Study Title:

ENGAGE Pilot Study: Promoting Participation and Health in People with Stroke-Related Disability

A multi-site, single-arm pilot study examining the feasibility, acceptability, and estimated effects of a self-management intervention with individualized application

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PRÉCIS

Study Title

ENGAGE: Promoting Participation and Health in People with Stroke-Related Disability

Objectives

The objectives of this study are to examine the feasibility, acceptability, and safety of a multi-site implementation of ENGAGE and to describe change in community participation among adults with stroke-related disability and low income.

Design and Outcomes

This is a multi-site, multi-phase (in-person, remote), single-arm community-based pilot study examining the feasibility, acceptability, safety, and estimated effects of ENGAGE. Indices of intervention feasibility, acceptability, and safety will be assessed. Community participation and measures of physical, social and emotional health will be administered before and after the intervention.

Interventions and Duration

All participants will receive a 6-week (12 sessions, 2 times per week) self-management intervention with social learning (group training) and guided skill development (individual application).

Sample Size and Population

Participant will have mild to moderate stroke-related disability for a minimum of 3 months and identified limitations in community participation.

1. STUDY OBJECTIVES

1.1 Primary Objective

The primary objective of this study is to examine the feasibility, acceptability, and safety of a multi-site, multi-phase implementation of ENGAGE to address community participation among adults with stroke-related disability and low income. We will partner with Washington University Community Research Fellows and the University of Pittsburgh Community PARTners to adapt and implement the intervention to address the needs of people with mild to moderate stroke-related disability and low income who live in Pittsburgh, St. Louis, and Chicago. We will clarify and describe the specific adaptations necessary to support this population. We will test this intervention through in-person and remote delivery methods. Feasibility will be indicated by >90% of target enrollment, >90% retention, and >90% intervention fidelity at each site; acceptability will be indicated by >90% participant satisfaction at each site; and safety will be indicated by <3% participants with a reportable event (i.e., injurious fall) at each site.

1.2 Secondary Objectives

The secondary objective of this study is to describe intervention response among

participants at each site, indicated by pre-post change in PROMIS Ability to Participate in Social Roles and Activities. We will also explore changes in satisfaction with participation (PROMIS Satisfaction with Participation in Social Roles and Activities), physical activity (step count/day), sedentary behavior (sitting time/day), social (PROMIS Social Isolation), and perceived health (PROMIS-29) to inform future studies.

2. BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Significant advancements in acute medical management have shifted stroke from an acute condition with a high prevalence of mortality to a chronic condition with high prevalence of morbidity. One of the leading causes of chronic illness and disability worldwide, stroke results in residual impairments in sensorimotor, cognition, and communication impairments. These impairments reduce over time, but few people have complete restoration of function. Hence, people with stroke-related disability do not resume pre-stroke levels of community participation (education; paid or volunteer work; civic, social, and religious activities; and leisure). Low levels of community participation are associated with inactivity, sedentary behavior, and social isolation, each contributors to cardiovascular disease, diabetes, obesity, pulmonary conditions, depression – and secondary stroke. These consequences are particularly problematic for people with low income who have limited resources.

It may be possible to improve community participation after stroke, despite residual disability. Unfortunately, interventions remain under-developed and under-studied. Thus, the NIH Research Plan on Rehabilitation identifies this as one of the critical focus areas for rehabilitation research. We need community-focused and individually-tailored, and culturally-responsive interventions to promote community participation, particularly in portions of the population most vulnerable to poor health outcomes.

2.2 Study Rationale

Our team of occupational therapy scientists has designed ENGAGE, a self-management training program that uses social learning and guided discovery to help people with mild to moderate stroke-related disability resume community participation, and to develop a strong network of social support. Our previous research demonstrates that self-management training with social learning results in significantly greater gains in self-efficacy for community participation, as well as improved "enfranchisement" (a sense of belonging) compared to a wait-list control group. That is, participants felt more confident and more integrated and valued in the community after the intervention (Cohen's d=1.45). Additional research demonstrates that guided skill development helps people with stroke-related cognitive impairments 1) identify and solve problems in everyday activities, and 2) achieve greater improvements in independence (Cohen's d=1.06) and executive functions (Cohen's d=1.38) compared to usual rehabilitation practices. Guided skill development teaches people how to identify problematic daily activities and barriers, and generate and evaluate their own strategies to address barriers. Instructors facilitate learning through

prompts and questions, rather than directly instructing participants. We posit that self-management training with social learning and guided skill development may comprise the optimal program to promote improved frequency and satisfaction with community participation, and subsequently improve overall health.

