

STUDY PROTOCOL

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# Randomized controlled pilot study of a SystemCHANGE™ weight management intervention in stroke survivors: rationale and protocol

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## Abstract

**Background:** Over 65% of stroke survivors are either overweight or obese and have multiple cardiovascular risk factors. However, few studies have examined the effects of comprehensive lifestyle behavior interventions to promote weight loss and control cardiovascular risk factors in stroke survivors. Thus, the purpose of this study is to examine a novel behavior change approach - SystemCHANGE™ - to promote weight loss and improve health and function in stroke survivors. SystemCHANGE™ focuses on redesigning the social environment to achieve a specific goal.

**Methods:** We will conduct a randomized controlled pilot study to examine the efficacy, feasibility, and safety of the SystemCHANGE™ weight management program in overweight and obese stroke survivors. The central hypothesis of the study is that the SystemCHANGE™ intervention will help overweight and obese stroke survivors lose 5% of their body weight, thereby improving health and function. Thirty-five stroke survivors will be randomized into either the 6-month SystemCHANGE™ intervention or a contact-control intervention. Outcome measures will be assessed at baseline and again at 3 and 6 months after the interventions. Body composition will be assessed using a Bod Pod. Patient-reported outcomes will be the Stroke Impact Scale and Reintegration to Normal Living Index. Objective outcomes will include the 6-Minute Walking Test and Rivermead Motor Assessment.

**Discussion:** This study will be the first randomized controlled trial to evaluate the efficacy and safety of a weight management intervention in stroke survivors using the SystemCHANGE™ approach. Furthermore, it will be the first empirically-examined comprehensive lifestyle intervention designed to target physical activity, nutrition, and sleep to promote weight loss in stroke survivors.

**Trial registration:** ClinicalTrials.gov Identifier: NCT01776034

**Keywords:** Stroke, Weight management, Obesity, Self-management, Exercise, Physical activity, Nutrition, Diet, Sleep hygiene

## Background

Over 65% of stroke survivors are either overweight or obese, and a projected 4.98 million stroke survivors in the USA have multiple cardiovascular risk factors [1]. Stroke survivors are at significant risk for deconditioning [2], elevated inflammatory markers [3], and

insulin resistance [4], which subsequently increases risk for secondary stroke and cardiovascular disease [5,6]. Engaging in healthy behaviors, such as physical activity, good sleep hygiene, and nutrition, to facilitate energy balance may help reduce the risk of secondary conditions and ultimately improve physical function and quality of life in stroke survivors [5,7].

However, stroke survivors can experience many barriers to engaging in a healthy lifestyle to achieve energy balance [8]. Mental and physical impairments interacting with a non-supportive environment can create multiple challenges

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to engagement in healthy behaviors, which can perpetuate a disabling cycle [9]. Specifically, inactivity, unhealthy eating, and poor sleeping habits can lead to obesity. Obesity can increase mobility problems, fatigue, depression, and further difficulties engaging in healthy behavior. Supporting stroke survivors to achieve energy balance and a healthy body weight may be a strategy to counteract the disablement process.

Most studies examining lifestyle interventions in stroke survivors have focused on promoting physical activity and/or teaching self-management skills [10], which only partially addresses behaviors associated with achieving energy balance [11]. Thus, effective strategies to promote weight loss in stroke survivors remain elusive. Research in the general population indicates weight management interventions should target both physical activity and nutrition [11], and that promoting good sleep hygiene may be an additional strategy to facilitate weight loss [12]. Furthermore, research in people with disabling conditions indicates that impairments often create barriers to engagement in healthy behaviors, but that utilizing self-management skills and having ample social support can facilitate overcoming such health-related barriers [13]. Thus, based on research in the general population and in people with disabling conditions, we contend that an effective weight management intervention in stroke survivors should target physical activity, nutrition, sleep, and self-management skills, as well as utilize strategies to foster a supportive social environment.

