SUMMARY STATEMENT

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(Privileged Communication)

Release Date: **12/09/2016**
Revised Date:

Application Number: **1 P01 AG052352-01A1**

Principal Investigators (Listed Alphabetically):

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LACROIX, ANDREA Z. (Contact)

Applicant Organization: UNIVERSITY OF CALIFORNIA SAN DIEGO

Review Group: **ZAG1 ZIJ-7 (J1)**
National Institute on Aging Special Emphasis Panel
Second Stage P01 Review

Meeting Date: **11/21/2016**
Council: **JAN 2017**
Requested Start: **04/01/2017**

RFA/PA: **PAR13-258**
PCC: **4CCTSSR**

Project Title: **Sedentary Behaviour Interrupted: Acute, medium and long-term effects on biomarkers of healthy aging, physical function and mortality**
SRG Action: **Impact Score:20**
Next Steps: **Visit http://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**
Gender: **2A-Only women, scientifically acceptable**
Minority: **1A-Minorities and non-minorities, scientifically acceptable**
Children: **3A-No children included, scientifically acceptable**
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	1,499,411	2,328,592
2	1,499,350	2,328,498
3	1,499,882	2,329,324
4	1,499,826	2,329,237
5	1,499,645	2,328,956
TOTAL	7,498,114	11,644,606

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

PROJECT 2: SEDENTARY BEHAVIOR INTERRUPTED: A RANDOMIZED TRIAL OF 3-MONTH EFFECTS OF BIOMARKERS OF HEALTHY AGING AND PHYSICAL FUNCTIONING IN THE REAL WORLD; Dr. Jacqueline Kerr, Project Leader (PL)

DESCRIPTION (provided by applicant): Project 2 of the Sedentary Time and Aging Research (STAR) Program will investigate how 3 month changes in standing time, brief sit-to-stand transitions and physical activity (PA) breaks, will impact biomarkers of healthy aging, and physical, emotional and cognitive functioning compared to healthy living attention controls. This 4-arm randomized controlled trial (RCT) will occur in the `real world' with postmenopausal women (N=592) who are not physically active, do not stand up frequently and spend at least 8 hours sitting per day, i.e. most older adults. The daily behavior targets in each condition of Project 2 (increase standing by 2 hours, increase sit-to-stand transitions by 30 per day, & increase PA breaks by 12) reflect the treatment conditions explored in Project 1. To date, there have been no RCT studies with health outcomes in older adults. Our multiple pilot studies, however, demonstrate the feasibility and acceptability of delivering intervention materials (including standing desks, trackers & ActivPAL feedback) to older adults and evaluating behavior change objectively with thigh-worn inclinometers. The interventions significantly reduced sitting time (up to 2 hours a day) and significantly increased sit-to-stand transitions (up to 40 per day). Increases in PA were minimal in the standing conditions, compared to our PA focused RCT in 307 older adults which increased short PA bouts. One pre-post pilot found that reductions in sitting time were significantly related to improved gait speed and decreased depressive symptoms. Project 2 will assess the impact of the 3 interventions to interrupt sitting compared to the attention control condition at 6 and 12 weeks. We will recruit 592 overweight, sedentary, postmenopausal women who will be randomized to one of the 4 conditions. We will employ tools such as standing desks, wrist-worn device alerts and condition-specific, tailored ActivPAL feedback. The primary outcomes are glucose regulation and blood pressure. Secondary outcomes include mitochondrial functioning (measured by muscle mitochondrial respiratory capacity), and physical, emotional and cognitive functioning. Exploratory outcomes include psychosocial and environmental mediators and moderators of behavior change. We will also explore the moderating effect of age on the intervention outcomes. Project 2 compliments the other projects by assessing 3 month intermediary outcomes. Project 2 will help validate the novel computational algorithms optimized in Project 1 and applied to Project 3. In addition, the Biostatistics Core will investigate the response patterns in Projects 1 and 3 and map them to Project 2. Project 2 will strengthen the public health evidence of how to interrupt sitting time in older adults, provide specific information on interrupting sitting as an alternative to longer PA bouts, and explore a range of targeted outcomes related to healthy aging.

