Protocol Title:	Multilevel Intervention for Promoting Physical Activity in Rural Communities
Protocol ID#:	201809089/Grant # R01CA211323
NCT#:	NCT03683173

Rural PA Promotion Aim 2

PI: Ross Brownson
IRB ID #: 201809089

Project Details

1. Demographics

1.1 Project Title:
Multilevel Intervention for Promoting Physical Activity in Rural Communities Aim 2

1.2 Short Title (required):
Rural PA Promotion Aim 2

1.3 Project is primarily:
Social Science/Behavioral (includes History/Anthropology)

1.4 Type of Study:
Other Interventional

1.4.a Is your research study one in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (NIH clinical trial definition).
Yes

1.5 Select how you plan to obtain consent:
- Letter or information sheet with no signature
- Script for use either in person or over the phone with no signature

2. Source(s) of Support

2.1 Source(s) of Support

Type/Source	Grant Title	Name of PI on Grant	Status
Federal Agency NIH, National Cancer Institute (NCI)	Multilevel approaches for promoting physical activity in rural communities	Ross Brownson	AWARDED

Attachment Name	Category	Version	Date Attached
Rural_PA_Budget.docx	Grant from funding source or private foundation/association	1	02/05/18
Year 1 Rural Communities_NIH_NOA_1R01CA211323-01A1.pdf	Grant from funding source or private foundation/association	1	02/05/18
PA Rural Communities_A1.docx	Grant from funding source or private foundation/association	1	02/05/18
R01_Rural PA final package.pdf	Grant from funding source or private foundation/association	1	09/11/18

3. Research Team

3.1 Principal Investigator

Name	E-mail	Title
Ross Brownson	rbrownson@wustl.edu	Steven H.& Susan U. Lipstein Dist. Professor

3.2 Team Members

Research Team Members

Role	Name	Role Desc	Student	Email	Title	School	Department	Cont
PI	Ross Brownson, PHD		No	rbrownson@wustl.edu	Steven H.& Susan U.	Brown School	Brown School Administration	Ye

					Lipstein Dist. Professor			
	Alan Beck, PHD		No	alan.beck@wustl.edu	Project Coordinator - Provost Office	Central Fiscal Unit (CFU)	CFU - Provost Office Strategic Planning - Administration	Ye
	Dixie Duncan, BA		No	dixieduncan@wustl.edu	Research Project Coordinator	Brown School	Brown School Administration	N
	Amy Eyler, PHD		No	aeyler@wustl.edu	Professor of Public Health	Brown School	Brown School Administration	N
	Amanda Gilbert, MSW		No	a.s.gilbert@wustl.edu	Graduate Teaching Assistant	Brown School	Brown School Administration	N
	Diana Parra Perez, BS, MPH, PHD		No	parrad@wustl.edu	Assistant Professor	Brown School	Brown School Administration	N
	Natalicio Serrano, MPH		No	nserrano@wustl.edu	Prevention Research Center	Brown School	Brown School Administration	N
	Yan Yan, MD, Ph.D, MD		No	yany@wustl.edu	Prof of Surgery (Public Health Sciences)	School of Medicine	Surgery - Public Health Sciences (PHS)	N

Team Member Financial Interest

Name	Financial Interests
Ross Brownson, PHD	none
Alan Beck, PHD	none
Dixie Duncan, BA	none
Amy Eyler, PHD	none
Amanda Gilbert, MSW	none
Diana Parra Perez, BS, MPH, PHD	none
Natalicio Serrano, MPH	none
Yan Yan, MD, Ph.D, MD	none

4. Other Institutional Reviews/Requirements

4.1 Do any of the objectives of this study involve the diagnosis, prevention, screening, evaluation, treatment or support of cancer patients?
Yes

4.2 Are more than 30% of the patients involved in this study likely to have an active cancer diagnosis?
No

4.12 Will a Certificate of confidentiality be used for this research?
Yes, certificate automatically issued by funding agency

4.13 Does this project need to be registered on ClinicalTrials.gov?
Yes

4.13.a Who is the Responsible Party for registering this study in ClinicalTrials.gov?
Principal Investigator

4.21 Mark all that apply to your study:

1. Protocol

1.1 Is there a separate, written protocol that will be submitted in addition to this form? (Note: a grant application is not considered to be a protocol)
No

1.2 Select up to three key words below that best describe this research study:
- Public Health

1.3 Provide a short summary/abstract of the purpose and procedures of the study proposed in this IRB application.

- DO NOT include information on studies not proposed in this application.
- Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.
- DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.

