FRAIL ELDERLY HOME CARE CLIENTS: THE COSTS AND EFFECTS OF ADDING NURSING HEALTH PROMOTION TO PERSONAL SUPPORT SERVICES

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KEY IMPLICATIONS FOR DECISION MAKERS

This is the first Canadian randomized trial with a full economic evaluation that gives evidence for the effectiveness and efficiency of having a nurse provide health promotion and preventive care to a general population of elderly homecare clients and their caregivers. It assessed the effects and expense of adding nursing health promotion and preventive care to usual homecare services in a national system of health and social insurance.

- This study provides scientific support for re-investment of professional nursing services in health promotion and preventive care for chronic and vulnerable elderly homecare populations.

- Providing seniors with nursing health promotion, compared to providing professional services on a reactive and on-demand basis, results in better overall mental health functioning, a reduction in depressive symptoms, and an enhanced level of perceived social support without increasing the overall costs of healthcare.

- Health promotion by nurses results in a clinically important improvement in caregivers level of social functioning (23.7 percent) versus 5.9 percent in the usual care group, and a reduction in depressive symptoms (1.5 percent) versus a 7.7 percent increase in the usual care group.

- The maintenance and promotion of mental health in seniors should be identified explicitly as a role for homecare. Homecare programs should have sufficient resources to overcome barriers to service access and provide effective care and support for clients with mental health issues, even if those clients do not have physical limitations.

- Organizations should provide a variety of professional development opportunities to support nurses in effectively developing strategies for promoting health, including assessing mental health status in seniors within the homecare sector.

- Organizational models of care delivery should allow for a flexible, client-centred approach and support nurses’ ability to develop continuous, uninterrupted, and meaningful relationships with elderly homecare clients and their caregivers. Nursing organizations should provide ongoing opportunities for discussion, education, and reflection to reinforce the importance of best practices.

- Support for elderly caregivers of clients with chronic health problems should be seen as an essential component of a publicly funded homecare program. A national public homecare program should provide a continuum of services, including health promotion and prevention and curative, rehabilitative, and palliative services.
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<tr>
<td>CCAC</td>
<td>Community Care Access Centre</td>
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<tr>
<td>RN</td>
<td>Registered Nurse</td>
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<tr>
<td>PSW</td>
<td>Personal Support Worker</td>
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<tr>
<td>CES-D</td>
<td>Centre for Epidemiologic Studies Depression Scale</td>
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<tr>
<td>SPMSQ</td>
<td>Short Portable Mental Status Questionnaire</td>
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<tr>
<td>MOS-SF-36</td>
<td>Medical Outcome Study Short Form -36</td>
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<tr>
<td>PCS</td>
<td>Physical Component Summary</td>
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<tr>
<td>MCS</td>
<td>Mental Component Summary</td>
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<tr>
<td>PRQ85</td>
<td>Personal Resource Questionnaire</td>
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<tr>
<td>ANOVA</td>
<td>Analysis of Variance</td>
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<td>ANCOVA</td>
<td>Analysis of Covariance</td>
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ABSTRACT

This single-blind, RCT, with a 6-month follow up, conducted in a home care programme in Southern Ontario, Canada, was designed to assess the effects and expense of adding nursing health promotion over 6 months to usual home care services in a national system of health and social insurance. Of 288 eligible and consenting subjects, who were randomly allocated at baseline to receive the nursing intervention or not, 242 or 84.0% were retained in the analysis. The demographic and social profile of study completers (n=242) versus those lost to follow-up (n=46) was similar with the exception of gender. A greater proportion of completers were female (76.9%) than those lost to follow-up (63.0%, p = 0.048). The study sample consisted of 242 seniors (75 years and older) eligible for personal support services through the home care programme. A nurse engaged 84.7% of those frail elderly participants who were randomly allocated to the nursing group at baseline. Subjects randomized to the nursing group received an average of 3.94 home visits and 1.81 telephone contacts over the 6-month follow-up.

At 6-months, results showed that providing seniors with nursing health promotion compared to providing professional services on a reactive and on-demand basis, results in better overall mental health functioning (p = 0.009), a reduction in depressive symptoms (p = 0.022), and an enhanced level of perceived social support (p = 0.009) at no additional expense from a societal perspective. This research is significant in that it is the first RCT in a Canadian home care setting, with a comprehensive cost assessment, that demonstrated that nursing health promotion, provided to a general population of frail seniors, 25.6% of whom were depressed and 93.4% of whom were functionally limited, enhanced quality of life while not increasing the overall costs of health care thus, making the intervention highly feasible. The results provide
scientific support for re-investment of professional nursing services in health promotion and preventive care for chronic and vulnerable elderly home care populations.

Of 288 eligible and consenting subjects, who were randomly allocated at baseline to receive the nursing intervention or not, 171 or 59.3% had an available and consenting caregiver. Of 171 caregivers, 116 or 67.8% were retained in the 6-month follow-up period. The demographic and social profile of caregiver completers (n=116) versus those lost to follow-up (n=55) was similar with the exception of use of prescription medications. Caregiver completers reported taking a higher mean number of prescription medications daily (4.22) compared to those lost to follow up (3.60, p = 0.03). A nurse engaged 65.1% of the available caregivers (n=86) of those elderly participants who were randomly allocated to the nursing group at baseline. Caregivers of subjects randomized to the nursing group received an average of 1.47 home visits and 0.92 telephone contacts over the 6-month follow-up.

At 6 months, results showed that providing caregivers with nursing health promotion results in a clinically important percent improvement in social functioning (23.7%) vs. 5.9% in the usual care group (p = 0.161), and a reduction in depressive symptoms (1.5%) vs. a 7.7% increase in the usual care group, (p = 0.365) at no additional expense from a societal perspective for a group of caregivers, 40.7% of whom are 75 years and older, 16.7% of whom are depressed, 35.3% of whom are functionally limited related to their physical health, and 60.3% of whom are limited in terms of social functioning. The study findings suggest that individuals who are elderly as well are caring for a significant proportion of elderly home care clients and facing significant issues related to later life themselves. Decision-makers and the public need to recognize and support the role of caregivers of elderly home care clients with chronic health needs. The overall conclusion from this present study results is that proactive nursing health
promotion and preventive care results in measurable gains in quality of life for frail elderly home care clients eligible for personal support services and their informal caregivers at no additional expense from a societal perspective.
INTRODUCTION AND BACKGROUND

Budget constraints, technological advances and a growing elderly population have led to major health care reforms across Canada. The result is fewer acute care hospitals and increasing pressure on community based services\(^1\). It has also led to increased debate about the reorganization of care and the allocation of health care resources\(^2\) (Bergman et al., 1997). For Canadian home care programmes, these changes have resulted in substantial increases in home care expenditures and the provision of care to older, more vulnerable, and frail individuals (Canadian Home Care Association (CHCA), 1999). While home care budgets are increasing, the facts suggest that additional funds are insufficient to offset the increasing demands for home care services (Canadian Association on Gerontology, 1999; Coyte & McKeever, 2001). Managers and policy makers alike face questions about the appropriate allocation of scarce home care resources and the mix of providers needed in this more community based and less hospital-oriented system.

Home care is defined as “an array of services enabling Canadians, incapacitated in whole or in part, to live at home, often with the effect of preventing, delaying or substituting for long-term care or acute care alternatives” (Health Canada, 1999, p. 10). In this paper, the term home care programme is used to mean the provision of case management, nursing, personal care, home support (or homemaking), occupational therapy and physiotherapy through community based agencies (MacAdam, 2000).

Home care can be segmented into three distinct functions:

- “a substitution function for other more costly services such as hospitals and long-term care facilities”;

\(^1\) Bergman et al. (1997).
• “a maintenance function which allows clients to remain in the current environment rather than moving to a new and often more costly venue”;’
• “a preventive function which invests in client service and monitoring at additional short-run, but lower long-run costs” (CHCA, 1999, p. 2).

This study focussed on evaluation of the preventive function of home care within a Canadian context.

Context

The reduction of premature institutionalization and enabling older people to remain in their homes has become a major thrust of government policy for several decades (Ontario Ministry of Health (OMH), 1993; van Haastregt et al., 2000). Over the past decade in Canada, hospital beds have been reduced by 30%, nursing home beds by 11%, and ambulatory care has increased (Statistics Canada, 2000). In response to these changes, home care spending has increased at a rate of about 20% a year over the last two decades (Coyte & Young, 1999), and Canadians over 65 years of age account for 64% of the total home care expenditures (Health Canada, 1996). Predictions are homecare expenditures will jump almost 80 percent between 1999 and 2026 (Romanow, 2002).

A number of factors may account for this growth in home care spending including expanded eligibility, increased accessibility, technological advances, system restructuring (Coyte & McKeever, 2001), and an increased expectation by the aging population to remain at home. However, a key factor that accounts for this increase in home care spending is the belief that significant public sector savings may be achieved by redirecting care away from institutions and toward the community (Coyte & McKeever; Hollander, 1994; Health Services Utilization and Research Commission (HSURC), 1996; OMH, 1993).
However, evidence for the cost effectiveness of home care in the Canadian context is limited and inconclusive. One of the problems is that research tends not to distinguish between different functions of home care; as a substitution for acute care, as a substitution for long-term care, and for maintenance and prevention. Most of the studies and literature reviews on the cost effectiveness of home care are American, and focus on the substitution of home care for acute or long-term care. These studies and reviews found very little compelling evidence for the cost effectiveness of home care (Health and Welfare Canada, 1990; Parr, 1996; Price Waterhouse, 1989). In addition, none of these studies included both a strong research design, such as a randomized controlled trial, and a full economic evaluation from a societal perspective (HSURC, 1996).

The place of home care in Canada’s publicly funded health care system has been the subject of debate for over a decade. Canada does not have a national home care program, nor are public home care services covered under the principles of the Canada Health Act (Coyte & McKeever, 2001; MacAdam, 2000). In the absence of national standards, home care policies; services and their delivery vary greatly within and between provinces/territories and across the country (CHCA, 1999; Coyte & McKeever, 2001; Coyte & Young, 1999; MacAdam, 2000). The National Forum on Health (1997) recommended that a national home care program be established in order to address these variations in the funding, availability, accessibility, and quality of home care throughout Canada. A national home care program has the potential to achieve equitable access to home care services by identifying and developing a standard ‘basket of services that would be publicly funded as well as provide recognition of the fact that home and community care are an essential part of the health care system.

Use of Home Care Services by the Elderly in Canada
Since the 1930’s there has been a steady increase in the proportion of older persons within the population. By the year 2041, seniors will account for 25% of the total population (George et al., 1994). As the senior population increases, there is an associated increase in the number of seniors living in the community with declining functional status related to chronic debilitating conditions such as arthritis and dementia (Hebert, Brayne, & Spieghalter, 1997; Hum & Simpson, 2002; Lindsay, 1999). A recent Canadian study of community-dwelling people found that the annual incidence of functional decline among previously stable people aged 75 years and above was approximately 12% (Hebert et al.). The survey also showed a significant increase in disability with age.

There are many interacting factors to examine when addressing the issue of functional decline that are physical, psychological, social, political, and economic in nature. For example, there is a higher prevalence of depression and depressive symptoms among elderly persons with functional limitations, compared to those without functional limitations (Barusch, Rogers, & Abu-Bader, 1999). Functional decline is one of the major challenges to the health care system. The main reason for the admission of elderly persons to institutions and for the disproportionate use of health services by the aging population is the functional decline that accompanies aging (Creditor, 1993; Fried & Guralnik, 1997; Gutman, Milstein, Killam, Lewis, & Hollander, 1993; Hebert, 1997; Markle-Reid, Browne, & Roberts, 1998); also depression and depressive symptoms have been associated with increased risk of hospitalization and service utilization (Colenda, Trinkle, Hamer, & Jones, 1991; Sarayav, Pollack, Steinberg, Weinschel, & Hubert, 1996).

While home care budgets across the country are increasing, the facts suggest that additional funds are insufficient to offset the increasing demands of an ageing population and the
increased demand for post-acute care resulting from health care restructuring and earlier discharge from acute care hospitals (CAG, 1999; Coyte & McKeever, 2001). Despite the growth in home care expenditures, homecare still accounts for only one out of every twenty dollars governments spend on health (Romanow, 2002). The result is increasing competition for publicly funded home care services and a shift in function of home care away from maintenance and preventive functions³ to acute care functions (Anderson & Parent, 2000; Boyle, 2001; CNA, 1998). This shift is based on the belief that reductions in services (particularly professional services) for preventive and maintenance functions save the system money.

However, empirical evidence for this assumption is limited and inconclusive (Aronson & Neysmith, 1996; OMH, 1993; MacAdam, 2000). On the contrary, for elderly persons living with chronic diseases and disabilities, these changes combine to create gaps in service and a fragmented system of health care delivery characterized by the provision of on-demand, and isolated services rather than a proactive system of care (Browne et al., 1999; Browne et al., 2001a). Hollander and Tessaro (2001) reported that people with low level needs, who experienced reductions in homemaking and personal care services, had higher death rates, and were more likely to be admitted to an institution.

Noteworthy, is that nursing is the service most frequently reported as being insufficiently provided by public home care programmes (Picard, 1999). For example, Hollander (2003) reported that approximately 90% of the expenditure for chronic home care services (providing maintenance and preventive functions), for people with chronic needs, were for home support services and 10% was for professional services. Multiple, interacting factors (physical, psychological, and social) determine the health needs of frail elderly people (Rockwood et al., 1994). Whereas Registered Nurses can perform “basic care” when needed, unregulated care
providers can only perform a narrow range of procedures and have limits to their independent judgment and ability (Helt & Jelinek, 1988; Weir & Browne, 1989). At the same time, the trend toward increasing acuity of home care clients combined with growing caseloads, has resulted in prioritization of case management activities with acute care taking precedence over the management and prevention of exacerbations of chronic illness (RNAO, 1999). Delays or errors in responding to the client’s changing health care needs increases both the potential for complications and the use of costly health care resources to address complications (CNA, 1998).

