

## Stroke Health and Risk Education (SHARE): Design, methods, and theoretical basis

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### ARTICLE INFO

#### Article history:

Received 15 September 2011

Received in revised form 8 February 2012

Accepted 29 February 2012

Available online 6 March 2012

#### Keywords:

Behavioral intervention

Stroke prevention

Diet

Physical activity

Self-Determination Theory

Motivational enhancement

Motivational intervention

### ABSTRACT

**Background:** Stroke is a disease with tremendous individual, family, and societal impact across all race/ethnic groups. Mexican Americans, the largest subgroup of Hispanic Americans, are at even higher risk of stroke than European Americans.

**Aim:** To test the effectiveness of a culturally sensitive, church-based, multi-component, motivational enhancement intervention for Mexican Americans and European Americans in reducing stroke risk factors.

**Methods:** Participants enroll in family or friendship pairs, from the same Catholic church in the Corpus Christi Texas area, and are encouraged to change diet and physical activity behaviors and provide support for behavior change to their partners. Churches are randomized to either the intervention or control group. Goal enrollment for each of the 10 participating churches is 40 participant pairs. The intervention consists of self-help materials (including a motivational short film, cookbook/healthy eating guide, physical activity guide with pedometer, and photo-novella), five motivational interviewing calls, two tailored newsletters, parish health promotion activities and environmental changes, and a peer support workshop where participants learn to provide autonomy supportive counseling to their partner. SHARE's three primary outcomes are self-reported sodium intake, fruit and vegetable intake, and level of physical activity. Participants complete questionnaires and have measurements at baseline, six months, and twelve months. Persistence testing is performed at 18 months in the intervention group. The trial is registered with [clinicaltrials.gov](http://clinicaltrials.gov) (NCT01378780).

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**Abbreviations:** EA, European American; ICC, intra-class correlation coefficient; MA, Mexican American; MI, motivational interviewing; SDT, Self-Determination Theory; SHARE, Stroke Health and Risk Education.

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### 1. Introduction

Mexican Americans (MAs) are the most numerous sub-population of Hispanic Americans, the largest minority population in the United States (US). Hispanic Americans comprised 12.5% of the total US population in 2000, and are projected to comprise 17.8% by 2020, and 22.3% by 2040 [1]. The Hispanic population is currently youthful, with only 7% ≥ 60 years of age. As the leading cause of adult disability

and fourth leading cause of death in the United States [2,3], stroke remains highly relevant to European Americans (EAs); however MAs suffer a comparatively disproportionate burden with respect to stroke [4]. Targeting stroke prevention for MAs and EAs addresses the two largest groups in the US and is especially critical as the MA population grows and ages.

Hispanic Americans have a higher prevalence of uncontrolled blood pressure, a potent risk factor for stroke [5], than EAs [6]. Lifestyle factors, often less favorable in Hispanic American than EA [7,8], can be important targets to facilitate blood pressure lowering. For instance, dietary changes can reduce systolic blood pressure by up to 11.5 mm Hg in participants with hypertension and 7.1 mm Hg in those without hypertension [9,10]. Physical activity can lower systolic blood pressure by 3.8 mm Hg and diastolic pressures 2.6 mm Hg [11]. Accordingly, increases in fruit and vegetable intake, reductions in sodium intake, and increases in physical activity are recommended by the American Stroke Association as part of primary stroke prevention [12].

Although faith and family are strong components of MA culture, few church-based interventions have been conducted with Hispanics, the majority of whom are Catholic [13]. Churches constitute a favorable venue for behavioral interventions, as they provide stable groups of participants and have resources that can be leveraged for motivational enhancement interventions. To address stroke risk reduction in MAs and EAs, we therefore designed the Stroke Health and Risk Education (SHARE) project, a church-based motivational enhancement intervention trial to reduce stroke risk by improving sodium intake, fruit and vegetable intake, and physical activity in the biethnic community of Corpus Christi, Texas.

## 2. Aims

The aim of SHARE is to test the effectiveness of a culturally sensitive, church-based, multi-component, motivational enhancement intervention for MAs and EAs in reducing important behavioral and biological stroke risk factors. We have four hypotheses:

**Hypothesis 1.** Participants randomized to the intervention group will have greater reduction in self-reported sodium intake, greater increase in dietary fruit and vegetable intake, and greater increase in physical activity than those in the control group (primary outcome).

**Hypothesis 2.** Participants randomized to the intervention group will have a greater reduction in systolic blood pressure than those in the control group (secondary outcome).

