Psychometric Testing: Cued vs. Learned Suppression

Protocol Number: NCT06074523.1

National Clinical Trial (NCT) Identified Number: NCT06074523

Principal Investigator*: Nancy B. Carlisle

Sponsor: Lehigh University

Grant Title: Examining Flexibility in Attentional Control

Grant Number: R15EY030247

Funded by: National Eye Institute

Version Number: v.1

2024-10-18

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the NIH terms of award.

Table of Contents

STATEMENT OF COMPLIANCE

(1) [The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: 10/18/2024

Name*: Nancy Carlisle

Title*: Associate professor of Psychology and Cognitive Science

Investigator Contact Information

Affiliation*: Lehigh University

Address: 17 Memorial Drive W, Bethlehem, PA, 18015

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Email: nbc415@lehigh.edu

1 PROTOCOL SUMMARY

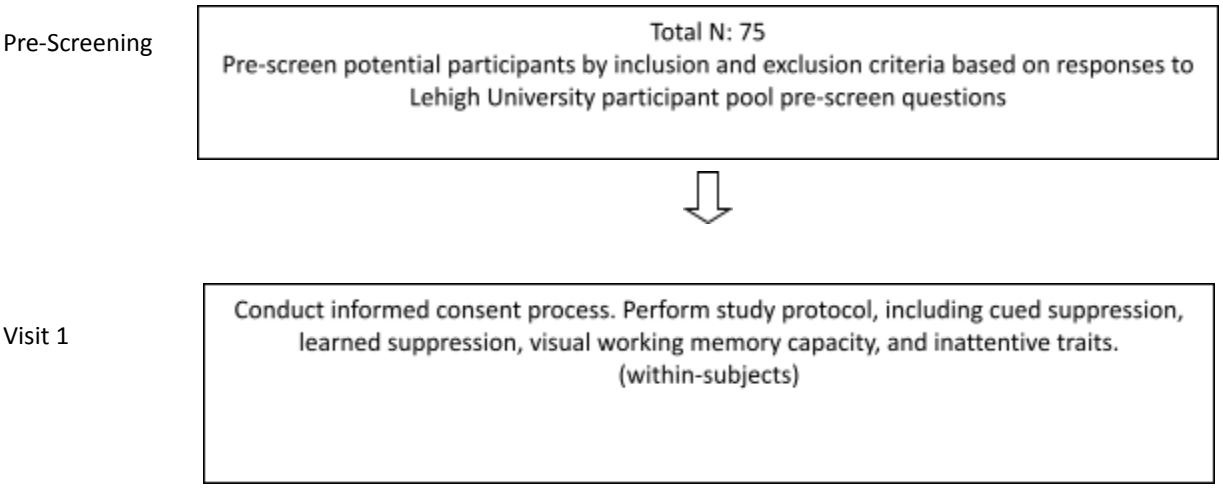
No text is to be entered in this section; rather it should be included under the relevant subheadings below. It may be useful to complete this section after the relevant sections in the protocol have been completed.

1.1 SYNOPSIS

Title:	**Examining Flexibility in Attentional Control**
Grant Number:	**R15EY030247**
Study Description:	*Examination of healthy participant's behavioral responses to determine if cued attentional suppression and learned attentional suppression rely on the same mechanisms*
Objectives*:	*The researchers will compare participants performance on a cued suppression task (distractor cue), learned suppression task (repeated distractor), working memory capacity, and inattentional traits.*
Endpoints*:	*One day measurement of cued suppression task performance, learned suppression task performance, working memory capacity, and self-report inattentive traits.*
Study Population:	*Healthy adults, recruited from Lehigh University*
Phase* or Stage:	*Phase 0*
Description of Sites/Facilities Enrolling Participants:	*Lehigh University*
Description of Study Intervention/Experimental Manipulation:	*Correlational study of four measures: cued suppression, learned suppression, working memory capacity, and inattentive traits.*
Study Duration*:	*4 months*
Participant Duration:	*60 minutes*

1.2 SCHEMA

Flow Diagram



1.3 Schedule of Activities

	Pre-screening (Pre-consent)	Visit 1 Day 1
Review Eligibility	X	
Informed Consent		X
Demographics		X
Outcome Evaluation		

