Discharge educational strategies for reduction of vascular events (DESERVE): design and methods

Aaron S. Lord[1], Heather M. Carman[2], Eric T. Roberts[2], Veronica Torrico[2], Emily Goldmann[2], Koto Ishida[1], Stanley Tuhrim[3], Joshua Stillman[4], Leigh W. Quarles[2], and Bernadette Boden-Albala[1,2,5]*

Rationale **Stroke and vascular risk factors disproportionately affect minority populations, with Blacks and Hispanics experiencing a 2·5- and 2·0-fold greater risk compared with whites, respectively. Patients with transient ischemic attacks and mild, nondisabling strokes tend to have short hospital stays, rapid discharges, and inaccurate perceptions of vascular risk.**

Aim **The primary aim of the Discharge Educational Strategies for Reduction of Vascular Events (DESERVE) trial is to evaluate the efficacy of a novel community health worker-based multilevel discharge intervention vs. standard discharge care on vascular risk reduction among racially/ethnically diverse transient ischemic attack/mild stroke patients at one-year postdischarge. We hypothesize that those randomized to the discharge intervention will have reduced modifiable vascular risk factors as determined by systolic blood pressure compared with those receiving usual care.**

Sample size estimates **Given 300 subjects per group and alpha of 0·05, the power to detect a 6 mmHg reduction in systolic blood pressure is 89%.**

Design **DESERVE trial is a prospective, randomized, multicenter clinical trial of a novel discharge behavioral intervention. Patients with transient ischemic attack/mild stroke are randomized during hospitalization or emergency room visit to intervention or usual care. Intervention begins prior to discharge and continues postdischarge.**

Study outcomes **The primary outcome is difference in systolic blood pressure reduction between groups at 12 months. Secondary outcomes include between-group differences in change in glycated hemoglobin, smoking rates, medication adherence, and recurrent stroke/transient ischemic attack at 12 months.**

Discussion **DESERVE will evaluate whether a novel discharge education strategy leads to improved risk factor control in a racially diverse population.**

Correspondence: Bernadette Boden-Albala*, 41 East 11th Street, 7th Floor, NY, NY 10003, USA.
E-mail: bb109@nyu.edu
@nyupublichealth
[1]Department of Neurology, New York University School of Medicine, New York, NY, USA
[2]Division of Social Epidemiology, College of Global Public Health, New York University, New York, NY, USA
[3]Department of Neurology, Mount Sinai School of Medicine, New York, NY, USA
[4]Department of Emergency Medicine, Columbia University College of Physicians and Surgeons, New York, NY, USA
[5]Department of Epidemiology and Health Promotion, New York University College of Dentistry, New York, NY, USA

Received: 6 January 2015; Accepted: 24 May 2015; Published online 9 September 2015

Conflict of interest: None declared.

DOI: 10.1111/ijs.12571

Key words: discharge, health education, mild, stroke, TIA

Introduction and rationale

In the United States, stroke disproportionally affects minority populations (1,2). Secondary prevention strategies in minority populations have been suboptimal due to cultural and behavioral factors not addressed in standard prevention modalities and poor integration into community resources (3,4). Current practices, with decreased length of stay and rushed discharges, fail to reinforce the 'warning nature' of nondisabling transient ischemic attacks (TIAs)/mild strokes (5,6). These practices reinforce the poor risk perception that many TIA/mild stroke patients associate with mild or resolved deficits (5,7). Intensive, interactive, and culturally tailored discharge education strategies based on health promotion theory may improve accuracy of risk perception and promote behavior change.

Methods

Design

The Discharge Educational Strategies for Reduction of Vascular Events (DESERVE) study is a prospective, randomized, multicenter trial of a novel, patient-paced discharge behavioral intervention. The interactive, culturally tailored intervention focuses on acquisition of three skills-based areas: risk knowledge, medication adherence, and patient–physician communication. The primary aim is to evaluate the efficacy of the behavioral intervention vs. standard discharge care on vascular risk reduction among racially/ethnically diverse TIA/mild stroke patients at 12 months postdischarge. We hypothesize that those randomized to the discharge intervention will have lower follow-up systolic blood pressure (SBP) compared with usual care.

Patient population

Study patients are prospectively identified through daily screening of potential TIA/stroke cases at four urban medical centers with a high percentage of African American and Hispanic patients. This process includes daily review of stroke admissions and consultations, participation in rounds, and an emergency department notification pager. Patients with stroke, TIA, or stroke-like symptoms are screened by study neurologists to confirm eligibility. Eligible patients are approached to obtain written informed consent.