Up to half of all cancer related deaths are preventable via evidence-based lifestyle changes such as increasing physical activity, enhancing nutrition, and reducing obesity.(1-3) Physical inactivity is a specific modifiable risk factor for breast and colon cancer.(4) Rates of physical inactivity are lower in rural communities as compared to their urban and suburban counterparts.(5) Nearly one-third of Missouri's population lives in rural counties,(6) and the "Bootheel" region suffers from a disproportionately high rate of cancer, in addition to physical inactivity and obesity.(7,8)

The purpose of the present study is to determine if a multilevel intervention (consisting of community events at local walking trails, formation of walking groups, and text messaging) will increase physical activity among rural residents. Intervention community members will receive the multilevel intervention while control communities will not. In the intervention communities, it is preferable for all participants to partake in all aspects of the intervention; however, not every person will partake in every level. We will create a dose-response variable hypothesizing participants who take part in all aspects of the intervention (i.e., attend walking events, takes part in walking groups, and receives text messages) will increase their physical activity more than people who engage in less of the intervention and those in control communities. As a part of the walking group formation in intervention sites, we will be utilizing the Stanford Healthy Neighborhood Discovery Tool application in order to receive feedback from participants related to the walking trails in their towns.

1.4 Specify your research question(s), study aims or hypotheses:
Test the independent and moderating effects of a multilevel intervention and the community environment on physical activity among rural residents.

1.5 Background and significance and/or Preliminary studies related to this project:
Key informant interviews were conducted in the intervention communities with three groups of people, walking trail users, walking trail non users, and stakeholders. We received feedback on the best methods by which to utilize local walking trails in the communities. Further, participants indicated to us their willingness to partake in future aspects of the study. Walking trail users and walking trail non users may be asked to participate as participants, while stakeholders may be asked to partake in a coalition to partner in increasing physical activity in rural southeast Missouri.

1.6 Literature cited/references (if attaching a grant enter N/A):
1. Colditz GA, Wei EK. Preventability of cancer: the relative contributions of biologic and social and physical environmental determinants of cancer mortality. Annu Rev Public Health. 2012;33: 137-156.
2. Colditz GA, Wolin KY, Gehlert S. Applying what we know to accelerate cancer prevention. Sc i Transl Med. 2012;4(127): 127rv124.
3. Curry S, Byers T, Hewit t M, eds. Fulfilling the Potential of Cancer Prevention and Early Detection. Washington, DC: National Academies Press; 2003.
4. Lee IM, Shiroma EJ, Lobelo F, P uska P, Blair SN, Katzmarzyk PT. Effect of physical inactivity on major noncommunicable
diseases worldwide: an analysis of burden of disease and life expectancy. Lancet.2012;380(9838): 219-229.
5. Parks SE, Housemann RA, Brownson RC. Differential correlates of physical activity in urban and rural adults of various socioeconomic backgrounds in the United States. J Epidemiol Community Health. 2003;57(1): 29-35.
6. US Department of Commerce. 2010 census of population and housing. http://www.census.gov/prod/cen2010/cph-2-27.pdf. Accessed December 28, 2015.
7. Centers for Disease Control and Prevention. Diabetes interactive atlas. http://www.cdc.gov/diabetes/atlas/countydata/atlas.html. Accessed August 20, 2016.
8. Missouri Department of Health and Senior Services. Chronic disease deaths. http://health.mo.gov/data/mica/mica/chronic_deathmap.php. Accessed December 28, 2015.
9. Freedman LS, Green SB, Byar DP. Assessing the gain in efficiency due to matching in a community intervention study. Stat Med. Aug 1990;9(8):943-952.
10. Gail MH, Byar DP, Pechacek TF, Corle DK. Aspects of statistical design for the Community Intervention Trial for Smoking Cessation (COMMIT). Control Clin Trials. Feb 1992;13(1):6-21.
11. Bock C, Jarczok MN, Litaker D. Community-based efforts to promote physical activity: a systematic review of interventions considering mode of delivery, study quality and population subgroups. J Sci Med Sport. May 2013;17(3):276-282.
12. Brownson RC, Ballew P, Brown KL, et al. The effect of disseminating evidence-based interventions that promote physical activity to health departments. Am J Public Health. Oct 2007;97(10):1900-1907.
13. Dobbins M, Hanna SE, Ciliska D, et al. A randomized controlled trial evaluating the impact of knowledge translation and exchange strategies. Implement Sci. 2009;4:61.
14. Gulliford MC, Adams G, Ukoumunne OC, Latinovic R, Chinn S, Campbell MJ. Intraclass correlation coefficient and outcome prevalence are associated in clustered binary data. J Clin Epidemiol. Mar 2005;58(3):246-251.
15. Gulliford MC, Ukoumunne OC, Chinn S. Components of variance and intraclass correlations for the design of community-based surveys and intervention studies: data from the Health Survey for England 1994. Am J Epidemiol. May 1 1999;149(9):876-883.
16. Jacobs JA, Dodson EA, Baker EA, Deshpande AD, Brownson RC. Barriers to evidence-based decision making in public health: a national survey of chronic disease practitioners. Public Health Rep. Sep-Oct 2010;125(5):736-742.
17. Turner RM, Thompson SG, Spiegelhalter DJ. Prior distributions for the intracluster correlation coefficient, based on multiple previous estimates, and their application in cluster randomized trials. Clin Trials. 2005;2(2):108-118.
18. Jacobs JA, Duggan K, Erwin P, et al. Capacity building for evidence-based decision making in local health departments: scaling up an effective training approach. Implement Sci. Sep 24 2014;9(1):124.
19. Donner A, Klar N. Design and Analysis of Cluster Randomization Trials in Health Research. London: Arnold; 2000.