2 INTRODUCTION

2.1 Study Rationale

Recent research has focused on two forms of distractor ignoring. In learned suppression, repeated salient distractors are presented and participants learn through experience to ignore the distractor color (Gaspelin & Luck, 2018). While salient distractors typically capture attention, learned suppression can lead to faster performance when a salient distractor is present compared to absent, suggesting that the salient distractor is suppressed. Other work on cued distractor suppression has demonstrated the existence of negative templates, also called templates for rejection (Arita, et al., 2012). Here, participants use their working memory to maintain cued colors, and then utilize top-down control to ignore items matching the distractor color. While both learned and cued suppression lead to ignoring of distractors, it is unclear if these two types of suppression rely on the same or different underlying mechanisms (Geng, et al, 2019).

2.2 Background

Much of the research on visual attention has focused on how humans direct attention towards our goals (Desimone & Duncan, 1995). However, recent research has identified two ways in which attention can be configured to ignore distractors, also improving attentional performance. In learned suppression (Gaspelin & Luck, 2018), repeated salient distractors are presented, and over learning, these salient items can become ignored. Participants are not instructed to ignore the salient items, however they learn through selection history to ignore the salient items. In cued suppression (Carlisle, 2023), participants are explicitly told to ignore a cued color presented before the search array. Here as well, participants are able to direct attention away from the cued color. However, although both tasks rely on suppressing colored items, it is unclear whether they rely on the same mechanisms. Learned suppression is an implicit phenomenon, while cued suppression is based on explicit top-down control.

Here, the researchers will look for correlations between the amount of suppression generated in cued suppression and learned suppression. The researchers will also measure working memory capacity, as an index of overall cognitive control. And researchers will take a measure of everyday distraction, an inattentive traits scale. The researchers will examine the correlations between all of these measures to determine if cued and learned suppression have shared underlying mechanisms.

2.3 Risk/Benefit Assessment

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

The following subsections should include a discussion of known risks and benefits, if any, to human participants. Text from the corresponding sections of the Human Subjects section of the grant application, and/or IRB package may be used here.

2.3.1 Known Potential Risks

The risks associated with the behavioral tasks are similar to working on a computer or playing a video game. They include possible eye strain, and boredom. Researchers will try to reduce the possibility of these risks by providing frequent breaks during the experiment (approximately every 5 minutes during data recording).

2.3.2 Known Potential Benefits

There are no direct benefits expected for the participants, however many participants enjoy being able to learn more about how The researchers use behavioral responses to understand more about cognition.

2.3.3 Assessment of Potential Risks and Benefits

Given that the risks are similar to daily tasks, the benefits to science are considered to outweigh the risks of the study.

3 OBJECTIVES AND ENDPOINTS

Provide a description of the study objectives and endpoints, as well as a justification for selecting the particular endpoints, in the table format included below. This will provide clear articulation of how the selected primary and secondary endpoint(s) are linked to achieving the primary and secondary objectives and an explanation of why endpoint(s) were chosen. Data points collected in the study should support an objective or have a regulatory purpose. Therefore, careful consideration should be given prospectively to the amount of data needed to support the study's objectives.

*An **objective** is the purpose for performing the study in terms of the scientific question to be answered. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose (e.g., feasibility, acceptability, engagement of the intervention target, identifying mechanisms of action, mediation, moderation, efficacy, effectiveness, dissemination, implementation).*

*A study **endpoint** is a specific measurement or observation to assess the effect of the study intervention. Study endpoints should be prioritized and should correspond to the study objectives and hypotheses being tested. Give succinct and precise definitions of the study endpoints used to address the study's primary objective and secondary objectives (e.g., specific diagnostic tests that define safety or efficacy, clinical assessments of disease status, assessments of psychosocial characteristics, patient reported outcomes, behaviors or health outcomes). A full description of study endpoints, including administration, scoring, psychometrics, adjudication of endpoints, etc., belongs in **Section 8**, **Study Assessments and Procedures**.*

A putative mechanism of action is the theorized explanation for how the intervention functions.

