Form Approved Through 03/31/2020 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY		
Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT (*Do not exceed 81 characters, including spaces and punctuation.*)
The Great Plains Internet Wellness for Aging Study: The GP I-WAS Project

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ■ NO ☐ YES
(If "Yes," state number and title)
Number: Title:

3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR

3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. eRA Commons User Name
McGrath, Ryan, Patrick	PhD MS BA	R.MCGRATH

3c. POSITION TITLE
Assistant Professor

3d. MAILING ADDRESS (*Street, city, state, zip code*)
1301 Centennial Blvd,
Fargo, ND 58102

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Health, Nutrition, and Exercise Sciences

3f. MAJOR SUBDIVISION
Exercise Science

3g. TELEPHONE AND FAX (*Area code, number and extension*)
TEL: 701-231-6043 FAX: 701-231-8872

E-MAIL ADDRESS:
ryan.mcgrath@ndsu.edu

4. HUMAN SUBJECTS RESEARCH	4a. Research Exempt	If "Yes," Exemption No.
☐ No ■ Yes	■ No ☐ Yes	

4b. Federal-Wide Assurance No.	4c. Clinical Trial	4d. NIH-defined Phase III Clinical Trial
IRB00001365	☐ No ■ Yes	■ No ☐ Yes

5. VERTEBRATE ANIMALS ■ No ☐ Yes — 5a. Animal Welfare Assurance No.

6. DATES OF PROPOSED PERIOD OF SUPPORT (*month, day, year—MM/DD/YY*)		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)
July 1, 2020	June 30, 2021	$50,000	$72,500	$50,000	$72,500

9. APPLICANT ORGANIZATION
Name: North Dakota State University
Address: 1340 Administration Ave.
Fargo, ND 58105

10. TYPE OF ORGANIZATION
Public: → ☐ Federal ■ State ☐ Local
Private: → ☐ Private Nonprofit
For-profit: → ☐ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER
DUNS NO: 80-388-2299 Cong. District: ND1

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name: Amy Scott
Title: Assistant Director of Sponsored Programs
Address: 735 NDSU Research Park Drive
Fargo, ND 58102
Tel: 701-231-8045 FAX: 701-231-8098
E-Mail: ndsu.research@ndsu.edu

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name: Amy Scott
Title: Assistant Director of Sponsored Programs
Address: 735 NDSU Research Park Drive
Fargo, ND 58102
Tel: 701-231-8045 FAX: 701-231-8098
E-Mail: ndsu.research@ndsu.edu

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE. I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 13.
(*In ink. "Per" signature not acceptable.*)
Amy B Scott