**Hypothesis 3.** Participants randomized to the intervention group will have greater reductions in other stroke risk factors such as diastolic blood pressure, fasting serum glucose, glycosylated hemoglobin, body mass index, fasting LDL cholesterol, fasting triglycerides, total dietary fat and dietary saturated fat and greater increases in HDL cholesterol than those in the control group (exploratory outcomes).

**Hypothesis 4.** In exploratory analysis, there will be no interaction between intervention group and ethnicity with respect to our primary outcomes.

## 3. Methods and design

### 3.1. Overview

The SHARE project is a theory-based, cluster-randomized, parallel group, church-based, multi-component motivational enhancement intervention trial designed to reduce stroke risk in MAs and EAs living in Corpus Christi, Texas. The primary outcome includes key behavioral stroke risk factors: sodium intake, fruit and vegetable intake, and level of physical activity. We will also obtain biological outcome measures to allow us to explore the potential effects of the intervention on blood pressure, cholesterol, blood glucose, and body mass index. Intervention and control participants are recruited and enrolled in family or friendship pairs, operationally defined as individuals who have weekly contact with each other. This strategy exploits natural social support systems inherent in MA culture and within the Catholic Church. A one-year multi-component, culturally sensitive, targeted and individually tailored intervention is delivered to the intervention group (Fig. 1). To maximize use of personnel and resources and allow for refinement of our recruitment procedures, the 1-year intervention is implemented in a staggered fashion in several partially overlapping cycles over a 25-month period. We project based on sample size calculations (see [Sample size calculations](#) section) that 200 pairs of individuals in each treatment group (40 pairs at each of 5 churches in each group) will be required at baseline to detect proposed treatment effects (total n = 800).

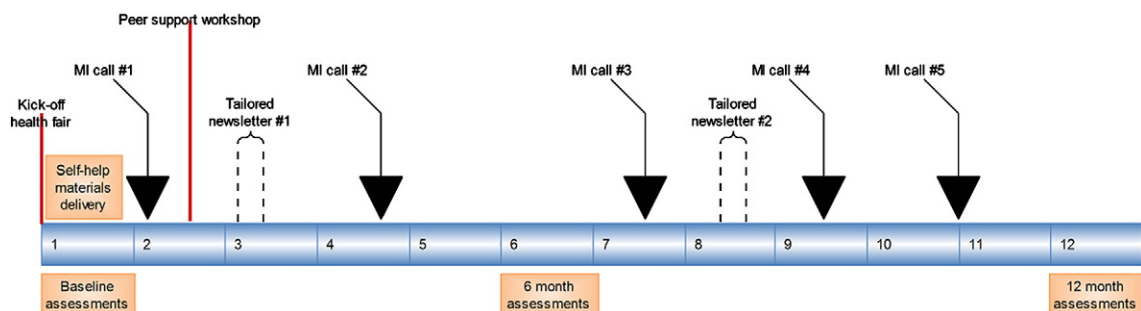


Fig. 1. Timeline of the 12-month intervention, SHARE project.

### 3.2. Theory

The intervention is rooted in Self-Determination Theory (SDT) [14,15]. SDT is a general theory of human motivation that focuses on the social–contextual conditions surrounding the individual that facilitate or hinder the internalization of autonomous (or self-determined) self-regulation of relevant behaviors. The theory proposes that all individuals have three innate psychological needs: perceived autonomy (e.g., volition), perceived competence (feeling able to achieve the desired outcome) and relatedness to other humans (positive, warm relationship with important others). If these needs are supported by important others (spouses, friends, or health care professionals), humans experience more and higher quality motivation that is likely to energize long term healthy behaviors, better mental health outcomes, and better quality of life [16]. Individuals are more likely to adopt new behaviors that are modeled or valued by people to whom they feel attached or related. Relatedness needs can be met by the involvement of significant others who demonstrate an understanding (acknowledgment and reflecting) of the individual's feelings and the difficulties he/she faces related to the behavior change, who show a genuine interest in the individual's well-being, are trusted to provide emotional support, and who avoid criticizing or blaming [17]. Perceived competence also plays an important role in the internalization of behaviors. Individuals are more likely to adopt a behavior that related others value when they feel competent doing the activity. Competence is facilitated by helping individuals understand the expected outcomes of the proposed behavior change, encouraging them to believe that they are capable of doing the behavior, and helping them to establish realistic behavioral goals. SDT stresses that the individual needs to be fully volitional (autonomous) before that person can feel fully competent, as autonomy is required for behaviors to be internalized. When autonomy is supported, individuals are more likely to perceive that they have more choices and opportunities for reaching their goals, to identify more opportunities to participate in their care, to be more likely to feel personally responsible for their behaviors, and to be more likely to make informed choices based on their own reasons, goals, and values (Table 1).

