IRB Application Form

Principal Investigator

Principal Investigator

A Principal Investigator (PI) must be designated for any human subjects research. The PI is responsible for ensuring university and federal regulatory compliance for all research activities and research personnel associated with this protocol. For the responsibilities of the PI, refer to the UIW IRB Manual.

Title	Dr.
First Name	Jeff
Last Name	Rabin
Address	9725 Datapoint Drive
City	San Antonio
State	TX
Zip Code	78229
Telephone Number	210-883-1197

College/School or University unit

School of Optometry

Human Subjects (CITI) Training completion date

05/30/2015

Is the PI a student?

- ○ Yes
- ◉ No

Other Project Personnel

Other Project Personnel

Do you need to list any other project personnel, including co-investigators, research associates, and student researchers who will be recruiting, consenting, collecting data, or working with data collected from human subjects?

- (•) Yes
- ( ) No

Name

Nirmani Karunathilake, BS

Role in Research

Co-investigator

Human Subjects (CITI) Training completion date

05/14/2017

Email

karunath@student.uiwtx.edu

Korey Patrizi, BS

Role in Research

Co-investigator

Human Subjects (CITI) Training completion date

05/15/2017

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Research Information

Title of Study

The Impact of Chocolate on Visual Performance: Psychophysics and Electrophsiology

Research Category

Research Category

- ○ Exempt
- ◉ Expedited
- ○ Full Board

Location of Research

Where will the research take place?

- ☑ On the UIW Campus or UIW facilities
- ☐ Off Campus (list all locations where the research will be conducted)

Number of Subjects

30

Number of Controls

0

Total duration of Study Activities, including total time required for subject recruitment, data collection, and analysis

1 Year

This research will involve the following (check all that apply)

- ☐ Inmates of penal institutions
- ☐ Institutionalized intellectually handicapped
- ☐ Institutionalized mentally disabled
- ☐ Committed patients
- ☐ Intellectually handicapped outptient
- ☐ Mentally disabled outpatient
- ☐ Pregnant women
- ☐ Fetus in utero
- ☐ Viable fetus
- ☐ Nonviable fetus
- ☐ Dead fetus
- ☐ In Vitro fertilization
- ☐ Minors (under 18)
- ☑ None of the above

Funding Disclosures

Funding source(s)

- ☐ Internal
- ☐ External
- ☐ Pending
- ☑ None

Purpose

Purpose

This section must briefly and succinctly state the purpose of the study and should derive logically from the summary of background and significance.

Our purpose is to determine if acute consumption of dark chocolate impacts:
(1) Visual perception and reaction time with and without verbal distraction
(2) Objective electrophysiological measures of retinal, optic nerve and visual cortical function.

Background and Significance

Background and Significance

This section should review appropriate literature to provide a clear rationale for the study including the anticipated outcomes and their significance. It should include discussion of how the proposed project will relate to or differ from what is already known. If the proposed research is a pilot study, make this clear and describe why pilot data are needed.

Consumption of dark chocolate has been associated with improved blood flow, cardiovascular function, slowing of degenerative aging processes, as well as enhanced mood and cognitive performance.(1-5) Dark chocolate is rich in cocoa flavanols which have both antioxidant effects to prevent and impede degenerative disease and as well as more immediate effects on local and cerebral blood flow. One study demonstrated an improvement in contrast sensitivity (CS) which is the visual ability to detect low contrast targets.6 Hence dark chocolate may enhance visual performance during critical task performance in military and law enforcement settings as well as every-day tasks such as driving. Whereas it is assumed that visual enhancements from dark chocolate derive from increased cerebral and/or retinal blood flow,6 direct measurements are lacking. Our prior research (7) demonstrated that hands free phone communication (verbal distraction) can delay reaction time and impair CS. Hence in this study our purpose is to determine if acute consumption of dark chocolate impacts:
(1) CS and reaction time with and without verbal distraction.
(2) Objective electrophysiological measures of retinal, optic nerve and cortical function.

In prior studies of acute effects of dark chocolate on cognition and CS, the dark chocolate was consumed 90-120 minutes prior to testing. In this study we are using a somewhat larger dose and beginning electrophysiological testing 1 hour after consumption with CS testing 90-120 minutes after testing. We believe this will capture possible more immediate blood flow changes in retina and cortex based on electrophysiological measures and CS and cognitive changes later in the session.