Consider whether primary and secondary endpoints should be adjusted for multiple comparisons, family-wise error rates, alpha inflation, etc. Details of any such adjustments should be included in ***Section 9.4.2, Analysis of the Primary Endpoint(s)*** *and* ***Section 9.4.3, Analysis of the Secondary Endpoint(s)****.*

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
To assess the degree of relatedness between cued and learned suppression	*Learned suppression performance, cued suppression performance, working memory capacity, inattentive traits*	*By measuring performance in both cued and learned suppression within the same individuals, the researchers can look for correlations indicating a shared underlying mechanism. Including measures associated with cognitive control (working memory capacity) and everyday distractability (inattentive traits), the researchers can further confirm whether shared mechanisms are at play.*

4 STUDY DESIGN

4.1 Overall Design

Hypothesis: Cued and learned suppression rely on separate underlying mechanisms. This is a Phase 0, single site study with a within-subjects design in healthy participants. Order of templates (intervention) within participants is counterbalanced.

4.2 Scientific Rationale for Study Design

Within subjects designs are considered a desirable design in cognitive studies, if possible. Within-subjects designs ensure that differences between conditions are not driven by differences in the individuals assigned to each group.

4.3 Justification for Intervention

Single-day designs are typical for the assessment of different attentional templates (Arita, et al, 2012; Carlisle & Nitka, 2019; Zhang & Carlisle, 2023).

4.4 End-of-Study Definition

A participant is considered to have completed the study if he or she has completed each of the tasks of the study.

5 STUDY POPULATION

5.1 Inclusion Criteria

Healthy adults aged 18+ with normal or corrected-to-normal visual acuity, and normal color vision will be recruited. Participants may be recruited from the Lehigh University student body as well as the local area. Some participants will be recruited through the University's online participant recruitment system, SONA, where participants will see a brief description of the study and choose to sign-up. Researchers may also post notices on Lehigh's daily emails (these notices will contain the same text as the provided flier). Participants may also be recruited through fliers (see example flier) and word-of-mouth. Fliers may be posted on campus, or in the local community on public bulletin boards (e.g. in a grocery store). All fliers will explain what characteristics The researchers are looking for in our participants, and the compensation provided to our participants. These participants may email or phone the researchers to express their interest, and may be contacted by email or phone to schedule their participation, or be directed to sign up for the SONA experimental participation system. Individuals who choose to participate may let others know about the studies by word-of-mouth.
Researchers will not require that participants see the fliers themselves in order for them to participate, but will allow all participants who meet the requirements the opportunity to participate. If a participant would like to be contacted about further studies in our lab when they finish their experiment, The researchers may also add them to a lab database of potential participants. This lab database may receive emails to let them know about new studies The researchers conduct in the lab (emails will contain the same information included in the flier, as well as 'We are recruiting participants for a new behavioral study on attention').

5.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Under age 18
2. Abnormal color vision
3. Visual acuity which is not normal, and has not been corrected to normal (20/20)

5.3 Lifestyle Considerations

- *N/A*

5.4 Screen Failures

Participants are pre-screened for eligibility before signing up for the study.

5.5 Strategies for Recruitment and Retention

- *Participants will be recruited from the Lehigh participant pool, which includes students who are currently enrolled in PSYC 001 and fulfilling a research experience requirement for the class.*

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 Study Intervention(s) or Experimental Manipulation(s) Administration

6.1.1 Study Intervention or Experimental Manipulation Description

Learned suppression : Participants will perform a learned suppression task, where the same color of salient distractor repeats across trials of a visual search task. Salient distractors do not appear on each trial, creating a baseline performance condition. Researchers will measure the effect of salient distractors by comparing reaction time on salient distractor present and salient distractor absent trials.

Cued suppression: Participants will perform a cued suppression task, where they receive an informative negative cue indicating the color of a large number of distractors on the upcoming search trials. On other trials they will receive a neutral cue which provides no information about the upcoming array. Participants will also perform a positive cue condition, where the cue indicates the color of the upcoming target. Researchers will examine the benefits from receiving the informative negative cue compared to the neutral cue.

Working memory capacity: Participants will perform a visual change localization task, leading to an estimate of their working memory capacity based on change localization performance.