### 3.3. Engaging community partners

The Bishop of the Diocese of Corpus Christi helped the study team form a Community Advisory Board consisting of Priests and other Catholic leaders in Corpus Christi. The Community Advisory Board informed the design of the project, provided advice on materials with respect to cultural appropriateness,

and helped develop religious messages used in the materials. Several Community Advisory Board Priests as well as Priests from the intervention parishes wrote prayers that were used in the materials. We also conducted a half-day “Priests as Partners Workshop” to introduce SHARE to the intervention parish priests, with a focus on the role of the parish in the SHARE program.

### 3.4. Study population

Corpus Christi, Texas is a stable, non-immigrant community of primarily MAs and EAs. The MAs living there are primarily at least 2nd or 3rd generation US citizens. We chose to include both MAs and EAs in SHARE. Targeting both MAs and EAs more accurately reflects the Corpus Christi community, will be more easily generalized to other populations, and could have a larger public health impact. Furthermore, exclusively targeting MAs in a church-based intervention may cause negative repercussions among parishioners and the community. Finally, both MA and EA Catholic church attendees in Corpus Christi have a high prevalence of stroke risk factors, and therefore both groups stand to benefit from the intervention [18].

Participants are eligible if they are EA or MA parishioners of a church involved in SHARE, greater than 18 years of age, speak English or Spanish, are permanent residents of the Corpus Christi area, and are willing to provide a mailing address and home telephone number to study personnel at the time of consent. A prior diagnosis of hypertension is not necessary. Participants must be able to identify a friend or family partner who is also willing to participate in the study. Consistent with SDT theory, enrollment in friend or family pairs is designed to augment behavior change through autonomy support. We suggest that the friend or family member be one with whom the participant speaks at least once per week. No other limitation is placed on partner selection. Known pregnancy is an exclusion criterion. To avoid second level clustering, only two individuals per household (the first to enroll) are eligible.

### 3.5. Recruitment and retention

Church bulletins advertise the health fairs that kick-off enrollment in each church. Parish Priests and study staff also make brief announcements from the pulpit to introduce the congregation to SHARE and to encourage participation in the health fair. The health fair is a public event at each church that includes community representatives from health and other organizations in addition to SHARE staff. Health fair attendees, if interested, provide contact information to study staff, or have the option to provide written informed consent at that time. Additionally, “parish liaisons,” informal lay leaders in the church typically recommended by the parish Priest, identify potentially eligible participants. These parishioners are invited to the health fair and may have their information given to study staff. In general, study staff provides information about SHARE over the phone; informed consent occurs in person prior to the baseline interview and assessments. Promotional items, such as a water bottle and t-shirt with the SHARE logo, are given to participants who enroll.

**Table 1**  
Self-Determination Theory (SDT) constructs addressed by the SHARE intervention components.

SDT construct	Intervention component
Perceived autonomy	Self-help materials, MI calls, tailored newsletters, parish social environmental change
Perceived competence	Self-help materials, tailored newsletters, MI calls
Relatedness	Partner support, MI calls, tailored newsletters

Monetary incentives are provided to the parish liaisons and participants according to Table 2.

### 3.6. Intervention

The intervention consists of five main components: self-help materials, partner support, motivational interviewing (MI) calls by trained counselors, tailored newsletters, and parish social environmental change. Plain language is used for all written materials, which are aimed at a 5th grade reading level. All materials are designed to be culturally and religiously sensitive to MA and EA Catholics in Corpus Christi. In the self-help materials, we show a mixture of MA and EA characters and families. We use “Tex-Mex” Spanish for the Spanish translations and have local callers fluent in this type of Spanish for the MI calls. We presented early phases of all materials, including short film story script and storyboards, and drafts of all materials to our Community Advisory Board for feedback. We also solicited feedback from individual Priests and Corpus Christi Catholic parishioners. Furthermore, we conducted one set of parishioner ( $n = 35$ ; 28 MAs, 7 EAs) and Priest ( $n = 3$ ) focus groups to gain feedback on materials during the early phases of materials development. We also sought advice from individual Priests and individuals on the Community Advisory Board during later stages of materials development. This feedback was vital in shaping the content, stories, and wording of materials so that they would be more likely to be experienced by the participants as supportive of needs (e.g., autonomy, competence and relatedness) and culturally relevant.