DATE
11-6-19

Protocol and Statistical Analysis

This Great Plains IDeA-CTR pilot project will utilize a prospective, within-participant design with multiple assessments across a 10-week intervention period and 1-month follow-up. Repeated measures optimize statistical power with smaller sample sizes and examination of within-person change over time. A 10-week intervention period was selected for this pilot project because this duration was consistent with the recommended amount of time it takes for habit formation to occur.[1] The 1-month follow-up period was chosen because of project resources and to maintain adherence to our 1-year project timeline. Our study will recruit 20 participants based on Aim 3, which provides 80% power in detecting a large standardized effect size of 0.72 in terms of change in the outcome (physical activity) after 1-month follow-up, with an alpha level of 0.05 using a two-sided Wilcoxon Sign-Ranked test, assuming that the actual data distribution is normal and a drop-out rate of 10%.[2] It should be noted that this is a pilot study with a smaller sample size. If the study yields smaller effect sizes when assessing the intervention effects, the study still provides useful information on feasibility, the trend of the intervention's effect, and accurate effect sizes for estimation that can be generalized to guide future large trials. Adults aged at least 65 years that can use the internet daily, have a body mass index $\geq$30 kg/m^2 , and are apparently healthy (i.e., medically able to participate in physical activity as determined by the PAR-Q+) will be eligible for study. We will utilize the North Dakota State University Research Participation Listserv for study recruitment. Word-of-mouth and flyers will also be used for recruitment purposes. Aim 1: Collaborate with stakeholders in all-phases of the internet-based wellness intervention to gain knowledge on the perspectives of the older adult population. Conducting community-based participatory research has demonstrated effectiveness in intervention studies and its use in research should be promoted, but few intervention studies in aging research exist where older adults have a research role.[3] An important component of community-based participatory research is to have stakeholders contribute to all phases of a study.[4] Specifically, we will recruit stakeholders to engage in the formative stages of the research, study execution, data interpretation, dissemination, and translation of results to practice.[4] The stakeholders will also provide our research with an additional perspective from the older adult population, thereby strengthening the impact of the investigation for older adults. [5,6] We intend for this pilot project to serve as a catalyst for future research projects that expand on the use of community-based participatory research such as developing a sustainable older adult community nucleus, allowing stakeholders to have equitable decision making of future research funding, and providing services to the older adult population that are outside of research.[4] Two stakeholders with wellness experience will be recruited from the local area through word-of-mouth and posting flyers at locations where older adults are known to gather. In order to better ensure representativeness, one stakeholder will be aged 65-69 years and the other will be aged at least 70 years. The Principal Investigator will select stakeholders for this project and they will be excluded as participants in the intervention. Based on our extant of the literature, a lack of professional guidance, inadequate distribution of appropriate educational materials, restrictions in transportation, and low motivation are barriers for older adults to engage in healthy behaviors.[7-9] Using behavior change theoretical framework in wellness interventions has been identified as a research requirement to advance the field.[10] Including motivation to engage in healthy behaviors for this project will come from two psychological theories that are often

applied to wellness motivation studies: self-determination theory and social cognitive theory.[11-14] Participation in physical activity, diet modification, and restorative sleep were targeted because they are each considered important for the health of older adults and can be impacted by motivation.[15, 16] Didactic information (e.g., videos and readings) for the health benefits of physical activity, a healthy diet, and restorative sleep will be delivered to participants, including how each of these factors effect health and longevity. With the help of the investigators and stakeholders, participants will design their own goal-oriented program. Progression towards longer-term goals will include a stepwise process of achieving short-term goals. Modifications toward these goals can be made based on progress and discussions with each participant. Intervention usability guidelines and resources from the United States Department of Health and Human Services will be used.[17] During the kick-off meeting, the investigators will introduce the initial conceptual model to the stakeholders. Discussions between the investigators and stakeholders will help to refine the strategies that will be used to enhance each construct relative to lifestyle behaviors. Investigators and stakeholders will develop a project plan and timeline, delegate roles and responsibilities, and refine the conceptual model. The contents of the internet-based wellness intervention will be uploaded on Google Classroom, a free online learning platform that can be used for administering internet-based health interventions.[18] There is always a risk that our intervention will not reflect the needs and priorities of the users; therefore, prior to launching the intervention, 3-5 individuals (non-participants) will pilot the contents in Google Classroom and measurement tools to provide feedback, thereby bolstering the reliability and quality of the platform, contents and measures. During the study period, the investigators will work with stakeholders in administering the intervention. The stakeholders will act as role models for participants by sharing experiences, initiating communications and providing information. Combining the use of a role model with other motivation factors has been recognized as a facilitator for practicing healthy behaviors in intervention studies with older adults.[19] Aim 2: Assess the feasibility of an internet-based wellness intervention for obese older adults. According to Bowen et al.'s[20] phases of intervention development, this stage of development for the intervention is key in assessing the "can it work?" components such as: acceptability, demands and implementation. These feasibility components are heavily focused on the actual use of the internet for a wellness intervention and any barriers or facilitators that participants may experience when using it. To evaluate potential efficacy, components that contribute to healthy behaviors such as acceptability, demand, and implementation will be evaluated. Specific items to be evaluated within these components include satisfaction with the platform, intent to continue, interest, recommendations to peers, usability, improved knowledge, and general recommendations for improvement. Each of the feasibility components will be evaluated with a 5-point Likert scale developed by the investigators and stakeholders, and may include open-ended items for more detailed feedback. Feasibility questionnaires will be completed online by participants at the mid-point and end of the intervention period. Participants will also be asked about their readiness to change wellness behaviors at the beginning, mid-point, and end of the intervention period by selecting their stage of change: pre-contemplation, contemplation, preparation, action, maintenance and termination.[21] Adherence and compliance will be quantified as the proportion of participants who fully completed the intervention. Results from the feasibility examination will be presented as mean and standard deviation or frequency