However, the combination of these elements has yet to be studied in people with chronic stroke-related disability who live with low income – one of the most vulnerable segments of the population. By partnering with the Community Research Fellows Program at Washington University and the Community PARTners Program at the University of Pittsburgh, this multisite team seeks to design and implement a culturally-responsive program to promote community participation among people with stroke-related disability and low income. This new collaboration is the next logical step in the development and examination of community-based interventions to promote self-management and community participation after stroke.

The self-management training will be administered by an occupational therapist and a peer-mentor in group sessions (social learning). Individual application of the self-management training content will be facilitated with guided skill development principles. The intervention will be 12 two-hour sessions, offered 2 times per week for 6 weeks, based on previous intervention dosing studies. There are limited known and potential risks because the intervention focuses on doing routine daily activities in the home and the community, as would normally be encountered in the course of everyday life. However, there is a minimal risk of frustration fatigue, fall, or injury that may result from increasing physical and social activity levels over the course of time. These risks will be minimized through supervision of licensed occupational therapists.

ADDENDUM: With the onset of the pandemic, we developed methods to deliver this intervention program remotely. People with stroke-related disability, particularly those in low income communities, face unique problems in the home and the community during pandemic conditions. We decided to add a second phase of the study, delivering the intervention remotely, to address these needs, and to compare metrics across phases (in person, remote).

3. STUDY DESIGN

This is a multi-site, multi-phase single-arm community-based clinical trial examining the feasibility, acceptability, safety, and variation in changes in community participation attributed to ENGAGE among community-dwelling adults with mild to moderate stroke-related disability and low income. The 6 week intervention (12 two-hour sessions, 2 times per week) intervention will be delivered in community-based settings (in person) or in the home (remote), and assessments will be delivered in the home or community-based settings (in person) or via teleconference (remote). Assessments will be administered by independent evaluators at each site, and all data will be collected electronically and stored in REDCap, a cloud-based data management system accessible to all investigators at all sites.

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

Inclusion criteria are: 1) ages 18 and older, 2) chronic stroke (minimum 3 months), 3) community-dwelling, 4) mild to moderate stroke-related disability (NIHSS ≥ 16), 5) restrictions in community participation (Activity Card Sort indicates retention of <80% of pre-stroke community participation activities), 6) low income (uninsured or underinsured), and 7) able to provide written informed consent.

4.2 Exclusion Criteria

Exclusion criteria are: 1) currently receiving rehabilitation services, 2) dementia diagnosis, 3) severe aphasia (0 or 1 on the Boston Diagnostic Aphasia Examination Severity Rating Scale), 4) current major depressive, bipolar, or psychotic disorder (PRIME-MD), or 5) substance abuse within 3 months (Mini-International Neuropsychiatric Interview).

4.3 Study Enrollment Procedures

We will recruit research participants from stroke and rehabilitation research registries and stroke recovery support groups. Interested participants will be encouraged to contact the study team by telephone or email, and the study team will follow up with an initial phone call using the approved recruitment script. If the potential participant provides verbal consent as per approved procedures, the study team will describe the purpose of the study, the procedures involved and the potential risks and benefits of study participation. Persons providing written or electronic informed consent will be asked to describe the study in their own words to ensure their understanding. In addition, persons providing informed consent will be invited to ask questions about the research study and will be provided time to think about study participation, prior to providing informed consent. Even after informed consent is obtained, participants will be invited to ask questions about the study and ongoing participation. All of these procedures will be documented in the research record via tablet and uploaded to REDCap, the cloud-based data management system.

All contacts with potential research participants will be documented in the screening log maintained in REDCap. Potential participants who do not provide informed consent or are ineligible will be identified by a code (NC1, NC2) and the reason for non-participation or ineligibility will be maintained. No identifiers will be maintained or linked to these codes. Participants who do provide informed consent will be identified by their assigned study identification code (with a linking file maintained separately). Study identification codes will be assigned through REDCap.

5. STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

The intervention, ENGAGE, will be delivered by trained occupational therapists and peer mentors. Therapists and mentors will deliver the 12 intervention sessions (2 sessions per week for 6 weeks) to groups of 6 to 8 participants, at a university-owned

or community center (in person) or via teleconference with provided technology and internet access (remote). Each session will be 2 hours and will be video recorded.

The intervention blends self-management training with social learning and guided skill development to promote community participation after stroke-related disability. For this project, ENGAGE will be tailored to the needs of people with low income who may have few resources or supports.