20. Epstein LH, Raja S, Gold SS, Paluch RA, Pak Y, Roemmich JN. Reducing sedentary behavior: the relationship between park area and the physical activity of youth. Psychol Sci. Aug 2006;17(8):654-659.

1.7 Describe EACH of your participant populations

- Include description of any control group(s)
- Specify the Inclusion/Exclusion criteria for EACH group

Intervention community members will be selected from seven communities in southeastern Missouri (n=600). Control community members will selected from seven communities in southeastern Missouri (n=600). Communities are matched based upon population, demographic makeup, and income; then, randomized to the control or intervention condition. Inclusion criteria for both groups are adults, able to consent (e.g., no known cognitive impairments), able to be physically active, residing in the targeted communities, and willing to complete a telephone survey at three time points.

1.8 Check all materials/methods that will be used in recruiting participants:

- Telephone script
- Website or Social Media (printed pages)
- Word of Mouth/Snowball sampling
- Referral
- Other Methods/Source - Address based sampling, Random digit dialing

Attachment Name	Category	Version	Date Attached
Heartland_Moves_Screenshot.JPG	Recruitment: Website	1	11/05/18
Flyer.rtf	Recruitment Script: Phone	1	03/27/19

1.10 Describe where the consent discussion will occur (check all that apply):

- By phone
- Other - At local events (e.g., health fairs, walking events)

1.11 Participants and/or their legally authorized representative will have (check all that apply to the consent process and explain process in Question 1.12 below):

- As much time as they desire to consider enrolling in the study, including:
  - An opportunity to thoroughly review the consent materials with knowledgeable members of the research team, and with family and/or friends as appropriate
  - Sufficient time to have all of their questions answered

1.12 Provide a description of the enrollment and consent process in sequential order and address EACH of the bulleted points below:

- Describe each study population separately including control population
- Describe when recruitment and consent materials are used
- Indicate how much time individuals will have to consider participation
- If eConsent will be used to obtain an electronic signature, describe how the eConsent will be presented to participants, how their questions will be answered and how the participant will receive a copy of the final, signed consent
- Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process

To recruit intervention community participants Washington University in St. Louis (WashU) project staff will reach out via telephone to those walking trail users and walking trail non users to determine their current interest in participating in this study (see section 1.5) using the telephone script. Further, WashU project staff will reach out to stakeholders to determine their interest in being a part of a coalition - in this capacity, project staff will use the informational sheet to reach out to stakeholder constituents to determine their interest in partaking in the study.

Recruitment in control communities is detailed elsewhere. Participants in both intervention and control communities may provide their consent immediately after asking any questions, or project staff can call the potential participant back at a later time (typically within a week). It will be stated to participants that participation is completely voluntary, and they are welcome to withdraw at any time.

