

Full Application

Title of Proposed Ancillary Study The effect of dietary composition on cognition during weight loss and weight-loss maintenance

Principal Investigator for Ancillary Study Ruth Remington, PhD, RN
Co-investigators Cynthia Bechtel, PhD, RN and Susan Mullaney, EdD, RN

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Abstract

The effect of good nutrition on cognition is not disputed in the literature. What is not clear is the ideal composition of the diet that promotes optimum cognitive performance. This study will evaluate the effect of weight loss and three weight-loss maintenance diets on cognition in young and middle aged adults who participate in the Framingham State Food Study. Cognition will be assessed by the California Verbal Learning Test, Trail Making Test, and Digit Span Test. Participants in the parent study will be invited to enroll in this ancillary study and meet four times to complete the assessment instruments, at baseline, at randomization, at week 10 and at week 20, concurrent with the regularly scheduled assessments for the parent study. The controlled feeding of the parent study will allow for comparison of the effect of three diets with varying carbohydrate to fat ratios on cognition, and the potential to identify a dietary composition that can maximize cognitive function in adults.

PROPOSED BUDGET

Personnel		Time/Effort		\$ Amount Requested		
Name	Project position title	%	Hours per week	Salary	Fringe benefits	Salary + Fringe
Student	Data collector – see below			2,700.00		
Student	Data entry			500.00		
Subtotal of personnel costs				3,200.00		
Supplies (itemize, expand any boxes as needed)						
Test manual, test booklets, scoring software				\$1,200.00		Subtotal= 4,400.00
Patient care costs (itemize)						
Remuneration for participants To encourage continued participation remuneration will increase at each test session completed, starting at \$10.00 for session 1, \$15.00 for session 2, \$20.00 for session 3 and \$25.00 for session 4				\$4,200.00		Subtotal= 8,600.00
Other expenses (itemize)						
Travel for dissemination of findings				\$1400.00		Subtotal= 10,000.00

Total Budget=\$10,000.00

Data Collectors:

Student data collectors to conduct four test sessions per participant, 60 participants (240 test sessions) each up to 45 minutes (total 180 hours) at \$15.00 per hour

BIOGRAPHICAL SKETCH

Provide the following information for the Principal Investigator. DO NOT EXCEED FOUR PAGES

NAME Ruth Remington		POSITION TITLE Associate Professor	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Rutgers University Newark NJ	BS	06/72	Nursing
UMass Worcester, Worcester MA	MS	06/92	Nursing
UMass Amherst and Worcester, MA	PhD	05/99	Nursing

A. Personal Statement

Briefly describe why your experience and qualifications make you particularly well-suited for your role as Principal Investigator on the proposed ancillary project. In the section, if appropriate, you also may explain how your expertise might contribute to the parent project.

The goal of this research is to identify the effect of weight loss and dietary carbohydrate to fat ratio on cognition in young and middle aged adults. Much of my research experience has been in the study of nutrition and cognition in adults, with and without dementia. In some of this work I have used the same measurement instruments that are named in this proposal. Most recently, I served as principal investigator of the study of nutritional supplements on cognition in dementia, sponsored by the Alzheimer's Association. The manuscript describing the results of this study is currently under review. Prior to that, I was co-principal investigator in studies of these nutritional supplements in healthy adults, in adults with early dementia, and in adults with advanced dementia. I also conducted smaller studies to identify the short term effect of the nutritional supplement, as well as the effect of apple juice consumption on cognition. The design of most of my research has been randomized clinical trials and has prepared me to lead the proposed study. Additionally, I recognize the importance of engaging students in research and feel this study will benefit the student participants as well as offer research experience for student data collectors.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors.

1992-2001 Nurse Practitioner, Adult Primary Care and Geriatrics,
Private practice, Berlin MA
2001-2012 – University of Massachusetts Lowell School of Health and Environment,
Department of Nursing
2007-2012 Associate Professor
2001-2007 Assistant Professor
2006 Teaching Excellence Award, University of Massachusetts Lowell Department of Nursing
2009 University of Massachusetts Lowell Outstanding Graduate Faculty of the Year.
2012-Present Associate Professor
Framingham State University
Nursing Department

C. Selected Peer-reviewed Publications

Limit the list of selected peer-reviewed publications, or manuscripts in press, to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed ancillary study or parent project.

