

Hartford Geriatric Social Work Faculty Scholars Program**Research Proposal****2002****A Preliminary Evaluation of the Depression Screen and Treatment Program (DSTP)
for Elderly Home Care Clients****Investigator: Zvi D.Gellis, Ph.D.
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Evidence is clear that depression is one of the most common mental health problems among the elderly (Gallo & Lebowitz, 1999). The NIH Consensus Statement on late life depression emphasized the prevalence of depressive disorders in medically ill and disabled elderly populations (Lebowitz et al., 1997). Yet, depression among the elderly is an illness that is often underdiagnosed and undertreated by health professionals (Bartels, Horn, Sharkey, & Levine, 1997; Higgins, 1994; Unutzer, Patrick, Simon, & Katon, 1997). Eight to 20 percent of elderly in the community and 37 percent in primary care settings exhibit depressive symptoms (Klausner & Alexopoulos, 1999; Gallo & Lebowitz, 1999). Elevated symptoms of depression have been correlated with a number of negative outcomes in the elderly (Schulberg, Schulz, Miller, & Rollman, 2001; Gallo, Rabins, Lyketsos, Tien, & Anthony, 1997). Serious consequences of depressive disorders include increased mortality related to suicide (Conwell, 1996; Hoyert, Kochanek, & Murphy, 1999), medical illness (Rovner, 1993), disability due to related medical and cognitive disorders (Bruce, 1999) and increased health care costs (Unutzer et al., 1996).

This proposal focuses on elderly home care clients for several reasons: (1) the elderly represent a large and growing proportion of all home care clients (Bruce et al., 2000), (2) elderly home care clients are likely to have elevated symptoms of depression due to physical disabilities

and comorbid medical problems (Alexopoulos, 1998), (3) medical conditions that mask depressive symptoms leave the illness undetected or untreated by primary health care professionals (Banazak, 1996), (4) standardized screening for depressive symptoms performed by home care providers is rare or nonexistent, and (5) less than 3 percent of elderly report seeing mental health professionals for treatment of depression or other mental health problems (Demmler, 1998). Home care settings are in a unique position to screen for and treat depression because they are the only health service setting that has access to clients at home.

Depressed elderly persons requiring home care often need brief and flexible access to a variety of in-home services as their conditions change over time. The current system is difficult for elderly persons to negotiate for several reasons: (1) home care workers are restricted to instrumental tasks leaving insufficient time to deal with the mental health needs of their clients, (2) home care providers receive limited insurance reimbursements for mental health services (Kane, 1999), and (3) barriers such as a lack of collaboration and coordination among aging and mental health service systems, lack of prevention and treatment services, and lack of trained professionals in the geriatric mental health field, impede the delivery of adequate services to older persons with mental health needs (Butler, Lewis, & Sunderland, 1998, Estes, Binney, & Linkins, 1994). Yet, based on recent study findings of a high rate of depression among home care clients in Westchester County, New York, Bruce and colleagues (2000) identified an urgent need to develop effective home-based screening and intervention programs for this group.

No psychosocial intervention models currently exist for depressed elderly home care recipients. Indeed, the greatest single mental health service gap is in home health care settings. Thus, a logical next step in approaching these problems is to develop and test a home-based intervention for late life depression from a social work perspective. This pilot presents an

opportunity to build on my previous clinical work delivering community mental health services to older adults. In line with the NIMH emphasis on the integration of mental health intervention research and behavioral science, the proposed pilot is positioned to translate evidence-based behavioral research into clinically relevant social work advances.

As a social work faculty, I want to prepare myself to be an independent intervention researcher in gerontological mental health. The project that I am proposing is a pilot study that needs to be completed in order to work out the flaws in intervention delivery. It is an evolving intervention, one that requires a small sample for testing in the community. A necessity of the pilot is to utilize a randomized field trial design to determine if the intervention is feasible and effective.

Research Aims

The goal of this feasibility pilot is to test for the feasibility and effectiveness of a depression screening and treatment program (DSTP) for elderly clients of the New York Capitol Region Home Care Program (HCP). DSTP is a highly structured and evolving home care depression treatment program delivered to elderly clients in their own homes by MSW-level social workers.

