NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

Concept Synopsis: FURRThER

Families/Friends
Understanding
Risk
Reduction
Through
Educational
Reinforcement

Bernadette Boden-Albala, DrPH, MPI: NYCC-RCC (NYU)
Michael Parides, PhD, Co-I Biostatistician; Aaron Lord, MD, Project Neurologist; Nina Parikh, PhD, Co-I; Emily Goldmann, PhD, Co-I; Joyce O'Connor, DrPH, Co-I; Rumi Chunara, PhD, Co-I; Heather Carman Kuczynski, MPH; Noa Appleton, MPH

PAST NIH FUNDING

- NINDS P50 NS049060 P3
- NIMHD 7U24MD006961
- NINDS RO1 NS072127
- NINDS U54NS057405 P1

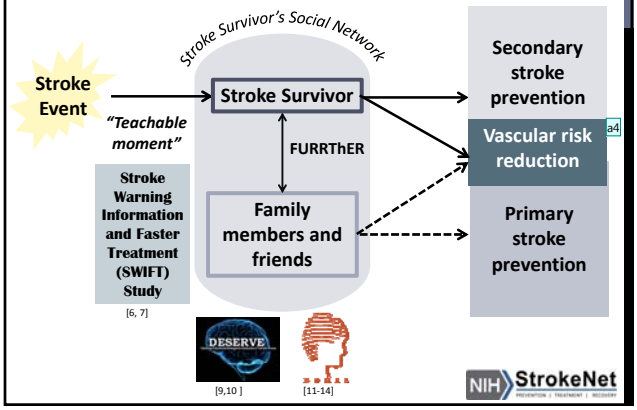
NIH StrokeNet

BACKGROUND

- **Stroke recurrence** and other vascular outcomes are **very common** among stroke survivors and **largely preventable**.[1]
  - 30% of stroke survivors experience a recurrent event within five years.[2]
- Many stroke survivors have a false sense of health security, poor stroke risk perception, feel that they have **"dodged the bullet,"** and consequently do not modify health behaviors or lifestyle to control vascular risk factors.[1,3-5]
- The post-stroke period is a "teachable moment," a critical time to **educate stroke survivors about modifiable health behaviors and factors**.[6-7]
- This extends to **social network members**, including family members and friends.
  - Dyad and family interventions were found to improve both stroke survivor and caregiver outcomes (e.g., physical function, health related quality of life, stroke knowledge).[8]

NIH StrokeNet

CONCEPTUAL DIAGRAM



NIH StrokeNet

Slide 4

a4 Moved these around, i think its a bit easier to read and also emphasizes the shared vascular risk reduction in 1ry and 2ry prevention

admin, 7/5/2017

VASCULAR RISK REDUCTION

- The American Heart Association Strategic Planning Task Force 2010 report identified 7 modifiable cardiovascular health behaviors or factors, **Life's Simple 7 (LS7)** to improve cardiovascular health and reduce CVD mortality.[15]
- It emphasizes **primordial prevention**, including 4 modifiable health behaviors and 3 modifiable biological factors.
- Yet, there remains a significant challenge implementing vascular risk reduction strategies that lead to sustainable health behavior change.[12,16, 17]

Life's Simple 7

SEVEN SIMPLE STEPS TO LIVE BETTER.

Component	Ideal (2 Points)	Intermediate (1 Point)	Poor (0 Points)
Smoking	Never or former >1 year	Former ≤1 year	Current
Healthy diet score*	4 to 5 points	2 to 3 points	0 to 1 points
Physical activity	≥4 bouts per week of intense physical activity sufficient to work up a sweat	1 to 3 bouts per week of intense physical activity sufficient to work up a sweat	No intense physical activity sufficient to work up a sweat
Body mass index	<25 kg/m^2	25 to 29.9 kg/m^2	≥30 kg/m^2
Blood pressure	<120/<80 mm Hg untreated	SBP 120 to 139 or DBP 80 to 89 mm Hg or treated to ideal level	SBP ≥140 or DBP ≥90 mm Hg
Total cholesterol	<5.18 mmol/L (<200 mg/dL) untreated	5.18 to 6.19 mmol/L (200 to 239 mg/dL) or treated to ideal level	≥6.22 mmol/L (≥240 mg/dL)
Fasting glucose	<5.55 mmol/L (<100 mg/dL) untreated	5.55 to 6.94 mmol/L (100 to 125 mg/dL) or treated to ideal level	≥6.99 mmol/L (≥126 mg/dL)

