A Brief Intervention to Improve Stroke Preparedness

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National Clinical Trial (NCT) Identified Number: xxx
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Sponsor: *The Regents of the University of Michigan*

Grant Title: Increasing Acute Stroke Treatment in a Minority Community
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xxx

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1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	A Brief Intervention to Improve Stroke Preparedness
Grant Number:	U01MD010579
Study Description:	This is a randomized controlled behavioral intervention trial to assess the efficacy of a brief intervention to increase stroke preparedness.
Objectives:	To test the efficacy of a brief intervention to increase stroke preparedness (recognition of stroke and the importance of calling 911).
Endpoints:	Primary Endpoint: • Behavioral intent to call 911 using a self-administered survey Exploratory Endpoints: • Stroke symptom recognition • Stroke self-efficacy, attitude, social norms
Study Population:	Adults in the Flint Community
Description of Study Intervention/Experimental Manipulation:	Randomized control study to assess the efficacy of a stroke preparedness intervention. Subjects will be randomized to a brief face-to-face stroke preparedness intervention compared to a healthy lifestyle stroke risk reduction intervention.
Study Duration:	About 30 minutes
Participant Duration:	Single-session

2.1 STUDY RATIONALE

With nearly 800,000 strokes in the US annually, stroke is a leading cause of disability.[1] The number of US stroke survivors is projected to increase from 7 to 10 million by 2030 given the aging baby boomer generation and declining stroke mortality.[1-4] Because most people survive their stroke, disability is the greatest challenge facing survivors and their families. About two-thirds of stroke survivors are left with disability.[5, 6] Acute stroke treatments reduce disability but

are underutilized particularly in African Americans. Acute stroke treatments will reduce the relative risk of post-stroke disability by over 30%.[7-10]

Specific Aim 1: To assess whether a scientific theory-driven, face-to-face brief behavioral intervention increases behavioral intent to call 911 among adults in Flint, MI.

Specific Aim 2: To assess whether a scientific theory-driven, face-to-face brief behavioral intervention increases stroke recognition and stroke self-efficacy among adults in Flint, MI.

2.2 BACKGROUND

Post-stroke disability is common, costly and projected to increase. Most of the more than 7 million stroke survivors in the US have disability. Acute stroke treatments, which include intravenous tissue plasminogen activator (tPA) and intra-arterial treatment, substantially reduce post-stroke disability but are administered to less than 5% of stroke patients. These treatments are particularly underutilized in Flint, Michigan, where the rate of acute stroke treatment is half the national rate. In fact, Flint has the lowest treatment rate of any region of its size in the entire US, which only exacerbates the existing health disparities in this predominantly African-American community. The low treatment rates of the Flint community are illustrative of racial disparities in stroke — African Americans have a higher incidence of stroke, receive acute stroke treatments less often and experience greater post-stroke disability than non-Hispanic whites. These inequities can be at least partially addressed with interventions to increase acute stroke treatment rates; but practical, cost efficient and sustainable interventions are lacking.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

The Stroke Ready workshop is community-based education with no more than minimal risk.

Physical risks: We do not anticipate our intervention will induce physical risks as it is all based on educational materials.

Psychological risks: We do not anticipate our intervention will induce psychological risks as we provide positive messages.

Financial risks: We do not anticipate any financial burden all Stroke Ready education and activities are free to the public.

Legal risk: We do not anticipate that our research protocol will include any additional legal risks.

2.3.2 KNOWN POTENTIAL BENEFITS

The goal of this project is to provide stroke preparedness education to increase acute stroke treatment rates. Participants will uniformly gain access to stroke knowledge and education. It is hoped that by increasing knowledge of stroke symptoms, stroke treatments and the importance of calling 911, subjects will be more likely to recognize a stroke and call 911 should they see it

occur in their community. This will decrease time to hospital arrival and allow us to better care for stroke patients.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

All members of the research team have been trained in research ethics, confidentiality protection, and HIPAA prior to and throughout the study period through the Program for the Education and Evaluation in Responsible Research and Scholarship (PEERRS) training program at the University of Michigan Medical School. Any additional research personnel must also pass PEERRS certifications.

3 OBJECTIVES AND ENDPOINTS

Table 1: Stroke Preparedness Brief Intervention Outcomes		
Primary Outcome		
Intervention Goal	**Outcome Measure**	**Timing**
Increase behavioral intent to call 911	STAT	Pre-post
Secondary Outcome		
Increase stroke recognition	Survey	Pre-post
Improve self-efficacy, attitude, social norms	Self-efficacy, Attitude, subjective norm	Pre-post
Satisfaction		Post

4 STUDY DESIGN

4.1 OVERALL DESIGN

This is a randomized controlled trial of a stroke preparedness intervention to increase behavioral intent to call 911 (Figure 1). The control group will receive a healthy lifestyle stroke risk reduction intervention. The intervention was designed as part of HUM00126955.