Specific Aims of the Two-Year Project are: (1) to develop a screening protocol and intervention manual for DSTP, (2) to develop and pilot test the DSTP program for feasibility and acceptability in home care settings, (3) to provide estimates of the effect size for a larger field trial, and (4) to assess the impact of DSTP on **depression, quality of life, self-efficacy, coping, and social support of elderly home care clients in the pilot sample.**

Hypotheses. The pilot will examine the following two hypotheses: (1) compared with elderly patients who receive usual home health care (UC), elderly patients in the DSTP will experience a significant ($p < .05$) short-term improvement in (a) symptoms of depression, (b) perceived health status, and (c) social support; (2) compared with elderly patients in the UC condition, elderly

patients in DSTP condition will maintain these changes 6 weeks, and 3 months after baseline measurement. I also propose to collect data on psychotropic medication use.

Theoretical Perspective

The DSTP intervention is grounded in the ecological perspective emphasizing the importance of person-environment fit and the reciprocal transactions between people and environments (Germain & Gitterman, 1996). The ecological model acknowledges the role of stress as a potential disruption of equilibrium that can ultimately lead to emotional disability. The intervention is focused on mobilizing and enhancing personal and environmental resources needed to motivate coping with life stress, building social support networks to elevate self-esteem and self-efficacy (Bandura, 1986), and to help manage and regulate depressed feelings aroused by life stress. The integration of Lazarus and Folkman's (1984) stress and coping perspective is germane because of the implications of this perspective for the development of interventions for older adults. Folkman and colleagues (1986) summarizing numerous studies on stress, coping, and adjustment noted that coping is a major factor in the relation between stressful events and adaptational outcomes such as depression.

Underlying the DSTP intervention is the cognitive-behavioral (CB) approach which has been shown to be effective with adult outpatients (Hollon, Shelton, & Davis, 1993) and with elderly outpatients with a diagnosis of major depressive disorder according to research diagnostic criteria (RDC; Thompson, Gallagher, & Breckenridge, 1987). The cognitive model of depression suggests that depressed individuals have stable cognitive schemas (assumptions or core beliefs) that develop as a consequence of early learning (Beck, Rush, Shaw, & Emery, 1979). These schemas predispose individuals toward negative interpretations of life events (i.e. cognitive distortions or automatic thoughts), which in turn lead the depressed person to engage in depressive behavior. The CB model for depression includes interventions conducted in a

progressive manner, focusing on overt behavior change, skills training in assessing and correcting situation-specific distortions in thinking, and identifying and modifying more stable depressive cognitive schemas (Beck et al., 1979; Thompson, et al., 1987).

Research Methods

Study Setting. The setting for this feasibility pilot study is a large home health care program, St. Peters Home Health Care Program (HCP), an HMO in Upstate New York serving over 1,000 older clients annually (83 clients per month) with more than 81,000 visits. Client composition of the home care agency includes 67% Caucasian and 33% African American adults based on the Year 2000 annual report. The HCP has a 55 staff complement of social workers, nurses, physical and occupational therapists, and consulting physicians. There is a strong organizational commitment to provide the necessary staff, space, and administrative support needed to conduct the pilot at this agency. Evidence for this commitment is the year-long working relationship that has been established between the applicant and the agency (See support letter: appendix, item J).

Subjects Eligibility for Randomization. The investigator will recruit 62 elderly adults (male and female, 60 years and over) receiving services from one large home care agency (St. Peters Home Health Care Program), and they will be initially screened for depressive symptoms. This recruitment period will be over an eight-month period from a pool of 1000 home care clients. Sample inclusion criteria are (1) 60 years of age and older, (2) clients meeting criteria for major depression based on the DSM-IV checklist, (3) a score of 8 or greater on the Geriatric Depression Scale-Short Form (GDS-SF), (4) cognitively intact, (5) willingness to take antidepressant medication, and (6) currently registered as a home care client. Exclusion criteria include (1) current psychotic symptoms or suicidal ideation or plan, (2) limited command of English, and (3) Organic Brain Disorder, or Dementia (collected by chart review).

The goals of this pilot specify that to be able to detect a situation where the treatment mean is 15 points lower on the Beck Depression Inventory (BDI) than the control group; that is, the required effect size is $\theta = -15$. The study specifies that such an effect be detected with 80% power ($\pi = .80$) when the significance level is $\alpha = .05$. Past experience with similar experiments- with medically ill older adults using the BDI suggests that the data will be approximately normally distributed with a standard deviation of $\sigma = 20$ points (Gallagher, Nies, & Thompson, 1982; Norris, Gallagher, Wilson, & Winograd, 1987). I plan to use a two-sampled pooled t test with equal numbers n of subjects in each group. Using statistical power analysis guidelines by Kraemer and Thiemann (1987) and nQuery power analysis software, a sample size of $n = 22$ per group is needed to achieve the stated goals. A power value of .80 is satisfactory to have a reasonable chance of detecting the effect size (Cohen and Cohen, 1983; Taylor & Muller, 1995). A sample of 62 will protect against attrition (hospital admission, etc.), and provide sufficient power to detect effects and mean trends for outcome measures. Institutional Review Board approval will be sought at the State University of New York at Albany for the study and informed consent procedures for participants prior to initiation.