Kulshreshtha et al. 2011 *The 5 components of an ideal diet are consuming: ≥4.5 cups/day of fruits and vegetables; ≥3.5 oz servings/week of fish; ≥3 1-oz servings/day of whole grains; <1500 mg/day sodium; ≤36 oz/week of sugar-sweetened beverages.

NIH StrokeNet

OBJECTIVE

- The **FURRThER Trial** aims to test the efficacy of **integrating stroke/TIA survivors' social networks** into an educational intervention to **optimize secondary prevention strategies in the stroke/TIA patient and promote primary prevention among the patients' social network members.**

- **Rationale**: One family member's stroke can be leveraged to motivate and galvanize a larger social circle in making powerful behavioral changes that will improve each member's vascular risk factor profile.

NIH StrokeNet

PRIMARY AIM

To evaluate the efficacy of a **social network-based chronic disease management intervention** that engages stroke patients together with family (FURRThER) compared to stroke survivor self-management techniques in **reducing secondary vascular events** in a multi-ethnic sample of stroke survivors.

NIH StrokeNet

SECONDARY AIMS

1. To evaluate the efficacy of FURRThER compared to stroke survivor self-management techniques in increasing **Life's Simple 7 (LS7) Scores** (a) in a multi-ethnic cohort of stroke survivors and (b) among the stroke survivors' social networks.
2. To **examine differences by race-ethnicity** in the efficacy of FURRThER compared to stroke survivor self-management techniques in (a) reducing secondary vascular events in a multi-ethnic sample of stroke survivors and (b) increasing LS7 Scores among stroke survivors and their social networks.

NIH StrokeNet

PATIENT INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:

1. Diagnosed with mild ischemic cerebral infarction (NIHSS < 8) or TIA
2. Age ≥ 18 years
3. Discharge plan for either home or acute rehabilitation center
4. Speaks one of the languages in which the survey is administered (site-specific)

Exclusion criteria:

1. Unable to give informed consent
2. Discharged to long-term nursing home or requires 24-hour care
3. Modified Rankin score ≥ 3 at baseline
4. Dementia, cognitive impairment, or any condition impairing his/her ability to participate in education
5. Life expectancy less than 1 year.

Patients randomized to the intervention group will be asked to identify between 2-5 social network members (i.e., people with whom they discuss important matters)

NIH StrokeNet

SOCIAL NETWORK MEMBER INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:

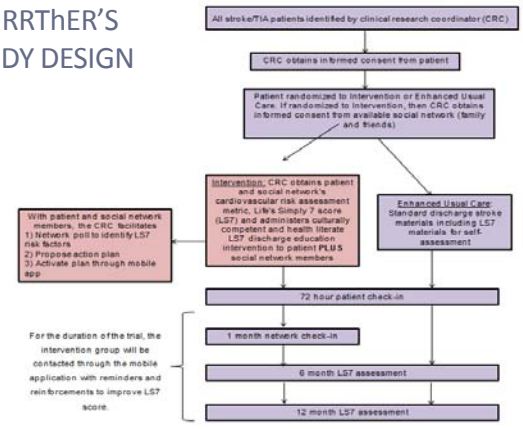
1. Aged ≥ 18 years at enrollment
2. Speaks one of the languages in which the survey is administered (site-specific)

Exclusion criteria:

1. Unable to give informed consent
2. Lives in a nursing home or requires 24-hour care
3. Dementia, cognitive impairment, or any condition impairing his/her ability to participate in education
4. Life expectancy less than 1 year

NIH StrokeNet

FURRThER'S STUDY DESIGN



INNOVATION

Pragmatic Study design

- Leverage existing AHA Life's Simple 7™ materials
  - PowerPoints, brochures, infographics, Info cards in English and Spanish
- Potential to accomplish both primary and secondary prevention

Behavioral Innovation Hub

- Centralized Technology hub
  - Facilitate and execute emails, text messages, polls, telephone, and Skype calls.
    - Obtain immediate feedback and support
    - Identify barriers and best practices and provide possible solutions in real time
  - Global Positioning Systems (GPS) Technology
    - Provide safe and walkable paths for the network based on location.
    - Identify and propose alternative destinations in case of inclement weather (e.g., local malls or indoor walking paths).