Inattentive traits task: Adult Attention Deficit Hyperactivity Disorder (ADHD) Self Report Scale (used on healthy adults), Inattentive Traits subscale. Higher values indicate more ADHD-like inattentive trait symptoms (0-45).

6.1.2 Administration and/or Dosing

Each participant will perform each task.

6.2 Fidelity

6.2.1 Interventionist Training and Tracking

Each participant will receive the same instructions before performing each task block. Research assistants will read from the same script to ensure equivalent information provided to each participant, and address any participant questions.

6.3 Measures to Minimize Bias: Randomization and Blinding

N/A

6.4 Study Intervention/Experimental Manipulation Adherence

Researchers check participant understanding of each task by having them perform a practice block. (No practice for answering the questionnaire.)

6.5 Concomitant Therapy

N/A

6.5.1 Rescue Therapy

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 Discontinuation of Study Intervention/Experimental Manipulation

Participants can discontinue performance of the study at any time, if they no longer wish to participate, by informing the research assistant. Participants will be asked why they are discontinuing participation, but will be able to discontinue participation without providing a reason.

7.2 Participant Discontinuation/Withdrawal from the Study

Researchers will attempt to have all participants complete study, but if time allotted is exceeded, they may not finish the study.

7.3 Lost to Follow-Up

If a participant leaves the study without telling the researcher, the participant will be lost.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 Endpoint and Other Non-Safety Assessments

Participants will be screened for inclusion. Participants will provide informed consent before commencing the study. Researchers will measure performance on visual search tasks, but the performance on working memory probe trials is the key measure of the study.

8.2 Safety Assessments

RAs will continuously monitor for any adverse effects, and report any issues to the PI immediately.

8.3 Adverse Events and Serious Adverse Events

8.3.1 Definition of Adverse Events

Adverse events would be any event that does not include the possible typical effects of boredom or eye strain from looking at a computer screen.

8.3.2 Definition of Serious Adverse Events

Any event beyond typical eye strain and boredom will be reported to the Lehigh IRB for evaluation as possible serious adverse events.

8.3.3 Classification of an Adverse Event

1.1.1.1 Severity of Event

Any AE beyond eye strain and boredom, especially those which lead to participant withdrawal, will be reported to the IRB. Evaluation of severity of adverse events will be undertaken in consultation with the Lehigh IRB.

1.1.1.2 Relationship to Study INTERVENTION/Experimental Manipulation

Any AE beyond eye strain and boredom, especially those which lead to participant withdrawal, will be reported to the IRB. Evaluation of likelihood of relatedness to study protocol of adverse events will be undertaken in consultation with the Lehigh IRB.

1.1.1.3 Expectedness

Any expected adverse events (boredom or eye strain) may be reported in our subject run sheet.

1.1.2 Time Period and Frequency for Event Assessment and Follow-Up

AE will be assessed during the single day of study, only during the measurement period.

1.1.3 Adverse Event Reporting

Research assistants will report all AEs to the PI. Any AEs beyond expected (e.g. beyond boredom or eye strain) will be reported to the IRB to initiate a discussion of the AE between the PI and Lehigh IRB.

1.1.4 Serious Adverse Event Reporting

Research assistants will report all AEs to the PI. Any AEs beyond expected (e.g. beyond boredom or eye strain) will be reported to the IRB to initiate a discussion of the AE between the PI and Lehigh IRB.

1.1.5 Reporting Events to Participants

N/A

1.1.6 Events of Special Interest

N/A

1.1.7 Reporting of Pregnancy

N/A

1.2 Unanticipated Problems

1.2.1 Definition of Unanticipated Problems

UPs include the inability to finish the study protocol, and would require a reevaluation of the current study procedures.

1.2.2 Unanticipated Problems Reporting

UPs will be discussed with Lehigh IRB

*See **CD Section 8.4.1** for additional example text applicable for devices.*

1.2.3 Reporting Unanticipated Problems to Participants

N/A

2 STATISTICAL CONSIDERATIONS

2.1 Statistical Hypotheses

Researchers hypothesize that cued and learned suppression rely on separate underlying mechanisms, leading to no correlation in suppression between the two tasks.