#### 3.6.1. Self-help materials

1. Short film—A 32-minute film was developed to motivate behavior change. The video tells the story of a MA Catholic woman with mildly elevated blood pressure who struggles to make behavior changes including lowering sodium, increasing fruit and vegetable intake, and increasing physical activity within the context of her complicated life. Consistent with SDT, the story illustrates autonomous forms of psychological support that are effective in helping the woman make recommended lifestyle changes. The film is available on DVD and VHS in English or with Spanish voice-over.
2. Photonovella—Comprising 33 pages in English and 33 in Spanish under one cover, the photonovella provides motivation for behavior change. Photonovellas present information in a dramatic story with written narrative in word balloons. The SHARE photonovella depicts the difficulties a MA Catholic woman faces in taking her blood pressure medicine

and reducing her blood pressure through behavior change. As with the short film, the photonovella illustrates instances of effective autonomous forms of social support. The characters and storyline are different in the photonovella from the film.

3. Cookbook—Participants are provided with a healthy eating guide that includes 31 nutritious, low-sodium, low-fat recipes that constitute a mixture of ethnic and non-ethnic recipes. Colorful photos accompany each recipe and the amounts of fruits and vegetables per serving are highlighted. Both English and Spanish versions are included under one cover. While the short film and photonovella are intended to encourage motivation to eat less salt/sodium and eat more fruits and vegetables, the cookbook is intended to help build competence by providing information on how to make these changes, as well as tools (such as the recipes) to actually take action. The cookbook also contains sections entitled “SHAREing Support,” which provide participants with tips on giving autonomy, competence and relatedness support to their SHARE partner around healthy eating. Relevant biblical quotations and prayers, many written by local Priests, are scattered throughout the text to provide religious relevance and motivation. Participants are also given fruit and vegetable wheels that provide information on selecting, cooking, and storing fruits and vegetables.
4. Physical activity guide—Participants are given a physical activity guide (30 pages in English and 30 in Spanish under one cover) that is intended to help build competence by providing information on how to be more physically active. Based on preliminary focus group data, the guide emphasizes walking as the primary physical activity. Consistent with SDT, participants are also provided with multiple options to “find their play” (autonomous self-regulation). Three levels of activity are described—beginner, intermediate, and advanced—based on the participant's current activity level, thus allowing the individual to choose an appropriate level of challenge (not too easy and not too hard) thereby supporting his/her competence. The overall goal is to achieve the recommended 30 min of moderate intensity physical activity most days of the week [12], but any increases over baseline are encouraged. Similar to the cookbook, the physical activity guide also includes “SHAREing Support” sections and relevant biblical quotations and prayers written by local Priests. A SHARE pedometer accompanies the guide. Participants are encouraged to set goals based on duration and frequency of activity, in addition to intensity. Self-monitoring with pedometers and written documentation are encouraged.

#### 3.6.2. Partner support

1. Weekly talks with partner—SHARE partners are asked to talk with each other by telephone or in person at least once a week about their SHARE goals and how things are progressing towards meeting the goals. Both the SHARE cookbook and physical activity guide provide suggestions for starting SHARE partner conversations (“SHAREing Support”). Having a SHARE partner from the parish to work with on changing health behaviors is intended to help meet the need for relatedness (SDT). We query the frequency of partner contact at the conclusion of the intervention.

**Table 2**  
Incentives for participation in the SHARE project.

	Intervention group	Control group
To Parish Liaison	\$20/enrollment	\$20/enrollment
To participants:		
Baseline assessment	\$0	\$20/participant
6 month assessment	\$20/participant	\$20/participant
1 year assessment	\$30/participant	\$30/participant
18 month assessment	\$5/participant	NA—assessment not done

2. Teaching partners to give autonomy support—Each participant pair is offered a 2-hour peer support workshop during the second month of participation where they learn to provide autonomy support to each other. Workshops are conducted in both English and Spanish by trained instructors, and are limited to 5–10 pairs so that workshop trainers can effectively monitor participant communication skills during practice activities. Based on evidence from MI research and SDT-based studies [17,19], trainers use a PowerPoint presentation, video clips, and partner activities to teach four communication skills: asking open-ended questions, reflective listening, building motivation, and summarizing/action planning [20,21]. Video clips show examples of peer partners having both directive (undesired) and autonomy supportive conversations. Two video clip examples are included as “outtakes” on the SHARE short film given to participants at the beginning of the SHARE program. Additionally, during the workshop each participant is provided with a 15-page workbook, in either English or Spanish, which includes a summary of the four communication skills and practice activities. Participants can use the video outtakes and workbook to review skills throughout the yearlong SHARE program.