CRITIQUE 1:

Significance: 2
Investigator(s): 1
Innovation: 1
Approach: 4
Environment: 1

Overall Impact:
This updated and revised Project 2 application aims to compare three interventions (increased standing, increased sit-to-stand transitions, and increased PA bouts) to disrupt sitting with a control group on markers of glucose regulation and blood pressure. As secondary aims, the investigators will assess whether these interventions impact muscle mitochondrial capacity; physical, emotional and cognitive outcomes. Finally, the effect of age, psychosocial and environmental factors on these relationships will be examined and the outcomes will be compared between interventions. This is an application from an experienced investigative team with a successful record of publications and funding

in the area of physical activity and sedentary behavior. The PL, Co-Is and consultants are all well positioned to successfully complete this project and disseminate the results. The research question within this application has important clinical, scientific and practical significance. The investigators were responsive to the previous review. However, changes to the physical activity intervention and a lack of detailed descriptions of the interventions has diminished the reviewer's enthusiasm for this application.

1. Significance:
Strengths

- Interventions that focus on interrupting or decreasing time spent in sedentary behaviors in this population may show a clinical benefit.
- The population of focus in this application would likely benefit greatly from reductions in sitting and increases in movement.
- Comparing changes in behaviors and biomarkers in response to interventions that aim to reduce sitting, increase disruptions to sedentary behavior, and increase physical activity will be highly informative to future interventions.
- Few studies have examined the impact of disrupting sitting time outside of the laboratory, therefore the results of this project will provide information on the efficacy of these interventions as well as on the outcomes listed.

Weaknesses

- The PA intervention changed from increasing PA by 30 min/day to taking 12 extra 2-5 min PA breaks per day. This is still a break to (potentially) sedentary behavior and may not be distinct enough from the other intervention conditions.

2. Investigator(s):
Strengths

- The PL is a mid-career investigator with a strong publication and funding history in this area of inquiry.
- The team has successfully worked together in the past and continue to work together on other projects.
- There appears to be sufficient and qualified personnel to carry out the research project (Health Educator, Project Coordinator, Recruiter, etc.).

Weaknesses

- None noted.

3. Innovation:
Strengths

- This Project will be the first RCT to examine and compare the effects of three interventions to disrupt and/or reduce sedentary behavior in post-menopausal women.
- There is a lack of RCTs examining interruptions to sitting.
- This project will be the first to examine the impact of using standing desks outside of the workplace or school to reduce sitting behavior.
- This project will compare three interventions to disrupt sitting- one with standing, one with increased sit-to-stand transitions, and one with physical activity.
- Comparing the effect of these interventions on muscle mitochondrial function is novel.

Weaknesses

- None noted.

4. Approach:
Strengths

- The use of valid and reliable measures of SB and PA is a strength.

- The application of RCT is a strong design, with a strong rationale supporting separation of standing and sit-to-stand transitions as separate interventions. This design and the outcome of this study will give researchers and clinicians an indication the effectiveness of sitting interruption interventions. Further, comparing 2 sedentary interventions to a PA group and a control group may allow the investigators to answer many questions about the efficacy of the standing interventions vs. PA interventions, pending distinctness of the interventions.
- The researchers have tried to isolate each intervention behavior – standing, transitions from sitting to standing, and PA.
- The use of the CTRI, the new AHA Center, and the numerous other Center connections will strengthen the application.
- The control group intervention is strong, with a clear indication of information that will be delivered.
- The inclusion/exclusion criteria pertaining to sitting, sit-to-stand transitions and physical activity are strong and will result in a study population that is highly likely to benefit from the intervention.
- The screening process is well described and thorough.