Location, Facility and Equipment to Be Used

Location, Facility and Equipment to Be Used

This section should identify the location, facility and equipment used to carry out the research project.

All measurements will be conducted in the University of the Incarnate Word Rosenberg School of Optometry (UIWRSO) Visual Neurophysiology Service (VNS) clinical facility, an air-conditioned clinical room with multiple standard and advanced measures of visual testing. Additional testing may be conducted in an air-conditioned research room equipped with CS testing. All subject data will be de-identified by assigning each patient a number and storing performance data in a password-protected Excel spreadsheet. CS and electro-physiological reports of performance will be printed as hard copy and/or PDF with subjects identified only by their subject numbers and stored in the Principal Investigator's locked office in a secured filing cabinet. All tests of vision are standard FDA approved clinical tests administered to patients in our VNS Clinic requiring no eye drops, dilation, or contact with the eyes.

Subjects and Informed Consent

Subjects and Informed Consent

This section should describe the subject population and procedures for obtaining subject informed consent. In describing the subject population, include number of subjects, source, and demographic factors. Describe how subjects will be identified, approached, and recruited. Describe specific criteria for inclusion or exclusion in the study and provide justification based on the hypothesis tested. Describe in detail how, when, and where signed Informed Consent will be obtained (particularly for any studies involving special populations or sensitive information), if subjects will be given a copy of the signed informed consent document, and how and where the consent forms will be securely maintained.

A total of 30 subjects will be recruited from UIW and RSO students, staff, faculty and patients. The age range will be 18 to 65 years and we will attempt to include comparable numbers of male and female participants. Inclusion criteria include visual acuity of at least 20/20 in each eye with no evidence of ocular, systemic or neurologic disease or ocular trauma. Based on prior research using repeated-measures designs, a difference of 0.1 log CS is considered significant and the estimated standard deviation is 0.13 log units. Hence the effect size = (mean difference)/SD = 0.1/0.13 = 0.76. The estimated minimum number of subjects to achieve significance at the 5% level with a power of 80%: (1/effect size)2 x 16 = (1/0.76)2 x 16 = 28 subjects.(8,9). Hence 30 subjects will be recruited to account for subject attrition during the course of the study.

Prior to obtaining written informed consent, each subject will be briefed on the nature of the study by one or more members of the research team. Subjects will be informed that they will be evaluated with standard vision tests one-hour after consuming a chocolate bar to assess its effects on performance. The dark chocolate and milk chocolate bars to be used (Figure 1) are commercially available from Trader Joe's and have comparable ingredients and nutrients except for the higher percentage (72%) of cacao dark chocolate in the experimental bar while the control bar contains 31% milk chocolate cocao solids which are not associated with acute beneficial effects on performance. As stated in the informed consent document, subjects will be asked if they have allergies to any of the ingredients contained in the chocolate bars illustrated in Figure 1, and will be excluded from participating if they answer affirmatively. As noted above, any subjects with ocular, systemic or neurologic disease, including diabetes and hypoglycemia, will not be allowed to participate in the study.

Subject Compensation

Subject Compensation

This section should describe in detail whether compensation will be provided as an inducement to subjects to participate in the study. Compensation is commonly offered to offset any inconvenience or expense that the subject may have. State the type and amount of compensation to be offered and when it will be paid. If there will be a delay in the receipt of payment, state the length of time. Whether a particular type of compensation for subject participation in research is appropriate or not will be evaluated on a per-protocol basis.

Each subject will be given a $25 gift card after completion of the study.

Duration

Duration

This section should describe the anticipated duration of the study including total time required for subject recruitment, data collection, and analysis.

One Year.

Research Design (Description of Experiment, Data Collection and Analysis)

Research Design (Description of Experiment, Data Collection and Analysis)

This section should describe how the study will be conducted including the methods to be used, experimental design, subject assignment and randomization procedures, duration of testing, data collection methods, and all other details necessary to fully describe the study. If subjects are involved with the study for more than one session, include the length of each session, and the total time required of each subject. Include information such as power analysis to justify the number of subjects to be recruited for the study. Describe who will perform which actions (e.g., which tasks will be performed by the principal investigator or co-investigator(s) or research staff under the supervision of an investigator).