Published evidence concludes that the provision of on-demand care by a health professional is inadequate and that seniors who present later with problems require more costly resources such as hospitalization and premature institutionalization (Browne et al., 1999; Kennie, 1986; Roos & Shapiro, 1981; Somers, 1984). Furthermore, this experience with the acute care system often undermines chronically ill older persons’ self-confidence, and interest and ability to participate in their own care. The result is a vicious circle of reliance on institutionalized care (McWilliam et al., 1997). Browne et al. (1999), in a review of 12 Randomized Controlled Trials evaluating a community-based approach to care in a Canadian setting, found that for clients with multiple problems, it is more expensive in the same year to not provide these clients with proactive and comprehensive interventions. Additionally, there is beginning evidence in a Canadian home care setting, using a rigorous study design, that it is more effective and less expensive to provide proactive RN health promotion and preventive care to a general population of frail seniors living with chronic circumstances than to provide professional services on a reactive and piecemeal basis (Markle-Reid, 2002).

A recent policy statement issued by the Canadian Association on Gerontology (CAG) (2001, p. ii) recommended that a stronger emphasis be placed on both “individualized health
promotion and preventive care than currently exists for seniors, and on the integration of health
promotion with traditional illness-oriented care”. In a position paper for the Ontario Ministry of
Health (OMH), the CNA (1998, p. 5) recommended a “national home care programme that
provides an integrated continuum of services, including health promotion, preventive, curative,
rehabilitation, and palliative services”.

The Romanow Commission (Romanow, 2002) and the Kirby Committee (Kirby &
LeBreton, 2002) made the following recommendations for future direction and policy in Canada
with respect to the role of home care services: (1) implementation of a National Post-Acute
Home Care program administered by hospitals to encourage shorter lengths of stay and greater
use of post-acute home care, (2) establishment of a National Palliative Home Care program cost
shared between the federal government and provinces and territories, and (3) examination of the
feasibility to provide Employment Insurance for those who chose to provide palliative care to a
dying relative at home.

The challenge of listing “what’s in and what’s not” in the “basket of publicly insured
home care services” is the risk of compromising client outcomes and/or the effectiveness and
efficiency of the health care system. A major gap in these policy recommendations is the lack of
emphasis on the role of home care services for people with chronic conditions, physical and
mental disabilities, and frail older adults. These reports and the First Ministers ‘Health Accord
have focused on short term, post- acute care functions of home care rather than on the
maintenance and preventive functions of home care. Yet, recent literature suggests that high
users of health care resources are much more likely than other users to have multiple, chronic
and complex health problems (Gill & Sharpe, 1999; Reid et al., 2003; Starfield et al., 1985; Zook
& Moore, 1980). For example, Reid et al (2003), in a Canadian study, found that high users of
physician services were overwhelmingly characterized by multiple and complex health problems compared to other users.

Recent evidence indicates that the prevalence of depression among those receiving home care is estimated to be between 26% and 44% - at least twice that among elderly people in general (Banerjee et al., 1993; Ilife, Haynes, Gallivan, Booroff, Goldenberg, & Morgan, 1993), and the presence of a co-morbid depression increases expenditure of use of health and social services by two to threefold largely related to use of expensive crisis resources, i.e. acute hospitalization (Browne et al., 1993). A recent report identified that home care is well positioned to contribute to seniors’ mental health (Parent, Anderson & Neuwelt, 2000). Yet, the maintenance and promotion of good mental health in seniors has not been identified explicitly as a role for home care in these policy recommendations nor has it been a priority in resource allocation decision-making for home care at the provincial, local or organizational level.

A recent report by Hollander (2003) on the role of chronic home care services argues that the focus on short-term (acute care) home care services is designed to deal with the output (discharge) side of the equation by facilitating reductions in hospital stays at the expense of dealing with the input (admission) side of the equation. Post-acute home care services do not address the ever-increasing demand for acute hospitalization and long-term care. “This input side is where support for chronic home care services can have a significant impact” (Hollander, 2003, p. ii).

While the Romanow (2002) report acknowledges the sustained energy and commitment that are required by caregivers, and sanction the need to financially support caregivers in their role, the carer allowance is based on the Employment Insurance System and thus, is linked to paid work. However, research has shown that caregivers are often elderly, and provide
approximately 80% of the care to community dwelling, functionally impaired elderly persons (Clark, 1996; Ferguson, 1995; National Advisory Council on Aging, 1999). Caregiving has been shown to result in particular strain and psychological burden (Kane & Penrod, 1995; Schulz, O’Brien, Bookwala, & Fleissner, 1995). Without adequate supports in place to enable caregivers to fulfil their roles, the cost of formal health care will rise substantially (Health and Welfare Canada, 1991; Canadian Nurses Association, 1998; Levine 1999; National Advisory Council on Aging, 1999). Yet, support for elderly caregivers of people with chronic circumstances has not been identified as an essential component of the basket of services for a publicly funded home care program. One of the dangers of focusing on post-acute home care is the potential for increasing demands on informal caregivers of people with chronic needs. This could lead to a negative cost spiral in which further funding for people with chronic needs is reduced, leading to greater demands on acute and long-term care services because people are no longer able to cope at home (Hollander, 2003).

Decisions regarding what is included and what is not included in a publicly funded home care system require the development of national standards for home care as well as supportive evidence, and it is here where research has a very important role. Decisions regarding the allocation of home care resources are largely driven by fiscal and demographic principles. These economically driven policies have not been well tested in terms of their impact on health outcomes or changes in real costs (Ontario Ministry of Health (OMH), 1993). With an aging population and limited health care resources, decisions must be made regarding what is the most cost effective and beneficial mix of services for whom, living in various circumstances. Is there enough funding in home care or is it a question or appropriate resource allocation? Scientific
evidence is needed to justify the kinds of services provided for what need, by whom and at what cost.

Objectives

Thus, there were several objectives of the study:

• Develop, implement, and evaluate a new model for delivering services to frail seniors living at home, focusing on home based health promotion and preventive care provided by a Registered Nurse within the context of home care services.

• Provide information on the health outcomes and costs associated with existing policies regarding the provision of maintenance and preventive home care services for frail seniors living at home.

• Provide scientific support for the role of a Registered Nurse in health promotion and preventive care within the context of home care services.

A randomized trial was used to evaluate two approaches to the promotion of health and prevention of decline in frail elderly seniors eligible for personal support services through a home care programme within the Province of Ontario, Canada. The treatment group received personal support services augmented by a 6-month home based health promotion and prevention care intervention by a Registered Nurse while a comparison group received personal support services under the existing model of service delivery. The groups were then compared on both the costs and the respective health outcomes of clients under each model.

The results of this study will position Ontario as a leader in providing scientific evidence for cost-effective and comprehensive models for delivering home care services to vulnerable clients and caregivers (such as people with chronic conditions and physical and mental
disabilities). Because these persons are more susceptible to the lack of availability and access to home care services, it becomes more expensive from a societal perspective to continue providing limited and fragmented care. The specific characteristics of clients and caregivers who benefit most from health promotion and preventive care interventions will be identified so that resources can be targeted to those for whom outcomes can be positively influenced. The research will also expand understanding of the impact of current home care policies on health outcomes and costs from a societal perspective. The results of this study will inform policy makers, administrators and clinicians regarding resource allocation decision-making and service integration which will make a national contribution to health care delivery reform for policy makers, administrators, clinicians, clients and their families.

State of the Knowledge: Effectiveness and Efficiency of Home Based Health Promotion and Preventive Care for Elderly Home Care Populations

Evidence is accumulating from several studies that suggests that early detection of older people at risk of functional decline or losing their autonomy, might decrease morbidity and prevent or delay the use of costly health care resources (Barber & Wallis, 1976; Currie, MacNeil, Walker, Barnie, & Mudie, 1974; Williamson, 1981). Several papers conclude that on-demand care is inadequate and that seniors who present later with problems require more costly resources, e.g. hospitalization and nursing home placement (Kennie, 1986; Roos & Shapiro, 1981; Somers, 1984). As a result, several studies of screening and case finding among elderly persons have been conducted in an attempt to proactively identify and address problems to reduce the use of costly resources later (Brown, Boot, Groom, & Williams, 1997; Browne et al.,
The literature also suggests that timely and proactive initiatives directed toward the caregiver can also save personal and financial costs in the long run. This includes early diagnosis of caregiver stress and depression, and the introduction of proactive initiatives to help caregivers cope with the stress and burden of caregiving. The extensive role played by family caregivers in meeting the needs of the frail elderly has been extensively documented in the literature (Greene & Monahan, 1989). Approximately 15% of the Canadian population are caregivers (Cochrane, Goering, & Rogers, 1997). One-third to one-half of caregivers are people living in chronic circumstances, with cognitive and functional limitations, who are burdened or overwhelmed with caregiving. This perception of burden is most likely related to caregiver depression (Browne & Roberts, 1999).

Evidence suggests, however, that screening and case finding alone is insufficient. Two meta-analyses of randomized controlled trials on the effectiveness of geriatric home assessment programmes confirmed that in order to be effective, a geriatric assessment programme must deliver an intervention that combines assessment or screening with sustained treatment (Stuck, Siu, Wieland, & Rubenstein, 1993b; Stuck et al., 2002). Stuck et al. (2002) found that the detection of risk factors for functional decline and the implementation of recommendations to address them (through multiple follow-up home visits) were key factors contributing to the success of in-home preventive programmes. Similarly, Jensen (1997) in a review of 12 randomized controlled trials of preventive programmes for older people concluded that preventive home visits have a beneficial effect on elderly people and that hospital and nursing
home admissions decrease. The underlying cause of this is not clear. However, the studies indicate that a) health care personnel have to undertake the visits, b) social and medical intervention is necessary, and c) visits have to be made on an ongoing basis.

Elkan et al. (2001) in a recent meta-analysis of randomized and non-randomized controlled trials on the effectiveness of home based support for older people, found that regular home visits to older people was associated with a significant reduction in mortality and admission to long term institutional care. Several other studies have documented the effectiveness of preventive home visitation programmes for community-dwelling seniors as a strategy for delaying or preventing functional decline and dependency, reducing hospital admissions, and promoting the appropriate use of health and social services (Barber & Wallis, 1976; Currie et al., 1974; Ramsdell et al., 1989; Williamson, 1981).

For the purpose of this study, preventive home visits included:

- Home visits to independently living elderly people.
- Multi-dimensional assessment of clients in medical, functional, psychosocial, spiritual, and environmental domains (Stuck et al., 1993a).
- Identification of needs and strengths leading to specific recommendations aimed at decreasing risk factors and enhancing client strengths.
- Multiple follow-up contacts to address these recommendations.

Available randomized controlled trials have confirmed that preventive in-home care of elderly patients reduce hospital admissions and lengths of stay in hospital (Bernabei et al., 1998; Hall et al., 1992; Hendriksen, Lund, & Stromgard, 1984; Pathy, Bayer, Harding, & Dibble, 1992; Zimmer, Groth-Juncker, & McCusker, 1985), improve functional status (Bernabei et al., 1998; Pathy et al., 1992; Stuck et al., 1995; Stuck et al., 2000), reduce mortality (Hall et al., 1992;
Hendriksen et al., 1984; Pathy et al., 1992; Vetter, Jones, & Victor, 1984), decrease admission to long-term institutional care (Bernabei et al., 1998; Gunner-Svensson, Ipsen, Olsen, & Waldstrom, 1984; Hall et al., 1992; Stuck et al., 1995; Zimmer et al., 1985), decrease the level of depression (Bernabei et al., 1998), increase use of health and social services (Hendriksen et al., 1984; Pathy et al., 1992; Stuck et al., 1995; Stuck et al., 2000; van Rossum et al., 1993; Vetter et al., 1984), reduce cost (Bernabei et al., 1998; Hendriksen et al., 1984; Stuck et al., 1995; Stuck et al., 2000; Zimmer et al., 1985), and improve caregiver outcomes (Zimmer et al., 1985).

However, none of the trials measuring affect (i.e. anxiety, loneliness) showed a significant effect (Hall et al., 1992; Hebert, Robichaud, Roy, Bravo, & Voyer, 2001; van Rossum et al., 1993; Vetter et al., 1984).

Noteworthy, is that the study of the effects of the intervention on the level of depression and caregiver well being has been largely ignored. In addition, only three studies addressed the impact of the intervention on perceived social support (Hebert et al., 2001), and level of social contacts (van Rossum et al., 1993; Vetter et al., 1984). None of the available studies addressed the level of acceptability or satisfaction with the study intervention.

These findings are significant and point to several limitations in the literature. The first limitation relates to the lack of focus on depression and perceived social support. In a systematic review of the literature, Stuck et al. (1999) found that depression and low frequency of social contacts were major risk factors for functional decline in community- dwelling elderly people. In comparison with the general elderly population, those clients who receive home care are older, more socially isolated, and have high rates of disability and depression (Banerjee, 1993). The prevalence of depression among those receiving home care is estimated to be between 26% and 44% - at least twice that among elderly people in general (Banerjee; Harrison, Savla, &
Kaftez, 1990; Ilife et al., 1993). The role of social support in buffering the effects of stress is well documented, and studies have shown an association between low social support and higher rates of depression (Bazargan & Hamm-Baugh, 1995; Chu, 1995; Lamb, 1996; Steffens, Hays, George, Krishnan, & Blazer, 1996). Although 80-90% of persons with depressive disorders can be successfully treated, only about one in three persons who suffer from depressive disorders seeks treatment in the general or specialty mental health sector (Reiger et al., 1988).