1.13 Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures

DESCRIBE:

- Control populations, if applicable
- Any randomization, if applicable
- What participants will be asked to do/what happens in the study (in sequential order)
- The time period over which procedures will occur
- Long-term follow-up and how it occurs

Control and intervention participants will conduct a telephone survey at baseline and one follow-up timepoint (n=1241). A subset recruited from the baseline telephone survey, will wear an accelerometer and global positioning devices for one

week at baseline and one follow-up timepoint(n=300).

1.14 Will participants be randomized?
Yes

1.15 Will any of the following be used to collect information from the participant or others?

- Screening questions or screening/eligibility questionnaires
- Surveys
- Questionnaires
- Stimuli
- Any other written assessments

Yes

Attachment Name	Category	Version	Date Attached
Amanda Program-Perryville.docx	Subject Data Collection Instruments	1	11/05/18
Amanda Program-Piedmont.docx	Subject Data Collection Instruments	1	11/05/18
Stanford Healthy Neighborhood Discovery Tool.docx	Subject Data Collection Instruments	1	11/08/18
[Master] E01 CareMessage Exercise 24 Weeks (v.2) - ENG E01 Accounts Schedule (1).pdf	Subject Data Collection Instruments	1	11/05/18
Telephone Survey 2 Baseline Intervention.docx	Subject Data Collection Instruments	3	05/18/20
Telephone Survey 2 Baseline Control.docx	Subject Data Collection Instruments	3	05/18/20

1.16 Does this project involve creating any audio, video, or photographs?
No

1.17 Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?
Examples:

- Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.
- Participants will be provided with false information regarding the particular behaviors of interest in the research.
- Procedures include a confederate pretending to be another participant in the study.
- Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.
- Study is designed to introduce a new procedure (or task) that participants are not initially told about.

No

1.18 Indicate any payments or reimbursements to participants (check all that apply)

- Gift or Debit Card

1.19 Does this study have a plan to have an individual or committee review combined data from all participants on a periodic basis (such as summary or aggregate safety and/or efficacy data)?
No

1.20 What have you done to minimize any risks?

- No forseeable risks

1.21 What are the potential benefits related to this project for:

- the participant (if any)
- benefits to society (if any)

An increase in physical activity may lead to improved health. The benefit to society is the project, if successful, has the potential to be scaled-up to reach a larger number of people.

1.22 Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.
The intervention is at the community, interpersonal, and intrapersonal levels, and the activity environment is classified at the individual level. The basic model for the individual level analysis is: $Yjk = \alpha j + \beta Ij + \gamma Xj + \eta Zjk + \theta Ij*Ejk + \varepsilon jk$; where Yjk is the change in physical activity for subject k in jth community (j = 1,2…12), I = 1 if intervention and 0 otherwise, X = a vector of community level covariates, Z = a vector of individual level covariates (including Ejk individual level of activity environment), and Ij*Ejk = intervention-by-environment interaction. The parameter αj is the random intercept, β is the main effect for intervention, and θ is the interaction effect. In this model, β is the expected difference in the physical activity level between intervention and control among those whose physical activity is mainly indoor, and (θ + β) is the expected difference in the physical activity level between intervention and control among those whose physical activity is mainly in the natural environment. Both main and

interaction effects are adjusted for community level and individual level covariates. The primary analyses will be conducted at the end of 1 and 2 year follow-up. In these analyses, baseline physical activity level will be used as one of covariates.

1.23 Provide the rationale or power analysis to support the number of participants proposed to complete this study.
This study uses a paired, group-randomized design. By using matching criteria, we will balance potential community-level confounding factors (e.g., community size, poverty level) with a gain in the statistical power [9,10]. Based on the literature, we estimated accelerometer-measured MVPA in the control group at 42.5 minutes per week (m/w).[9] In the intervention group, we assume a 16% increase (42.5*1.16 = 49.3), based on a recent meta-analysis [11]. We used a much larger SD of 16 rather than that reported (6.2) to ensure a sufficient sample size both for testing the intervention effect and for testing the intervention-by-environment interaction (moderation) effect. We assumed ICC estimates in the range of 0.01-0.03, based on our pilot studies and values of ICCs in the literature [12-18]. With 12 communities and an average of 48 study subjects in each (a total of 576 subjects for accelerometry), the study has power >90% with 2-sided α = 5% to detect the mean difference in MVPA between the control (42.5) and intervention (49.3) groups, using Donner's method [19]. For intervention-by-environment interaction, we assume in the natural environment, the intervention and control difference is 57 m/w versus 44 m/w, and in the indoor environment, the difference is 43 m/w versus 41 m/w. Estimates of interaction are based on our pilot work and existing studies [20]. With a common SD in each of four subgroups = 10, we have 84% power to detect a significant interaction using factorial analysis of variance methods (F-test) adjusting for clustering (ICC = 0.03). Our simulation using two-level mixed effect models also indicates the power to detect the assumed interaction effect >90%. Our sample size is determined for accelerometry subjects at the end of Year 2. With a yearly follow-up rate of 80%, which is achievable given our previous work, we need to enroll 576/0.64 = 900 at baseline for accelerometry. For telephone survey subjects, we need to enroll 900/0.75 = 1,200 at baseline.