A single-blinded crossover design will be used to assess possible effects of the dark or milk chocolate bars (72% cacao dark chocolate; see Figure 1)) on visual performance and visual electrophysiological signals. Double-blinding (experimenter unaware of the type of chocolate) is not tenable due to the difference in coloration and aroma of the two chocolate bars and not likely to be a significant source of variability given the objective nature of the visual performance measures. Subjects will be tested in two one-hour sessions separated by at least 72 hours. Each subject will consume a different chocolate bar one-hour prior to testing with the order of bars (dark vs. milk chocolate) counter-balanced across subjects. Subjects will be asked to refrain from consuming coffee or caffeinated drinks on the day of testing and to consume the bar without milk or milk products which can lessen beneficial effects of dark chocolate.

The patient will be presented the bar in its original wrapper but with the name masked by tape and she/he will be given a paper plate and napkins and asked to remove and return the wrapping to the research team member(s). The subject will be offered water during consumption of the bar which will take place in the research room. Insofar as many of the subjects will be in-house student volunteers, she/he will then remain in UIWRSO to study, work-study, finish clinical records, etc. for about 30 minutes. The patient will then undergo preliminary evaluation to prepare for the testing to commence at least 1 hour after chocolate bar consumption. This will include measurement of distant visual acuity followed by refraction to best visual acuity if the patient does not achieve 20/20 in each eye with their habitual correction. Hence the patient will either wear their habitual correction or lenses in a trial frame to achieve best vision during testing. The patient will then be prepped for electro-diagnostic testing including visual-evoked potentials (VEPs) and electro-retinograms (ERGs) which objectively assess visual cortical and retina/optic nerve function, respectively. VEPs will be recorded using the Diopsys® system. The subject is seated comfortably before a reversing checkerboard display. The back of the head, forehead and temple will be wiped clean using an FDA approved non-abrasive cleaner. High and low contrast VEPs will be recorded from the back of the head using disposable skin electrodes with reference and ground electrodes at the forehead and temple, respectively. Cone specific color VEPs10 will also be recorded using the Diagnosys, LLC system. All VEPs will be recorded binocularly and not be initiated until one-hour following consumption of the chocolate bar. The Diopsys® system will be used to record pattern ERGs (optic nerve function), flicker ERGs (cone function) and the photopic negative response (phNR; cone, bipolar cell and optic nerve function). Half of the subjects in control and experimental sessions will be tested with ERGs first and half with VEPs first to control for order effects. These FDA approved electro-diagnostic tests will be followed by letter chart measures of large and small CS (Precision Vision, Inc.). Each subject will then be tested with the Innova Systems, Inc. computer controlled Cone Contrast Test which assesses red, green and blue cone CS as well as large and small black/white letter CS using an adaptive staircase (like a hearing test) to determine the lowest visible contrast and overall response time. As described in our previous study,7 each subject will undergo computer-based CS testing with and without verbal distraction during testing with order counter-balanced across subjects. The verbal distraction will be broadcast on a hands-free blue-tooth device to simulate an incoming phone call consisting of scripted questions to assess memory and cognitive performance while completing the CS tasks. Following these tests, you will be asked to perform a brief (<10 minute) Wii™ shooting game using the Wii™ zapper which is shaped like a small rifle—no training is necessary. Two-way repeated measures ANOVA will be used to assess CS across distraction and chocolate bar conditions and post-hoc paired t-tests conducted to identify specific differences. Within subject ANOVAs and post-hoc t-test comparisons also will be used to assess amplitude and latency parameters of VEPs and ERGs across dark and milk chocolate conditions.

Risk Analysis

Risk Analysis

This section should identify all risks subjects will be subjected, including their frequency (e.g., x in 100) and severity. The level of risk categorization (e.g., no risk, minimal risk, more than minimal risk) must be stated and special precautions to minimize risk must be described (particularly for any subjects requiring specific precautions). Although medical emergencies are not expected, accessibility to CPR trained health care professionals should be described, if necessary for the proposal. In greater than minimal risk studies, the IRB may require use of a medical monitor.

This a minimal risk study with no greater risk than that associated with a standard eye exam. No subjects with stated allergies to any of the chocolate bars will be included. All testing will be conducted with FDS-approved clinical diagnostic equipment.

Confidentiality

Confidentiality

This section should describe how individual subject records and computer files will be safeguarded. Describe methods to ensure confidentiality and to whom information will be given, what information will be furnished, and the purpose of the disclosure.