Shea, T.B. & Remington, R. (2012). Alzheimer's disease: Are we intervening too late? Yes, by years if not decades. *Journal of Neural Transmission* 119(12), 1529-1532. DOI:10.1007/s00702-012-0849-0
Remington, R. (2012). Neurocognitive diagnostic challenges and the DSM-5: Perspectives from the front lines of clinical practice. *Issues in Mental Health Nursing*, 33, 626-629. DOI: 10.3109/01612840.2012.704136
Shea, T.B., Rogers, E., & Remington, R. (2012). Nutrition and dementia: Are we asking the right questions?

Journal of Alzheimer's Disease, 30(1), 27-33. DOI: 10.3233/JAD-2012-112231.

Lortie, J.J., **Remington, R.**, Hoffman, H., & Shea, T.B. (2012) The WAIS Digit Span test: A sensitive indicator of cognitive decline in mild cognitive impairment. *International Journal of Alzheimer's Disease*, doi: 10.1155/2012/829743.

Shea, T. B. & **Remington, R.** (2011). Efficacy of randomized start design for clinical studies of cognitive performance. *Journal of Alzheimer's Disease*, 26(4). <http://www.j-alz.com/letterseditor/index.html> Oct 2011

Remington, R., Chan, A., Lepore, A., Kotlya, E., & Shea, T.B. (2010). Apple juice improved non-cognitive symptoms in moderate- to late-stage Alzheimer's disease in an open-label pilot study. *American Journal of Alzheimer's Disease & Other Dementias*, 25(4), 367-371.

Chan, A., **Remington, R.** Kotoya, E., Lepore, A., Zemianek, J., & Shea, T. (2010). A vitamin/nutraceutical formulation improves memory and cognitive performance in community-dwelling adults without dementia. *Journal of Nutrition, Health and Aging*, 14(3), 224-230.

Remington, R., Chan, A., Tchantchou, F., Ortiz, D., & Shea, T. B. (2009). Neuroprotective effects of apples on cognition and Alzheimer's disease. *AgroFood Industry Hi-Tech*, 20(6), 30-32.

Remington, R., Chan, A., Shea, T. B. (2009). Efficacy of a vitamin/neutraceutical formulation for moderate to late Alzheimer's disease: A placebo-controlled pilot study. *American Journal of Alzheimer's Disease & Other Dementias*, 24, 27-33.

2009 Chan, A., Paskavitz, J., **Remington, R.**, Rasmussen, S., & Shea, T. B. (2009). Efficacy of a vitamin/nutraceutical Formulation for early-stage Alzheimer's disease: A one-year, open-label pilot study with an 11-month caregiver extension. *American Journal of Alzheimer's Disease & Other Dementias*, 23, 571-585.

Chan, A., **Remington, R.**, & Shea, T. (2008). The Clock-Drawing Test: Time for a change? *American Journal of Alzheimer's Disease & Other Dementias*, 23(4), 377-381.

Futrell, M, Melillo, K. D., & **Remington, R.** (in press 4/14). Wandering: Evidence-based practice guideline. *Journal of Gerontological Nursing*

Melillo, K.D., Abdallah, L., Dodge, L., Dowling, J., Prendergast, N., **Remington, R.**...Thornton, C.. (in press 3/14) A Guide to Developing a Dedicated Education Unit in Long-Term Care. *Geriatric Nursing*.

Simons, S. & **Remington, R.** (2013). The Percutaneous Endoscopic Gastrostomy Tube: A Nurse's Guide to PEG Tubes. *MEDSURG Nursing*, 22(2), 77-83.

The 2012-2015 Research Agenda Taskforce (**R.Remington** Chair). (2012). Hospice and Palliative Nurses Association 2012-2015 Research Agenda. *Journal of Hospice and Palliative Nurses Association*, 14(2), 158-163.

D. Research Support

List selected ongoing and completed research projects for the past five years. Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and your responsibilities.

Alzheimer's Association 2008--2012

Nutraceutical Formulation: An over-the-counter, formulation that provides antioxidant protection and prevents cognitive decline in aging: A clinical trial.