A second limitation relates to the lack of focus on quality of life. Effectiveness has been predominantly measured within an objective context focusing on objective rather than subjective measures of effectiveness. What outcomes would older adults select as indicators of effective services (Clark, 2001)?

A third limitation relates to the lack of attention to informal caregivers. Caregivers, rather than professionals, are the main providers of care to the chronically ill (Morris, Sherwood, & Morris, 1996). Approximately 80% of community dwelling, functionally impaired elderly individuals receive assistance entirely from informal care providers (Clark, 1996; Ferguson, 1995; National Advisory Council on Aging (NACA), 1999). Clinicians, practitioners and policy makers have acknowledged the sustained energy and commitment that are required by caregivers, and clearly sanction the need to support family caregivers in their role (Ontario Ministry of Health (OMH), 1998; Minister of Long-term Care with Responsibility for Seniors (MLTCRS), 1999; NACA, 1999). This is related to the recognition that without adequate supports in place to enable caregivers to fulfill their roles, the cost of formal health care will rise substantially (CNA, 1998; Health and Welfare Canada, 1991; Levine, 1999; NACA, 1999), particularly related to institutionalization (Hu, Huang, & Cartwright, 1986; Weinberger et al., 1993), and potential secondary disability in the primary caregiver (Roberts et al., 1999).
A final limitation relates to the lack of studies, which include a strong cost assessment. A potential barrier to the implementation of preventive home visits is the reluctance to fund additional services in times of fiscal constraint. Even if preventive home visits demonstrate a reduction in use of hospitalization and/or an increase in health status, they are unlikely to be introduced without clear evidence of costs averted (Hirdes, Naus, & Young, 1994). None of the studies addressed the level of acceptability or satisfaction with the study intervention.

In summary, published evidence supports the effectiveness of home-based health promotion and preventive care, when compared with standard care, for older people. However, the findings of the various studies failed to show a consistent pattern in terms of whether the home visits could prevent or reduce functional decline, mortality, hospitalization, and nursing home admissions. This is likely related to the diversity of programme components, populations assessed, types of outcomes measured, and contexts among the studies (Rubenstein, Stuck, Siu, & Wieland, 1991; Stuck et al., 1993a; Stuck et al., 2000). In addition, the majority of studies focus on preventive care (reflecting a biomedical approach), rather than the promotion of health. Studies are further limited by the lack of evidence for the effectiveness of a preventive intervention on emotional health outcomes such as depression, perceived social support, and a strong cost assessment.

No single set of programme features emerged as important in distinguishing highly effective programmes from those that are less effective. In addition, the relative contribution of each of these variables to programme success is unclear. Stuck et al. (2002) noted that factors associated with effects on mortality (mean age < 80 years), differed from those predicting effects on functional status (CGA and follow-up), and nursing home admissions (> 5 follow-up visits). These findings suggest different programme features and processes of care may be important in
mortality and functional status outcomes (Stuck et al., 2002). One of the challenges of evaluating health promotion and preventive interventions in a community based setting is the difficulty of isolating the contribution of single elements of the intervention to any observed change in outcome (Holder, Treno, Saltz, & Grube, 1997). This problem is a result of the complex interaction between different parts of the intervention (Koelen, Vaandrager, & Colomer, 2001).

The investigator tried to relate the findings of various studies to the characteristics of the intervention to identify the factors that distinguish highly effective programs from those of lesser effectiveness. Completion of an initial and ongoing assessment with an established assessment team, identification of the need for and co-ordination of community services, and an individualized and interdisciplinary approach to care seemed to be important elements for achieving favourable outcomes. These results are consistent with Rubenstein et al. (1991) who concluded that effective preventive programs have the following features: an established assessment team, appropriate targeting criteria, availability of careful follow-up after the assessment, and availability of rehabilitation services.

However, accumulation of empirical evidence alone is insufficient to direct practice. A theoretical approach is needed to provide direction to both the design and evaluation of health promotion programmes to allow for wider application (Green, 2000). In a review of the literature on the study of frail elderly people, Bowsher et al. (1993, p. 876) noted that “two commonly observed deficits in nursing research relating to frail elderly people are the absence of a clear theoretical base and the reliance on non-nursing models to provide a theoretical structure”.

Common methodological problems may also account for some of the inconsistencies in the results of studies on the effectiveness of in-home preventive programmes. The main shortcomings were found in the areas of intention to treat analysis, reporting on co-interventions, the reliability and validity of the outcome measures, content, compliance with and cost of the intervention, blinding procedures, and handling of dropouts.

Discrepant results were also found amongst the available meta-analyses (Elkan et al., 2001; Rubenstein, Siu, & Wieland, 1989; Stuck et al., 1993b; Stuck et al., 2002) systematic reviews (Stuck et al., 1993a; van Haastregt et al., 2000) and literature review (Hirdes et al., 1994) examining the effectiveness of in-home preventive care for older adults. The lack of consistency in the results may be explained by differences in the number and type of studies included in the review. For example, several articles combined trials of in-home preventive programmes with trials of home based care for clients discharged from hospital (Elkan et al., 2001), trials involving screening and referral only (Stuck et al., 1993a; Stuck et al., 1993b), and trials of hospital and community based comprehensive geriatric assessment programmes (Rubenstein et al., 1989). This observation reflects a lack of consensus in the literature regarding the definition and scope of in-home preventive programmes. The number of studies included in the analysis influenced the power of detecting programme effects and the difference in results. For example, Stuck et al. (2002) pooled the findings of 16 trials to study the impact on functional status whereas Elkan et al. (2001) pooled the findings of 7 trials.

A final limitation of the literature is related to the dearth of evidence for preventive home programmes in both a Canadian context and within the context of community support services, i.e. home care. Contextual or environmental variables are key variables to consider since models
of health promotion and preventive care need to be developed in concert with local and regional resources.

Purpose of the Study

Thus, the purpose of this study was to implement and evaluate a new model for delivering services to frail seniors living at home, focusing on home based health promotion and preventive care provided by a Registered Nurse. The study was designed to address the conflicting findings, methodological difficulties and major omissions in the literature that limit the usefulness of the current research for informing policy and practice within a Canadian System of National Health Insurance by:

1. Developing an in-home health promotion and preventive care programme and providing evidence of its effectiveness in a Canadian home care context utilizing a rigorous study design (randomized controlled trial).

2. Providing evidence of the effectiveness of preventive home visits on costs using a strong cost assessment that includes the full range of health and social services.

3. Provide evidence of the effectiveness of preventive home visits on health related quality of life including depression.

4. Provide evidence of the effectiveness of preventive home visits on level of perceived social support.

5. Providing information on the health outcomes and costs associated with current policies regarding the provision of home care services for frail elderly clients and their caregivers.

6. Providing support for the role of a Registered Nurse in health promotion and preventive care a Canadian Home Care context.
7. Providing empirical support for a comprehensive theoretical approach to health promotion and preventive care within the context of home care services.
CONCEPTUAL FRAMEWORK

The Model of Vulnerability: Theoretical Approach to Health Promotion and Preventive Care

Given the lack of a comprehensive framework for the identification and management of frailty (Markle-Reid & Browne, 2003), the investigator returned to the level of definition. A consistent theme in the literature is that frailty is a relative term that is characterized by an at-risk or vulnerable state (Brown, Renwick, & Raphael, 1995; Buchner & Wagner, 1992; Rogers, 1997).

Based on this, the investigator used the model of vulnerability developed by Rogers (1997) as an alternative theoretical approach to the identification and management of frailty in this study population. The model of vulnerability was then operationalized to provide the theoretical basis for the development, implementation and evaluation of a comprehensive health promotion and preventive care intervention. The following implicit and explicit assumptions that underlie the model of vulnerability (Rogers) help to address the major problems, omissions, and inconsistencies in the current models and definitions of frailty in the literature:

1. The degree of vulnerability is context dependent and, therefore, is greatly affected by the subjective perception of the individual. Thus, the concept of vulnerability allows for individual variability (Rogers, 1997).

2. The concept of vulnerability is multi-dimensional consisting of intersecting physical, psychological, social and environmental factors.

3. The concept of vulnerability is not age-related and, therefore, does not portray a negative and stereotypical view of aging. While the frail elderly have been identified as a vulnerable population, other vulnerable populations have been identified including those who are poor, homeless, chronically ill or disabled, people with AIDS, abusing families,
pregnant adolescents and their children, immigrants and refugees, and those who are mentally ill (Rogers, 1997).

4. The concept of vulnerability reconciles the disparity in the literature between the micro- and macro-level approach by suggesting that *vulnerability can originate from within the individual or from conditions occurring in the environment* (Rogers, 1997). The conceptualization of vulnerable populations requires a community health perspective. “A community health perspective views communities as responsible for the collective well-being and health of their citizens, rather than a focus on individual responsibility for health” (Flaskerud & Winslow, 1998, p. 1). Therefore, the model looks at the broader influence of the environment on health.

In a review of the literature on the study of frail elderly people, Bowsher et al. (1993, p. 876) recommended that “gerontological research, particularly that of frail populations, be constructed within more holistic and optimistic developmental models. Such models focus on positive aspects of aging and redefine health to include the quality of life despite chronic conditions and functional limitations”. Nursing models, such as the model of vulnerability (Rogers, 1997) offer such a theoretical perspective by projecting a positive view of aging - the potential for health that does not depend solely on traditionally perceived functional capacity.

In a vulnerability index, vulnerability is a net result of an interaction between the person’s personal resources (cognitive, emotional, intellectual, behavioural) and their environmental supports (social, material, cultural) (Rogers, 1997), both of which, along with biological characteristics (age, gender, genetic endowment), are determinants of health. Based on published evidence (Browne et al., 2001b; Rogers, 1997), the investigator hypothesized that expenditure of use of health and social services increases proportionately with the level of
vulnerability. Therefore, the original model of vulnerability developed by Rogers (1997) was extended to include a health and social services index (see Figure 1).

Personal resources can be defined as either inborn or acquired characteristics, which interact with the environment to influence health. Inborn characteristics that influence health include non-modifiable factors such as the person’s age, gender, race, temperament, genetic predisposition to disease, susceptibility to illness, sensitivity to drugs and chemical imbalances (Rogers, 1997). Acquired characteristics are modifiable factors such as trauma, the presence of disease, lifestyle, recent life events, and coping skills that are often the result of life experiences (Rogers). Both the inborn and acquired characteristics affect the individual’s ability to handle stress.

Environmental supports can be defined as factors, which interact with personal resources to influence health. The environment in which the individual lives includes the immediate environment (temperature, light, noise), as well as the broader context of family, community, and society. Societal attitudes and stereotypes of aging will affect the functioning of the older individual in the environment. Environmental factors also include modifiable factors such as social support, education, employment and income (Rogers, 2000).

Within an individual, personal resources and environmental supports intersect, as shown in Figure 1, and can be synergistic and cumulative (Browne et al., 2001b). The relationship between personal resources, environmental supports, and degree of vulnerability is conceptualized in Figure 1. The base of the triangle represents the degree of vulnerability (Rogers, 1997), and thus also their expenditure of use of health and social services. An individual is continually adapting to threatening or stressful events that can originate from within the individual or because of conditions occurring in the environment (Rose & Killien, 1983).
Through creating “equilibrium” between the individual’s personal resources and environmental supports, adaptation is facilitated (Rogers, 1997).

The continua of personal resources and environmental supports are each represented by the other two sides of the triangle. To estimate an individual’s degree of vulnerability, one would locate the person’s level of environmental supports on one side of the triangle and draw a straight line from this point to the opposite apex. The same would be done for the person’s personal resources. At the point where the two lines intersect, a line would be dropped perpendicular to the base to intersect the vulnerability continuum. This point of intersection, the degree of vulnerability, therefore, represents an outcome of the interaction of personal resources and environmental supports (Rogers, 1997, p. 68).

Thus, even if personal resources hold constant, changes in the individual’s environmental supports can greatly alter their degree of vulnerability, and thus their use of health and social services. What is needed is “a ‘fit’ between the needs and resources of the person and the demands and resources of the environment” (Rogers, 1997, p. 68). Proactive, individualized, multi-disciplinary interventions either targeted at the individual or the environment can be developed to identify and strengthen available resources to considerable economic effect (Browne et al., 1999). One published study was found that provided support for the model of vulnerability in a population of elderly surgical patients with acute confusion (Rogers, 2000). Conclusions regarding the theoretical support or refutation of this extended vulnerability model in a frail elderly home care population will be drawn.

The vulnerability model was operationalized to form the basis for a proactive and individualized health promotion and preventive care intervention. Theory is essential to the design of both programmes and evaluations due to its explanatory and predictive capabilities.
Empirical evidence alone is insufficient to direct the design and evaluation of interventions. Theory enhances the generalizability of the results by providing the basis for informing the systematic development and implementation of intervention strategies as well as evaluation indicators (Green, 2000; Nutbeam, 1999). The key concepts and assumptions of the model provided the structure for a comprehensive health promotion and preventive care intervention in the study and an important construct for evaluation.

The operationalization of the model of vulnerability required extensive research and preliminary groundwork that included:

1. Examination of the concepts of health promotion and preventive care, including issues surrounding measurement of effectiveness of health promotion and preventive care in a community based setting, to guide the development and evaluation of a health promotion and preventive care intervention.

2. Critical appraisal of the research evaluating the effectiveness of home based health promotion and preventive care for older adults to determine the state of the knowledge in this area and ‘best-practice’.

3. Evidence from the literature on risk factors for functional status decline among community dwelling elderly persons to identify key personal and environmental study variables to address through the study intervention.

4. An environmental scan of the current home care delivery system for this population including practice patterns to design an intervention that fit within the existing structure and financing of home care services. This involved three organizations and their providers: the regional home care organization (CCAC of Halton), and two visiting
nursing agencies (Victorian Order of Nurses (VON) Halton Branch and St. Elizabeth’s Nursing (SEN) Community Health Care).