Participants will be identified by HCP staff upon initial screening for approval of home care services (during the regulatory-required nursing assessments), and also from the existing pool of clients. Potential participants will be asked to talk with the investigator about a new program to improve treatment of depression within the home care program. Screened clients eligible for the study will read and sign consent forms if they wish to volunteer for the study. They will be informed about time requirements, their random eligibility to be placed in the usual care or intervention condition, and risks and benefits that could ensue from participation. Thirty-one elderly clients will be randomized into the intervention condition and will receive the DSTP program. Another thirty-one elderly clients will be assigned to the control condition and will

receive the usual care services. Subjects are asked to participate in baseline (prior to intervention) and follow-up assessments that will take approximately one hour for each session (see Figure 1). Participants will be paid \$20 for their time.

Design. The proposed pilot study will employ a 2 X 3 randomized control group design to test the hypotheses. Subjects will be randomly assigned to the two arms of the pilot, ie., the DSTP condition or the usual care (UC) condition. There will be 3 times of measurement at baseline, within one week after the intervention, and three months after the intervention. The measurement periods are proposed in order to examine both the immediate and longer-term effects of intervention. Data collectors will be kept blind to the pilot project hypotheses.

Usual Care. Eligible participants will be asked for informed consent to participate in a randomized trial of "an intervention designed to improve the care of depression." Participants randomly assigned to the usual care condition will receive a psychiatric assessment by the mental health nurse practitioner and referred to their primary care physician for treatment of depression. In most cases, usual care for depression given by the primary care physician involves a prescription of an antidepressant medication and 2 visits over the first 3 months of treatment.

Intervention. A highly structured community-based depression screen and treatment program that is described in a 60-page manual is in process of completion. The program includes both behavioral treatment, targeted at teaching cognitive behavioral skills to manage depressive symptoms, and counseling to improve medication adherence. Six home visits are scheduled with Masters-level social workers trained in cognitive therapy, and employed in the home care agency. Total direct treatment time is 6 hours plus a 1-hour initial psychiatric assessment by a mental health nurse practitioner, who will prescribe and monitor medication (as needed) under the guidance of a psychiatrist. As part of the intervention, the social worker makes telephone contact with the home care patient 2-times per week as reinforcement during the 6-week

intervention period. The brief intervention is multimodal and is based on the social learning theory model of Beck and his colleagues (1979) and social cognitive theory of Bandura (1986). The content of the 6 sessions includes education, skills training, and homework assignments designed to improve mood and facilitate generalization of skills to daily life. Prior to the first session, elderly clients assigned to the intervention are provided with a booklet titled *If you're Over 65 and Feeling Depressed: Treatment Brings New Hope*, which explains methods of managing depression. At each home visit, patients complete the mood monitoring form, a pleasant events form, and a brief checklist for DSM-IV-TR major depressive symptoms. The mental health nurse practitioner will also screens patients for potential side effects to antidepressant medication, check dosage, and patient adherence. The protocol includes a consultation option for a direct visit with the consulting psychiatrist.

The two-year research plan for the Hartford Social Work Faculty Scholars Program will build on the clinical and research experience of the applicant described in item C. It will add preliminary data about culturally diverse elderly home care patients with mental health problems, for which there is little empirical data, and increase our understanding of psychosocial intervention variables that are effective for this frail population.

Study Screening Measures

Geriatric Depression Scale (GDS). (Yesavage, Brink, Rose, & Leirer, 1983). This is a 15-item self-rating scale that has proved useful in detecting depression in medically ill elderly (Rapp, Parisi, & Walsh, 1988). It has demonstrated reliability and validity Yesavage et al., 1983). Its sensitivity and specificity have generally been high among cognitively intact elderly.

A brief checklist for DSM-IV-TR (APA, 2000) major depressive symptoms for current depressive level will be used for each patient by the mental health nurse practitioner.

Short Portable Mini Mental Status Questionnaire (SPMSQ) (Pfeiffer, 1975). To ensure that cognitive impairments of the care recipients do not compromise the validity of their personal

interview data we propose to use the SPMSQ. The 10 item SPMSQ is widely used, can be adjusted for educational level and ethnic background, and provides ranges of scores related to degree of impairment (Pfeiffer, 1975). It correlates well with clinical diagnoses and has good test-retest reliability ($r=.83$) (Pfeiffer, 1975). For the purposes of this demonstration project, after adjustments for educational level and ethnic background, a score of 8 or less by a care recipient on the SPMSQ will be used to signify the presence of a cognitive impairment.