Weaknesses

- The descriptions of the interventions are lacking. It is not clear what will be asked of the participants in the intervention arms. Are the participants given suggestions on what to do to once they stand up? Will they be restricted to standing only? What types of PA will be recommended? Further, is it not clear how distinct the interventions will be from each other, once the participants start carrying out the interventions. The potential overlap in the interventions will result in an inability to decipher the unique effects on the outcomes of interest.
- The rationale for the 2-5 min PA breaks is not clear. This PA recommendation is not in line with the PA recommendations.
- The dose of activity in each of these interventions is not equated, which will make it difficult to compare the outcome to standing, sit-to-stand transitions, to PA.
- The validation of machine learning algorithms is not well integrated into the application.

5. Environment:

Strengths

- The University, the CTRI, and the Centers are well- equipped and supportive of the successful completion of this application.
- Outstanding.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable risks and adequate protections.

Data and Safety Monitoring Plan:

Acceptable.

- While a DSMP is not needed, it provides and additional layer of protection for the research participants.

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically.
- Race/Ethnicity: Distribution justified scientifically.
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable.
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically.

- The inclusion of women only is justified in the application.

Resubmission:

- The investigators address most of the comments provided by the reviewers. However, one arm of the intervention was changed from a 30-minute PA intervention to 12, 2-5 minute PA breaks. The reviewer is not convinced this will be distinct enough from the sit-to-stand intervention.
- The interventions are not well described. It is not clear what the participants will be told to do in each of the interventions. For instance, if they stand up, can they move to go get a drink of water?
- With the removal of the biomarkers core, there were 4 additional personnel added to this Project, which will strengthen the quality and dissemination of the project.

Budget and Period of Support:
Recommend as Requested.

CRITIQUE 2:

Significance: 1
Investigator(s): 1
Innovation: 2
Approach: 5
Environment: 1

1. Significance:
Strengths

- Sedentary behavior is important risk factor for older adults and there is a need to understand lifestyle approaches to avert these effects.
- Results have the potential to inform lifestyle approaches to reduce negative health effects of sedentary behavior.

Weakness

- None noted.

2. Investigators:
Strengths

- The investigative team is outstanding and well qualified to conduct the proposed trial.

Weakness

- None noted.

3. Innovation:
Strengths

- This will be the first RCT to focus on changing sedentary behavior in overweight postmenopausal women.
- Multiple approaches will be assessed.
- Concurrent measures of glycemic control and endothelial function outcomes.

Weaknesses

- Although post-menopausal women have not been studied before in a randomized trial, it is not abundantly clear why other older adults at risk are not included.

4. Approach:
Strengths

- Use of mobile tools to track sitting interruptions in real time and also summarized at the daily/weekly level.
- Feasibility supported by large-scale pilot trials.

Weaknesses

- The rationale for the PA condition is confusing. It is stated that the 2-5 min breaks were selected to be in line with the PA guidelines. However, the PA guidelines are focused on accumulation of moderate intensity activity in bouts of 10 min or more. Thus, the investigators related to the accumulation of moderate to vigorous intensity activity of 30 min over the course of a day. However, the bouts are referred to a “light” PA bouts which would not be consistent or related to PA guidelines. The intensity of the PA breaks is not described. If light intensity, then the recommended PA breaks are not consistent with current PA guidelines.
- Given that the total amount of time that participants take break from sedentary behavior vary across conditions, the findings of the proposed study may be difficult to interpret since it would not be clear if changes were due to a dose effect or type of activity effect.
- Power is limited to detect differences across intervention conditions. This is a significant weakness given the potential importance of this question for health recommendations for older adults.

5. Environment:

Strengths:

- The Environment to conduct the planned study is outstanding.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections.

- No concerns.

Data and Safety Monitoring Plan:

- Acceptable.

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically.
- Race/Ethnicity: Distribution justified scientifically.
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable.
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals).

Resubmission:

- Investigators were very responsive to recommendations from previous submission.

Budget and Period of Support:

Recommend as Requested.