Shirley Moore recently developed such an intervention approach called SystemCHANGE™ [14], a new behavior change intervention drawing from social ecological theories [15-17]. SystemCHANGE™ focuses on redesigning the environment using trial-and-error 'experiments' to achieve a specific goal. SystemCHANGE™ is in contrast to cognitive-behavioral interventions that focus on changing a person's viewpoint of a situation and increasing motivation. In SystemCHANGE™, individuals are taught a set of skills to assist them in incorporating habitual lifestyle behaviors into their daily systems so they succeed despite wavering motivation. Strategies include identifying a chain of steps/events that comprise the system in which the desired change is to occur, keeping track of data about the system process to understand it, implementing short trials of possible improvement solutions, evaluating success by reviewing data, and making provisions for holding the gains. Given the novelty of SystemCHANGE™ to focus on an individual's surrounding environment rather than an individual's motivation and willpower to change behavior, this approach is now being tested in various population segments (for example, overweight children and patients with HIV). We propose to adapt the SystemCHANGE™ intervention approach to promote weight loss in overweight and obese stroke survivors. This study will

represent the first empirically-examined comprehensive lifestyle intervention designed to target physical activity, nutrition, and sleep to promote weight loss in stroke survivors.

The specific aims are to engage stroke survivors and their families as co-designers to adapt the SystemCHANGE™ intervention, and then conduct a randomized controlled pilot study to provide preliminary estimates of the intervention's efficacy in 35 stroke survivors. Herein, we will focus on describing the methodology for the pilot randomized controlled trial rather than the qualitative methodology. The pilot study will provide effect size estimates on the following primary outcomes: body weight and patient-reported and objective outcomes of health and function. Secondary outcomes include questionnaires on symptoms, healthy behaviors, psychosocial mediators, and biomarkers of cardiovascular risk. The central hypothesis of the study is that the SystemCHANGE™ intervention will help overweight and obese stroke survivors lose 5% of their weight, thereby improving health and function. Hypothesized mechanisms of action will involve significant improvements in healthy behaviors, symptoms, psychosocial constructs, and cardiovascular risk.

## Methods

### Trial design

We will conduct a single-center, randomized, controlled, parallel-group, rater-blinded pilot study. Thirty-five participants will be recruited and randomized into the SystemCHANGE™ intervention or a contact-control information-only intervention. Both interventions will be delivered over a 6-month period. All outcomes will be administered before the interventions and again at 3 and 6 months. The Cleveland Clinic Institutional Review Board approved this study. We will obtain informed consent from each stroke survivor that participates in the study.

### Participants

The following methods will be used for recruitment: (1) fliers distributed at support groups; (2) referrals from clinicians; and (3) medical chart reviews. Individuals will undergo a three-part screening to confirm eligibility (phone, physician, and in-person). Subjects who meet the eligibility requirements over the phone will be mailed a demographic sheet and a release form to contact their physician. Once we confirm eligibility from their physician, arrangements will be made to re-confirm eligibility in person, obtain informed consent, collect pre-test data, and randomize participants into the SystemCHANGE™ intervention or the control intervention. Main inclusion criteria are: (1) a physician-confirmed unilateral ischemic or hemorrhagic stroke (at least 6 weeks post-stroke); (2) physician consent to participate; (3) age 30 to 75 years; (4)

a BMI between 25 to 40 kg/m<sup>2</sup>; and (5) a stable weight for the past 4 weeks. Individuals will be excluded if they have: (1) heart disease (that is, myocardial infarction, congestive heart failure, coronary artery bypass grafting, or valve replacement during the past 3 months, serious cardiac arrhythmias, hypertrophic cardiomyopathy, and severe aortic stenosis); (2) pulmonary embolus; (3) uncontrolled resting blood pressure (that is, 140/90 mmHg) or abnormal blood pressure or heart rate response during the 6-Minute Walking Test [18] (for example, drop in systolic blood pressure of >10 mmHg from baseline), (4) uncontrolled diabetes (hospitalized in the past 6 months); (5) unable to communicate (for example, severe aphasia); (6) severe cognitive deficits (weighted score <12 on the short version of the Blessed Orientation Memory Concentration test [19]); (7) pregnancy; (8) three or more falls in the past month; (9) inability to walk 3 meters with or without a mobility device; (10) weight loss medications or medications that cause excessive weight gain (for example, corticosteroids and antipsychotic); and (11) gastric bypass surgery.