Once this preliminary work was completed, the model of vulnerability could be utilized as a framework for a proactive health promotion and preventive care intervention with a frail elderly home care population, incorporating evidence from empirical studies, with usual providers, within already existing services and programmes.

*The Model of Vulnerability: Conceptual Approach to Health Promotion*

Although the concept of health and prevention of health problems is identified by Rogers (1997), she does not specifically address the concepts of health promotion and preventive care in the Model of Vulnerability. However, inferences can be made from the model as noted below.

Health promotion and preventive care are conceptually distinct but complementary processes with the goal of enhancing health and well-being (Pender, Murdaugh, & Parsons, 2002; Stachtchenko & Jenicek, 1990). Health promotion is the process of enabling people to take control over the determinants of health and thereby improve their health (Epp, 1986). Health promotion is “behaviour motivated by the desire to increase well-being and actualize human health potential” (Pender et al., 2002, p. 7). Preventive care (also referred to as health protection or disease prevention), is any intervention that reduces the chance that a disease or disorder will affect an individual by interrupting or slowing the progress of a disorder or reducing disability (Dietrich et al., 1999; Stachtchenko & Jenicek). Preventive care is “behaviour motivated by a desire to actively avoid illness, detect it early, or maintain functioning within the constraints of illness” (Pender et al., p. 7).

The concept of health in the Vulnerability model is depicted as a positive and multi-dimensional concept that is determined by physical, psychological, social, environmental and
political factors that are context specific and subjectively defined. This theoretical approach is consistent with the concept of health in health promotion, which is holistic, subjectively defined, and includes several distinct dimensions: physical health (functional and structural integrity), mental health (emotional and intellectual functioning), social functioning, role functioning and general perceptions of well being (McWilliam et al., 1996; Pender et al., 2002; Stachtchenko & Jenicek, 1990). In contrast, the concept of preventive care, defines health as the absence of disease - health promotion is not illness or injury specific whereas preventive care is (Maville & Huerta, 2002).

The strategies for enhancing health in the Vulnerability model include altering personal and environmental factors, which are the determinants of health. This theoretical approach for altering personal and environmental factors can be inferred as health promotion that includes preventive care strategies.

According to the World Health Organization (WHO), health promotion strategies include: developing personal health skills, creating supportive environments, strengthening community action, reorienting health services, and building healthy public policy (Pederson, O’Neil, & Rootman, 1994). Thus, health promotion strategies are multi-level focussing not only on individuals but also on family, community and societal health. Health promotion is not only concerned with enabling the development of life skills, self-concept, and social skills, but also concerned with environmental intervention through a broad range of political, legislative, fiscal, and administrative means (Stachtchenko & Jenicek, 1990). Similarly, strategies for enhancing health in the model of vulnerability are multi-level. Vulnerability is a result of conditions originating from within an individual or from conditions occurring within the environment.
Therefore, strategies must be aimed at both individual and societal levels in order to reduce vulnerability and improve health and well being (Rogers, 1997).

Health promotion strategies are based on a participatory model of health (Stachtchenko & Jenicek, 1990). A participatory model seeks to expand an individual’s positive potential for health whereas preventive care, which is grounded in the traditional biomedical model of health (Stachtchenko & Jenicek, 1990), seeks to avoid risks or decrease risks to health and well being (Pender et al., 2002). Thus, the focus of the model of vulnerability on identifying areas of strength as well as deficits, as a strategy for enhancing health, is consistent with the concept of health promotion (Rogers, 1997). Rogers (1997) proposes that vulnerability can be decreased through strategies that identify and strengthen personal and environmental resources.

A participatory approach to enhancing health involves activities that seek to empower individuals and to promote positive attitudes, knowledge and skills to maintain and enhance health (Maville & Huerta, 2002; McWilliam et al., 1997; Stachtchenko & Jenicek, 1990). Health promotion interventions are developed, implemented and evaluated together with individuals, families, and stakeholders from different organizations (Koelen et al., 2001). Empowerment for health goes beyond illness and the management of a specific disease. Its success is seen in terms of enhanced health, well being, quality of life, sense of self-esteem and self-worth (Pederson et al., 1994).

While health promotion is approach motivated, preventive care is avoidance motivated (Pender et al., 2002). That is, preventive care tends to focus on the individual as the focus of care and involves strategies that are directive and concern a specific medical problem in order to avoid or reduce risk to health and well being (Maville & Huerta, 2002; Stachtchenko & Jenicek, 1990). Its success is seen in terms of reducing morbidity or mortality (Clark, 2001; Pederson et
The model of vulnerability proposes that by determining what factors in the individual or the environment are most predictive of problems with health, nurses can intervene earlier to alter personal or environmental factors (Rogers, 1997). This strategy for enhancing health is consistent with the concept of preventive care, which focuses on reducing or avoiding the risk of illness or disability (Stachtchenko & Jenicek). Three levels of prevention are described in the literature: primary prevention (to prevent problems from occurring in the first place), secondary prevention (early detection of health problems), and tertiary prevention (to avoid further decline) (Maville & Huerta, 2002). While the intervention in this study directly focused on the individual as the focus of care, the results will have implications for the broader systems by informing public policies, which promote and maintain health.

**Economic Evaluation**

Economic analysis consisted of comparing both the effects and expense of usual home care services\(^5\) versus RN health promotion and preventive care for frail elderly home care clients with the goal of maximizing improvements in health and well-being using a fixed pool of available resources (Browne et al., 1999). An important part of any type of economic evaluation is the perspective or viewpoint taken. A study’s viewpoint determines which costs are considered in an economic evaluation. The costs in this study were examined from a societal perspective. A societal perspective collects all costs, regardless of who paid. The wider the perspective taken, the more applicable the study is to broad social policy decisions (Drummond, O’Brien, Stoddart, & Torrance, 1997). As depicted in Figure 2, Birch and Gafni (1996) identified nine possible outcomes of economic evaluation of health programmes. “This approach can be used to classify the main effects and expense of comparative community health interventions” (Browne et al., 1999, p. 2).
Technical efficiency relates to fewer resources consumed by a proposed programme when the benefits produced are the same as the current programme. If the resources consumed are the same in both programmes, the one with greater benefits is the technically efficient choice (Birch & Gafni, 1996).

Primary Research Questions

Thus, this project was designed to address the following research questions:

1. Does proactive nursing health promotion and preventive care in addition to usual home care services improve the outcomes for a frail elderly home care population and their caregivers with respect to functional health status and quality of life?

2. What are the comparative expenditures for health and social service utilization at 6 months with nursing health promotion and preventive care versus usual home care services for a frail elderly home care population and their caregivers from a societal point of view?

3. Does proactive visiting nursing health promotion and preventive care in addition to usual home care services improve the outcomes for a frail elderly home care population with respect to mental status (presence of depression), coping and perceived social support?

4. Does proactive visiting nursing health promotion and preventive care in addition to usual home care services improve the outcomes for caregivers of frail elderly home care clients with respect to mental status (presence of depression) and level of burden associated with caregiving?
METHODOLOGY

Study Design

The study design is a randomized controlled trial of a RN health promotion and preventive care intervention compared to usual care, with baseline (pre-randomization) and 6-month follow-up for a frail elderly home care population eligible for personal support services and their primary caregivers.

Study Setting

This study has been a collaborative project between the Community Care Access Centre (CCAC) of Halton, the System-Linked Research Unit (SLRU), McMaster University, the Ontario Ministry of Health and Long-Term Care (OMHLTC), two non-profit visiting nursing agencies: the VON Halton Branch and SEN Community Health Care, and three homemaking service provider agencies: the VON Halton Branch, the Canadian Red Cross Homemakers Halton, and Para-Med Home Health Care. The CCAC of Halton provides publicly funded home care utilizing a contractual model of service delivery. This model reflects the Ontario model of home care as organized through its 43 CCACs (Anderson & Parent, 2000). In this model, community boards that are accountable through service agreements to the Ontario Ministry of Health and Long-Term Care manage the CCACs. Publicly funded employees (case managers) contract out professional and home support services to for-profit and not-for-profit agencies, which provide care to clients. CCACs also provide long-term care facility placement, and information and referral to other community services (Coyte & Young, 1999).

Selected Registered Nurses provided the experimental intervention from both VON and SEN Community Health Care. Visiting nurses are organized by district. Therefore, the assignment of study clients to nurses was based on the geographical location of the clients as
opposed to medical or diagnostic groupings. A selected group of nurses from each of the nursing agencies were trained to provide the study intervention in order to provide coverage for all of the districts within the Region of Halton. Case management services through the CCAC of Halton were part of both the control (usual care) and the experimental intervention. This service consisted of intake, eligibility assessments, and regular ongoing eligibility assessments by the CCAC case manager.

Study Population

_Elderly CCAC Clients_

Elderly subjects were those referred to the CCAC of Halton in Southern Ontario, Canada from acute care hospital, community and other institutional settings. For the purpose of this research project and this evaluation, “frail elders” are defined as persons aged 75 years and over who are living in their own homes, but who have been assessed and eligible for personal support services through the CCAC of Halton\(^6\). Subjects were selected based on evidence from the literature that suggests that preventive interventions are more effective for individuals 75 years and over (Hall et al., 1992; Hirdes et al., 1994; Newbury & Marley, 2000; Pathy et al., 1992; van Haastregt et al., 2000; van Rossum et al., 1993). Subjects were not selected on the basis of their risk status, due to the lack of consensus in the literature regarding the effectiveness of in-home preventive programmes with high risk versus low risk elderly persons.

Clients were considered _eligible_ for the study if they met the following criteria:

- \(\geq 75\) years;
- newly referred to and eligible for personal support services\(^7\) through the CCAC from acute care hospital, community (including outpatient clinics), and other institutional settings, i.e. long-term care settings;
• client and/or caregiver communicates in English;

• expect to receive treatment and/or reside in the Halton Region for the 6 months of the study.

Clients and caregivers were considered *ineligible* for the study if they were newly referred to the CCAC for nursing (RN level) services.

Clients who are considered by the CCAC case manager to be ineligible for the study (based on the inclusion and exclusion criteria) were assigned the appropriate level of care provider and classified as ineligible. The reason(s) for this decision was documented. It was not necessary for a subject to have a family caregiver to participate in the study.

*Caregivers*

The recruitment criteria for family caregivers of elderly CCAC clients included:

• the elderly client met the eligibility criteria for the study

• the caregiver was defined as an unpaid person, either a family member or friend, who is perceived by the elder or his/her family as being the most responsible for day-to-day decision-making and provision of care to the elder who has a self-care limitation which makes it difficult to care for oneself (MSHA1 Research Group 1995; Schultz & Quittner, 1998).

**Study Groups: Models of Service Delivery**

Case management services through the CCAC of Halton were part of both study groups. This service consisted of intake, eligibility assessments, and regular ongoing eligibility assessments by the CCAC case manager. Standard case management services, following
admission, for the management of frail elderly clients receiving personal support services included in-home reassessment visits by the CCAC case manager:

- when clients’ condition changes, e.g. when client is in unstable medical condition;
- when assessing the need for additional personal support or other in-home services due to an identified change in clients’ condition;
- yearly thereafter to reassess service requirements and the care plan (Community. Care Access Centre (CCAC) of Halton, 1998).

Control Group (Usual Care)

The control group represents the standard model of care for frail elderly clients who are assessed as eligible for personal support services through the CCAC in a Canadian setting. As standard routine, the CCAC Case Manager determined eligibility and priority level for home care services and decided the amount and level of personal support and other services required on admission to the programme and ongoing based on predefined criteria.

Experimental Group (RN Health Promotion and Preventive Care)

Clients and caregivers receiving the RN health promotion model of service delivery received standard care provided by the CCAC plus regular in-home or telephone contacts by a Registered Nurse over a period of 6-months. Utilizing a client centred approach to care, the visit encompassed both health promotion and preventive care. Preventive care included primary prevention (prevention of problems from occurring in the first place), secondary prevention (early detection of health problems), and tertiary prevention (to avoid further decline) (Maville & Huerta, 2002). Client centred care was defined as “an approach in which clients are viewed as whole persons; it is not merely about delivering services where the client is located. Client
centred care involves advocacy, empowerment, and respecting the client’s autonomy, voice, self-determination, and participation in decision-making” (RNAO, 2000).

Application of the Model of Vulnerability to the Design of the Study Intervention

The model of vulnerability (Rogers, 1997) provided the conceptual approach to the development; implementation and evaluation of a health promotion and preventive care intervention (Figure 3). Theory is essential to both the design and evaluation of health promotion programmes due to its explanatory and predictive capabilities, thereby enhancing the generalizability of the results (Green, 2000; Nutbeam, 1999). Operationalization of the model of vulnerability was a complex process that involved extensive research and preliminary groundwork that included:

1. Evidence from the literature evaluating the effectiveness of home based health promotion and preventive care to identify gaps in the literature as well as ‘best’ practice.
2. Evidence from the literature on risk factors for functional status decline.
3. Operationalization of the concepts of health promotion and preventive care to identify strategies for health promotion and disease prevention.
4. Information on the current home care delivery system for this population including practice patterns.

In a recent meta-analysis of home visiting programmes, Elkan et al. (2001) recommended that a greater focus be placed on the process of delivering care, including a description of the components of the home visiting intervention. The vulnerability model provides a schema of the basic components of a health promotion and preventive care intervention for enhancing health. Specifically, the study intervention was designed to alter the level of vulnerability and, thus expenditure of use of health and social services, by bolstering personal resources and/or
enhancing environmental supports - both of which are considered determinants of health (Rogers, 1997). The study intervention focussed on both the client and caregiver as the recipients of care and utilized a client centred approach. Client centred care is an approach in which “clients are viewed as whole persons; it is not merely about delivering services where the client is located. Client centred care involves advocacy, empowerment, and respecting client’s autonomy, voice, self-determination, and participation in decision-making” (RNAO, 2000).