NIH StrokeNet

SAMPLE SIZE

- Our primary analysis will invoke the intent-to-treat principle. That is, in order to preserve the probability space created by the randomized allocation of subjects to interventions, all subjects must be analyzed, and in the intervention arms to which they were initially assigned, irrespective of subsequent events or behavior.
- Proposed number of subjects to be enrolled: 1500 probands
  - 2-5 network members per proband (3000-7500)
  - Total sample: 4500-9000

STATISTICAL ANALYSES – PRIMARY AIM

Aim: To evaluate the efficacy of a social network based chronic disease management intervention that engages stroke patients together with family (FURRThER) compared to stroke survivor self-management techniques in reducing secondary vascular events in a multi-ethnic sample of stroke survivors.

- Working hypothesis: Secondary vascular events will be lower among stroke survivors randomized to the network-based intervention compared with those in the self-management group.
- Analysis: The difference in the incidence of a recurrent event between groups will be determined using survival analysis (Cox proportional hazards) models for binary outcomes. The model will include an indicator for randomization group.

STATISTICAL ANALYSES – SECONDARY AIM 1

Aim: To evaluate the efficacy of FURRThER compared to stroke survivor self-management techniques in increasing of Life's Simple 7 (LS7) Score (a) in a multi-ethnic cohort of stroke survivors and (b) among the stroke survivors' social networks.

- Working hypotheses: Among stroke survivors, those in the network-based intervention will have higher LS7 Scores at six months and one year compared to those assigned to enhanced usual care. Among family, those in the network-based intervention will have higher LS7 Scores at six months and one year compared to baseline scores.
- Analysis: We propose to calculate a Life's Simple 7 (LS7) total score in the same manner as Thacker et. al. by assigning each component 2 points for ideal, 1 point for intermediate, or zero points for poor cardiovascular health (CVH), then summing all 7 items to yield a total score ranging from zero (worst CVH) to 14 points (best CVH).[18] This total score will be categorized as 0 to 6 (low), 7 to 8 (middle), and 9 to 14 points (high). Proportional odds regression models will be used to assess group differences for patients and for their networks. A generalized estimating equation (GEE) approach will be used to account for assumed dependence in LS 7 category for individuals within the same network.

STATISTICAL ANALYSES – SECONDARY AIM 2

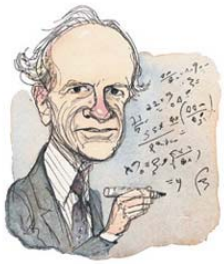
Aim: To examine differences by race-ethnicity in the efficacy of FURRThER compared to stroke survivor self-management techniques in (a) reducing secondary vascular events in a multi-ethnic sample of stroke survivors and (b) increasing LS7 Score among stroke survivors and their social networks.

- Working hypotheses: Secondary (stroke survivor) vascular events will be lower and LS7 Score increase larger among participants randomized to the family-based network intervention compared with self-management group in all race-ethnic groups, but the reduction in vascular events and the increase in LS7 score will be larger in Hispanic and Black participants compared to White participants.
- Analysis: Similar analytic approaches as those described in Secondary Aim 1 will be used but will include indictors of race/ethnicity as well as products of the indicators for race/ethnicity and randomization group as an interaction term and/or they will be stratified by race/ethnic group.

THANK YOU NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

"It doesn't matter what you or I do. It's how the whole group behaves."