Study criteria were selected to help ensure patient safety, create a homogeneous sample of mild to moderate impairments, minimize confounders, and avoid ceiling effects. We are excluding individuals >75 years of age to minimize risk of weight loss, muscle atrophy, and functional declines. Individuals with serious heart conditions are being excluded because of the prescription of a physical activity program. We are also excluding people with uncontrolled blood pressure or diabetes because these individuals need medical treatment, which will likely result in prescribing or changing medications that can confound study results.

## Interventions

### SystemCHANGE™

The SystemCHANGE™ intervention will be delivered over a 6-month period involving 12 face-to-face group sessions (1.5 h each) held weekly for 3 months, followed by 3-monthly 'booster calls'. Intervention groups include up to 10 patients, and family is encouraged to attend. Intervention sessions consist of 30-min of behavior change activities and 60-min focused on healthy behaviors. Sessions will be led by a health education specialist and held at local community centers. Below we outline each topic area of the SystemCHANGE™ intervention.

### Diet

The recommended diet will be consistent with the *Dietary Guidelines for Americans 2010* document [20]. Emphasis will be placed on restricting fatty foods and consuming more fruits and vegetables. Total recommended daily caloric intake will be consistent with recommended degrees of weight reduction, based on a graded reduction

in total daily caloric intake adjusted to meet goals and avoid rapid weight loss. Each participant will receive a personalized diet plan based on their food diary.

### Physical activity

The goal will be to increase physical activity levels, reduce sedentary behaviors, and encourage participation in a strength training program. The physical activity program will be based on the patients' preference and goals. In a graded fashion, we will encourage participants to achieve recommended physical activity guidelines, which will include a strength training program of major muscle groups.

### Sleep

The sleep component will address recommended sleep duration, the process and stages of sleep, benefits of sleep, and the relationship of sleep to hunger, stress, fatigue, and obesity. Good sleep hygiene and barriers to adequate sleep will be discussed. Strategies will include minimizing procrastination, regularizing a sleep schedule, learning the components of stimulus control therapy, and relaxation strategies.

### Symptom management

Kate Lorig's self-management framework [21] will be used to guide the symptom management component. The overall goal of this component will be to provide specific strategies on managing symptoms and to teach participants the necessary skill set to incorporate these strategies into their lives. We will focus on teaching skills related to managing emotions, communicating with caregivers, and managing fatigue (for example, taking rest breaks and re-organizing work spaces) and pain (for example, visualization and breathing exercises).

### Contact-control intervention

In contrast to the SystemCHANGE™ arm, participants assigned to the information-only group will receive pamphlets that contain information on healthy eating, physical activity, sleep, and symptom management, and will be telephoned at the same time points as the SystemCHANGE™ sessions. These 20-min phone calls are intended to teach participants recommended guidelines for engaging in healthy behaviors and reducing cardiovascular risk. However, the skills taught in the SystemCHANGE™ intervention (for example, identifying a chain of steps/events that comprise the system in which the desired change is to occur) will not be taught in the control intervention. Thus, we will be able to determine whether it is the skills taught in the SystemCHANGE™ intervention or simply the learning of guidelines that promotes engagement in healthy behaviors. Furthermore, the phone calls in the contact-control intervention will provide an

equivalent number of contacts with the health education specialist as in the SystemCHANGE™ intervention. Thus, we will be able to determine whether it is the skills taught in the SystemCHANGE™ intervention or simply the interactions with the health education specialist and creating accountability that promotes engagement in healthy behaviors.

#### **Booster sessions**

In the SystemCHANGE™ intervention, the booster sessions will assist participants to use strategies taught in the face-to-face sessions to manage the maintenance phase of behavior change. The health education specialists will talk to patients about their efforts in self-monitoring and assist them to identify situations that are high risk for relapse. In the contact-control intervention, the booster sessions will be generic and answer questions about engaging in healthy behaviors.

#### **Treatment fidelity**

To promote standard application of the interventions in both the SystemCHANGE™ group and the control group, a manual of operating procedures and lesson plans outlining each session will be provided to the health education specialist and incorporated into their training. We will use the same person to deliver the interventions in both groups to facilitate standardized delivery. The health education specialist will also be given a checklist to review and use in each session and will be monitored in-person at random intervals to determine the extent to which the lesson plans are followed. Intervention fidelity will be further monitored by tracking participant attendance, monitoring completion of homework assignments, and administering quizzes to assess participants' understanding of the material.