### 3.6.3. Motivational interviewing

The goal of MI is to enhance autonomous motivation for behavior change. The SHARE MI protocol is based on Resnicow and Rollnick's [22] three-phase model for MI encounters—Explore, Guide and Choose. In the Explore Phase the MI caller focuses on building rapport with a participant, obtaining a behavioral history, and collaboratively determining the barriers that make behavior change difficult for that particular individual. In the Guide Phase, the MI caller tries to elicit change talk from the participant, builds discrepancy between a participant's behaviors and values, and attempts to elicit a commitment to change. In the final Choose Phase, if a commitment to change has been made, the MI caller helps the participant identify a goal and create an action plan to meet that goal.

The SHARE MI callers are college-educated with training in a helping profession (e.g. counseling, social work, nursing, dietetics, health education). During a two-day skills-based workshop, potential MI callers learn basic tenets of MI and practice the core skills of open-ended questions, reflective listening, building motivation, and creating an action plan. Following training and evaluated practice MI conversations, quality control mechanisms are used to select MI callers, including review of an MI call with a standardized patient [23]. MI callers are paid per interview for making regularly scheduled MI calls to assigned SHARE intervention participants. At least two MI calls per interviewer are assessed during the course of the intervention for quality assurance and as a process measure for fidelity, using the 1-Pass system [23].

Throughout the intervention year, SHARE participants are scheduled to receive five MI telephone calls. When possible, MI callers will be matched with the participant on gender and ethnicity. Also when possible, the same MI caller will perform all five calls. Participants who prefer to speak Spanish will be matched with an MI Caller fluent in both Spanish and English. Throughout the calls, MI callers refer to SHARE self-help materials and other relevant components of the project. The first call starts with positive feedback about a baseline test result or

behavior. Callers encourage participants to talk with their physician about their blood pressure if baseline results are elevated. If the participant takes blood pressure medicine, adherence issues are discussed. For many, this concludes the discussion for the first call. However, if time permits, and the participant is willing, the caller and participant discuss one of the primary outcome topics (salt/sodium, fruits, vegetables, or physical activity). For calls 2–5, participants select a primary target behavior to address e.g. salt/sodium intake, fruit intake, vegetable intake, or physical activity. The goal is to discuss all primary outcomes at least once. For the fifth call, if a participant has previously discussed all four primary outcomes, he/she may choose to talk about weight loss/maintenance or one of the primary outcome topics. The calls also assess how partner support efforts are working and address how the participant can provide support to his or her partner, using the autonomy support skills covered in the peer workshop. Following each completed call, MI callers make notes in a secure online form to document the call and inform future MI conversations.

### 3.6.4. Tailored newsletters

Tailored newsletters are used to provide individualized feedback to participants about building motivation for healthy dietary and physical activity changes and improving adherence to hypertension treatment. Newsletters also encourage participants to provide each other with autonomy support (acknowledge and reflect, provide options, minimize controlling language) for health-related behavior changes. Participants receive two 4-page newsletters during the intervention year, either in English or Spanish language based on their preference. The first newsletter primarily addresses baseline blood pressure and physical activity. The second newsletter primarily addresses fruit, vegetable, and salt intake. Newsletters are mailed to the participant's home address. Both newsletters are customized for individual participants based on information provided by the participant at the baseline interview, for the first newsletter, and at the 6-month assessment, for the second newsletter. These data include participant's name, age, gender, blood pressure level and treatment, having a physician, salt intake, fruit intake, vegetable intake, level of physical activity and SHARE partner's name. Consistent with SDT, the newsletters also include tailored messages based on the participant's perceived competence to change his or her behavior, as well as on perceived support from his or her SHARE partner. In addition to tailored messages, both newsletters provide generic content about the overall benefits of behavior change, available community resources, tips for providing autonomy and competence support to the SHARE partner, and opportunities for realistic goal setting. Both tailored and generic content include spiritual themes, quotes, and references that enhance the religious relevance of behavior change for participants. Photos are used to add interest, and depict MA and EA individuals of both genders, at a range of ages, engaged in various activities related to eating fruits, vegetables, salt and performing physical activity. Newsletters are created in the Michigan Tailoring System (MTS) version 3.0, an open source software package.

### 3.6.5. Parish social environmental change

Disease prevention programs that address multiple levels of change are more likely to result in initiation and maintenance

of behaviors that reduce risk for stroke [24]. As part of the SHARE intervention, parishes are asked to make social environmental changes that will enhance opportunities for parishioners to choose healthy diets and to be more physically active.

