. annoyance, frustration). ?

Participants might feel frustrated by the name retrieval task, which was designed to be difficult.

Describe how the risks are reasonable in relation to the anticipated benefits.

The potential for frustration is minor compared to the knowledge to be gained.

Describe safeguards that will be taken to protect participants' rights, welfare, and reduce risks (e.g. medical consultation, counseling, etc.).

The consent form tells people that their participation "is entirely your choice. If you decide to take part, you can change your mind and stop participating at any time during the study session."

Is your study conducted virtually, or in some other manner, where participants will not provide a wet signature on a paper consent? (i.e. you need to request a waiver of documentation of consent, see help for details) ?

Yes

Choose the most appropriate option:

Other

Other explanation

The consent form will be shown to the participant via Zoom videoconference call through the "Share Screen" option; therefore, the researcher will be the only one with control over the screen. The participant will read through the consent form and asks the researcher to scroll down on the page when the participant has finished reading through the sections on the screen. Once the participant reaches the end of the document, the researcher will say: "Now you've read through this document, please say out loud 'Yes, I consent' or 'No, I don't consent' and I will check the appropriate box." Then the participant will give verbal consent and the researcher will click on the appropriate option.

Are you requesting an alteration of informed consent (i.e. no consent, consent is altered to omit certain required elements)? ?

No

Describe the consent process, including who will be obtaining the consent.

The consent form will be presented to participants prior to beginning the study.

Please describe the amount of time participants will be committing to, in order to participate in the study (i.e., 2 hours a week plus 30 mins travel to study site).

60-75 minutes

Will research participants be offered compensation for participating in the research?

Yes

Describe the nature of the compensation, including dollar value and schedule of payment. This information should also be stated in the informed consent document.

2.5 points of SONA credit upon study completion for UCCS students (ages 18-35) and $15 electronic gift card to non-student participants (ages 60-80).

Describe any plans to share results of the research with participants.

None