Baseline, Demographic and Other Study Measures

Demographic data to be collected on subjects at baseline will include: age, education, marital status, income, race/ethnicity, and medical condition. These data are available for each patient through the medical chart.

Outcome Measure--Beck Depression Inventory (BDI) (Beck, 1978). This measure will be assessed at baseline, 6 weeks, and 3 months after randomization by interviewers who are blind to patient's randomization status. This is a widely used, 21-item self-report questionnaire that assesses the severity of current depressive symptoms. It has high internal consistency and reliability, and is sensitive to clinically significant change in depressive symptomatology (Beck, Steer, & Garbin, 1988).

Outcome Measure--Hamilton Rating Scale for Depression (HRSD) (Hamilton, 1960). This second self-report measure of depression severity will be given at baseline, 6 weeks, and 3-months after randomization by interviewers who are blind to patient's randomization status. This is a widely used interviewer-based measure of depression severity that correlates well with BDI ratings (Edwards, Lambert, & Moran, 1984).

Outcome Measure--Patient Satisfaction With Management of Depression (PSQ-18) (Marshall & Hays, 1994). At the 6 week point interview after randomization, satisfaction with management of depression will be rated on the modified Patient Satisfaction Questionnaire(PSQ-

18), an 18-item instrument with seven subscales (measuring global satisfaction, technical quality, interpersonal manner, communication, financial aspects of care, time with home care worker, and accessibility). Perceived helpfulness of antidepressant medications will be rated on a 4-point ordinal scale from helping "not at all" to helping "a great deal." This will be assessed at 6 weeks after randomization.

Outcome Measure--Adherence to Antidepressant Medication will be assessed a 6 weeks and 3 months after randomization. Participants will be asked if they are still taking an antidepressant medication and will be considered adherent if they report taking this medication at least 25 of the last 30 days.

Medical Outcomes Study (MOS) Short-Form Health Survey (SF-12) (Ware, Kosinski, & Keller, 1996). This is a brief 12-item self-report questionnaire that assesses health-related quality of life. Dimensions include physical, role functioning, social functioning, bodily pain, vitality, and mental health and general health perceptions. It has well-established reliability and validity, and has been shown to be appropriate in diverse populations (Ware, Kosinski, & Keller, 1996). This will be assessed at 6 weeks and 3 months after randomization.

Mastery Scale (Pearlin and Schooler, 1978). This is a seven-item self-report scale that assesses individual self-efficacy. It has well-established reliability and validity. This will be assessed at 6 weeks, and 3 months after randomization.

Moos Coping Response Inventory (MCRI), (Moos, 1997). Participants' coping will be assessed using the 48-item Moos (1997) coping scale. This scale measures different types of coping responses with eight subscales that measure problem-solving or avoidance (emotion-focused) coping responses. Higher scores indicate more frequent use of the response. The MCRI has good reliability and validity (Moos, 1997). This will be assessed at 3 months after randomization.

DUKE Functional Social Support Questionnaire (DFSSQ), (Broadhead, 1988). This eight-item scale measures a person's satisfaction with the functional and affective aspects of their social support. It can be used to examine the interactions between social support and other determinants of health. Its practicality in a health care setting is a strong asset. The DFSSQ has good psychometric properties (Broadhead, 1988). This will be assessed at 3 months after randomization.

Data Analyses. At baseline, to assess for equivalence of the treatment and control conditions, continuous variables will be analyzed using Student's *t*. Chi-square analyses with correction of continuity will be used to examine treatment group differences (intervention vs usual care) at 6 weeks and 3-month follow-ups, on adherence to antidepressant medication and satisfaction with treatment for depression. Treatment group differences on the depression outcome variables (BDI and HRSD) will be assessed using mixed modeling technique for repeated measures (Proc Mixed procedure in SAS), to test whether there is a difference in the extent of improvement between intervention and control patients over time, after adjusting for key clinical and demographic variables. Mixed models provide solutions to commonly observed problems of missing data, serial correlation, and time varying covariates, and they accommodate systematic person-specific deviations from the average time trend (Gibbons et al., 1993). For significant interaction effects, univariate tests will be examined to determine where the groups differed in their rates of change.

Potential risks. The primary risks of the pilot study are that participants will fear that their participation or refusal to participate will affect their treatment, or that their information will not be kept confidential. Though it is unlikely, some participants may experience discomfort during treatment procedures. Risks will be reviewed and listed in the consent form.

