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Living Well with Stroke: Design and Methods for a Randomized-Controlled Trial of a Psychosocial-Behavioral Intervention for Post-Stroke Depression

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Abstract

Background—Depression is a sufficiently common sequela of a completed stroke to warrant intervention to improve mood, social and functional outcome. Pharmacologic trials suggest short-term mood improvement from antidepressant treatment but no studies to date have determined

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whether these short-term gains can be enhanced and extended by a brief psychosocial/behavioral intervention delivered by advanced practice nurses. Nor have drug trials reported on functional outcomes such as limitations in ability, limitations in participation and overall quality of survival. This randomized controlled trial is designed to evaluate the short and long-term efficacy of a new brief psychosocial/behavioral intervention adjunctive to antidepressant treatment in reducing post-stroke depression (PSD) and improving functional outcomes.

Methods—101 ischemic stroke survivors with PSD are randomly assigned to receive a brief psychosocial/behavioral intervention plus antidepressant or usual care, including antidepressants.

Outcome measures—The primary outcome is reduction in depressive symptom severity (Hamilton Depression Rating Scale) at 12 months following stroke. Secondary outcomes are reductions in limitations in activity (Barthel Index), reduction in limitation in participation and overall stroke impact (Stroke Impact Scale) at 6, 12, and 24 months post- stroke. Factors influencing best response to psychosocial intervention will also be explored.

Discussion—This paper provides detail on the design and treatment methods of this randomized trial in progress. Findings from this study will provide important information regarding the long-term efficacy of such a behavioral intervention in reducing PSD and subsequent impaired aspects of psychosocial and physical recovery.

Keywords

post-stroke depression; psychosocial treatment; efficacy trial

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Depression is a prevalent sequela of cardiovascular and cerebrovascular disease, estimated to affect roughly 33% of stroke survivors at early, middle or late stages of recovery. [1] Post-stroke depression (PSD) has been shown to significantly and adversely influence stroke outcome. Patients with PSD, compared to non-depressed post-stroke patients, have more functional dependence, [2,3–5] poorer cognitive status, [6] increased medical costs, impaired rehabilitation response, [5,7] delayed return to social function, [8] and delayed return to work. [9] These negative outcomes are evident in the acute phase and as much as two years post-stroke. [4,6,10] Further, depression in the first few months post-stroke is associated with increased long-term mortality from all causes. [6,11,12]

Despite these adverse consequences of PSD there have been few trials to determine effective treatment. A 2004 Cochrane review of treatments for PSD found nine trials of pharmacotherapy and only two of psychotherapy. Lack of standardized diagnostic and outcome criteria, and differing analytic methods precluded clear determination of the ability of either pharmacotherapy or psychotherapy to produce remission of PSD. [13] Only one of the pharmacologic trials measured effects on mood longer than 12 weeks following initiation of antidepressant therapy.[14] The few that measured limitations in ability (functional outcome) did not follow patients outside the rehabilitation setting or longer than 3 months. Only one of the reported studies to date have followed patients long enough to determine the duration of the improvement in mood. [14] Nor have drug trials reported on functional outcomes such as limitations in ability, limitations in participation and overall quality of survival.

Two well-designed trials been reported recently that used various means of psychosocial support in depression. These reported short-term (3 months) improvements, but did not report on long-term duration of effect. [15,16] Finally, although there is some indication that serotonin transporter gene polymorphisms (5HTTLPR) may be predictive of response to antidepressant therapy in older depressed adults[17,18], no trials that we are aware of have also examined the relationship of 5-HTTLPR polymorphisms to occurrence of PSD or response to its treatment. This trial will add knowledge of the efficacy and duration of efficacy of a psychosocial

intervention adjuvant to antidepressants, as well as the role of genetic polymorphisms in expression of depression and in response to treatment.

The success of behavioral, problem-solving and psychosocial support therapies in other forms of depression led us to test these interventions with PSD patients. Teri and colleagues' successful adaptation of cognitive and behavioral therapy to depressed Alzheimer's patients [19–21] forms the basis for the intervention in our study. We add this brief psychosocial-behavioral therapy to antidepressant drug therapy that is provided as standard care to patients with PSD. We reason that unless there is a change in behaviors commonly associated with depressed mood, there will not be a long-lasting change from the initial mood elevation seen with antidepressants. We expect the combined behavioral and pharmacologic intervention to be more effective than pharmacotherapy alone in sustaining the improvement in depression for the experimental group. Secondary aims are to examine the effect of the psychosocial/behavioral intervention time course and sustainability of response to treatment, effect on limitations in ability, limitation in participation and overall stroke impact in community-dwelling post-stroke patients. We will also examine subgroups for whom the psychosocial treatment has the greatest benefit, including an exploration of the 5-HTTLPR genotype (s/s, s/l, or l/l) and its association with ischemic stroke survivors who are and are not depressed within the first four months following stroke.