1.25 Will any data from this project be stored for use in future research studies?
No

1.26 Does this project involve the collection or use of biological samples or genetic data?
No

1.27 Are you requesting institutional certification to contribute human data or samples to a repository or database for broad sharing (public or restricted access)?
No

2. Participants

2.1 Will there be any adult participants?
Yes

2.1.a How many adult participants do you expect to consent or enroll under a waiver for this project?
1200

2.1.b What is the age of the youngest adult participant?
18.0

2.1.c What is the age of the oldest adult participant?
No age limit

2.2 Will there be any minor participants?
No

2.3 Will there be any emancipated minor participants?
No

2.7 Do you plan to recruit/enroll non-English speaking people?
No

2.8 Do you propose to enroll any of the following in this study as participants?

- Employee of the PI or employee of a research team member
- Individual supervised by PI or supervised by member of research team
- Individual subordinate to the PI or subordinate to any member of the research team
- Student or trainee under the direction of the PI or under the direction of a member of the research team

No

2.9 Is this project about pregnant women?
No

2.10 Will this project involve fetuses?
No

2.11 Does this project involve the use of fetal tissue from any source?

No

2.12 Does this project recruit adult participants who may be incompetent or have limited decision-making capacity on initial enrollment into the study?
No

2.13 Does this project involve prisoners as participants?
No

3. Performance Sites

3.1 Indicate type of site(s) where research will occur (check all that apply):
- Academic Institution

3.2 Where will project procedures take place (check all that apply)?
- Danforth Campus
- U.S. off-campus - Mississippi State University

3.3 Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?
Yes

3.3.a What is your site's role(s) for this project (check all that apply)?
- Coordinating Center

3.3.b Indicate the requirements for participating sites to report unanticipated problems to the coordinating center/lead site:

Timeframe	Contact Method
• 24 Hours or less	• Email • Phone

3.3.c Indicate the requirements for the lead site to report unanticipated problems to the participating sites:

Timeframe	Contact Method
• 24 Hours or less	• Email • Phone

3.3.d Indicate the requirements for the lead site to communicate protocol modifications to the participating sites:

Timeframe	Contact Method
• Within 1 week	• Email • Phone

3.3.e Indicate the requirements for the lead site to communicate interim results to the participating sites:

Timeframe	Contact Method
• Within 1 week	• Email

3.3.f Indicate the requirements for the lead site to communicate other new information to the participating sites:

Timeframe	Contact Method
• Within 1 week	• Email

3.3.g What are participating site roles for this project?
- Contract Research Organization - Mississippi State University Survey Research Laboratory

5. Privacy & Confidentiality

5.1 Indicate your plans to protect the privacy interests of the participants during the conduct of the study (check all that apply):
- Only the minimum necessary private information is collected for the purposes of the study
- Any procedures or interventions conducted as part of the study will be conducted in private setting to the extent possible
- Recruitment/consent will occur in a private setting
- Participants will be able to ask questions in a private setting

5.2 Are you collecting or using the Social Security Number of any participants for any purpose?
Yes

5.2.a Provide the intended usage of SSN:
- To provide compensation to participants

5.3 Project uses paper or hard copy consents, surveys, data collection forms, research subject binders, or other hard copy materials (check all that apply):
Yes
- All materials are stored in secured environment
- Access is limited to research team members only

5.4 Project collects, stores and/or transmits electronic data on mobile devices, desktop computers, servers including cloud servers, email, or any other information in electronic form (check all that apply):
Yes
- Password protected
- Access is limited to research team only

5.5 Project collects or uses biologic specimens (check all that apply):
No

5.6 Identify any additional protections in place for data and or samples (check all that apply):
- Formal research staff training process