—Gary Becker, PhD

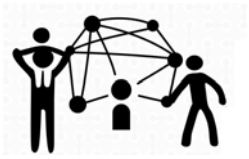


REFERENCES

1. Elkind, M.S., *Outcomes after stroke: risk of recurrent ischemic stroke and other events.* Am J Med, 2009. 122(4 Suppl 2): p. S7-13.
2. Burn, J., et al., *Long-term risk of recurrent stroke after a first-ever stroke. The Oxfordshire Community Stroke Project.* Stroke, 1994. 25(2): p. 333-7.
3. Furie, K.L., et al., *Guidelines for the prevention of stroke in patients with stroke or transient ischemic attack: a guideline for healthcare professionals from the american heart association/american stroke association.* Stroke, 2011. 42(1): p. 227-76.
4. Johnston, S.C., *Transient ischemic attack: a dangerous Harbinger and an opportunity to intervene.* Semin Neurol, 2005. 25(4): p. 362-70.
5. Mozaffarian, D., et al., *Executive summary: heart disease and stroke statistics-2015 update: a report from the american heart association.* Circulation, 2015. 131(4): p. 434-41.
6. Boden-Albala, B., et al., *Perception of recurrent stroke risk among black, white and Hispanic ischemic stroke and transient ischemic attack survivors: the SWIFT study.* Neuroepidemiology, 2011. 37(2): p. 83-7.
7. Boden-Albala, B., et al., Comparison of Acute Stroke Preparedness Strategies to Decrease Emergency Department Arrival Time in a Multiethnic Cohort: The Stroke Warning Information and Faster Treatment Study. Stroke, 2015. 46(7): p. 1806-12.
8. Bakas, T., et al., Evidence for stroke family caregiver and dyad interventions: a statement for healthcare professionals from the American Heart Association and American Stroke Association. Stroke, 2014. 45(9): p. 2836-52.
9. Boden-Albala, B., et al., *A stroke preparedness RCT in a multi-ethnic cohort: design and methods.* Contemp Clin Trials, 2010. 31(3): p. 235-41.
10. Lord, A.S., et al., Discharge educational strategies for reduction of vascular events (DESERVE): design and methods. Int J Stroke, 2015.
11. Sacco RL, Boden-Albala B, Abel G, et al. Race-ethnic disparities in the impact of stroke risk factors: the Northern Manhattan Stroke Study. Stroke 2001;32:1725–1731 [PubMed]
12. Sacco, R.L., Achieving ideal cardiovascular and brain health: opportunity amid crisis: Presidential Address at the American Heart Association 2010 Scientific Sessions. Circulation, 2011. 123(22): p. 2653-7.
13. Willey, J.Z., et al., Social determinants of physical inactivity in the Northern Manhattan Study (NOMAS). J Community Health, 2010. 35(6): p. 602-8.
14. Boden-Albala, B., et al., Social isolation and outcomes post stroke. Neurology, 2005. 64(11): p. 1888-92.
15. Lloyd-Jones, D.M., et al., Defining and setting national goals for cardiovascular health promotion and disease reduction: the American Heart Association's strategic Impact Goal through 2020 and beyond. Circulation, 2010. 121(4): p. 586-613
16. Mozaffarian, D., et al., Heart disease and stroke statistics--2015 update: a report from the American Heart Association. Circulation, 2015. 131(4): p. e29-322.
17. Yang, Q., et al., Trends in cardiovascular health metrics and associations with all-cause and CVD mortality among US adults. Jama, 2012. 307(12): p. 1273-83.
18. Thacker, E.L., et al., *The American Heart Association Life's Simple 7 and incident cognitive impairment: The REasons for Geographic And Racial Differences in Stroke (REGARDS) study.* J Am Heart Assoc, 2014. 3(3): p. e000635.

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

Concept Synopsis: FURRThER



Families/Friends
Understanding
Risk
Reduction
Through
Educational
Reinforcement

Bernadette Boden-Albala, DrPH, MPI: NYCC-RCC (NYU)
Michael Parides, PhD, Co-I Biostatistician; Aaron Lord, MD, Project Neurologist; Nina Parikh, PhD, Co-I; Emily Goldmann, PhD, Co-I; Joyce O'Connor, DrPH, Co-I; Rumi Chunara, PhD, Co-I; Heather Carman Kuczynski, MPH; Noa Appleton, MPH