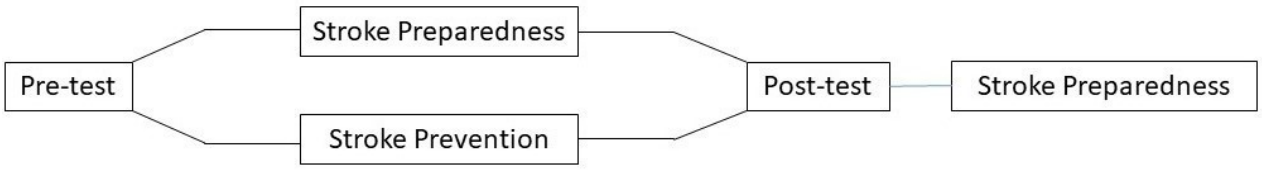

Figure 1: Trial Design

Brief Intervention

Peer leaders will deliver the brief stroke preparedness intervention.

These core components include, and are defined as follows:

1. **What is Stroke:** defines what a stroke is and what causes it.
2. **Stroke Happens :** facts about incidence and prevalence of stroke, as well as defining the consequences of stroke.
3. **Stroke Signs (FAST):** Review of signs of stroke—face drooping, arm weakness, speech difficulties, and time to call 911, as well as how to check for each sign.
4. **Stroke is treatable. TPA—the clot bluster:** visual demonstration and/or illustration showing what happens during a stroke and how TPA works to remove a blockage in the brain.
5. **Time is everything**: explanation that medicine to treat stroke can only be given in the hospital, and that earlier treatment is given, the better the chance of recovery.
6. **Stroke Ready Action Plan**: a step-by-step plan to guide a person through calling 911 if they see signs of stroke, and a reminder of the steps to follow when doing so.

The healthy behavior intervention consists of patient materials from the American Heart Association.

The intervention will be conducted by members of the research team in space provided by the community clinics and senior center, similar to our previous procedures (HUM00084543, HUM00145724). The interaction (pre-test—intervention—post-test) will take about 30 minutes. We will provide the subjects $20 in cash in appreciation of their time. Identifiers will not be collected and thus we will not collect identifiers of subjects who are paid for their participation.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

We selected a randomized controlled trial design to account for temporal trends, test-retest bias and participant selection. The Stroke prevention group will be offered the opportunity to completed the stroke preparedness intervention if they chose.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

Adults over the age of 18 years.

5.2 EXCLUSION CRITERIA

None

5.3 STRATEGIES FOR RECRUITMENT AND RETENTION

Subjects will be recruited from Hamilton Community Health Center and Senior Centers. We have recruited from both of these venues in the past (HUM00093846, HUM00145724).
The subjects will be invited to participate when asked by a team member or member of the clinic medical staff. Subjects from the senior center will be recruited during center events. Recruitment announcements, flyers, internet platforms, and word-of-mouth may also be used.

There is no retention. Subject identifiers are not collected and subjects are not contacted after initial interaction.

Subject agreement will be sought at the start of the interaction by members of the research team. Any subject who declines will be thanked for their participation and the interaction will cease. A copy of the agreement form will be provided to subjects.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 ENDPOINT

The primary outcome will be change in behavioral intent to call 911. It will be measured using a 16 item assessment, of which 4 are non-stroke distractors, based on a previous assessment used in the Flint community as well as a larger sample in Michigan (HUM00036399 and HUM0006687).[11, 12]

Secondary outcomes: The tertiary/exploratory outcomes include change in stroke recognition based on the BRFSS,[13] stroke self-efficacy, outcome expectations and social norms based on questions used in a previous intervention in this community.[14]

STATISTICAL CONSIDERATIONS

6.2 STATISTICAL HYPOTHESES

6.2.1 ANALYSIS OF ENDPOINT(S)

The primary analysis will fit a linear regression model with the outcome of change in behavioral intent to call 911 (post minus pre) and main effect-coded binary predictor intervention group. Results will be reported as parameter estimates, 95% confidence intervals, or as the average

marginal effects and 2-sided p-values. We anticipate the tertiary/exploratory variables will be analyzed using the same strategy, although logistic regression models may be used depending on the properties of the collected data.

Previous studies note a 6 point improvement (sd=6) in behavioral intent to call 911 based on (21 stroke vignettes) after a 15 minute video intervention.[15] There was no control group and thus we cannot assess the test and re-test properties of their measure. Given our measurement instrument is fewer questions and has higher baseline estimates than the previously used estimate,[11] STAT, that the sample size calculations are based off of,[15] we anticipate less improvement. We estimate a 3 point improvement in the intervention group and a 2 point improvement in the control group (test-re-test). Thus with sd (2), power 80, alpha 0.05, we plan to enroll 63 subjects in each arm.

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Version	Date	Description of Change	Brief Rationale

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Section B

Tell us a little about yourself. Please mark the answer that best describes you.

9. Are you...
   - Man
   - Woman
   - Other _____
   - Prefer not to answer

10. How old are you?

11. What is your race?
   - Black or African American
   - White or European American
   - Other *(please write in)*:

_____

12. Are you Hispanic *(optional)*?
   - Yes
   - No
   - I'm not sure

13. How much school have you completed? (please mark all that apply)
   - Less than High School
   - High School graduate/GED
   - Trade School
   - Some college
   - College or University graduate
   - Advanced degree

14. Have you or someone you know had a stroke? Check all that apply.
   - Yes, I have had a stroke.
   - Yes, someone I know has had a stroke.
   - No

Thank you so much for participating in Stroke Ready and completing this survey!!