Self-management training sessions comprise 12 topics (building community participation plans, understanding the stroke experience, engaging in the community, advocating for self and others, using social networks, strategies for participation, staying active and well, civic and volunteer activities, applying what we learned, sharing what we learned). During each of these sessions, therapists and mentors will use social learning and guided skill development principles to aid participants in identifying individual and collective goals, addressing these goals, and debriefing to support application. Participants will use the Activity Card Sort (published standardized tool with photos of activities in the home and community, sorted by importance to the participant) and workbooks to guide these activities during and between sessions. Refer to the intervention manual for specific procedures.

5.2 Handling of Study Interventions

Prior to recruitment, the investigators will meet with community members and peer mentors to discuss adaptations to the intervention protocol, language, and materials to optimize the delivery of the intervention for this study population. Also prior to recruitment, the occupational therapists and peer-mentors at each site will undergo training in intervention principles and standardized procedures. All intervention procedures will be documented using standardized forms available via tablet, and uploaded to REDCap. During the study, the occupational therapists and peer mentors will participate in weekly calls to discuss the implementation of the intervention and assess the need for adaptation. Refer to the intervention manual for specific procedures.

5.3 Concomitant Interventions

5.3.1 Allowed Interventions

All concurrent treatments and services will be permitted, with the exception of concurrent rehabilitation services.

5.3.2 Required Interventions

No interventions beyond ENGAGE are required.

5.3.3 Prohibited Interventions

People receiving concurrent occupational, physical, and speech language pathology rehabilitation services will be excluded from the study.

5.4 Adherence Assessment

Participant adherence will be indicated through attendance at ENGAGE sessions

(90%, 10 of 12 sessions). This will serve as one measure of feasibility. Therapist and peer-mentor adherence, or fidelity to standardized intervention principles, will be assessed using a fidelity checklist in combination with video recordings and session documentation. Refer to the intervention manual for specific procedures.

6. STUDY PROCEDURES

6.1 Schedule of Evaluations

Assessment	Screening: (Day -14 to -1)	Pre-Intervention (Day -14 to -1)	Intervention Sessions (Day 0 to 42)	Post-Intervention (Day 43 to 57)
Referral Log				
Informed Consent				
Screening Assessments	X			
Screening Checklist	X			
Participant Characteristics		X		
Comorbidity Questionnaire		X		
Cognitive Assessment		X		
Social Support Survey		X		
Ability to Participate		X		
Satisfaction with Participation		X		X
Social Isolation		X		X
Global Health		X		X
Community Participation		X		X
Participation Activation		X		X
Participation Self-Efficacy		X		X
Patient Activation		X		X
Chronic Disease Self-Efficacy		X		X
Sedentary Behavior		X		X
Physical Activity Scale		X		X
ActivPal		X		X
Intervention Record			X	

6.2 Description of Evaluations

6.2.1 Screening Assessment

The screening assessment will be administered by trained evaluators and will take 1 hour.

- The National Institutes of Health Stroke Scale is a valid and reliable scale to assess neurological impairment associated with stroke. Items test alertness, orientation, command following, eye and limb movements, vision, language and sensory perception.
- The Activity Card Sort is a valid and reliable assessment of community participation.
- The Boston Diagnostic Aphasia Examination severity scale assesses aphasia impairment severity in three domains: comprehension, expression, and fluency.
- The PRIME-MD with Mini-Neuropsychiatric Interview module assesses presence of mood disorders.

N. B. As part of the assessment of mood, we are including items to address risk of suicidality, a potential risk associated with depression. This action was advised by a physician co-investigator and geriatric neuropsychiatrist Ellen Whyte, who advises all assessments of depression including these items. If in the course of assessment it is determined that an individual has either major depressive disorder or suicidality, we will 1) refer the participant to local services (in Pittsburgh, the RESOLVE Crisis Network, a 24 hour service that directs individuals with major depressive disorder and/or suidicality to immediate care), 2) notify the contact person identified by the participant, and 3) notify the treating physician on service at the time of referral. We will document these actions in the study records. This 3-step plan has been effective when we encountered major depressive disorder in our previous studies with this population (over the last 10 years).

6.2.2 Pre-Intervention Assessment

The pre-intervention assessment will be administered by trained evaluators and will take 1.5 hours.