Bolstering Personal Resources

Proactively Identifying At Risk Frail Elderly Clients

A key component of successful home visiting programmes for the elderly is a multidimensional assessment (Stuck et al., 1993b; Stuck et al., 2002). During the in-home visit, the RN conducted a functional health assessment of the client, emphasizing physical, psychological, and social functioning, and identified any emergent or predictable changes in the client’s condition. This included assessing acquired and modifiable personal resources such as coping skills, trauma, presence of disease, lifestyle, and recent events (Rogers, 1997), in order to identify unrecognized problems and risk factors for functional decline.

In a systematic review of the literature, Stuck et al. (1999) identified several key risk factors for functional decline among community-living people that can be classified as personal resources: cognitive impairment, depression, disease burden (co-morbidity), increased and decreased body mass index, lower extremity functional limitation, low level of physical activity, no alcohol use compared to moderate use, poor self-perceived health, smoking and vision impairment. This aspect of the intervention reflects both primary prevention (prevention of health problems from occurring in the first place)\(^8\), and secondary prevention (early detection of health problems)\(^9\) (Maville & Huerta, 2002). Assessment findings and the plan of care were
documented using the existing documentation forms, which were unique to each community-nursing agency.

One of the limitations in the literature evaluating preventive home visits for elderly persons is the lack of focus on emotional health outcomes of clients such as depression. Depression has been identified as a key risk factor for functional status decline in community-dwelling elderly people (Murphy, 1982; Stuck et al., 1999). A recent Canadian report of home care explored the capacity of the home care system to meet the mental health needs of older persons. This report suggested that it is rare for home care services to focus on mental health issues. Home care providers have reported lack of knowledge or fears about mental illnesses, and uncertainty about the best ways to support people (Parent et al., 2000). One of the key standards that emerged from this report for meeting the needs of people with mental health issues was access to home care for people with serious mental illness. Any individual with a primary diagnosis of serious mental illness should have their mental health needs identified and assessed with a standardized tool (Parent et al. 2000).

In a recent review of the literature on questionnaires for depression, Gilbody, House and Sheldon (2001), concluded that the recognition of depression seems to be increased only when there is some form of screening procedure, whereby an instrument is administered, scored by someone other than the clinician, and the results of those with high scores only fed back to the clinician. This feedback is most effective when it is accompanied by an educational programme, and designated outside referral agencies that will assume responsibility for management (Gilbody et al., 2001). The recommendations from this review provided the framework for early detection of depressive symptoms in subjects and their caregivers.
The nurses utilized the Centre for Epidemiologic Studies Depression Scale (CES-D) (Radloff, 1977) as a screening tool to assess the frequency of depressive symptoms in both the elderly study participant and the caregiver. The CES-D was formally administered and scored by the study nurses on the second in-home visit. Following this, the nurses utilized the questions in the CES-D for ongoing assessment of depressive symptoms in both the frail elderly client and the caregiver. Respondents were asked to indicate how frequently they experienced 20 different symptoms within the past week on a scale of 0 (rarely) to 3 (most or all of the time). Total scores can range from 0 to 60 with higher scores indicating higher levels of depressive symptoms. The questions on the CES-D identified the presence of depressive symptoms but not the disorder (Depression Guideline Panel, 1993).

The CES-D should identify possible or probable cases of depression, without overwhelming the practitioner with too many false positives that could potentially lead to unnecessary or costly follow-up assessment and/or treatment. With this in mind, as well as the potential for stigma and resistance involved in the identification of depression, the cut-off score in this study was set at 21/60 in order to obtain the best balance of false positives and negatives. The rationale for this cut-off score is described in detail in the following section on outcome measures. If subjects scored 21 or more on the CES-D, they were referred to the Family Physician for further assessment and management. With the client’s consent, the nurse documented the depressive symptoms that the client was displaying using a standard letter, which was sent directly to the family physician (see Appendix A for complete CES-D scale and letter to physicians). A copy of the letter was also given to the client and/or caregiver. The nurse also offered to contact the physician directly to book an appointment for follow-up. The appointment date, time, and physician’s name was included in the letter. The success of this
communication mechanism was dependent upon whether the nurse implemented the letter and
whether the family physician complied with the recommendations.

Proactively Addressing Identified Problems

Consistent with a participatory model of health promotion, identified risk factors or
health issues were addressed through interventions that were developed, implemented, and
evaluated together with individual clients and their caregivers. Clients and their caregivers were
encouraged to be responsible for, and actively participate in, their own care. The main focus of
the visit was on mutual identification of goals and the development of personal health skills,
utilizing a problem-solving approach, with referral to appropriate community services. At each
visit, the client and caregiver’s health plan was reviewed, new problems were identified, healthy
lifestyle behaviors were reinforced, existing problems were monitored, and encouragement was
given.

The nurse helped each client devise a personal health plan based on his/her needs in the
areas of health care or health problems addressing modifiable and acquired personal factors such
as disease management, lifestyle modifications, and coping skills that can affect the level of
vulnerability (Rogers, 1997). Specific short- and long-term goals were outlined in relation to
each of these factors for this 6-month intervention. Specific strategies were implemented to
avoid or reduce risk to health and well being. This approach is consistent with tertiary
prevention, which seeks to address a combination of risks or factors (Hodgson, Abbasi, &
Clarkson, 1996) to avoid further decline (Maville & Huerta, 2002).

Consistent with successful health promotion programmes (Hodgson et al., 1996), the
nurse used a combination of intervention methods to empower individuals and to promote
positive attitudes, knowledge, and skills to maintain and enhance health (Maville & Huerta,
These methods included providing health education; encouraging subjects to be independent enhancing their independent decision-making skills, and ability to participate in self-care. Coping skills are one of the acquired personal factors that affect vulnerability (Rogers, 1997).

**Bolstering Environmental Supports**

*Increasing Level of Perceived Social Support*

In a systematic review of the literature, Stuck et al. (1999) identified low frequency of social contacts as a key risk factor for functional decline among community-living people. Social support is a major determinant of vulnerability and increased levels of support can bolster a client’s environmental resources (Rogers, 1997). However, the literature evaluating the effectiveness of health promotion and preventive care interventions is limited by the lack of focus on perceived social support. One of the characteristics of a high quality health promotion intervention is that it includes the client’s social network, i.e. caregiver (Hodgson et al., 1996). The role played by family caregivers in meeting the needs of the frail elderly has been extensively documented in the literature (Greene & Monahan, 1989). Therefore, in this study, the nursing intervention was designed to identify and address the needs of the caregiver as well as the frail elderly subject. Specifically, the nurse assessed the ability of the caregiver to cope with the everyday stress and problems associated with caregiving, and provided various types of supports as required.

*Providing an Individualized and Interdisciplinary Approach to Care*

One of the key components of successful home visiting programmes for the elderly is an individualized and interdisciplinary approach to care with an established team, thus providing continuity of provider. The importance of developing trusting and caring relationships between
clients and home care nurses to the delivery of effective nursing care has been well documented in the literature (McNaughton, 2000; Trojan & Yonge, 1993). In a review of the qualitative research on home visiting, McNaughton (2000) found that the success of specific interventions in a visit, such as health education, depends on the ability of the nurse to get to know and build a relationship with the client. Development of a trusting and caring relationship with the client is a complex and multi-stage process that occurs over a period of time (McNaughton, 2000; Trojan & Yonge, 1993). Based on this, subjects were assigned a primary nurse who visited the client and caregiver (if applicable) during the entire intervention period.

In order to promote an individualized and interdisciplinary approach to care, formal mechanisms were put into place to promote a collaborative working relationship between the study nurses, the CCAC Case Manager, the primary personal support worker assigned to the study client, and the family physician.

Guidelines for communication between the nurse and case manager were reinforced and consistent with current home care practice. Subjects receiving personal support services through the CCAC had a minimum of two joint visits with their primary personal support worker (PSW) and the study nurse over the 6-months of the intervention. The joint visits occurred on the second and final in-home visit. The overall goal of the joint visits was to promote teamwork, continuity of care, and client autonomy, independence, and compliance with the plan of care. The framework for the joint visit is depicted in Figure 4. Between these two joint visits, additional joint visits were arranged as required. In order to promote the collaborative nature of the intervention, the nurses were expected to communicate and consult with the PSW on a regular basis during the study. The mode of communication between the nurse and the personal support worker was agency specific, and occurred through direct verbal communication or
through documenting in the client record that remained in the home. The nurses reported any changes in the client care plan, related to the role of the personal support worker, to the homemaking supervisor.

A major challenge of in-home preventive programmes is their integration within the primary care system (Stuck et al., 1993a). In this Canadian home care setting, the nurses worked independent of the primary care physician. Therefore, the success of the programme was dependent upon whether or not the nurse communicated the detected problems and recommendations to the primary care physician and whether the primary care physician complied with the recommendations. The importance of communication between the study nurse and the family physician is highlighted by the fact that upon completion of the 6-month study period, it was expected that most of the clients would be discharged from formal home care to care provided by their primary care physician. One mechanism for promoting communication between the nurse and the Family Physician was the letter that identified clients as exhibiting depressive symptoms (see Appendix A for letter to physicians).

**Coordinating Access to Community Services**

Another key component of successful home visiting programmes for the elderly and an important role of the nurse in health promotion is identification of the need for and coordination of community services. This included advocating for client’s needs and facilitating access to services to address these needs. The success depended upon whether or not clients were able to access services within the current climate of fiscal constraint. Each nurse and study client receiving the RN augmented intervention was given a directory of health and social services, which included a list of community mental health resources for this local region.

*Intensity, Duration and Cost of the Study Intervention*
The literature suggests that both initial and ongoing home visits and follow-up is an important factor contributing to the success of health promotion and preventive care interventions. Based on this, the nursing group received a minimum of one contact per month by a RN over a 6-month period (minimum 6 contacts). These contacts consisted mainly of in-home visits. In exceptional circumstances, the nurse telephoned the client in place of a home visit. The average time between randomization and the first nursing visit was 5 days. The initial assessment served as the basis for a personal health plan, which was developed jointly with the client. The second and final contacts were also home visits, which included a joint visit with the subject’s primary personal support worker if the client was receiving personal support services during this time frame. Because the intervention was focussed on both the client and caregiver, whenever possible, visits were arranged to accommodate available caregivers.

Consistent with a client centred approach to care, the type, frequency, and duration of the remaining nursing contacts were based on client and caregiver needs and preferences. Between the visits, subjects could also contact the nurse by telephone to discuss problems or to ask for an extra visit. The average duration of the visits was 60 minutes. If subjects were institutionalized for less than two weeks during the intervention period, the visits continued as before. If a subject required more intensive nursing services during the intervention period (> 3 visits per month), the client was discharged from the study intervention, referred to CCAC nursing services, and interviewed at the 6-month follow-up period.

The estimated cost of the 6-month intervention was $228.00 (Canadian) per client based on current CCAC Nursing rates or an initial investment of $556.00 (Canadian) per person for 1 year. The main components and the flow of the study intervention is depicted in Figure 5.

*Study Personnel*
Initially, the study initially employed 9 Registered Nurses from two community nursing agencies that had current service contracts with the CCAC. Each nurse was responsible for conducting the home visits in one geographical district within the Region of Halton. The study nurses level of experience with home visiting ranged from 2 to 30 years. The majority of the study nurses had a Nursing Diploma from a Community College. Only one nurse had a Bachelor of Science in Nursing (BScN). Several of the nurses had additional education in areas such as physical assessment, palliative care, wound care, oncology, and foot care.

**Study Procedures**

*Assessment of Setting*

To understand the background in which the intervention was being delivered and if changes had occurred over the duration of the study, an environmental analysis of the CCAC of Halton was conducted prior to the initiation of the study and upon study completion.

*Developing a Model of Collaborative Research*

Operationalization of the model of vulnerability necessitated an understanding of the current home care delivery system for a frail elderly home care population, including practice patterns. This involved six organizations and their providers: the regional home care organization (CCAC of Halton), two visiting nursing agencies with the CCAC (VON Halton Branch and SEN Community Health Care), and three homemaking services provider agencies with the CCAC (VON Health Services Division - Halton Branch, Para-Med Home Health Care - Halton Branch, Canadian Red Cross Homemakers – Halton Branch). One of the criteria for determining the usefulness of the results of a study to clinical practice is whether or not the intervention is feasible in a given context, and whether the intervention ‘fits’ within the existing
system (Roberts & Bennett, 1997). Therefore, the study intervention was designed to fit within the existing Canadian home care delivery system for a frail elderly population.

A number of mechanisms were put into place to provide these organizations with information regarding the study progress, and opportunities for direct collaboration and participation in the research process. As depicted in Figure 6 the result was the development of a collaborative research model. This collaborative forum contributed to the design of a comprehensive health promotion and preventive care intervention, as well as confirm the ownership, commitment and legitimacy of the participating organizations to the goals and completion of the study - all essential principles of collaboration (LeGris et al., 2000).

The design and methods of the study, took into account what was known and considered feasible with respect to time, expected participation by staff and managers, and desired outcomes. Service and research role conflicts were addressed as anticipated. “Deliberate strategies ensured that the research requirements would not interfere with the service provision and, alternatively, that the rigour of the research would not be compromised” (LeGris et al., 2000, p. 70). While clinicians’ roles reflect values of relevance, realism and immediate applicability, researchers value the adherence to the rigour of the design, precise data gathering techniques and a clearly stated research problem (Baker, Boyd, Stasiowski, & Simons, 1989).