2.2 Sample Size Determination

Data collection procedures

Researchers requested 75 participants in this study. 75 completed the task by the end of participant recruitment. Participants were at least 18 years old. It was a standard lab experiment. This study took 60 minutes to complete.

In this experiment, participants received verbal instructions from the experimenter before performing each task.

Both their color vision and their visual acuity have to be normal or corrected-to-normal (with glasses or contacts) (inclusion criteria).

No files selected

Sample size

A power analysis thus suggested that 48 participants would be sufficient (by using G*Power 3.1, when setting alpha error = to 0.05 and 90% power, with two-tailed testing). Researchers decided to include a larger sample size (75) to ensure enough power to detect the correlation, following participant exclusion.

Sample size rationale

Regarding the hypothesis on correlations, researchers anticipate discovering a moderate effect size of 0.45. This assumption is based on the previous studies discussed in the introduction, suggesting strong relationship between cued- and learned-suppression, as well as relationships with visual working memory and distractibility in everyday life thoughts.

A power analysis thus suggested that 48 participants would be sufficient (by using G*Power 3.1, when setting alpha error = to 0.05 and 90% power, with two-tailed testing).

Stopping rule

Researchers planned to use as many good participants as the researchers were able to collect within the sample of 75 requested. 21 participants were excluded for either bad accuracy in one of the cognitive tasks (n = 11) or for incomplete data recording (n = 10).

2.3 Populations for Analyses

Participants will be recruited from Lehigh's participant pool

2.4 Statistical Analyses

2.4.1 General Approach

Statistical models

To explore if the capacity to suppress cued distractors relies on the same mechanisms that the learned-suppression, Pearson correlation analysis will be performed between raw behavioral performance or indices (e.g., RT benefits and probe suppression) between the cued- and the learned-suppression task. In the same manner, to explore if the attentional suppression abilities (cued- and learned-suppression) were similarly associated with the visual working memory ability and the everyday life suppression ability, Pearson correlation has been used.

No files selected

Transformations

Researchers *will calculate cued suppression benefits from informative negative cues in the search task by comparing informative cue RT/accuracy to neutral.*

Researchers will measure the singleton presence effect by contrasting the reaction time when a salient singleton item is presents compared to absent in the array.

*For the visual working memory task, k score was computed for each subject in line with Zhao et al. (2022): k = (Accuracy*N2 − N)/(N − 1), where the setsize N equals 6.*

Based on Stanton et al., 2018, reseachers isolated a set of items in the ASRS to measure the inattentive and hyperactivity/ impulsivity traits of each individual. A confirmatory factor analysis (CFA) with the factor Inattention (Q1, Q2, Q3, Q4, Q7, Q8, Q9, Q10, Q11) and the factor

hyperactivity/impulsivity (Q5, Q6, Q12, Q13, Q14, Q15, Q16, Q17, Q18) was conducted to verify that a priori selected items reflect the same inattentive trait construct in the current dataset. The CFA revealed that the model did not fit the data correctly, as revealed by X2(134) = 198, p < 0.001; and the fit indices CFI = 0.74; RMSEA = 0.093. In the next step, Q10 was excluded from the analysis because of a bad estimate for the Inattentive traits factor. After exclusion, the model fit the data with X2(118) = 130, p = 0.213; and appropriate fit indices CFI = 0.94; RMSEA = 0.043.

Inference criteria

Significant level of 0.05 will be used in all tests.

Data exclusion

Participants with 2.5 deviation below the mean accuracy will be excluded.

Trials with RT less than 300 ms, greater than 2.5 sd above the mean for that condition, will be excluded from all analyses. Trials with incorrect responses will be excluded from the RT analysis.

Missing data

If a subject misses a cue condition, that subject will not be included in the analysis.

Exploratory analysis

N/A

2.4.2 Analysis of the Primary Endpoint(s)

Statistical models

To explore if the capacity to suppress cued distractors relies on the same mechanisms that the learned-suppression, Pearson correlation analysis will be performed between raw behavioral performance or indices (e.g., RT benefits and probe suppression) between the cued- and the learned-suppression task. In the same manner, to explore if the attentional suppression abilities (cued- and learned-suppression) were similarly associated with the visual working memory ability and the everyday life suppression ability, Pearson correlation has been used.