Inclusion criteria

1. Presentation/transfer to enrolling site with one of the following diagnoses:

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- TIA
- Ischemic stroke (IS) with National Institutes of Health Stroke Scale (NIHSS) <5 at enrollment
- Intracerebral hemorrhage (ICH) with NIHSS <5 at enrollment

2. Age >18 years
3. New York area resident with phone
4. One or more vascular risk factors:
   - Hyperlipidemia
   - Hypertension
   - Current smoker
   - Diabetes mellitus, type 2
   - Metabolic syndrome
5. Can participate in educational sessions in English or Spanish

Exclusion criteria

1. Discharged to nursing home or requiring 24-hour in-home care
2. Baseline modified Rankin score (mRS) of >2
3. Dementia
4. End-stage disease with life expectancy less than one-year

Randomization

Subjects are randomized, stratified for language, into intervention or usual care groups in a 1:1 ratio using a computerized permuted block randomization program (Table 1).

Study arms

All patients receive a baseline interview including questions on demographics, social resources, health literacy, medication adherence, and validated measures of stroke knowledge/preparedness (5,8). Baseline SBP, anthropometric measures, glycated hemoglobin (HbA1c), and lipid panel are measured. Charts are abstracted for additional history and clinical information. All participants receive a bag containing a tape measure to monitor waist circumference and a pillbox to organize medications.

All participants are followed up in-person at 6 and 12 months postdischarge. At each in-person assessment study, health workers conduct a brief structured interview to determine changes in stroke risk factors, risk behaviors, medication compliance, social support status, quality of life, and physical activity scale. Measurements of SBP, HbA1c, and anthropometric indices are repeated.

Intervention

Patients randomized to intervention engage in an educational session with a community health worker (CHW) and watch a culturally tailored motivational video of stroke survivorship narratives prior to discharge. Intervention patients receive a take-home patientpaced, copy of the workbook (Figure 1) and video (Figure 2) comprised of interactive, skill-based modules emphasizing DESERVE's three thematic areas: patient–physician communication, medical adherence, and accurate risk perception. In addition to the 6- and 12-month follow-ups for all subjects, intervention subjects receive calls scheduled at key intervals from CHWs to motivate behavior change, promote access to resources, and provide social support.

The DESERVE intervention is rooted in the Transtheoretical Model (TTM) for behavioral change. TTM emphasizes 'stages of change' as the pathway for sustainable behavior change. We posit the TIA/mild stroke 'teachable moment' propels the stroke survivor to the preparation stage for risk-reduction strategies. Data from the Stroke Warning Information and Faster Treatment (SWIFT) trial provides evidence that patients and family members request action steps to address risk reduction (4). The DESERVE intervention utilizes the key TTM process of self-evaluation to continue to identify realistic, rational ways to change behavior and incorporate the changes into a new self-identity.

The DESERVE intervention also employs constructs from the Chronic Care Model (CCM), including community-based interventions, to improve care integration (9,10). Utilizing CCM in

Table 1 Intervention summary

	Baseline	Discharge	72 h	One-month	Three-months	Six-months	12 months
Intervention group	• Baseline interview	• Educational PowerPoint Presentation • Motivational Video	• Poststroke contact form • Delivery of workbook • Verify follow-up doctor's visit	• One-month follow-up form • Reminder about doctor's visit • Review patient/physician communication in workbook • Follow-up call after doctor's visit	• Three-month follow-up form • Follow-up other doctor's visits • Review main components of workbook • Discuss other resources	• In-person visit/form • BP, HbA1c, Anthopometrics • Re-review workbook	• In-person visit/form • BP, HbA1c, Anthopometrics • Re-review workbook
Standard care group	• Baseline interview	• Standard discharge education	• Patient-guided contact	• Patient-guided contact	• Patient-guided contact	• In person visit/form • BP, HbA1c, Anthopometrics	• In-person visit/form • BP, HbA1c, Anthopometrics

BP, blood pressure; HbA1c, glycated hemoglobin.