Methods

Patient Population

One hundred one patients with ischemic stroke who are clinically depressed (DSM IV criteria) and within four months of index stroke have been recruited from four hospitals in the Pacific Northwest. Patients with hemorrhagic stroke, receptive or global aphasia, reduced level of consciousness (GCS <15), or psychosis were excluded. Enrollment began in November 2002 and ended in April 2007. The sample size is adequate to detect a 0.5 standard deviation difference in average Hamilton Depression Scale score or approximately 30% difference in recovery from depression between the two groups. The study was approved by the University of Washington Human Subjects Division (IRB) for protection of human subjects and has been renewed annually. Demographics and salient stroke descriptors at entry to the study are shown in Table 1.

Design

This is a randomized treatment efficacy study with active control, comparing antidepressant plus brief psychosocial/behavioral intervention to antidepressant and 'usual care' follow-up. Outcome assessors and clinician investigators with patient contact are masked to subject allocation. Patients hospitalized with ischemic stroke, verified by CT or MRI, and who endorse feeling sad or blue are screened for depressive symptoms with the 30 item Geriatric Depression Scale (GDS).[22] Those who score ≥11 are offered the opportunity to consent for the intervention study, with diagnosis of depression validated by diagnostic interview using DSM IV critieria.[23] Because of the short length of stay for ischemic stroke, all subsequent contacts with study participants occur either in home visits, at clinic follow-up or in rehabilitation or skilled nursing facilities.

At entry to the study, but prior to randomization, the full baseline dataset is obtained through interview, direct assessment and medical records. Randomization status is generated by a computer algorithm that balances four key factors affecting stroke outcome: severity of stroke (indexed by the NIH stroke scale (NIHSS)), severity of depression (measured by the Hamilton Depression Rating Scale – HDRS), gender, and age. Every time a new subject is randomized, an imbalance score is computed for each of the two possible outcomes of the randomization.

This imbalance score measures how different the two groups are with respect to mean age, gender, mean initial NIH stroke score, and initial HDRS, and number of subjects. As new subjects are randomized, probabilities are modified so that there is greater than 50% probability of being randomized to the group that results in better balance. The greater the discrepancy in the two imbalance scores, the closer this probability is to 100%.

Protocol

At entry, all participants (and caregiver if participating) are given written materials from the American Stroke Association regarding recovery from stroke, including information about depression. All participants are also given a medication diary to complete during each of the first seven weeks of the trial. Participants in the usual care group mail these to the research coordinator; those in the intervention arm bring the diary to each counseling visit. Research coordinators call to remind participants who have not sent in their medication diary. Thus, both intervention and control participants have weekly contact with study nurses during the intervention time period.

Because selective serotonin reuptake inhibitor (SSRI) antidepressant treatment is an informal standard of care in this community, the participant's own provider prescribes the SSRI, based on his or her own assessment or notification through the letter we send to each participant's provider. The study psychiatrist (RV) recommends sertraline due to a relatively lower incidence of cardiovascular side effects. Thus far, most providers have elected to use this drug.

Usual care arm—Participants in the usual care arm see their stroke care provider as scheduled by that provider. They participate in all the regular follow-ups at 9 and 21 weeks post-entry, and 12 and 24 months post-stroke. If there is an informal caregiver, that person also participates in these visits. These visits are either in their home or at the School of Nursing clinical studies unit. We did not design an arm with equivalent time and attention but without the depression content because the Seattle Protocol trials had already demonstrated that an 'attention control' as well as a waiting list control had significantly less improvement in depression than did the active intervention. [19,24,25]

Intervention arm—These participants meet with the nurse interventionist for 9 visits over 8 weeks. With the assistance of stroke survivors who have been depressed, we adapted the written materials from Dr. Teri's earlier studies in which behavioral treatments have been designed and evaluated to reduce the disability associated with Alzheimer's Disease, to use the language of stroke (rather than Alzheimer's) so that they could be used by a stroke survivor alone, or with help from a significant other or caregiver. These treatments, referred to collectively as the Seattle Protocols are based upon social learning and gerontological theory. [21, 22, 26] Participants are taught to view depressive symptoms as observable and modifiable behaviors that are initiated and maintained by person-environment interactions. Similar to Alzheimer's Disease, the cognitive and physical sequelae of stroke often cause individuals to lose the ability to initiate and participate in many activities they once enjoyed. They can no longer function as independently as they once did, and are often frustrated and depressed. The fewer pleasant events they experience, the more depressed they feel; the more depressed they become, the less they do, and so on. Treatment, therefore, works on increasing the level of pleasant social and physical activity in order to improve mood. To accomplish this, physical and cognitive challenges to such activity are addressed as a structured and clear behavioral plan is developed and implemented