CRITIQUE 3:

Significance: 2
Investigator(s): 1
Innovation: 1

Approach: 2
Environment: 1

Overall Impact:
The outcomes of this Project, if achieved, have important clinical and practical significance to the field of health promotion and PA. This is a well-written application from experienced team who have demonstrated by previous work that they are likely to achieve this ambitious project. Project 2 is innovative, comparing 3 interventions to attention/education controls. This Project will have multiple outcomes, from those demonstrating mechanisms of improvement in health from objective measures (NIRS, glucose regulation, BP) to self-reported physical, psychosocial, cognitive, and other exploratory outcomes. Enthusiasm for this project is high and is likely to have a substantial impact on the science of SB and PA and how they may improve health. Weaknesses are focused primarily on the approach. Main concerns include attrition of subjects, overlap of the conditions of the 3 arms, compliance with the intervention conditions by subjects.

1. Significance:
Strengths
- Developing effective interventions for older women, other than PA, that will improve health (glucose regulation, BP, etc.) is important to improve methods for lifestyle counseling.
- There is a need to study older adults who frequently have metabolic impairments and who could likely show maximal benefit from interrupting SB especially since many older adults do not regularly exercise due to perceived or real barriers.
- Improves scientific evidence of methods of interrupting SB and which method would be superior in terms of important metabolic outcomes.
- If this Project is successful and outcomes achieved, it is likely to have great impact on the field of health promotion & disease prevention.
- Improved rational for scientific evidence of outcomes

Weaknesses
- Not provided.

2. Investigator(s):
Strengths
- Successful team, demonstrated outcomes, highly qualified to conduct this ambitious program.
- Preliminary data and pilot studies performed provide confidence in ability to complete ambitious project.

Weaknesses
- None noted.

3. Innovation:
Strengths
- Comparing 3 treatment conditions of reducing SB and comparing metabolic outcomes of each group is highly innovative and not accomplished to date.
- Adding mitochondrial measures -NIRS- helps determine mechanisms of action of reducing SB and is innovative.
- Whether emotional and functional outcomes will improve by interrupting SB using different methods is an innovative question, yet particularly salient for older adults.

Weaknesses
- Interventions methods/components of changing SB behaviors not highly innovative and may not be pragmatic.

4. Approach:

Strengths

- 4 arm comparisons.
- Objective measures and self-reported measures for primary, secondary and exploring mediators and moderators.
- Shorter outcome time in resubmission to test interventions will lesson attrition and improve probability of success.
- Measures of adherence for each condition, important to measure satisfaction with protocol to inform future studies.
- Improved clarity of inclusion/exclusion criteria (and rationale for), measures of PA/SB with both ActivPAL and Actigraph.
- Investigators very responsive to suggestions from previous submission & improved methods.
- Biostatistics support excellent.

Weaknesses

- Intervention components are very ambitious. Not sure if older women will accept the burden of intervention components (many visits to medical center, multiple phone calls, blood draws; packaged dinners, nothing by mouth status); not sure they can accomplish the requirements of each arm, thus limiting variability in outcomes.
- Remained concerned with recruitment and retention of participants and 10% attrition rate is over ambitious (most PA trials at least~20%).
- There is a concern about experimental condition overlap; e.g. standing breaks and brief sit to stand transitions are very similar and subjects may not perform correctly, e.g. PA short breaks may be taken instead of just standing in place.
- Intervention not pragmatic, difficult to enact & would be difficult to replicate in clinical practice because each intervention is testing multiple components that have a menu of choices/different components for each woman to perform. Will each arm be representing the same treatment?
- 20 minute MVPA arm replaced with PA breaks; rational for the latter is lacking, more important to include one arm with the current recommendation (20 min MVPA).
- Motivational interviewing is mentioned as a behavioral strategy in intervention, but components not supported by Table 1, maybe just motivational components and self-efficacy.

5. Environment:

Strengths

- Superior research environment.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections.

Data and Safety Monitoring Plan:

Acceptable.

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically.
- Race/Ethnicity: Distribution justified scientifically.
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable.
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals).

PROGRAM PROJECT AGGREGATE ROSTER
NATIONAL INSTITUTE ON AGING
January 2017 Council Round

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NATIONAL INSTITUTE ON AGING
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11/21/2016

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