The development of this collaborative model was complex, involving extensive groundwork over a 5-month period prior to commencing the study. Briefly, the steps involved:

**Initiation and Entry**

- Identification of decision-makers at clinical, managerial and organizational levels for each of the participating organizations.
• Confirming with decision makers the importance of the research question to current research priorities at local, provincial and national levels.

• Creating awareness of the study and initiate interest and involvement for all levels of the organizations through formal presentations, individual team meetings, and electronic mediums.

• Assessment of the organizational climate, including previous experience and knowledge of the research process, and human resource issues/capacities.

• Identify and help to blend clinician and researcher values and needs.

Development of the Study Intervention

• Scheduled problem-solving meetings with management and front-line staff at the CCAC to define the study process, the roles and responsibilities of Case Management staff in relation to the study, and resource requirements.

• Scheduled problem-solving meetings with the Community Nursing agencies involved in providing the study intervention to define the study intervention, the roles and responsibilities of the nurse in relation to the study intervention, and resource requirements.

• Scheduled problem-solving meetings with management staff from the three CCAC homemaking service provider agencies to define the structure and process of the joint visit.

Development of Mechanisms for Ongoing Collaboration

• Establishment of a steering committee for the study that included management and front-line staff from the CCAC, the investigator, and the project co-coordinator. The steering
committee provided a collaborative forum for the initiation, implementation, and completion of the study. The steering committee met monthly for the first year of the study, and then every two months for the remainder of the study. The specific responsibilities of the committee included: a) identifying and addressing issues related to service and research role conflicts, b) ensuring that the research requirements do not interfere with service provision and, alternatively, the rigour of the research is not compromised, c) easing access to decision-makers and ensure an ongoing collaborative problem-solving process, and d) monitoring the progress of the study, and address any issues related to the study in a proactive and timely manner.

- Development of guidelines and identification of mechanisms for ongoing communication between the investigator, the CCAC case management staff, and the Community Nursing and Homemaking service provider agencies with the CCAC.
- Regular (monthly) e-mail contact with management and front-line staff at the CCAC of Halton regarding the progress of the study.
- Regular (monthly) e-mail contact with management from the Community Nursing agencies and the CCAC homemaking service provider agencies regarding the progress of the study.
- Bimonthly meetings with management and front-line staff from the Community Nursing agencies with the CCAC who were directly involved in providing the study intervention.

Linkage with Decision-Makers at Local, Provincial, and National Levels

- Identifying, developing and maintaining ongoing linkage and exchange with local, provincial, and national decision-makers involved in community care of the elderly in order to maximize the potential impact of the research. This included working closely
with decision makers to identify implications of the results for policy and effective knowledge transfer strategies. Some of the mechanisms for ongoing linkage and exchange include letters, teleconferences, e-mail, newsletters, poster presentation, formal presentations, and voicemail. Summaries of the agencies that were contacted, the mode of dissemination, and response (including letters of support) to the research are available upon request.

Study Nurses and CCAC Case Management Staff: Training

Scheduled orientation sessions were held with all CCAC health professional and clerical staff to provide a general overview of the study prior to its commencement. This was achieved through all staff meetings and individual meetings with each of the case management teams at the CCAC. The orientation focussed on the project goals, expectations of professional and clerical Case Management staff with respect to the study, and addressing staff questions and concerns. Orientation booklets were developed in collaboration with the CCAC and distributed to all CCAC staff during the orientation. In addition, a study information/resource binder was developed and distributed to all CCAC case management teams. Study referral sheets and information sheets were distributed to each individual Case Management team.

A total of 9 nurses and 2 nursing supervisors from two community nursing agencies that had current service contracts with the CCAC initially underwent a period of training for the study. To standardize the intervention, the study nurses and their supervisors received the same training. In addition, the nurses were given written guidelines for the assessment. The assessment included both personal resources and environmental supports (Rogers, 1997). Additional information was given to enable them to assess for mood disorders, i.e. depression.
The study nurses were also educated regarding the nature and management of depression, and given a list of various community mental health agencies within the Halton Region.

The investigator developed specific written guidelines for communication between the CCAC Case Manager, homemaking agency, and investigators. Guidelines for communication with the CCAC Case Manager were consistent with current CCAC policy. The framework for the joint visits was distributed to the study nurses and the personal support workers (see Figure 4). Information regarding the personal support worker’s scope of practice was also distributed to the study nurses. Recruitment and data collection commenced upon completion of this phase of the study.

Recruitment and Consent

Elderly subjects and their caregivers were recruited from the CCAC of Halton, Ontario. Access to home care is initiated by referral to the CCAC by community, hospital, or self-referral. Following referral, clients are assigned to a case manager who determines eligibility for home care services, the type and amount of services required, and which service agency is appropriate for the care required.

Community Care Access Centre (CCAC) Case Managers reviewed new and eligible referrals for personal support services at the CCAC of Halton on a daily basis to identify potential subjects for the study. An eligibility screening form was used by the Case Managers to identify potential study participants. Case Managers were also given written guidelines for approaching potential subjects. Case Managers contacted potential participants (telephone and in-person) within 5 days of referral to the CCAC to introduce the study and obtain a verbal consent to participate. Within two or three days of obtaining a verbal consent, trained interviewers contacted potential participants to arrange an in-home interview. Interviewers also
contacted available caregivers of eligible elderly subjects if the Case Manager obtained verbal consent for their participation from the elderly subject.

At first contact with the potential participant and the caregiver (if available), the interviewers explained the study in more detail including their rights regarding participation, safeguards to preserve confidentiality, and the risks and benefits of participation. The interviewers distributed an information sheet to eligible clients and caregivers during this initial (baseline) interview. Potential participants were told that they have a 50% chance of receiving nursing services in addition to their other homecare services. The interviewers obtained informed (written) consent from those clients and caregivers that were willing to participate in two interviews at baseline and 6 months.

The client’s primary care physician was contacted using a standard letter regarding the client’s participation in the study, but not their group allocation (see Appendix B for study referral sheet, guidelines for obtaining verbal consent, information letter, consent forms, and letter to physicians). When a client was not mentally capable to consent, the attorney for personal care as identified by the CCAC Case Manager was approached to obtain the written consent and answer questions on behalf of the client. The sampling and study flow diagram is depicted in Figure 7.

The investigators did not have direct contact with the subjects. All eligible subjects and caregivers that consented to participate in the study were told that they were free to withdraw from the study at any time. The decision to withdraw either during or after the study did not impact on the standard care provided by the CCAC.

Randomization
Once an informed (written) consent was obtained, the participants were randomized to usual care or the RN health promotion and preventive care intervention using a computer generated schedule of randomization, which randomly assigns subjects to two groups. Participants who were living together were always allocated to the same group. Available and consenting caregivers were allocated to the same group as their elderly relative/friend. Eligible and consenting participants and their caregivers were not aware of treatment assignment until after randomization, which was controlled centrally by the project coordinator keeping the nurses blind to the randomization schedule. Because of the nature of the intervention (that is, a change in the provision of care), all the CCAC Case Managers concerned were aware of the assignment of clients to the intervention group.

Data Collection

Data were collected from participants at two points in time: upon receipt of an informed (written) consent (T1), and at six months (T2) following randomization. Information was obtained from a variety of sources including: a) a structured personal (in-home) interview with clients and available caregivers at baseline (before randomization) and 6 months following randomization, b) the CCAC admission assessment form, and c) monthly visit reports from the nurses. An in-home interview was utilized to obtain a high response rate and eliminate bias related to non-response. When an in-home interview was not feasible, interviews were conducted via the telephone.

The 10-item Short Portable Mental Status Questionnaire (SPMSQ) (Pfeiffer, 1975) was administered (prior to randomization and at 6 months) as a screening mechanism to determine if clients and available caregivers were ineligible to complete the questionnaires for the study. The SPMSQ is short, easily administered and has been designed, tested, standardized and validated.
Test-retest correlations ranged between 0.82 and 0.83. Greater than 4 errors on the SPMSQ indicates some degree of intellectual impairment (Pfeiffer, 1975) (see Appendix C for complete SPMSQ). When a client was not mentally capable to consent (> 4 errors), the attorney for personal care (as identified by the CCAC Case Manager on the study referral sheet) was approached to obtain the written consent and answer the questions on behalf of the client. If the client was physically unable to participate in the interview, the attorney for personal care or caregiver was asked to respond on behalf of the client. When a proxy respondent was used, the reliability and completeness of self-reported data for subjective health measures such as depression, self-rated health, and perceived social support may have been limited.

Trained interviewers who were blinded to the treatment assignment, scheduled a follow-up in-home interview with study participants 6 months after randomization. All subjects were contacted for the 6-month interview including those in hospitals and long-term care facilities. For participants in the RN augmented intervention, interviews were scheduled following completion of the final in-home nursing visit. Elderly study participants completed the questionnaires with the interviewers through a structured interview that appraised their functional status and quality of life, mental status (level of depression), coping ability, perceived social support, and use of health and social services. Available caregivers also completed questionnaires with the interviewer through a structured interview that appraised their role functioning related to physical and emotional health, social functioning, mental status (level of depression), level of burden associated with caregiving, and use of health and social services. With an elderly population, this method of data collection helped to avoid loss of data due to visual deficits, literacy problems or difficulties related to feeling too ill or fatigued.
Clients were measured (prior to randomization and at 6 months) in terms of their age, gender, education, culture, income, and living arrangements using a sociodemographic questionnaire developed by the investigator. Additional information was collected from the CCAC admission assessment form on the source of referral and the client’s primary and secondary diagnoses (see Appendix C for complete sociodemographic questionnaire for elderly study participants). Caregivers were measured (prior to randomization and at 6 months) in terms of their age, gender, relationship to elderly participants, education, culture, and income using a sociodemographic questionnaire developed by the investigator (see Appendix C for complete sociodemographic questionnaire for caregiver participants).

Outcome Measures

Elderly Study Participants

The conceptual framework and the literature guided the selection of study variables and their measures. The main goal of the study intervention was to reduce the level of vulnerability and enhance health outcomes thereby reducing expenditure of use of health and social services for frail elderly home care clients. This was achieved through bolstering personal resources and environmental supports known to influence health and functional status. A summary of the constructs in the vulnerability model and the corresponding study variables and their measures for elderly study participants is illustrated in Table 1 and Figure 8.

The primary measure of effect was functional health status and quality of life. The secondary measures of effect included expenditures for the reported use of health and social services, mental health (presence of depression), coping style and perceived social support. Consistent with the model of vulnerability, the outcomes are context dependent, emphasizing the subjective perception of the individual. Therefore, in evaluating a proactive health promotion
and preventive care intervention, a measure, which provides data on the subjective assessment of health outcomes, was considered appropriate.

The selection of outcome measures was also guided by recommendations from the literature regarding the study of frail elderly people (Bowsher et al., 1993). Two commonly reported reason for the unsuccessful use of available measures with elderly people is the low energy or high fatigue level of frail elderly people, and the inability to understand what is expected because of reduced cognitive abilities. This is particularly true for those with either acute or chronic illness (Bowsher et al., 1993). Therefore, outcome measures were also selected on the basis of their length, level of complexity of questions, and ease of administration.

*Primary Outcome Measure: Functional Health Status and Quality of Life*

In this study, functional health status and quality of life was chosen as the primary outcome. Functional health status and related quality of life is a modifiable acquired personal factor which influences, and is influenced by, the level of vulnerability (Rogers, 1997). This variable was measured using Version 2 of the Medical Outcome Study Short Form (SF-36) Health Survey (Ware, Kosinski, & Dewey, 2000) (see Appendix C for complete MOS SF-36 Health Survey). The SF-36 health survey was originally developed for the Medical Outcomes Study (Ware & Sherbourne, 1992).

The SF-36 has been widely tested and the development and validation of this instrument has been extensively documented in a variety of client populations, including the frail elderly (Stewart & Ware, 1992; McHorney, Ware, & Lu, 1993; McHorney, Ware, & Raczek, 1994; Ware, Snow, Kosinski, & Gandek, 1993). The SF-36 is a subjective and multidimensional measure of general health status that is consistent with the conceptual framework for this study (Rogers, 1997). A distinct advantage of the SF-36 over other generic measures of health is the
fact that it can be administered in 10-15 minutes. However, there has been very limited research analysing the SF-36 as an outcome measure for evaluating nurses’ contribution to client outcomes (Irvine et al., 2000). In a comparison of the SF-36 with the Quality of Life Profile: Senior Version (QOLPSV) in a home health care setting, Irvine et al. (2000) found the SF-36 to be more sensitive to changes over time, and more sensitive to several nursing variables including skill mix and the intensity of the client’s health status than the QOLPSV.

The SF-36 is a multi-dimensional 36-item instrument that consists of a set of eight multi-item scales with 2-10 items and two summary measures. The scales measure the following dimensions of health: physical functioning (10 items), role limitations related to physical problems (4 items), bodily pain (2 items), general health perception (5 items), energy/vitality (4 items), social functioning (2 items), role limitations related to emotional problems (3 items), and mental health (5 items) (Ware & Gandek, 1998). There is an additional single item asking respondents about health change over the past year. Each of these eight scales is scored separately on a scale of 0 to 100 - the higher the score, the more favourable the health status (McHorney et al., 1993).

These eight scales contribute to two summary scores, the Physical Health Component Summary (PCS), and the Mental Health Component Summary (MCS), which were used in this study. The Physical Health Component Summary measure includes the physical functioning, role limitations related to physical health, bodily pain, and general health perception scales. A sixth item is included in this domain but is not included in the score: amount of change in general health status over a 1-year period. The mental health component summary measure includes the energy/vitality, social functioning, role limitations related to emotional health, and mental health scales (Ware & Kosinski, 2001). Figure 9 provides a graphic summary of the
items and corresponding scales and summary measures for the SF-36 as described by Ware and Kosinski (2001, p. 6). Scores for each of the eight scales and the two summary measures were calculated in this study.