The majority of the time is spent directly with the stroke survivor participant in an effort to build a relationship that will facilitate training. Family members, however, are encouraged to participate since they are viewed as potential allies and supporters of the patient's efforts. Two

sessions are scheduled the first week to optimize motivation and establish a structure for treatment; seven sessions are then conducted weekly for a total of 9 sessions over 2 months.

Behavior change is an essential component of this intervention. Our focus is on decreasing the depression accompanying post-stroke recovery. In addition, due to the physical and cognitive limitations that often accompany stroke, strategies for coping with these difficulties are central. Participants learn to use behavioral strategies to reduce or prevent behavioral and mood disturbances characteristic of stroke. Specific problem-solving approaches are taught to participants, and solutions to behavioral challenges are individualized to meet the needs of each person. An outline of sessions is provided in Table 2. A manual is available upon request from the first author.

In Session 1, interventionists introduce study logistics, discuss common emotional and physical aspects of stroke recovery, and present a rationale for treatment. Realistic expectations for what could be expected, given the nature of the stroke are discussed and participants are encouraged to identify their goals for treatment. This is particularly important as participants have varying levels of understanding as to what is and is not realistic. Participants are given ASA reading materials to help them understand stroke recovery and are asked to complete The Pleasant Events Schedule[27] to facilitate discussion of pleasant events in subsequent sessions.

Session 2 introduces the concept of Pleasant Events and discusses the importance of identifying pleasant events that are realistic given the physical and cognitive sequelae of the individual patient's stroke. The relationship between depression and a lack of pleasant activities for the person with stroke is discussed. The Pleasant Events Schedule is used to identify activities that the person with stroke might enjoy, based on what they enjoyed in the past. A daily mood and activity form is introduced at this session to help patients and their caregivers track their experiences.

Session 3 and 4 continues the Pleasant Events Schedule discussion, focusing on ways to plan and schedule pleasant events. The importance of understanding current limitations and working through those limitations is underscored, along with practical advice regarding activity engagement and methods of problem-solving around obstacles to activity.

Session 5 shifts the focus of discussion from the participant to the informal caregiver, if such caregivers have opted to be part of the treatment. Issues such as caregiver burden and depression are addressed with the caregiver and resources that might help them help themselves are discussed. Interventionists encourage caregivers to identify areas where they need or want more support and help them identify people and resources to enrich the care network, including both informal support from family and friends and formal support from adult activity centers, overnight respite services, and health care providers. They also discuss the importance of advance planning to identify resources that would be available in an emergency (e.g. illness or hospitalization). If there is no caregiver involved, session 4 content (Problems and Planning) is reviewed and session 6 (Problem-Solving) is introduced.

Session 6 addresses basic principles of behavior change, identifying problems of the participant's choosing. Participants are taught to pinpoint a problem, gather information about it, and discover what potential antecedents that triggered the problem or consequences that maintained the problem might be. They are then helped to set realistic goals for problem-solving and establish a plan. Using examples from the participants' weekly diaries, the participant and interventionist brainstorm strategies to modify antecedents or consequences and develop behavior change plans for the following week. At subsequent sessions, interventionists review these plans, evaluate progress, modifying and adjusting strategies as needed.

Session 7 focuses on altering negative thinking so common in depressed individuals. Participant are encouraged to keep track of negative statements they find themselves making and track when they happened, how often, and around what situation and people. They are then encouraged to brainstorm possible ways to change their negative thinking to more positive strategies.

Sessions 8 and 9 serve as a summary of progress made as well as a structure for insuring continued improvement. Participants again rate the frequency and their reactions to "target" behaviors identified in the first session. Interventionists and participants review treatment gains, identified skills and strategies the participants plan to continue using, and develop workable plans for implementing or maintaining these strategies.

Outcome Measures—The primary outcome is reduction in depressive symptom severity - measured by the Hamilton Depression Rating Scale – HDRS[28,29] at one year following study entry. Additional outcomes measured at 9 weeks, 21 weeks post entry (roughly 6 months post-stroke) and 12 months and 24 months post-stroke are: overall stroke impact (Stroke Impact Scale – SIS and percent perceived recovery[30]), limitation in ability (Barthel Index[31,32] and SIS subscales: ADL, affected side, strength, mobility), and limitation in participation (SIS subscales: mood, work-recreation, communication). If there are family or other informal caregivers are participating, measures of depression (Geriatric Depression Scale[22]) and caregiving burden and benefit (Sense of Competence Scale[33]) are measured at entry, and the same time intervals as the primary participant.