- The Participant Characteristics Form will record age, sex, race, ethnicity, education, vocational status, residential status, social support, stroke characteristics, and stroke chronicity.
- The Self-Administered Comorbidity Questionnaire is a participant-reported measure of comorbidities. Participants are asked to report on the presence or absence of specific chronic diseases, if they receive treatment for the disease, and if the disease interferes with their daily life activities.
- The Montreal Cognitive Assessment is brief, standardized measure of cognitive function. Participation are asked to complete a series of cognitive tasks assessing attention, memory, visuospatial function, and selected executive function domains, and their performance is scored by a trained assessor.
- The Medical Outcomes Survey Social Support Survey is a brief questionnaire that assesses companionship, assistance and support from others.

- The PROMIS Ability to Participate in Social Roles and Activities 8-item short form will be the primary measure of community participation. The measure assesses difficulty participating in social roles and activities (1=always difficult, 5=never difficult).
- The PROMIS Satisfaction with Social Roles and Activities 8-item short form will be used to assess satisfaction with community participation (1=always satisfied, 5never satisfied).
- The PROMIS Social Isolation 8-item short form will be used to assess perceptions of social isolation (1=never, 5=always).
- The PROMIS Global Health 43-item short form will be used to assess perceived global health (1=excellent health, 5=poor health).
- The Community Participation Indicators Scale is a detailed questionnaire that assesses the frequency of community participation activities, satisfaction, and degree of enfranchisement (belongingness) that individuals with stroke-related disability have with respect to community participation.
- The Community Participation Activation Scale is a brief questionnaire that assesses the active role that people with stroke-related disabilities take in engaging in community participation.
- The Participation Self-Efficacy Scale assesses confidence in understanding and managing one's community participation.
- The Chronic Disease Self-Efficacy Scale assesses confidence in understanding and managing one's health condition and associated symptoms.
- The Patient Activation Scale assesses the active role that people with take in managing their health and symptoms.
- The Sedentary Behavior Questionnaire asks participants to report time spent in 9 specific sedentary behaviors during a typical weekday and weekend. This assessment demonstrates validity and reliability for measuring sedentary behavior in the adult population.
- The Physical Activity Scale for Individuals with Physical Disabilities will measure self-reported physical activity. This questionnaire asks participants to report time spent in 13 types of physical activity over the past 7 days.
- ActivPAL(TM) monitors will be used to assess sedentary behavior and step count over 7 days. The ActivPAL is a small, lightweight monitor that quantifies time spent in sitting, reclined, standing, and stepping. The participant will be provided the "ActivPAL Guide" as a reference guide. We will follow a 24-hour wear protocol in which the participants will wear the device on their thigh for 7 days. A trained assessor will train the participant on appropriate care and use of the device. The ActivPAL will be waterproofed and fastened to the individual's thigh using a non-latex, gentle adhesive (Tegaderm). Prior to adhering the device, the assessor will conduct a gross sensation tactile localization screen to detect impairment in sensation on the participant's anterior thigh. The assessor will ask the participant to close their eyes and will lightly touch the participant's anterior thigh in the region where the ActivPAL will be positioned (anterior, upper half). He/she will ask the participant to indicate when and where the researcher touched. If impaired gross sensation is detected, or the participant reports sensitivity to adhesives, alternative strategies for positioning the device and alternate wear

schedules (such as removing the device during non-waking hours or wearing the device for fewer than 7 days) will be identified. Participants will also be asked to record their bedtime and waking time in the "ActivPAL Diary". Sedentary bouts, sedentary breaks, and steps per day will be assessed using the ActivPAL monitor.

6.2.3 Blinding

There is no blinding in this single arm study. That said, independent evaluators will compete the post-intervention assessments.

6.2.4 Post-Intervention Assessment

The post-intervention assessment will be administered by trained independent evaluators and will take 1 hour.

- PROMIS Ability to Participate in Social Roles and Activities
- PROMIS Satisfaction with Social Roles and Activities
- PROMIS Social Isolation
- PROMIS Global Health
- Community Participation Indicators Scale.
- Community Participation Activation Scale
- Participation Self-Efficacy Scale
- Chronic Disease Self-Efficacy Scale
- Patient Activation Scale
- Sedentary Behavior Questionnaire
- Physical Activity Scale for Individuals with Physical Disabilities
- ActivPAL(TM) (7 day wear)
- Client Satisfaction Questionnaire

7. SAFETY ASSESSMENTS

7.1 Adverse Events

Given the benign nature of the intervention and assessment procedures, we anticipate minimal to no adverse events. Nonetheless we will monitor physical safety of participants during the intervention period, to assess the potential for adverse events.