#### **Outcomes**

Body fat and muscle composition will be assessed using a Bod Pod, which uses air displacement plethysmography to determine body composition [22]. Patient-reported outcomes will be the Stroke Impact Scale [23] and Reintegration to Normal Living Index [24]. Objective outcomes of health and function will be the 6-Minute Walking Test [18] and Rivermead Motor Assessment [25]. Assessors will be blinded to treatment groups.

Secondary outcomes to examine health behavior change will include a 3-day food diary, the Physical Activity and Disability Survey [26], and sleep quality measured with Neuro-QOL [27]. Fatigue, pain, anxiety, and depression will also be measured with Neuro-QOL [27]. Potential psychosocial mediators that will be measured include self-efficacy for diet [28], physical activity [29] and self-management [30], and social support for healthy behaviors [31]. Finally, assays will be performed

for cholesterol, triglycerides, C-reactive protein, and hemoglobin A<sub>1c</sub>.

#### **Sample size**

Our goal to recruit 35 stroke survivors is consistent with recommendations in the literature for pilot studies. Hertzog [32] has shown that samples of 10 to 20 participants per group are often adequate for evaluating feasibility in a pilot study. Furthermore, Dobkin [33] has suggested that 15 participants in each research arm are sufficient for determining whether a larger multicenter trial should be conducted.

#### **Randomized allocation procedure**

Allocation will be performed using a permuted block randomization procedure to help ensure a 1:1 ratio in each group. The allocation sequence will be determined using a computerized random number generator with block sizes of four participants. The allocation sequence will be concealed from the health education specialist and researchers who are enrolling potential participants with a sequential number of opaque sealed envelopes. Envelopes will be opened only after all pre-test data is collected. A researcher with no involvement in the delivery of the interventions or the screening of participants will prepare the envelopes.

#### **Blinding**

It will not be possible to blind the health education specialist or participants to group assignment. However, steps will be taken to blind the researchers who administer the outcome measures. Researchers who administer the outcome measures will be different from the researchers who conduct the screenings and deliver the interventions. Participants will be instructed not to tell the assessor of their group assignment.

#### **Statistical methods**

Recruitment and data collection efforts will be managed with Research Electronic Data Capture [34]. The first step in the analysis will be to compute summary statistics, calculate outcome scores, and conduct quality control assessments. Outcome measures will be analyzed using multivariate repeated measures or one-way ANOVAs (assuming data are normally distributed). Between-subject effects will be examined by subtracting baseline scores from post-test scores and utilizing one-way MANOVA to determine whether there are significant improvements in change scores in the SystemCHANGE™ group compared to the contact-control group. Within-subject effects will be examined with repeated-measures MANOVA comparing baseline data immediately before the SystemCHANGE™ intervention to data at 3 and 6 months after receiving the SystemCHANGE™ intervention. To help minimize missing



data, we will follow recommendations by Little *et al.* [35] (for example, providing monetary incentives). Effect sizes will be calculated as Cohen's *d*. Feasibility and safety of the intervention will be assessed with descriptive statistics (frequencies, percentages, means, and standard deviations); number of contacted *versus* recruited subjects, reasons for non-participation, attrition (with timing and reasons), time required to train health education specialist and arrange follow-up phone calls, and adverse event monitoring (control *versus* treatment group).

### Risk and safety monitoring

The risk level of this protocol is low to moderate due to recruiting overweight and obese patients and the unknown risks of encouraging weight loss in stroke survivors. Participants will be asked to exercise and change their dietary habit, which poses some risk; however, inclusion-exclusion criteria will help minimize these risks. Data on physical function, weight loss, muscle loss, and other health status changes (that is, cardiac, musculoskeletal, or digestive) will be monitored closely.

### Discussion

This pilot study will represent the first randomized controlled trial to evaluate the efficacy and safety of a weight management intervention in stroke survivors using a SystemCHANGE™ intervention approach. The trial is designed to obtain effect size calculations and examine the feasibility and safety of conducting a larger clinical trial. While it will not be possible to conduct a double-blinded study, the implementation of a contact control group will help enhance retention and allow us to determine whether the actual strategies used in the SystemCHANGE™ intervention are more effective in promoting behavior change than contacts with a health education specialist. Using both self-report and objective measures of function and obtaining body composition measurements throughout the study will be important components in monitoring for potential adverse events.