The goal of this randomized clinical trial was to identify the effect of a vitamin/nutraceutical formulation on cognition in adults with dementia

Role: PI 2011-2012; Co-PI, Project Director 2008-2011

US Apple Educational Research Council 2007-2009

Does Apple Juice Improve Cognitive Performance?

The goal of this randomized clinical trial was to identify the effect of daily apple juice consumption on cognition in healthy adults

Role: Co-Investigator responsible for site identification, data acquisition, data analysis and manuscript writing

Vice Provost for Research 2011-ongoing

Comparative analysis of alternative primary care models in institutional long term care residents using the Medicare Current Beneficiary Survey

The goal of this secondary analysis of data is to compare practice patterns of physicians and nurse practitioners in long-term care

Role: Co-Investigator evaluating data related to health promotion practices

American Psychiatric Nurses Foundation 2010-2012
Nursing Educational Needs for Caring for People with Serious Mental Illness (SMI) at End-of-Life
The goal of this qualitative study was to identify nurses perceptions of their educational preparation and need for education to help them care for persons with serious mental illness at the end of life
Role: Co Investigator: Data acquisition and analysis

Massachusetts Department of Higher Education 2011-2012
UMass Lowell-D'Youville Translational Care Dedicated Education Unit Partnership - Enhancing Faculty, Student and Staff Education and Opportunities in LTC
The goal of this project was to test a novel method of clinical teaching for pre-licensure nursing students. Both qualitative and quantitative studies were conducted
Role: Co-Investigator: Data acquisition, data analysis and manuscript writing

Health Resources and Services Administration 2010-ongoing
Comprehensive Geriatric Education and Mentoring across Settings
The goal of this project is to provide education to healthcare providers, in a variety of settings, on issues related to geriatrics.
Role: Co-Investigator: Data acquisition and manuscript writing

DISCLOSURES

Title of Proposed Ancillary Study The effect of dietary composition on cognition during weight loss and weight-loss maintenance

Principal Investigator for Ancillary Study Ruth Remington PhD RN

Please report relationships that were present during the 36 months prior to submission of your full application.

Section 1. Work Under Consideration for Funding

Do you anticipate receiving receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the proposed work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 2. Relevant Financial Activities Outside of the Work Under Consideration for Funding

Do you have financial relationships (regardless of amount of compensation) with entities such as a government agency, foundation, commercial sponsor, or academic institution (other than Framingham State University)?

The relationship may be in the form of **1)** a grant, **2)** personal fees (monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony, employment, or other affiliations), **3)** non-financial support (examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, or administrative support), or **4)** other.

Are there any relevant conflicts of interest? Yes No If yes, please list below.

Name of Entity	Grant?	Personal Fees?	Non-financial Support?	Other?	Comments
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 3. Intellectual Property – Patents and Copyrights

Do you have any patents (planned, pending or issued) broadly relevant to the proposed work? Yes No

Section 4. Relationships Not Covered Above

Are there other relationships or activities that could be perceive to influence, or that give the appearance of potentially influencing, how you conduct the proposed ancillary study?

Yes, the following relationships/conditions/circumstances are present (explain below):

No other relationships/conditions/circumstances that present a potential conflict of interest

RESEARCH PLAN

Study Aims and Hypotheses

Much of the research conducted on nutrition and cognition has focused on children, older adults, or specific disease states. This study will focus on healthy young and middle aged adults, a group that is under-studied in the literature. Our long-term goal is to identify the effect of nutrition on cognition. The overall objective for this application is to determine the effect of weight loss and weight-loss maintenance on cognition. It is our central hypothesis that carbohydrate to fat ratio in the diet influences cognitive function in young and middle aged adults. We have formulated this hypothesis based on our own previous work (RR and CB) with nutritional supplements and cognition, as well as the published work of Best and colleagues (2010), Wengreen and colleagues (2013) and others.