2.4.3 Analysis of the Secondary Endpoint(s)

N/A

2.4.4 Safety Analyses

N/A

2.4.5 Baseline Descriptive Statistics

N/A

2.4.6 Planned Interim Analyses

N/A

2.4.7 Sub-Group Analyses

2.4.8 Tabulation of Individual Participant Data

No.

2.4.9 Exploratory Analyses

N/A

3 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

3.1 Regulatory, Ethical, and Study Oversight Considerations

3.1.1 Informed Consent Process

Participants will provide written informed consent.

3.1.1.1 Consent/assent and Other Informational Documents Provided to participants

Text of the consent form is as follows:

CONSENT FORM

Studies on Attention and Cognition: Behavior

You are invited to be in a research study of visual attention and cognition. You were selected as a possible participant because you are 18 years of age or older, have normal or corrected-to-normal visual acuity and normal color vision. We ask that you read this form and ask any questions you may have before agreeing to be in the study. Your participation is entirely voluntary.

This study is being conducted by: *Dr. Nancy Carlisle, Assistant Professor of Psychology, Lehigh University*

Background Information

The purpose of this study is:
Learn more about how we are able to control our attention, and why we are sometimes distracted. We are looking at aspects of behavioral performance to learn more about the cognitive abilities underlying this performance.

Procedures

If you agree to be in this study, we would ask you to do the following things:
We will be recording your behavioral responses including reaction times and accuracy while you perform various types of tasks. For instance, in one task you may be looking at simple shapes on the computer screen pressing buttons after you find a target and responding to an aspect of the target. Another example task involves performing simple arithmetic tasks. For each task, you will receive clear instructions before performing the task and will need to follow the task instructions. You may ask your researcher now if you would like an overview of all the simple tasks you will be asked to perform today. The tasks will involve using your attention and/or other aspects of cognition to perform to the best of your ability. This study will not use random assignment to treatment conditions. For some studies, we may ask you to return for a second session. This study does not provide a clinical treatment, meaning there are no alternative treatments or procedures available.

Risks and Benefits of being in the Study

The study involves the following foreseeable risks: *The risks associated with the behavioral tasks are similar to working on a computer or playing a video game. They include possible eye strain, and boredom. We will try to reduce the possibility of these risks by providing frequent breaks during the experiment (approximately every 5 minutes during data recording). This study does not include any foreseeable risks to an embryo, fetus, or nursing infant.*

The benefits to participation are: *There are no direct benefits expected for the participants, and no clinical benefits, however many participants enjoy being able to learn more about how we use behavioral measures to understand more about cognition. More broadly, this research will help us learn more about how attention works, which is a critical aspect of daily life.*

Duration

Participation in the study involves the following time commitment:
Studies may last from 0.5-2 hours, with the expected time for your study being _____ hours. You will receive participation credit or compensation for the amount of time required to complete the study.

Compensation

If you have signed up for this study using the for-credit SONA system at Lehigh University, you will be granted credit within the system that may serve as partial completion of an experimental psychology requirement or extra credit for a course. You will be granted credits for the amount of time you participate.

You will receive payment:
If you have signed up for this study for compensating payment, you will receive payment at a rate of $12/hr for your participation. You will be paid based on the amount of time you participate.

Confidentiality

Participation in research involves some loss of privacy. The researchers will make every effort to ensure that information about you remains confidential, but cannot guarantee total confidentiality. Your identity will not be revealed in any publications, presentations, or reports resulting from this research study.

We will collect your data through behavioral responses and eye tracking. This data will be stored in a restricted access folder on Google Drive, secure Lehigh drives, and/or on password protected machines. This informed consent form will be kept for at least three years after the study is complete, and then it will be destroyed.

Any personal information that could identify you may be removed from the data you have provided and then the de-identified data may be used for future research studies, or distributed to another investigator for future research, without asking for your additional permission.