and percentage where appropriate. During weekly meetings, the investigators and stakeholders will assess if they are able to effectively communicate with participants using the internet, time commitment for learning, and overall feasibility of the intervention. Guidelines from the United States Department of Health and Human Services for program evaluation will help to guide how we determine feasibility.[22] Aim 3: Determine if completing an internet-based wellness intervention improves healthy behaviors among obese older adults. Participants will be asked to visit Exercise Science Labs at North Dakota State University at the beginning and end of the intervention, and at 1-month follow-up. After providing written informed consent, each participant will complete a descriptive questionnaire at the beginning of the intervention period, and a health-related questionnaire at the beginning and end of the intervention, and at follow-up that includes self-rated health, current smoking status, smoking history, alcohol use, morbid conditions, functional disability, and depression status. Standing height and waist circumference will be collected with a tape measure. Body weight and composition will be measured with the InBody 570 (InBody; Cerritos, CA). Previous research has demonstrated that the InBody 570 has strong reliability and validity for measuring body composition that is comparable to duel x-ray absorptiometry.[23,24] Anthropometric and body composition assessments will be collected from participants at the beginning and end of the intervention, and at follow-up. 6 Objectively Measured Physical Activity and Sleep Physical activity will be collected with an ActiGraph GT9X-BT accelerometer (ActiGraph; Pensacola, FL). The ActiGraph accelerometer has strong reliability and validity for capturing free-living physical activity.[25] Accelerometers will be given to participants during lab visits and sent back in a pre-paid mail envelope after wearing the accelerometer for all hours of the day on their waist for 7 consecutive days. Data will be considered valid if participants wore the accelerometer for at least 10 hours/day during waking hours, for at least four days including one weekend day.[26] The Choi et al.[27] non-wear algorithm will be used for determining wear time compliance. Accelerometer specific cut-points will examine time spent sedentary and in each intensity of physical activity. [28,29] As part of the physical activity measurements, the ActiGraph accelerometer will also measure total sleeping time. ActiGraph accelerometers have strong reliability and validity for assessing sleep.[30,31] Participants will be asked to wear the accelerometer during sleep and record periods of sleep in a log.[32] The Cole-Kripke algorithm embedded in Actilife 6 software will be used to score the sleep actigraphy.[33] Physical Activity Recall Use of time will be quantified using the Multimedia Activity Recall for Children and Adults, a computerized 24- hour recall. Each participant will recall their daily activities using a segmented day format with a resolution of 5 minutes or more. Participants choose from 500 different activities organized under a number of rubrics such as “self-care”, “occupation”, and “leisure”, with each activity linked to a compendium of energy expenditures.[34] The adult version shows excellent test-retest reliability and good convergent and criterion validity with accelerometers and doubly-labeled water, respectively.[35-37] The Multimedia Activity Recall for Children and Adults will be administered by 30 minute computer-assisted telephone interviews, with two consecutive days being recalled each time. The same 4 days will be recalled at each time-point (intervention beginning and end, and follow-up), including at a weekday and weekend day. Dietary Recall Participants will complete the Arizona Food Frequency Questionnaire (AFFQ) to assess dietary intake at the beginning and end of the intervention, and at 1-month follow-up. The AFFQ is a modified version of the Health Habits