Specific Aim #1: To evaluate the effects of 3 diets varying widely in carbohydrate-to-fat ratio (high-carbohydrate, moderate-carbohydrate, low carbohydrate) on cognition in young and middle-aged adults

Hypothesis

1 Cognition will differ among test diets at 20 weeks

Primary outcome: memory (assessed by California Verbal Learning Test – Second Edition (CVLT) and Digit Span Test)

Secondary outcomes: processing speed and executive function (as assessed by Trail Making Test Parts A and B)

Specific Aim #2: To evaluate the effect of weight loss on cognition in young and middle-aged adults

Hypothesis

2 Cognition will differ following weight loss during the run-in phase

Primary outcome: memory at 12 weeks of run-in diet (assessed by California Verbal Learning Test – Second Edition and Digit Span Test)

Secondary outcomes: processing speed and executive function at 12 weeks of run-in diet (as assessed by Trail Making Test Parts A and B)

In addition to the anticipated long-term health benefits of weight management, such as the reduction of cardiovascular and metabolic risk factors, maximizing cognition can promote successful scholastic and professional performance in the short-term.

Background

The effect of proper nutrition on cognition is well recognized in the literature. What is not clear is the ideal composition of a diet that promotes optimum cognitive performance. According to the Merriam-Webster Dictionary (2014), the term *cognition* refers to the *Act or process of knowing. Cognition includes every mental process that may be described as an experience of knowing (including perceiving, recognizing, conceiving, and reasoning), as distinguished from an experience of feeling or of willing.* Cognition is a concept closely interrelated with learning, memory and memory retention, processing, decision making, judgment, and critical thinking, abilities necessary to success in academia and the work environment. Factors that can impact these capacities in positive ways, such as nutrition and weight loss, are viable topics for study in order to identify ideal approaches to maximizing function.

Protein, carbohydrate, and fat ingestion have all been associated with improved cognitive performance. It has been additionally suggested that blood glucose levels, glycemic index, insulin levels, and serotonin may be involved, either alone or in combination (Kaplan, Greenwood, Winocur, & Wolever, 2001). Cognitive performance was shown to improve when participants consumed diets (a) with a low glycemic index (Brindal et al., 2012; Dauncey, 2009; Micha, Rogers, & Nelson, 2010), (b) high in carbohydrates (Halyburton et al., 2007), (c) both decreased and increased fat content (Halyburton et al., 2007; Vizuete et al., 2010), and (d) high in protein (Brindal et al., 2012). Conversely, dietary cholesterol and saturated fats were associated with reduced cognitive function in healthy adults, independent of other risk factors (Devore et al., 2009; Kalmijn, Bostel, Ocke, Verschuren, Kromhout, & Launer, 2004).

Varied methodologies, study durations, and self-reported dietary compliance found in existing studies limit the ability to explicitly link specific diet composition or combinations of nutritional components to cognitive performance. Two reviews found that there was inconsistent and insufficient evidence to make dietary recommendations related to carbohydrate intake and cognitive performance (Gilsenen, deBruin, & Dye, 2009; Ooi, Loke, Yassen, & Hamid, 2011). Investigating the effects of three diets with known variations in carbohydrate-to-fat ratio on young and middle-aged adults may identify specific nutritional elements that can have a significant influence on cognitive ability among those in these age groups.

Much of the research accomplished to date relating to nutrition and cognition was conducted with school-aged children in the process of developing their cognitive ability or with older adults with declining cognitive ability due to age-related cognitive decline or diseases. A title search of research studies from 2000 to 2013 in the Cumulative Index of Nursing and Allied Health (CINAHL) using the key words *nutrition*, *cognition*, and *children* yielded 73 studies. Repeating the search with *older adults* yielded 70 studies, with *young adults* yielded 2 studies, and with *middle-aged adults* yielded 22 studies, most of which had a primary outcome associated with disease states such as hypertension, diabetes, cardiovascular disease, and cancer. Thus, young and middle-aged adults represent an understudied population with respect to nutrition and cognition. Identifying the optimal dietary composition that will enhance cognitive performance is essential for success in college and in the workforce for this faction.

Study Outcomes and Assessment Methods Outcomes

The primary outcome is learning and memory after weight loss and during weight-loss maintenance as measured by the California Verbal Learning Test II- Short Form (CVLT II) and the Digit Span Test. Secondary outcomes include executive function and processing speed as measured by the Trail Making Test Parts A and B.

Instruments. Three instruments will be utilized for this study, California Verbal Learning Test 2nd ed. (CVLT II), Digit Span Test, and the Trail Making Test Parts A and B.