After data entry, items, scales, and summary measures were scored in 3 steps as recommended by Ware (1993):

1. Item recoding: Data was checked for out of range values and the following 10 items were reverse scored: 9 (d & h), 6, 9 (a & e), 1, 11 (b & d), 7 & 8.

2. Compute raw scale scores.

3. Transform raw scale scores to a 0 (worst possible health state) to 100 (best possible health state) transformed scale score.

The original 8 dimensions on the SF-36 health survey were reduced to these two summary measures in order to lower the number of statistical comparisons, and thus reduce the role of chance in obtaining statistically significant differences in comparisons (McHorney et al., 1994). The PCS and MCS summary measures were identified through factor analysis. The summary measures have been shown to be reliable and to provide results that reflect those of the eight dimensions (Jenkinson, Layte, & Lawrence, 1997). To date, several studies utilizing the SF-36 have established content, concurrent, construct, criterion, and predictive validity of the measure (Ware & Gandek, 1998).

Secondary Outcome Measures

Expenditures for the Use of Health and Social Services

The economic evaluation consisted of an assessment of the use and expenditures for acute hospitalization and other health and social services during the 6-month follow-up period. The hypothesis in this study was that health and social service utilization is an environmental
factor that can influence (Rogers, 1997), as well as be influenced by, the level of vulnerability.

Expenditures for the use of health and social services were measured using the Health and Social Service Utilization Inventory (Browne et al., 2001). It consists of questions about the respondent’s use of eight categories of direct health care services: primary care, emergency room and specialists, hospital episodes and days, emergency room, and use of seven types of other health professionals, and laboratory services. Inquiries are restricted to the reliable duration of recall span as demonstrated through a Canadian study. The reliable recall is restricted to six months for remembering a hospitalization, emergency room visit, and visit to a physician, and 2 days for the consumption of a prescription medication. To calculate annual utilization measures, the various spans of time are extended to yield an annual rate of utilization per category of health service and multiplied times the 2001 unit charges for each service to yield a measure of expenditures for health and social service.

This inventory was also designed to assess direct out of pocket expenditures, e.g. the number and type of medications and indirect costs, e.g. number of days off work. Cash transfer effects of people’s circumstances are assessed by multiplying the amount by the number of cheques received in the previous 2 weeks, e.g. unemployment. This measure has been previously tested and assessed for reliability and validity. High levels of observed agreement (.72 - .99) between the clients’ report and the clinic record were recently reported (Browne et al., 2001) (see Appendix C for complete Health and Social Service Utilization Inventory). In over 17 studies, the use of the health and social service utilization inventory distinguishes groups (palliative care, illnesses with and without depression or poor adjustment, and treated and untreated groups) (Browne et al., 1999).

*Mental Health (Presence of Depression)*
Mental health (presence of depression) was measured using the Center for Epidemiological Studies in Depression Scale (CES-D) (Radloff, 1977). Mental status is a potentially modifiable acquired personal factor that affects the level of vulnerability (Rogers, 1997). The CES-D scale is a 20-item self-reported questionnaire that assesses current frequency of depressive symptoms. Respondents are asked to indicate how frequently they experienced 20 different symptoms within the past week on a scale of 0 (rarely) to 3 (most or all of the time). Total scores can range from 0 to 60; the higher the score, the more depressed. The items on this scale form four subscales assessing: a) depressed mood (7 items), b) psychomotor retardation (7 items), c) lack of well being (4 items), and d) interpersonal difficulties (2 items) (Schein & Koenig, 1997).

Reliability coefficients obtained on the CES-D have been high (0.85 – 0.91) (Himmelfarb & Murrell, 1983), and factor structures are stable (see Appendix A for complete CES-D scale). The four-item factors have been shown to be highly intercorrelated which justifies the use of the total CES-D score on empirical as well as conceptual grounds (Hertzog et al., 1990). This measure of mental status reflects a multidimensional perspective of mental health that is consistent with the conceptual framework for this study (Rogers, 1997).

The CES-D has been shown to be an appropriate tool to measure depressive symptoms in the frail elderly (Davidson, Feldman, & Crawford, 1994; Irwin, Artin, & Oxman, 1999) and has been extensively used in research among older adults (Blazer, Burchett, Service, & George, 1991; Davidson et al., 1994; Roberts, Kaplan et al., 1997). The CES-D demonstrates good internal consistency (Cronbach’s α=.84) for the general population (Corcoran & Fisher, 1987) and correlates strongly (R=. 87) with the Beck Depression Inventory (Santor et al., 1995).
Another advantage of the CES-D for a frail elderly population is its ease of administration (Radloff & Teri, 1986).

Radloff (1977) suggested that a cut-off score of 16 on the CES-D could discriminate between depressed versus non-depressed clients. Using a cut off of ≥ 16, the CES-D scaled had high sensitivity and specificity for depressive symptoms in the previous month in a community based sample of older adults (Beekman et al., 1997). However, other studies have questioned the use of the standard cut-off score of 16 to determine ‘caseness’, claiming that this score is too low (Himmelfarb & Murrell, 1983; Husaini et al., 1980). Several alternative cut-off scores have been suggested in the literature for depressed versus non-depressed clients. Shulberg et al. (1985) found that in a group of primary care outpatients that the use of the standard cut-off score yielded nearly perfect sensitivity but very poor specificity as compared to DIS classification of depression. As a result of their findings, these researchers suggested an alternative cut-off score of 27, which was found to substantially reduce the rate of false-positives without sacrificing the sensitivity of the instrument.

Himmelfarb & Murrell (1983) compared cut-off scores of 20 and 23 and concluded that a cut-off score of 20 yielded the optimal balance between false positives to false negatives for older adults. Similarly, Schein & Koenig (1997) found that a cut-off score of 20 provided the most accurate diagnostic score in the absence of other information. The standard cut-off score of 16 was found to produce an unacceptably high false-positive rate (Schein & Koenig). Other authors have suggested a cut-off score of 23 (Husaini et al., 1980).

Schein & Koenig (1997) suggest that the reason for the need for a higher cut-off score for the older adult is the influence of co-morbidity on depressive symptoms. Individuals with chronic conditions may score high on the somatic items in the CES-D because they represent
symptoms of current medical problems rather than depressive symptoms. Mills (2001) examined the relationship between self-reported depressive symptoms and chronic illness among older adults. They found that self-reports of depressive symptoms were greater among those individuals reporting chronic conditions compared to those who did not. Based on this review of the literature, the investigator chose a cut-off score of $\geq 21/60$ to distinguish between depressed and non-depressed elderly clients.

Perceived Social Support

Perception of social support (subjective) was measured using the Personal Resource Questionnaire 85 (Part Two) (Weinert & Brandt, 1987). Perceived social support is a potentially modifiable environmental factor that affects the level of vulnerability (Rogers, 1997). The PRQ85 – Part Two is a 25-item scale that measures perceived social support along the following dimensions: a) provision for attachment/intimacy, b) social integration: being an integral part of a group, c) opportunity for nurturing behaviour, d) reassurance of worth as an individual and in role accomplishments, and e) the availability of informational, emotional, and material help. These dimensions were derived from Weiss’s (1974) model of relational functions. The scale ranges from 1 to 7 indicating low to high degree of agreement with 1 being the lowest and 7 the highest. One item within each dimensional subscale (d, g, j, p, & x) is negatively worded and was recoded to reflect the positive direction of the other twenty items (Weinert & Brandt) (see Appendix C for complete PRQ85 – Part Two Questionnaire).

The maximum score that can be attained is 175 - the greater the score, the greater the perception of social support. Previous studies reported reliability coefficients for the total scale, which ranged from .86 to .93 using Cronbach’s Alpha. Reliability coefficients for the subscales ranged from .54 to .90 (Weinert, 1987). Construct and content validity for the PRQ85-Part Two
were assessed as good on the basis of three separate studies involving older adults (Brandt & Weinert, 1981; Weinert, 1987; Weinert & Brandt, 1987). The basic premise is that the PRQ85-Part Two measures the multidimensional construct of social support. The idea is not to delineate subscales, but to measure it as a global construct (Weinert & Brandt, 1987). Therefore, the total scale score was calculated and reported for each frail elderly subject. The PRQ85-Part Two is based on a subjective conceptualization of social support that is consistent with the conceptual framework for this study.

Coping Style

Coping style was measured using the coping questionnaire (Moos, Cronkite, Billings, & Finney, 1985) (see Appendix C for complete Coping Questionnaire). Coping style is a potentially modifiable acquired personal factor that affects the level of vulnerability (Rogers, 1997). The coping questionnaire focuses on the cognitive and behavioural coping responses that individuals use when a stressful event has occurred. Respondents are asked to rate their frequency of use (4-point scale) of 33 different coping responses. Responses are classified into two major categories: (a) the method of coping which includes active cognitive coping, active behavioural coping, and avoidance coping, and (b) the focus of coping which includes problem solving, logical analysis, emotional distress, affective regulation and information seeking (Moos et al., 1985).

For this study, we revised and expanded the original coping questionnaire (Moos et al., 1985) by outlining a classification scheme in which responses are categorized within three domains of coping that vary according to their focus of coping:

1. Appraisal focussed coping: logical analysis - efforts to understand the stressor and assess the consequences of possible coping strategies.
2. Problem-focussed coping: (a) seeking information - trying to find out more about the situation and obtaining guidance from social network members, and (b) problem-solving - taking specific action to directly deal with a situation, and negotiating and compromising toward a resolution.

3. Emotion-focussed coping: (a) affective regulation - direct efforts to control stress-related emotions by suppressing impulsive acts, and (b) emotional discharge - verbal expressions of unpleasant emotions and indirect efforts to reduce tension, for example, by eating or smoking more (Billings, Cronkite & Moos, 1983).

Figure 10 provides a graphic summary of the items and corresponding categories for the coping questionnaire.

*Description and Dose of the Nursing Intervention*

The study nurses completed a monthly report, which identified the frequency of in-home visits and telephone contacts with each subject randomized to the nursing health promotion intervention and their caregivers. For the purpose of this study, dosage refers to the frequency and duration with which an intervention is given to produce the expected changes in outcomes (Scott & Sechrest, 1989). Frequency refers to the number of times the home visits and telephone contacts are performed over the 6 month follow up. Duration refers to the total length of time the intervention is to be implemented for the expected effects to take place (Scott & Sechrest). The dose or frequency of the intervention was based on the study protocol combined with client needs, and the nurses clinical experience and expertise. Engagement rate in this study is equivalent to the frequency of the intervention and was defined as at least one home visit or telephone contact for treatment.

*Caregivers*
The vulnerability model guided the selection of outcomes and their measures. A summary of the constructs in the vulnerability model and the corresponding study variables and their measures for caregiver participants is illustrated in Table 2. Caregiver variables were analysed in two ways: (1) as a direct measure of the effect and expense of the nursing health promotion intervention on caregivers of elderly study participants, and (2) as a potentially modifiable environmental factor that affects the level of vulnerability of the elderly study participant (see Figure 11) (Rogers, 1997).

Functional Health Status and Quality of Life

Functional health status and quality of life of the caregiver participants was measured using selected scales in the SF-36 Health Survey (Ware et al., 2000) (see Appendix C for complete MOS SF-36 Health Survey). Three scales in the SF-36 health survey were utilized to measure the following dimensions of health in caregiver participants: role limitations related to physical problems (4 items), social functioning (2 items), and role limitations related to emotional problems (3 items) (Ware & Gandek, 1998). Each of these three scales is scored separately on a scale of 0 to 100 - the higher the score, the more favourable the health status (McHorney et al., 1993).

Role functioning can be defined as the degree to which an individual performs, or has the capacity to perform, activities typical for a specified age and social responsibilities (Sherbourne, Stewart & Wells, 1992). Social functioning can be defined as the degree to which health problems (physical and emotional), interfere with normal social activities (Sherbourne et al., 1992). In a systematic review of the literature, White, Lauzon, Yoffe and Wool-Dauphince (2003) reported that although quality of life has been identified as an important outcome of the caregiving experience, there is little research examining the quality of life of family caregivers.
How caregivers assess their ability to manage the caregiving role has shown to be related to caregiver outcomes (Aneshensel et al., 1995; Boss, Caron, Horbal, & Mortimer, 1990). White et al. (2003) reported that the ability to master the many facets of the caregiving role increases their confidence which in turn, contributed positively to their quality of life.

_Mental Health (Presence of Depression)_

Mental health (presence of depression) in caregiver participants was measured using the Center for Epidemiological Studies in Depression Scale (CES-D) (Radloff, 1977) (see Appendix C for complete CES-D scale).

_Caregiver Burden_

The level of burden associated with caregiving was measured using the Caregiver Reaction Assessment Scale (CRA) (Given et al., 1992) (see Appendix C for complete CRA scale). Caregiver burden is a potentially modifiable environmental factor that affects the level of vulnerability (Rogers, 1997). The CRA is a 24-item multidimensional instrument that assesses the reactions of family members or friends caring for elderly persons with physical or mental impairments. Each item is scored from 1 to 5 from strongly disagree to strongly agree. There are five subscales: (a) esteem, (b) family support, (c) finances, (d) impact on schedule, and (e) impact on health. Five items (C3, C7, C13, C15, & 19) are negatively worded and were recoded to reflect the positive direction of the other nineteen items. These dimensions of caregiving were derived from reviews of research reports describing burdens of caregiving and family members reactions, coupled with a series of in-depth interviews with caregivers (Given et al.). These factors were developed by factor analysis and construct validity was reported as good (Given et al., 1992). Figure 12 provides a graphic summary of the items and corresponding subscales for the caregiver reaction assessment scale.
The caregiver esteem subscale measures the extent to which caregiving imparts individual self-esteem or a sense of value and worth. The family support subscale assesses the extent to which family supports and works together with the caregiver. It also assesses the caregiver’s perception of being “dumped on” or abandoned. The subscale, impact on finances, looks at the “adequacy, the difficulty, and the strain of the financial situation on the caregiver and family” (Given et al., 1992, p. 275). Impact on schedule, the fourth subscale, measures “the extent to which caregiving interrupts usual activities, causes the elimination of some activities, and interferes with relaxation time” (Given et al., 1992, p. 275). The final subscale, impact on health, “measures the caregiver’s physical capability and energy to provide care. It also assesses the caregiver’s health in relation to the caregiving role” (Given et al., 1992, p. 275).