### Obesity paradox

The relationship between nutritional status, disabling conditions, and physical function is complex and not fully understood [36,37]. A recent observational study indicated an 'obesity paradox' in stroke survivors [38]; that is, being either overweight or obese was associated with significantly better early and long-term survival rates compared to those with normal BMI. In a review article, Lavie *et al.* [39] noted that obesity is associated with a more favorable prognosis in at least 10 different disabling conditions, such as heart failure, advanced cancers, and HIV. Furthermore, research also indicates that weight loss is related to muscle atrophy, which can

subsequently result in functional decline [40]. Thus, the existing literature raises an important question: Will weight loss adversely affect physical function or morbidity in stroke survivors?

Preliminary research in older adults and patients with heart disease or cancer suggest that modest weight loss does not adversely affect health outcomes [39]. It has also been argued that findings of the obesity paradox may be confounded by selection bias and that the use of traditional BMI categories may not be appropriate for people with disabling conditions because it does not account for muscle atrophy [36,39]. In the 2011 study showing the obesity paradox in stroke survivors, Vemmos *et al.* [38] concluded that 'results cannot support recommendations to overweight or obese patients not to lose weight after acute ischemic stroke. On the contrary, taking into account the numerous studies that linked increased BMI with cardiovascular events, prevention of weight gain should be strongly promoted.' Clearly, there is a need to move beyond observational studies to randomized controlled trials that can truly determine the effects of weight loss and reductions in percent body fat on health and function. We contend that weight management interventions in stroke survivors should emphasize strength training to help prevent muscle loss and use percent body fat and waist circumference as indicators of success and safety monitoring rather than body weight alone.

### Potential limitations and confounders

Potential limitations and confounders to the study are the following: (1) changes in medication or dose; (2) evaluating a comprehensive lifestyle intervention rather than focusing on changing one particular behavior; and (3) a subgroup of participants may be non-responsive to a behavioral intervention.

- (1) An important component of the study will be excluding individuals who are taking medications known to cause extensive weight gain or loss. Medication changes will also be monitored at each assessment time-point and their possible confounding effects will be examined in our preliminary review of the data. We will also contact the patients' physician to request that changes in medication causing weight gain or loss only occur when medically necessary.
- (2) Although it is difficult to determine which components of an intervention (that is, active ingredients) are effective when evaluating a comprehensive lifestyle intervention, we feel it is necessary to implement such an intervention because multiple behaviors influence weight loss (that is, physical activity, nutrition, reduced stress,

and adequate sleep), and stroke survivors experience health-related barriers that can be overcome through teaching self-management skills.

- (3) Behavioral approaches to weight loss may not be effective for all patients. However, we expect that new SystemCHANGE™ approach will be more effective. Furthermore, we will explore patient characteristics that influence the intervention's effectiveness. In the trend towards personalized medicine, an important goal of future studies will be to identify those patients who are non-responsive to behavioral interventions and to make recommendations for alternative interventions, such as bariatric surgery.

We lastly note that observational studies indicate that people with disabilities are two to four times more likely to either be overweight or obese [37,41,42]. However, a dearth of research has evaluated intervention strategies promoting energy balance among people with disabilities. Thus, developing and evaluating a weight management intervention for stroke survivors could also help to fill research gaps within the broader disability literature. Furthermore, examining the effects of the SystemCHANGE™ intervention is novel in the disability literature. SystemCHANGE™ focuses on changing the surrounding social environment rather than a person's motivation to change behavior, which may be particularly relevant for people with disabling conditions who often rely on formal and informal caregivers for tangible social support, such as grocery shopping and meal preparation [43].

## Trial status

The status of the trial was ongoing and actively recruiting stroke survivors at the time that the protocol was submitted for publication.

## Competing interests

The authors declare that they have no competing interests with this particular study.

## Authors' contributions

Each author has made contributions to the conception, design, or implementation of the study. MP, SM, JA, and JK contributed to the research design. SM designed the intervention and MP adapted the intervention for stroke survivors. FF, SJ, and IK contributed to the implementation of the study. All authors have read and approved the manuscript for submission.

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