Each parish is asked to form a Parish Health Committee, if not already in existence, and the committee is provided with \$500. The Parish Health Committee is asked to map the parish health environment with respect to events where food is served and opportunities for physical activity. Once the parish needs and assets are mapped, we charge the Parish Health Committee with working to enhance the parish environment by developing strategies to assure that low salt and high fruit and vegetable content foods are included at parish functions that serve food. Consistent with SDT, we do not ask the parish to eliminate foods entirely, but rather to serve a balance between more and less healthful items. The Parish Health Committee is also asked to organize group activities that address the goals of SHARE, such as walking groups, or cooking classes. The specific activities are left to the discretion and interest of the parish.

Parish Priests and members of the Parish Health Committee receive bi-monthly SHARE newsletters that provide suggestions for enhancing the parish social and physical environment to support healthy eating and physical activity. SHARE staff members are also available to provide technical support to the Parish Health Committee as needed. Twice during the intervention year, Parish Health Committees are asked to complete a brief form documenting their SHARE activities and accomplishments.

### 3.7. Comparison group

Participants of comparison churches undergo the same baseline, 6 month, and 12 month assessments as the intervention group. During the primary intervention time period, they receive skin cancer awareness education materials including educational print materials and sunblock at 3 months and 9 months. We also maintain contact with the comparison group by sending holiday cards. We attempt to make frequent contact with the control participants to limit the possibility that a difference between treatment groups in outcome is due to greater attention paid to the intervention group. Following completion of the 12 month assessments, the stroke prevention program intervention are delivered to the control participants, with the exception of the peer counseling workshop.

### 3.8. Baseline and follow-up assessments

A schedule for data collection is found in Table 3. The three primary outcomes, salt, fruit and vegetable intake, and physical activity are measured at baseline, 6 months, 12 months, and at 18 months only in the intervention group. The baseline, 12 month, and 18 month assessments are performed during home visits by trained study coordinators, while the 6-month questionnaires may be administered by phone. Dietary data are obtained by self-report using the Block 2005 Food Frequency Questionnaire, modified for a six-month reference period and to include foods often eaten by Hispanics, and are analyzed commercially [25]. Total average daily sodium intake (mg) is summed from all foods. Fruit servings are calculated from average total daily cups of fruit intake, including fruit juices. Because we want to measure vegetable intake with legumes but without potatoes, average total daily vegetable servings are calculated from the average daily cups of vegetable (no potatoes) and legume intake. Physical activity, measured in kcal/kg/day, is assessed with the Stanford 7-day recall physical activity questionnaire [26]. The secondary outcome measure is systolic blood pressure, measured by an automated device (OMRON-HEM-780) [27], and is measured at baseline and 12 month visits. Participants are seated quietly for a minimum of 5 min. Blood pressure is measured in the right arm (unless medically contraindicated) in the seated position with the arm supported at the mid-sternal level. We take 3 consecutive readings and average the last two. Exploratory outcomes, measured at baseline and 12 months, include biological measures of diastolic blood pressure, LDL cholesterol, HDL cholesterol, glucose, glycosylated hemoglobin, triglycerides, body mass index, and dietary measures of total dietary fat and dietary saturated fat. Venipuncture is performed by study staff after an overnight fast. Blood pressure medication adherence is also ascertained at baseline and 12 months using the single question “How often in a typical week have you missed a prescribed dose of your blood pressure medicine or medicines?” This measure is graded using a 5-point response scale ranging from “never” to “very often” and has been validated in national studies [28]. At baseline and 12 months, a relatedness questionnaire [29], modified versions of the Health-Care Climate Questionnaire [30], (modified to refer to support from an “important other”), Perceived Competence Scale [30], and Treatment Self-Regulation Questionnaire [30] (modified to refer to the three specific primary outcome measures) are administered for use in the tailoring procedures and as exploratory

**Table 3**  
Schedule for data collection in the SHARE project.

	Baseline	6 months	12 months	18 months (intervention group only)
Baseline questionnaire	+			
Self-Determination Theory questionnaires <sup>a</sup>	+	+	+	
Block Food Frequency Questionnaire [25]	+	+	+	+
Stanford 7-day recall physical activity questionnaire [26]	+	+	+	+
Blood pressure	+		+	
Blood work—lipid panel, glucose, HbA1C	+		+	
Waist circumference	+		+	
Weight	+		+	
Height	+			

<sup>a</sup> Includes assessment of competence and perceived partner support adapted from Williams et al. [30].

ry outcomes. The Health-Care Climate Questionnaire and Perceived Competence Scale are also administered at 6 months to update the information used for tailoring.