All subject data, including CS values, reaction times, and electrophysiological amplitudes and latencies, will be de-identified by assigning each subject a number and storing these performance data in a password-protected Excel spreadsheet accessible only to the Principal and Co-Investigators. CS and electro-physiological reports of performance will be printed as hard copy and/or PDF with subjects identified only by their subject numbers and stored in the Principal Investigator’s locked office in a secured filing cabinet.

Literature Cited

Literature Cited

Literature cited should list relevant references cited in the Research Protocol.

1. Katz DL, Doughty K, Ali A. Cocoa and Chocolate in Human Health and Disease. Antioxidants & Redox Signaling. 2011;15(10):2779-2811. doi:10.1089/ars.2010.3697.
2. Petyaev IM, Dovgalevsky PY, Chalyk NE, Klochkov V, Kyle NH. Reduction in blood pressure and serum lipids by lycosome formulation of dark chocolate and lycopene in prehypertension. Food Science & Nutrition. 2014;2(6):744-750. doi:10.1002/fsn3.169.
3. Rostami A, Khalili M, Haghighat N, et al. High-cocoa polyphenol-rich chocolate improves blood pressure in patients with diabetes and hypertension. ARYA Atherosclerosis. 2015;11(1):21-29.
4. Nehlig A. The neuroprotective effects of cocoa flavanol and its influence on cognitive performance. British Journal of Clinical Pharmacology. 2013;75(3):716-727. doi:10.1111/j.1365-2125.2012.04378.x.
5. Balboa-Castillo T, López-García E, León-Muñoz LM, et al. Chocolate and Health-Related Quality of Life: A Prospective Study. PLoS ONE. 2015;10(4):e0123161. doi:10.1371/journal.pone.0123161.
6. Field DT, Williams CM, Butler LT. Consumption of cocoa flavanols results in an acute improvement in visual and cognitive functions. Physiol Behav. 2011 Jun 1;103 (3-4):255-60. doi: 10.1016/j.physbeh.2011.02.013.
7. Rabin JC, Bradshaw TL, Chacon, Johnston, Yu DB. Hands-free phone calls impair visual performance. Am J Prev Med. 2016 Oct;51(4):e117-8. doi: 10.1016/j.amepre.2016.05.006.
8. Dawson B, Trapp R. Basic and Clinical Biostatistics. McGraw-Hill, New York, 2001.
9. Norman G, Streiner D. PDQ Statistics (3rd Edition). BC Decker, Inc. Hamilton, Ontario, 2003.
10. Rabin JC, Kryder AC, Lam D. Diagnosis of normal and abnormal color vision with cone-specific VEPs. Transl Vis Sci Technol. 2016 May 17;5(3):8. eCollection 2016 May.

Recruitment

Upload recruitment materials (e.g., emails, flyers, scripts for in-person recruitment)

Type	Name	File Name	Date	Version	Size
Recruitment Materials	Recruitment Statement_rabin_2017	Recruitment Statement_rabin_2017.pdf	05/23/2017 12:00:00 AM	1	329.7 KB

Informed Consent

Upload informed consent documents (e.g., consent forms, emailed invitations to surveys)

Type	Name	File Name	Date	Version	Size
Consent Documents	JRABIN CONSENT FORM 2017	JRABIN CONSENT FORM 2017.pdf	05/26/2017 12:00:00 AM	2	127.3 KB

Data Collection

Upload data collection instruments (e.g., surveys, interview questions)

Other

Upload other supporting documents (e.g., site access letters, IRB approval from collaborating institutions)

Type	Name	File Name	Date	Version	Size
Other Supporting Documents	FIGURE 1	FIGURE 1.pdf	05/23/2017 12:00:00 AM	1	136.3 KB

Principal Investigator Signature

I certify that the information above is accurate and complete. I will request prior IRB approval for any changes to the approved protocol and/or informed consent forms, and will not implement those changes until I receive IRB approval. I will report any adverse effects to the IRB immediately. I agree to comply fully with the ethical principles and regulations regarding the protection of human subjects in research.

Principal Investigator

Signed: This form was signed by Dr. Jeffrey Rabin (rabin@uiwtx.edu) on 05/26/2017 21:02

Submission Reminder

Important Reminder

Don't forget to click "Submit" AFTER the application has been signed! Student applicants, that means you will need to log back in and click "Submit" AFTER your Faculty Supervisor has signed the application, otherwise it will not be received!