Questionnaire and has demonstrated strong reliability and validity for assessing dietary intake.[38,39] The semi-quantitative, scannable, 153-item AFFQ asks respondents to report how often they consumed each particular food item during the last month. Participants will receive a report of estimated nutritional intake compared to recommendations with each AFFQ. In addition, each report will contain a personalized message from the dietitian to each participant. Intake of nutritionally dense foods (e.g., vegetables, lean proteins) and decreased intake of calorically dense foods (e.g., high sugar foods) will be compared to assess dietary change. Statistical Analysis Analyses will be conducted with SAS 9.4 software (Cary, NC). Means and standard deviations for continuous data or proportions for categorical data will be used for presenting the measures at baseline and measures at each data collection time point during the study period. Linear mixed effects models for continuous data or generalized linear mixed effects models for categorical data with fixed time effects, and random person effects will be used to evaluate changes in the outcomes. Repeated measures analysis requires consideration of the correlation between outcomes across the intervention period (covariance structures). To examine optimal covariance structures, Akaike information criterion will be used to determine the model of best fit. Potential covariates include age, sex, ethnicity, marital status, self-rated health, current smoking status, smoking history, alcohol use, morbid conditions, functional disability and depression status. Separate models will be used to assess changes in 1) physical activity, 2) diet, and 3) sleep. An alpha level of 0.05 will be used for all analyses.

1. Gardner B, Lally P, Wardle J. Making health habitual: the psychology of 'habit-formation'and general practice. Br J Gen Pract. 2012;62(605):664-6.
2. Cohen J. Statistical power analysis for the behavioral sciences. Ann NY Acad Sci; 2013.
3. Riffin C, Kenien C, Ghesquiere A, et al. Community-based participatory research: understanding a promising approach to addressing knowledge gaps in palliative care. Ann Palliat Med. 2016;5(3):218- 24
4. Horowitz CR, Robinson M, Seifer S. Community-based participatory research from the margin to the mainstream are researchers prepared? Circulation. 2009;119(19):2633-42.
5. Wallerstein NB, Duran B. Using community-based participatory research to address health disparities. Health Promot Pract. 2006;7(3):312-23.
6. Salimi Y, Shahandeh K, Malekafzali H, et al. Is community-based participatory research (CBPR) useful? A systematic review on papers in a decade. Int J Prev Med. 2012;3(6):386-93.
7. Hernandez DC, Johnston CA. Individual and Environmental Barriers to Successful Aging: The Importance of Considering Environmental Supports. Am J Lifestyle Med. 2017;11(1):21-23.
8. Bennett JA, Winters-Stone K. Motivating older adults to exercise: what works? Age Ageing. 2011;40(2):1148-9.
9. Nicklett EJ, Kadell AR. Fruit and vegetable intake among older adults: a scoping review. Maturitas. 2013;75(4):305-12
10. Sheeran P, Maki A, Montanaro E, et al. The impact of changing attitudes, norms, and self-efficacy on health-related intentions and behavior: a meta-analysis. Health Psychol. 2016;35(11):1178-88.
11. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. Am Psychol. 2000;55(1):68-78.
12. Bandura A. Social cognitive theory of mass communication. Media Psychol. 2001;3(3):265-99.
13. Deci EL, Ryan RM. Self-determination theory: A macrotheory of human motivation, development, and health. Can Psychiatr Assoc J. 2008;49(3):182-5.
14. Bandura A. Health promotion by social cognitive means. Health Educ Behav. 2004;31(2):143-164.
15. Teixeira PJ, Carraça EV, Markland D, Silva MN, Ryan RM. Exercise, physical activity, and selfdetermination theory: a systematic review. Int J Behav Nutr Phys Act. 2012;9(1):78.
16. Teixeira PJ, Silva MN, Mata J, Palmeira AL, Markland DJ. Motivation, self-determination, and long-term weight control. Int J Behav Nutr Phys Act. 2012;9(1):22.
17. United States Department of Health and Human Services. Available at: https://www.usability.gov/. Accessed November 14, 2019.
18. Iftakhar S. Google classroom: what works and how? Int J Educ Soc Sci. 2016;3(1):12-8.
19. Jopp DS, Jung S, Damarin AK, Mirpuri S, Spini D. Who is your successful aging role model? J Gerontol B Psychol Sci Soc Sci. 2016;72(2):237-47.
20. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. Am J Prev Med. 2009;36(5):452-7.

21. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. Am J Health Promot. 1997;12(1):38-48
22. United States Department of Health and Human Services. Centers for Diseasee Control and PRevention. Introduction to program evaluation for public health programs: a self-study guide. Available at: https://www.cdc.gov/eval/guide/CDCEvalManual.pdf. Accessed November 14, 2019.
23. Ling CH, de Craen AJ, Slagboom PE, et al. Accuracy of direct segmental multi-frequency bioimpedance analysis in the assessment of total body and segmental body composition in middleaged adult population. Clin Nutr. 2011;30(5):610-5. 9
24. Sartorio A, Malavolti M, Agosti F, et al. Body water distribution in severe obesity and its assessment from eight-polar bioelectrical impedance analysis. Eur J Clin Nutr. 2005;59(2):155-60.
25. Montoye AH, Nelson MB, Bock JM, et al. Raw and count data comparability of hip-worn actigraph GT3X+ and Link accelerometers. Med Sci Sports Exerc. 2017;50(5):1103-12.
26. Tudor-Locke C, Camhi SM, Troiano RP. A catalog of rules, variables, and definitions applied to accelerometer data in the National Health and Nutrition Examination Survey, 2003–2006. Prev Chronic Dis. 2012;9:E113.
27. Choi L, Liu Z, Matthews CE, Buchowski MS. Validation of accelerometer wear and nonwear time classification algorithm. Med Sci Sports Exerc. 2011;43(2):357-64.
28. Sasaki JE, John D, Freedson PS. Validation and comparison of ActiGraph activity monitors. J Sci Med Sport. 2011;14(5):411-16.
29. Kozey-Keadle S, Libertine A, Lyden K, Staudenmayer J, Freedson PS. Validation of wearable monitors for assessing sedentary behavior. Med Sci Sports Exerc. 2011;43(8):1561-7.
30. Slater JA, Botsis T, Walsh J, et al. Assessing sleep using hip and wrist actigraphy. Sleep Biol Rhythms. 2015;13(2):172-80.
31. Rosenberger ME, Buman MP, Haskell WL, et al. Twenty-four hours of sleep, sedentary behavior, and physical activity with nine wearable devices. Med Sci Sports Exerc. 2016;48(3):457-65.
32. Keadle SK, Shiroma EJ, Freedson PS, Lee I-M. Impact of accelerometer data processing decisions on the sample size, wear time and physical activity level of a large cohort study. BMC Public Health. 2014;14(1):1210.
33. Cole RJ, Kripke DF, Gruen W, Mullaney DJ, Gillin JC. Automatic sleep/wake identification from wrist activity. Sleep. 1992;15(5):461-9.
34. Ainsworth BE, Haskell WL, Whitt MC, et al. Compendium of physical activities: an update of activity codes and MET intensities. Med Sci Sports Exerc. 2000;32(9 Suppl):S498-504.
35. Gomersall SR, Olds TS, Ridley KJ. Development and evaluation of an adult use-of-time instrument with an energy expenditure focus. J Sci Med Sport. 2011;14(2):143-48.
36. Mace CJ, Maddison R, Olds T, Kerse NJ. Validation of a Computerized Use of Time Recall for Activity Measurement in Advanced-Age Adults. J Aging Phys Act. 2014;22(2):245-54.

37. Foley LS, Maddison R, Rush E, Olds TS, Ridley K, Jiang Y. Doubly labeled water validation of a computerized use-of-time recall in active young people. Metabolism. 2013;62(1):163-9.
38. Thomson CA, Giuliano A, Rock CL, et al. Measuring dietary change in a diet intervention trial: comparing food frequency questionnaire and dietary recalls. Am J Epidemiol. 2003;157(8):754-62.
39. Block G, Hartman AM, Dresser CM, Carroll MD, Gannon J, Gardner L. A data-based approach to diet questionnaire design and testing. Am J Epidemiol. 1986;124(3):453-69.