Procedures to minimize risks. Participants in the pilot study will be informed that all information is confidential, and will not be used for the purpose of evaluating them. They will be informed

that participation, discontinuation of participation, or refusal to participate will in no way affect the treatment they receive. They will be informed that they may discontinue participation at any time and that they do not have to answer any question they do not want to. All research staff will sign confidentiality statements to remind them of their confidentiality obligations. Identifying information will be removed from forms, and coded forms will be stored in locked cabinets. Computer databases will be password protected. The information gathered will be used only in scientific papers, reports, and conference presentations, and will contain no identifiers.

Risk to benefit ratio Participants will benefit from receiving free clinical treatment for depression, referrals to community agencies, and increased social supports. The potential

benefits to home health care services include new knowledge about treating depression in this population and developing successful depression screening and intervention services for older clients of various ethnic backgrounds.

Strengths and Limitations: This proposal has six advantages. First, the intervention modality has not been tested with the home care population nor with ethnic elderly. Ethnic minority senior citizens, who are in most need of mental health services, have not been well represented in psychosocial research (Arean & Gallagher-Thompson, 1996). Second, the study design allows for examination of feasibility and applicability of the intervention for the home care elderly. During the past year, the applicant has provided education and training for this intervention model to the home care staff in order to achieve a level of readiness for a proposed pilot study. Third, a feasibility study such as this one brings us into the world of actual practice, with time-pressured clinical social workers taking care of large numbers of clients with complex comorbidities. Fourth, the two groups in this design are likely more comparable because confounding variables are probably balanced. Fifth, there is a greater likelihood that participants,

staff, and assessors, can be blinded. Sixth, most statistical tests rest on the assumption of random allocation.

Some limitations are inherent in this design. Those participants who volunteer may not be representative of all elderly home recipients. A potentially effective treatment is withheld from some participants (control). However, the control participants will receive usual care including consultation with a physician. The intervention will be provided to home care clients in the future with added training of home care staff across the state and the nation.

Significance

Depression is one of the most common clinical psychiatric disorders among elderly persons, and is the leading cause of disability worldwide, but treatment rates in primary care are low, and in home care are rare (Bruce, 1999; Goldman, Wise, & Brody, 1998; Lebowitz et al., 1997; Schoenbaum et al., 2001). There is also evidence that African-Americans and Latinos are at higher risk for depression than whites and other ethnic minorities (Eaton & Kessler, 1981; Gary, Brown, Milburn, Ahmed, & Booth, 1989). Elderly clients with depression tend to have higher medical costs and greater social disability than patients with medical illnesses such as hypertension or arthritis (Unutzer et al., 1996). The proportion of individuals receiving treatment for mental health problems is lower for persons age 65 years or older than for any other adult age group (Olfson & Pincus, 1996). Researchers have reported that following acute psychiatric care, depressed elderly continue to experience psychosocial and environmental problems requiring immediate intervention (Morrow-Howell, Proctor, Rubin, Li, & Thompson, 2000). Practice guidelines for depression management are available in primary care settings, yet quality of care and outcomes remain poor. To our knowledge, there are no social work practice guidelines for depression management in home care settings. This preliminary onvestigation would develop

such an initiative for home care settings in collaboration with the New York State Home Health Care Association.

Benefits of this research include the development of an evidence-based social work practice intervention (Reid & Fortune, 2000) to improve the quality of treatment for depression among community-dwelling elderly. Brief psychosocial interventions have the potential to improve short-term clinical outcomes relative to usual care at modest cost (Lebowitz et al., 1997; Thompson et al., 1987). Improving quality of care for depression in elderly home care clients could potentially increase well-being for older persons, their families, other informal caregivers, and society at large (Rogers, 1999; Morrow-Howell & Proctor, 1998; Rosen & Persky, 1997). Psychosocial interventions are expected to be an increasingly significant component of treatment for major depressive disorders among the elderly (Reynolds & Kupfer, 1999). Brief and effective treatments may assist elderly clients to cope with late life stressors such as loss of loved ones and functional disability (Bruce et al., 2000). In addition, brief standardized interventions target stressors and losses common in late life with an aim of reducing psychopathology and enhancing quality of life (Klausner & Alexopoulos, 1999). As well, demographic data also indicate that the aging population is increasingly becoming more diverse (USDHHS, 1999). New knowledge gained from this project can be adapted to develop culturally sensitive intervention programs to meet the challenges of practice with ethnically diverse groups.