### 3.9. Statistical considerations

#### 3.9.1. Randomization

Stratified randomization was used to assign churches within the Diocese of Corpus Christi to intervention or control group. Churches were stratified into four groups defined by size (small vs. large based on number of registered families) and income (high vs. low income neighborhood by census tract). Stratification of churches by factors that may be associated with the endpoint, such as income, will increase statistical power by decreasing outcome variability. Since more churches were available than were needed for the intervention, randomization occurred in two steps. From each size and income stratum, churches were randomized to participation in the study or not. Subsequently, churches were randomized to intervention or control group.

#### 3.9.2. Statistical analysis

**3.9.2.1. Primary analyses.** The church was the level of randomization and the individual will be the unit of analysis. We will account for the correlation of observations within individuals, individuals within pairs, and pairs within churches using mixed effects models for nested data [31]. The primary endpoints of interest will be change across the baseline, 6 month, and 12 month time points in dietary salt, fruit and vegetable intake, and physical activity. Significant changes (at a significance level of 0.05/3) in at least one of these endpoints will be indicative of intervention success. Repeated measures analyses using mixed effects model will include 3 repeated measures of each outcome in separate models. The hypotheses of interest will be tested by assessing the significance of time by treatment interaction terms, which are interpreted as the differences in the rate of change of the outcomes over time associated with treatment (i.e. the difference in secular trends in the control group vs. secular + treatment trends in the treatment group). Models will be adjusted for covariates to reduce the impact of intra-cluster correlation [32]. Although sample size calculations (below) are based on assuming two measures of change (from baseline to 6 months and 6 months to 1 year), repeated measures analyses including the baseline measure as part of the outcome was selected for the primary analyses because they are more efficient than calculating and modeling two measures of change [31]. In the intervention group only, persistence of the effects of the intervention will be assessed by calculating the baseline-adjusted average change in each of the outcomes from baseline to 18 months and testing the hypothesis that it differs from zero. The same type of analyses will be conducted on the secondary endpoint, SBP.

**3.9.2.2. Mediation analysis.** To elucidate mechanisms by which the SDT-based intervention achieves its effect, we will examine the mediating effects of autonomous motivation, perceived relatedness, and partner autonomous support. In the presence of a treatment effect, a variable is declared a mediator if it meets three criteria: it is affected by the treatment, it

predicts the endpoint of interest, and the treatment effect is attenuated when the potential mediating factor is adjusted for. Mediation analysis will be conducted by including mediating factors in the mixed model regression analyses. Mediating factors will be included in the models individually, as well as with other factors, to estimate the relative mediating role of each factor. We hypothesize that autonomous motivation, perceived relatedness, and partner autonomous support are mediators of the main treatment effects. If a treatment effect is observed in the secondary endpoint, SBP, then the mediating role of the three primary outcomes on SBP change will be assessed in a similar fashion.

**3.9.2.3. Exploratory analyses.** We will assess whether the influence of the intervention on the primary and secondary endpoints differs by ethnicity by testing the statistical interaction of the treatment effect with an indicator variable of ethnicity (i.e. treatment by time by ethnicity interaction). If a significant ethnicity interaction is found, stratified analyses will be conducted to assess if the role of mediating factors vary by ethnicity.

#### 3.9.3. Sample size calculations

We calculated sample sizes necessary to detect meaningful changes in each of the three primary outcomes. We assumed that the correlation between the two measures of change (from baseline to 6 months and from baseline to 12 months) was at least 0.6; this value may be conservative, as larger values would lead to an increase of power. We fixed the significance level at 0.05/3, to correct for multiple testing (i.e. three primary outcomes), and the power at 80% ( $\beta = 0.2$ ). The value of the ICC pertains to the correlation of participant units within churches. We used a range of plausible ICC values estimated based on prior studies [32]. In these sample size calculations, we conservatively treated each pair as only providing one independent observation because we expected high correlations within the pair. Depending on the degree of correlation within pairs, the actual power will range from 80% (100% correlation) to 90% (approximately 50% correlation). Using sample size formulas for cluster-randomized trials [33, 34], and assuming given values of change ( $\delta$ ), ICC, and variance ( $\sigma$ ) for each the outcome, Table 4 outlines the number of churches necessary to provide this power for an average of 40 pairs recruited from each church.

**Table 4**

Number of churches needed per group, assuming 40 individuals per church, varying intra-class correlation coefficient (ICC), SHARE project.