California Verbal Learning Test 2nd ed. (CVLT II). CVLT II is one of the most widely used neuropsychological tests in North America. The CVLT II is used to obtain a detailed and comprehensive assessment of verbal learning and memory in older adolescents and adults ranging in age from 16-89 years of age. The CVLT II offers a standard, alternate, and short form for testing. The short form will be used in this study to limit participant fatigue in completing tests. During this test the examiner reads a list of nine words in three categories (fruits, tools, and clothing) in a 15 minute time period plus two delay periods totaling 15 minutes. Participants are asked to recall as many words as possible. Extensive clinical data are available which are nationally normed on a representative sample. Healthy adults test-retest correlation coefficients for CVLT II measures in standard/standard (0.80-0.84) (Delis, Kramer, Kaplan, & Ober, 2014; NINDS CDE, n.d.; Woods, Delis, Scott, Kramer, & Holdnack, 2006).

Digit Span Test. The Digit Span Test is a very short test that evaluates a person's cognitive status. The Digit Span Test includes digits forward and digits backward. Administering the test forwards assesses both attention and short-term memory. When the backwards version of the test is given, it also measures working memory. The participant is asked to repeat a list of three numbers read by the examiner in a random order at the rate of one digit per second. Subsequently the forward digits are increased by one digit. The score is the total number of items correctly repeated forwards prior to two consecutive errors at the same digit length.

Digits backwards is administered as above, but the participant is asked to repeat the numbers in reverse order. The range for digits forward is 0-12 numbers, while the range for digits backwards is 0-7 (Heerema, 2013; Alzheimer's Disease Research Center, n.d.).

Trail Making Test (TMT) Parts A and B. The TMT provides information on visual search, scanning, speed of processing, mental flexibility, and executive functions. The TMT consists of two parts. TMT-A requires an individual to draw lines sequentially connecting 25 encircled numbers distributed on a sheet of paper. Task requirements are similar for TMT-B except the person must alternate between numbers and letters (e.g., 1, A, 2, B, 3, C, etc.). The score on each part represents the amount of time in seconds required to complete the task (Tombaugh, 2004).

Sample. A sample of 60 participants will be recruited from participants in the Framingham State Food Study (parent study). Inclusion and exclusion criteria will be identical to those of the parent study. Participant remuneration will consist of a credit to the Framingham State Bookstore. Participants will have the potential to receive a total of \$70 in bookstore credit for completion of four test sessions (\$10.00 for the first, \$15.00 for the second, \$20.00 for the third and \$25.00 for the fourth)

Procedure. The assessment protocol will require up to 30 minutes of time for the participant at each testing session, which may be added to the scheduled assessments for the parent study or scheduled separately. Administration of the CVLT will begin and during the long delay period (10 minutes), the Trail Making and Digit Span tests will be administered, then the CVLT completed.

The risks associated with participation in this ancillary study are no greater than those encountered in daily life. It is recognized that the cognitive testing may upset a participant. If that happens, data collectors will provide the phone number for the Framingham State University Counseling Center or escort the participant to the Counseling Center if necessary.

Statistics

Sample size estimates are based on an effect size of 6.03 from our prior work. With a level of significance (α) of .05, power ($1-\beta$) of .80, and an effect size of .60, a sample size of 54 (18 participants in each of 3 groups) is predicted to be adequate to identify significant results if they do in fact exist.

Internal consistency of the measurement instruments will be measured by the Cronbach's alpha coefficient. Data will be examined using descriptive statistics including measures of central tendency and measures of variation. One-way analysis of variance will be used to test differences in cognition following the run-in phase. After the run-in phase and prior to analysis, to address the aims of interest, a one-way analysis of variance will compare the levels of cognition in the three groups prior to intervention as a check on the adequacy of randomization. Multivariate repeated measurements analysis of variance will be performed to compare the profiles of cognition over time among the three treatment groups.

Limitations

There are some limitations to this study. Using a non-probability convenience sample restricts participants to students, faculty and staff enrolled in the parent study, thus limiting the sample in size and range of ages, genders and ethnicities. It must be assumed that all participants respond to the measurement instruments accurately, honestly, and to the best of their ability. Data collectors will not be blinded to group membership introducing the potential for bias. The use of a standardized protocol will minimize that risk.

REFERENCES

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