7.2 Reporting Procedures

Any adverse events will be reported to the IRB immediately and documented in the regulatory binder.

7.3 Safety Monitoring

The Executive Committee will meet weekly to review participant safety. Any adverse events will be reported to the IRB immediately and documented in the regulatory binder.

8. INTERVENTION DISCONTINUATION

There are no foreseeable circumstances that may result in intervention

discontinuation, barring unforeseen medical events prohibiting participation (e.g., recurrent stroke).

9. STATISTICAL CONSIDERATIONS

9.1 General Design Issues

This pilot study is a descriptive study. Data will be plotted visually and characterized through descriptive statistics with appropriate indices of variation when indicated.

9.2 Sample Size and Randomization

Given the focus on feasibility and the prematurity of hypothesis testing, we estimated the sample needed to assess feasibility of a multi-site implementation of the intervention protocol. With a minimum of 20 participants per site we will have a sufficient sample to examine feasibility, acceptability, safety, and the range in magnitude of change in community participation measures within each site (Cohen's d). With 60 participants, we will have 80% power to detect a moderate effect (Cohen's d=.37) of within-participant change using a two-tailed paired samples t-test with α=.05. Our pilot studies' effect sizes ranged from d=.37 to .97 and our detectable effects fall within this range.

9.3 Definition of Populations

All participant data will be analyzed regardless of study completion.

9.4 Interim Analyses and Stopping Rules

Given the pilot phase of this study and the benign nature of the intervention and the intended outcome, no interim analyses or stopping rules will be used.

9.5 Outcomes

9.5.1 Primary Outcome

Feasibility will be indicated by >90% of target enrollment, >90% retention, and >90% intervention fidelity at each site; acceptability will be indicated by >90% participant satisfaction at each site; and safety will be indicated by <3% participants with a reportable event (i.e., injurious fall) at each site, and by phase.

9.5.2 Secondary Outcomes

We will also characterize variation in change of community participation within subjects within and between sites, within each phase, using change scores, effect sizes and confidence intervals.

9.6 Data Analyses

We will conduct descriptive analyses to address the feasibility, acceptability, and safety benchmarks in the primary aim. We will examine univariate and bivariate distributions of variables, and plot community participation scores to visually

characterize changes in community participation within and between sites to address the secondary aim. We will also calculate within subjects change in community participation as well as Cohen's d effect sizes of change for both sites combined, and each site.

10. DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

All data will be collected using electronic data entry (with the exception of the participant workbooks used in the interventions). Electronic data will be uploaded into a single REDCap site, a cloud-based data management system maintained at the University of Pittsburgh, but accessible to all investigators at all sites.

10.2 Data Management

Data will be collected using tablets, and uploaded and maintained in REDCap, hosted at the University of Pittsburgh.

10.3 Quality Assurance

10.3.1 Training

Intervention staff will be trained by site principal investigators at a two day course and monitored through weekly meetings during active periods of intervention. Assessment staff will as be trained by site principal investigators and monitored through monthly meetings.

10.3.2 Protocol Deviations

Protocol deviations will be identified through regularly scheduled audits of study files, paper and electronic, as well as through team meetings. These deviations will be reported to the IRB immediately, and documented in the regulatory binder.

10.3.3 Monitoring

The Executive Committee will meet weekly to review recruitment and retention, data collection, issues of confidentiality, and data integrity. The University of Pittsburgh research team will assess data integrity through regularly scheduled reviews of REDCap.

11. PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document and any subsequent modifications will be reviewed and approved by the single IRB process, with the University of Pittsburgh serving as the IRB of record.

11.2 Informed Consent Forms

All participants will provide written or electronic informed consent. The consent form describes the purpose of the study, the procedures to be followed, and the risks and benefits of participation. Participants will be given the opportunity to ask questions prior to giving consent, and ongoing consent will be assessed as the study proceeds. Participants will be given a copy of the consent form, and this process will be documented in the research record.

11.3 Participant Confidentiality

All data, records, and video recordings will be identified only by study identification code to maintain confidentiality. Paper files will be kept in a locked file cabinet. Electronic data will be entered, maintained, and analyzed in a secure manner, consistent with approved data security procedures.

11.4 Study Discontinuation

The study may be discontinued at any time to ensure that research participants are protected.

12. COMMITTEES

The study will be led by an Executive Committee comprised of the site principal investigators who will meet weekly throughout the duration of the study. The Executive Committee will oversee the design, implementation, conduct, and reporting of study findings.