Outcome	ICC	Number of churches necessary
Sodium (mg) [46] $\delta = 548, \sigma = 1200$	0.001	3
	0.005	3
	0.01	3
Fruits and vegetables (servings) [47] $\delta = 3, \sigma = 3.6$	0.001	1
	0.005	1
	0.01	1
Physical activity (kcal/kg/day) [48] $\delta = 0.86, \sigma = 2.3$	0.001	4
	0.005	4
	0.01	5

#### 4. Discussion

SHARE is a cluster-randomized, multi-component motivational enhancement intervention study that tests the effectiveness of this rigorously designed, theory-based motivation enhancing intervention in reducing sodium intake, increasing fruit and vegetable intake, and increasing physical activity. This is the first motivation intervention trial to target stroke risk behaviors in MAs, the most represented subgroup of Hispanic Americans, the largest minority group in the US. We anticipate that SHARE will demonstrate an improvement in at least one of the primary outcome measures, at a significant level of  $p = 0.05/3$ . If effective, materials from this study can be disseminated more widely and adapted for other communities.

The study community of Corpus Christi is a predominantly biethnic population. The SHARE project has been designed to be sensitive to both MAs and EAs in order to extend the generalizability of the materials and approach to the two largest race/ethnic groups in the US. This design aspect of the study is important given the changing demographic profile of the US with the rising number of Hispanics.

This project includes a novel approach to psychological needs support for autonomy, competence, and relatedness. SHARE includes both partners in the study equally, and involves teaching reciprocal autonomy support using a multifaceted approach. Typically, in motivation intervention trials based on SDT, important others or practitioners are trained to provide autonomy support [19]. In SHARE, both partners contribute data to the results, taking into account correlations, which should increase the power of the trial. The partners' balanced participation may enhance participants' trial experience through shared experiences and goals with their partners.

Although churches frequented by African Americans have to date been used as the primary conduit for introducing many behavioral interventions [20,35–41], MAs are rarely targeted as part of church-based interventions [42]. The large majority (approximately 70%) of Hispanics in the US are Catholic, and in Corpus Christi, based on church records, this percentage is even higher (70–80%) [13,43]. Forty-five percent of Hispanic adults say that they attend church services once a week or even more frequently; while, only 7.5% indicate that they never attend religious services [43]. Religion has a significant influence on health practices and beliefs in MAs [44,45]. Given the sense of religiosity in the MA community and high frequency of church attendance among MAs, the church is a practical conduit to reach a large proportion of MAs, while also including EAs, and suggests benefits in implementing a stroke prevention program that targets MAs in a church-based context.

The primary outcomes in this trial are self-reported measures that are subject to measurement error and response bias, given that the trial is not masked. Although dietary recall is superior to food frequency assessments, they are less feasible, especially given our sample size of 800 participants. The one-year study time frame should reduce seasonal variations in dietary intake and physical activity, if present. An alternative to these behavioral outcomes, blood pressure, was not selected as the primary outcome given the moderate intensity of the intervention and the inclusion of participants with normal blood pressure, which could contribute to a floor effect.

Other aspects of the intervention, such as generalizability, have limitations. Although the Catholic, cultural, and regional influences on the materials are strengths in the context of this trial, intervention materials may need to be adapted for religious and cultural content before potential dissemination to other groups and communities. Given the multifaceted nature of the intervention, identifying specific components' contributions may also be difficult. Lastly, recruitment and retention are often challenging in trials. We have built in incentives and use parish liaisons from the community to assist in recruitment. Nonetheless, recruitment goals may be harder to achieve in the smaller churches randomized to participation, such as our smallest church with approximately 100 registered families. To some extent, we may be able to increase enrollment in larger churches to compensate if needed, as our largest church has over 3000 registered families.

The SHARE project tests a novel study design to reduce important stroke risk factors in two large segments of the US population. If successful, it can be adapted for and disseminated to other communities to address a crucial public health problem, the high risk of stroke in EAs and the especially high risk in MAs.

#### Ethics and registration

The University of Michigan Institutional Review Board approved this study. Participants provide written informed consent. The trial is registered with clinicaltrials.gov (NCT01378780).

#### Conflicts of interest

None.

#### Funding source

SHARE is funded by R01NS062675.

#### Acknowledgments

We are grateful to the SHARE Community Advisory Board (Monsignor Mark Chamberlain, Rosie Garza RN, Monsignor Michael Heras, Teresa Martinez RN, Monsignor Morgan Rowsome, Mary Welch RN PhD) and the Diocese of Corpus Christi for their partnership.

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