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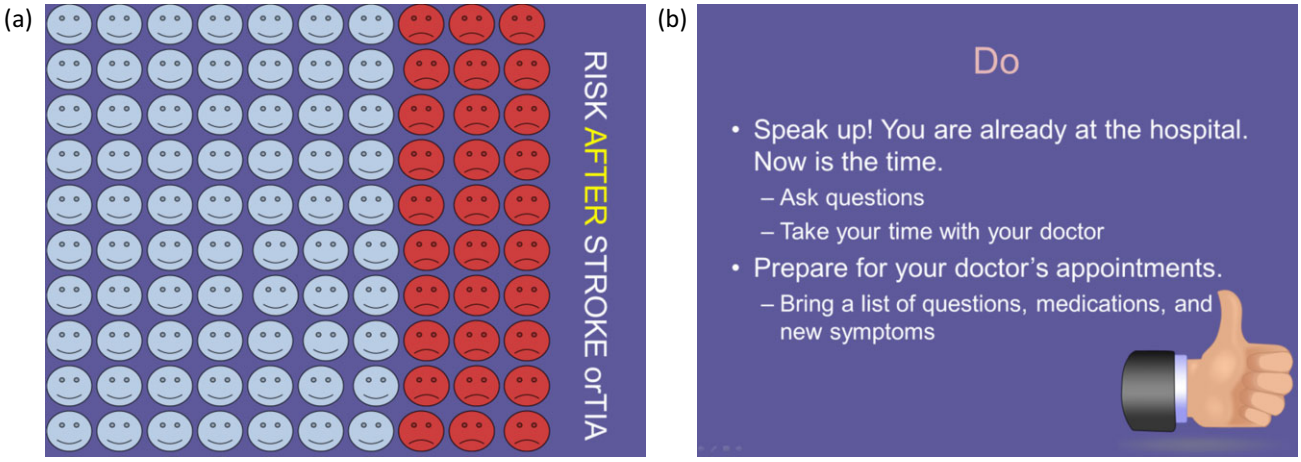

Fig. 1 Informational and motivational presentation on stroke pathophysiology, risk factors, and lifestyle modification. (a) Graphic demonstration of increased risk after initial ischemic event; (b) graphic demonstration on empowering patients at doctors' visits.

Fig. 2 Motivational video (a) 'I Had No Idea': Patients describe their initial stroke and inaccurate assessment of vascular risk. (b) The Spanish version is culturally tailored to notions of faith and community. (c) 'Don't Give Up': Patients provide motivation in their own words: 'Please don't give up, and above all, put in your heart that pity don't live there'. (d) 'Keep on the Plan': patients advise on how to be proactive at doctors' visits.

medically underserved communities is critical in addressing complex issues within communities. DESERVE utilizes bilingual CHWs to maximize cultural congruence in the intervention which is specifically tailored to minority TIA/mild stroke survivors.

Usual care

Usual care includes standard stroke care and treatment and distribution of standard stroke pamphlets in English or Spanish from the American Heart Association. Usual care subjects are given study contact information in case they have further questions. Any phone calls initiated by study participants will be documented.

Primary outcome

The primary outcome is difference in SBP reduction between the intervention and standard care arms in mmHg at 12-month follow-up.

Secondary outcomes

Secondary outcomes include between-group differences in reduction of other vascular risk factors: HbA1c, body mass index (BMI), waist circumference, and smoking. Additionally, between-group differences in medication adherence, appropriate self-assessment of stroke risk, and medical appointment compliance will be assessed. We will also perform an analysis looking at the incremental cost of the intervention based on the average time

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spent by each health worker on each intervention patient times an expected cost per time unit. We will then compare this cost with other methods of blood pressure control.

Data and safety monitoring

While a data and safety monitoring plan was not required for this low-risk educational intervention, protocols were established for cases where severe BP elevations or depression were detected during follow-up.

Sample size

A randomized pilot study of 50 TIA/mild stroke patients demonstrated an 8 mmHg reduction in SBP in the intervention vs. standard care group. We then conducted power analysis using a lower 6 mmHg estimate of SBP change and an assumed variability of 23 mmHg as seen in the pilot study. Given 300 subjects per group and $\alpha = 0{\cdot}05$, power is 89·1%.

Statistical analysis

We will utilize two-sample *t*-tests in an intent-to-treat analysis for the primary outcome. We will evaluate the association between intervention assignment and change in SBP using linear regression controlling for relevant confounders including language. We will conduct repeated measures analysis using the changes in SBP at 6 and 12 months as a vector of outcome. We will fit a generalized estimating equation (GEE) model using the intervention indicator, time, and interaction between the intervention indicator and time as covariates. We will utilize multiple imputation for missing data in the intention-to-treat analysis.

Study organization and funding

NIH P50-NS049060 to Dr. Boden-Albala. The trial was registered at clinicaltrials.gov (#NCT 01836354).

Discussion

DESERVE will assess whether a novel, patient-paced, culturally tailored education intervention can facilitate reduced vascular risk factors in survivors of mild stroke/TIA in a diverse, urban population. This intervention goes beyond typical lifestyle modification programs of diet and exercise and utilizes a theoretical construct to aid behavior change. We have made special considerations for commitment to family, communalism, religion/spirituality, fatalism, mistrust, worry about isolation, and death. Importantly, the DESERVE intervention is based on numerous pilot studies integrating input from African American and Latino stroke survivors and their family members, ethnically diverse community focus groups, community health advocates, and key community leaders. By utilizing patient-paced workbooks and videos, we hope to make these interventions sustainable and practical in nonstudy settings with often limited resources.

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