Statistical Analysis

The primary endpoint is HDRS at 12 months post-stroke, with groups to be compared by ANCOVA controlling for baseline HDRS. Secondary analyses will consist of repeated measures ANOVA to evaluate HDRS scores as a function of condition (treatment or control) by time (immediate post-treatment, 6, 12 and 24 months). Hypotheses regarding the efficacy for limitations in ability, limitation in participation and overall stroke impact will be evaluated using repeated measures analysis of variance. Final analyses will explore the subgroups for whom the psychosocial treatment has the greatest benefit. We will use graphical displays and repeated measures analysis of variance to identify if there is a differential response to the psychosocial/behavioral intervention by gender, 5HTTLPR and other SERT polymorphism status, major or minor depression, severity of stroke, and level of social support, all factors associated depression in the literature.

Discussion

A number of studies have demonstrated the efficacy of psychosocial treatments for depression in non-stroke populations.[34] Such treatment has been effectively delivered by community health nurses, with better effect on return to work and reduction of lost work time than psychosocial care delivered by primary care practitioners. [35,36] Cognitive-behavioral therapy and problem-focused therapy [37] have been tested as adjunctive to pharmacotherapy in randomized controlled trials in general depression, and have shown significantly greater reduction in depression scores and significantly higher proportion of recovery compared to antidepressant alone or behavior therapy alone. [34,36,38–40] Further, psychosocial therapy combined with antidepressant has been demonstrated to be significantly more successful in preventing recurrent depression in older adults than was medication alone or psychosocial therapy and placebo. [41] Similarly, counseling and behavioral tailored problem-solving interventions for depressed medically ill elderly delivered by psychogeriatric teams and psychosocial nurse specialists in the home compared to "standard" care have shown a reduction in level of depression, improvement is self perceived health, and sometimes improved

functional status. [42,43] These trials in other depressed populations suggest the possibility of good response for people with PSD. Two trials have just been reported in stroke survivors that show a reduction in depression with general care management and with motivational interviewing. [15,16] The brief psychosocial intervention in our trial is related to but not the same as the interventions in the recently completed trials. Thus this trial will add to knowledge of the range of behavioral interventions effective in this population. Further, this will be the first trial to examine longer-term efficacy at both one and two years post stroke.

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Table 1

Baseline demographic, stroke and clinical variables (N=101)

Demographic Variables	
Age (mean years, standard deviation, min.-max.)	57 (13) range 25-88
Gender – percent female	39.6
Marital status (percent)	
Single	14.9
Married or partnered	40.1
Widowed	14.9
Divorced or separated	27.7
Educational level (percent)	
< 12th grade	7.9
High school diploma or GED	31.7
AA, vocational, or some college	44.5
Bachelor or higher degree	15.9
Racial category (percent)	
More than one race	21.8
White only	63.4
Asian only	3.9
Pacific Islander only	1.0
African-American only	9.9
Stroke variables	
NIH Stroke Scale total score (mean, SD)	6.2 (5.1) range 0-19
Hemisphere affected (percent)	
Left	45.5
Right	54.5
Barthel index (mean, SD)	83.8 (22.6) range 0-100
Subjective rating of percent recovery (mean %, SD)	51 (21.7) range 0-100
Depression variables	
Hamilton Depression Rating Score (mean, SD)	19.9 (4.33) range 10-29
History of prior depression (percent)	72
Pertinent medical history variables	
Co-morbidities (mean number)	2.8 range 0-12
History hypertension (percent)	89.1
History of diabetes	43.6
History of coronary heart disease	27.7
History of hyperlipidemia	81.2

Table 2

Topics for each session

Session 1	Introduction to Behavioral Therapy for Depression After Stroke
Session 2	Introduction to Pleasant Events (PE): Identifying PEs
Session 3	Continued PEs: Planning and Scheduling Pleasant Events
Session 4	Continued: Scheduling PEs—Problems and Planning
Session 5	Coping with Caregiving: Caregiver Burden OR, (if no Caregiver involved) Problem-Solving Techniques started
Session 6	Managing Depression Behaviors: Problem-solving Techniques
Session 7	Changing Negative Thoughts and Behaviors
Session 8	Problem-Solving Continued
Session 9	Review of Skills: Maintaining Gains and Generalizing to other situations