It is unlikely, but possible, that we may be required to share the information you give us from the study to ensure that the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so. The monitors, auditors, IRB, and regulatory authorities will be granted direct access to your original medical records (if provided) and data for verification of clinical trial procedures and data, without violating the confidentiality of the participant, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the participant or their legally authorized representative is authorizing such access.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Voluntary Nature of the Study

Participation in this study is entirely voluntary:
Your decision whether or not to participate will not affect your current or future relations with the Lehigh University. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contact About Future Studies

If you would like to be contacted about future studies being run in the lab for monetary compensation, we can add you to our participant database which includes email addresses of interested participants. The database is be maintained on password-protected computers and password-protected online storage (Lehigh storage and Lehigh Google Storage). Your email address will not be associated with your data or participation information, and you can remove your email at any time by contacting the researchers or replying to an email about a study opportunity. You are not obligated to participate in any future research if you add your email to the database.

Print your email address here only if you wish to be contacted about future studies: _____

Contacts and Questions

The Institutional Review Board (IRB) for the protection of human research participants at Lehigh University has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator (610) 758-5122 or nbc415@lehigh.edu. If you have questions about your rights or would simply like to speak with someone other than the research team about the questions or concerns, please contact the IRB at (610) 758-2871 or inirb@lehigh.edu. All reports or correspondence will be kept confidential.

You will be given a copy of this information to keep for your records.

Statement of Consent

I have read the above information. I have had the opportunity to ask questions and have my questions answered. I consent to participate in the study.

*Signature:*_____ *Date:* _____

*Signature of Investigator:*_____ *Date:* _____

3.1.1.2 Consent Procedures and Documentation

Participants will be given a brief overview of the study requirements (e.g. see stimuli and respond) and then be given the consent document.

3.1.2 Study Discontinuation and Closure

If multiple AEs are reported, or SAE, discontinuation of the study will be discussed and decided in consultation with the Lehigh IRB.

3.1.3 Confidentiality and Privacy

Consent documents will be maintained in a locked space. All participant data will be saved using a participant code at recording, and will be analyzed in this anonymous format. All reported data will be anonymous.

Coded data will be maintained on password-protected machines or storage, and will be anonymous. Nothing in the data could be used to identify who provided the data.

3.1.4 Future Use of Stored Specimens and Data

Any personal information that could identify the participant will be removed from the data you have provided and then the de-identified data may be used for future research studies, or distributed to another investigator for future research, without asking for additional permission from participants.

3.1.5 Key Roles and Study Governance

Principal Investigator
Nancy B. Carlisle, PhD
Lehigh University
Chandler-Ullmann Hall
610-758-5122
nbc415@lehigh.edu

3.1.6 Safety Oversight

Safety oversight will initially be conducted by the research assistants conducting the study, and oversight will be provided by the PI.

3.1.7 Clinical Monitoring

Monitoring will be provided by the research assistants, and oversight will be provided by the PI.

3.1.8 Quality Assurance and Quality Control

RAs will be trained by senior researchers in appropriate informed consent and task instruction procedures, and given oversight until satisfactory performance is achieved.

3.1.9 Data Handling and Record Keeping

3.1.9.1 Data Collection and Management Responsibilities

Data collection will be the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data, and electronic data will be maintained and backed up regularly.

3.1.9.2 Study Records Retention

Study documents will be retained for a minimum of 2 years after publication. Researchers plan to upload anonymized study data to OSF for further use.

3.1.10 Protocol Deviations

Senior researchers will look for evidence of protocol deviation. RAs will be trained to follow scripts and observed before independently testing participants.

It will be the responsibility of the site investigator to use continuous vigilance to identify and correct any deviations in protocol.

3.1.11 Publication and Data Sharing Policy

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers x years after the completion of the primary endpoint by contacting Dr. Carlisle or examining the OSF repository for this study. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

3.1.12 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NEI has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

3.2 Additional Considerations

N/A

3.3 Abbreviations and Special Terms

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
DRE	Disease-Related Event
EC	Ethics Committee
eCRF	Electronic Case Report Forms
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FFR	Federal Financial Report
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GWAS	Genome-Wide Association Studies
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ITT	Intention-To-Treat
LSMEANS	Least-squares Means
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance

QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOC	System Organ Class
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

3.4 Protocol Amendment History

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Version	Date	Description of Change	Brief Rationale

4 REFERENCES

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