*Expenditure of Use of Health and Social Services*

The economic evaluation consisted of an assessment of the use and expenditures for acute hospitalization and other health and social services during the 6-month follow-up period by caregiver participants. The hypothesis in this study was that health and social service utilization is an environmental factor that can influence (Rogers, 1997), as well as be influenced by, the level of vulnerability. Expenditures for the use of health and social services by caregivers were measured using the Health and Social Service Utilization Inventory (Browne et al., 2001) (see Appendix C for complete HSU inventory).

**Recruitment and Retention Strategies**

Retention is defined as “the continued involvement of research participants over the projected study duration” (Davis, Broome, & Cox, 2002, p. 47). A 6-month follow-up period is
realistic since attrition rates for the frail elderly are higher than for younger subjects (Bowsher et al., 1993). Several strategies were used to enhance recruitment and retention of eligible subjects and available caregivers. In a review of the literature, Davis et al. (2002) identified a number of suggestions for increasing both recruitment and retention of eligible subjects in community based clinical trials. Several of these strategies were incorporated into the study:

- *Establish a project identity.* Study participants are more likely to participate in the study if they can identify and describe it (Davis et al., 2002). A study information sheet and staff business cards printed with the CCAC of Halton and McMaster University logo were distributed to all study participants to establish study visibility and legitimacy with participants.

- *Emphasize study significance.* Participants are more likely to remain in a study if they understand the importance and relevance of the study (Davis et al., 2002). The study purpose and significance was explained to each subject by both the recruiters (prior to obtaining informed written consent) and the interviewers. After informed consent was secured, the study nurses reinforced the significance of the study and the expectations for participation in order to enhance subject retention. The project coordinator and the investigator were also available to participants if they had any further questions or concerns regarding their involvement in the study.

- *Provide interpersonal skill training for project staff.* Several studies have concluded that well trained staff is a critical factor in high retention studies (Bowsher et al., 1993; Davis et al., 2002). The project coordinator and the investigator provided individualized orientation sessions to all project staff including the recruiters, interviewers, and study nurses. In addition, orientation packages were developed which outlined the study
objective, process, role expectations, and communication guidelines. The development of positive communications with subjects has been identified as a key factor for increasing retention in longitudinal studies of frail elderly people (Given, Keilman, Collins, & Given, 1990). This included verbal expressions of appreciation from members of the research team which has also been shown to enhance retention (Given et al., 1990).

- *Individualize data collection.* Respect for subject’s time and flexibility in data collection procedures are factors that have been shown to increase retention (Bowsher et al., 1993; Davis et al., 2002). Recruiters and interviewers approached eligible subjects at a time that was convenient to the subject. A time frame of 5-7 days was allotted between identifying eligible subjects and obtaining a verbal consent. This time frame was implemented because the majority (70%) of new and eligible referrals for personal support services originate from an acute care hospital setting. Clients were often too unwell and/or overwhelmed to be contacted. In some cases, a telephone interview was conducted in place of an in-home interview to help keep participants in the study. A time frame of 2 weeks was allotted between the 6-month post-randomization time and completion of the final 6-month interview. If participants were physically unable to participate in the interview at the designated 6-month follow-up time, they were contacted again within the two-week period to reschedule to help keep these participants in the study.

- *Use a participant-tracking database.* A participant-tracking plan was initiated in a hierarchical manner: first, with repeated telephone calls, second, by communicating with alternate contacts (i.e. family, friends), and third, by contacting the CCAC of Halton. An average of three contacts was made before dropping a participant from the study.
Study Quality Control

Protocol and Data Collection

The procedures for screening for eligibility, recruitment and consent, intervention delivery and monitoring, data tracking, interviewing procedures, data entry and management were delineated in the study protocol and used by the investigator and study staff. All potential participants were recorded and explanations were noted if they did not enter the study. These included reasons for refusal and why specific eligibility criteria were not met.

The nurses involved in the study were monitored on a regular basis and feedback was given to ensure adherence to the intervention protocol. In addition, the study nurses and designated nursing supervisors met together with the investigator and the project coordinator every two months to discuss the study progress and any problems, share information, and to compare experiences. During the meetings, the investigators reinforced aspects of the intervention and addressed any learning needs related to the intervention, i.e. depression screening, assessment of risk factors for functional status decline, communication with the interdisciplinary team. Relevant literature related to the intervention was given to each nursing agency on an on-going basis based on their identified learning needs. Between the meetings, the nurses could contact the project co-ordinator or the principal investigator by telephone with any questions or concerns. The principal investigator also kept in regular contact with managers of the four-homemaking agencies that had current service contracts with the CCAC.

Study outcome data were collected from participants by trained interviewers who were independent from those providing the intervention. Every effort was made to schedule the same interviewer for both the baseline and 6-month follow-up interview. At each point in data collection, the project coordinator scrutinized the questionnaires for any missing or questionable
responses. This way, problems could be corrected immediately with the interviewer and subject if needed. The project co-ordinator used a computer programme to track the study status of participants throughout the project. In addition, the interviewers met with the project coordinator and the investigator on a regular basis to discuss the study progress and any problems. Strategies for recruitment and retention of study participants were evaluated and reinforced on a regular basis with the CCAC Case Manager recruiters, interviewers, and study nurses during the regularly scheduled meetings.

Database

Data were entered into SPSS/PC (Version 11) on a Pentium computer. Where possible, upper and lower limits on response categories were set for each individual variable. Logical errors were detected by the programme and highlighted for the research assistant responsible for data entry to clarify before proceeding with further data entry or analysis. Following data entry, the investigator scrutinized the data for out of range values, any missing or questionable responses, and items that need to be recoded due to reverse scoring.

Statistical Analysis

Representativeness

The characteristics of those deemed ineligible and who were lost to follow-up at any decision point of the study were compared, in aggregate form, to those who completed the study. Statements about the representativeness of the sample were made and the direction of the bias associated with those subjects lost to follow-up was also highlighted. Elderly study participants were compared to all CCAC clients 75 years and older and eligible for personal support services in terms of living arrangement and geographical area of residence. The critical level of significance for all tests was $p < 0.05$. 
Comparability

Elderly participants and available caregivers who completed the 6-month follow-up in both control and experimental groups were compared on their baseline characteristics to determine the equivalence of the groups at baseline using chi-square tests. A paired t-test was utilized to compare the mean number of total errors on the SPMSQ in the two groups at 6 months.

Test of Hypotheses Using Two Group Comparisons

Primary Null Hypothesis

The investigator tested the null hypothesis that there would be no difference in the level of health related quality of life and function over a period of 6-months on the basis of exposure/non-exposure to RN augmented to usual care.

Primary Analysis

A repeated measures analysis of variance was utilized to compare the change in mean scores for each of the eight scales and the two summary measures in the SF-36 health survey between the two groups over the 6 month period (Polit & Hungler, 1997). An analysis of covariance (with pre-intervention scores as covariates) was also utilized to compare the mean scores for the two summary measures in the SF-36 health survey between the two groups at the 6 month follow-up. Analysis of covariance (ANCOVA) is a statistical procedure used to test mean differences among groups on the mean scores on the SF-36, while controlling for pre-intervention scores on the SF-36 (covariate) (Polit, Beck, & Hungler, 2001).

Secondary Analysis

A repeated measures analysis of variance was utilized to compare the change in mean scores on the CES-D, the Personal Resource Questionnaire, the Coping Questionnaire, and the Caregiver Reaction Assessment Scale between the two groups over the 6 month follow-up period.
(Polit & Hungler, 1997). An analysis of covariance was also utilized to compare the mean scores on the CES-D, the Personal Resource Questionnaire, the Coping Questionnaire, and the Caregiver Reaction Assessment Scale between the two groups at the 6 month follow-up. The non-parametric Mann-Whitney U test was used to compare the mean expenditures for use of health and social services by service type between the two groups because utilization data is typically in a skewed distribution. Missing responses were assigned a 0 value in the analysis.

Subgroup Analysis

Selected characteristics of frail elderly subjects were examined (age, presence of depressive symptoms (CES-D score ≥ 21), cognitive status (≥ 5 errors on SPMSQ), problem-solving and logical analysis coping styles, and living arrangement) in terms of their interaction with the approach to treatment to explain the improvement in client’s SF-36 mental health component summary score utilizing multiple regression.

Description and Dose of the Study Intervention

The mean number of nursing visits, telephone calls, and duration of the intervention (number of months) were calculated. Mean differences were compared by using the independent t-test.

Justification of Sample Size

The sample size estimation was based on detecting a clinically important difference between the two groups in the SF-36 mental health component summary measure for the elderly study participant. Since the mental health component summary measure defines many more levels of health than any of the SF-36 scales alone and has been shown to be as reliable or more reliable, one can assume that this summary measure has greater statistical power in detecting
differences in mental health (Ware & Kosinski, 2001). Therefore, the mental health component summary score was used to calculate the sample size.

In a similar randomized controlled trial of the effectiveness of an in-home preventive programmes, Stuck et al. (1993a) defined improvement in functional status as a change that exceeded \( \frac{1}{4} \) to \( \frac{1}{2} \) of the standard deviation of that function measure at the time of randomization. According to this, with a standard deviation of 19.48 at baseline, the sample size was calculated to detect a difference of 4.87 in mean change scores for the mental health component summary score between groups. Based on published tables by Beyer (1966), for a probability of a type 1 error of 0.05 and power of 80\%, 115 subjects per group were required to detect a 5-point difference in the mental health component summary change scores, using a standard deviation of 14 for the change scores. Therefore, with an expected 20\% dropout rate, 138 subjects per group were allocated to each group for a total of 276 elderly study participants.

Calendar of Events

Consenting and eligible clients and caregivers were assessed at baseline and 6 months to determine the effects and expense of the nursing health promotion intervention. A recent pilot study (Wishart et al., 1999) indicated that on average, 30 new eligible CCAC referrals for personal support services occurred in a month. Of these, it was expected that 40\% would refuse randomization, resulting in the randomization of approximately 18 subjects per month. The study was conducted over a period of 3 years and 4 months (September 1, 1999 - December 31, 2003), as in the calendar of events displayed in Figure 13.

Efforts to Minimize Bias

A randomized controlled trial with concealment was utilized in order to minimize bias. Interviewers assessing baseline and follow-up outcome measures were masked to the type of
care the client received in order to achieve a single blind trial. It was anticipated that there would not be differential interventions between the groups. However, all interventions (including home care services, medications and health provider visits) for all study participants were monitored and recorded. Dropout events after randomization were recorded and the direction and impact of any difference or biases on the results were highlighted.

The analysis was completed on an intention to treat basis. This means that all the elderly study participants and caregivers who completed the questionnaires at follow-up were included in the analysis as part of the groups to which they were randomized regardless of whether they adhered to the interventions or not (Jadad, 1998). The CCAC Case Managers were blind to subjects allocated to the usual care (control) group. However, because of the nature of the intervention (that is, a change in the provision of care), the CCAC Case Managers were aware of the assignment of subjects to the intervention group. Family physicians were aware of the client’s participation in the study but not the type of care that the client received. Finally, a statistician/data analyst independent of the investigator performed the analysis.

Ethical Implications

In accordance with the ethics of human research, subjects’ consent, confidentiality, and protection of rights were adhered to in the study. Subjects were under no obligation to participate in the study. Study participants were assured that their decision to participate in the study would in no way affect the care they would receive from the CCAC. Subjects were assured that they would not be identified individually in any verbal or written reports of the study. They were informed that they could withdraw from the study at any time for any reason, that information collected during the study would be kept confidential, and used only for the purposes of the study analysis.
Confidentiality was assured by assigning code numbers to study participants. Only the project co-ordinator had access to data that linked subject’s names with study identification numbers. The original data and the identifying code numbers with participants’ and nurses’ names were kept by the project coordinator in a locked filing cabinet in the McMaster University SLRU. Computer data were accessible only to the principal investigator, project co-ordinator and other designated research staff of the SLRU at McMaster University. The project co-ordinator and the principle investigator supervised access to the data to ensure that confidentiality was maintained. Data were analysed by group without the ability to identify specific patients.

Ethical approval for the study was obtained from the McMaster University, Research and Ethics Board and renewed yearly as required. Prior to commencement of the study, administrative approval was received from each of the participating agencies (CCAC of Halton; VON of Nurses, Halton Branch; and SEN Community Health Care) (see Appendix D for letters of ethical approval).
RESULTS

This 6-month follow up proceeded as follows. Participant elderly CCAC clients and their caregivers in the 6-month follow up were compared to those lost to follow up on their general characteristics at baseline. Statements about the representativeness of study clients and their caregivers are made.

The comparability of participant elderly CCAC clients and their caregivers in each of the two study groups were assessed on their baseline characteristics. Even though randomization was used as a means of ensuring comparable groups at the onset of the trial, dropout events after randomization may have rendered study groups non equivalent on characteristics known to affect the outcome. The direction and impact of any differences or biases on the results are highlighted.

The dose and type(s) of interventions in each group are described. The hypothesis that proactive nursing health promotion and preventive care in addition to usual home care services improves health outcomes at no additional expense from a societal perspective is tested in a two-group comparison on all clients and their caregivers allocated to groups (intention to treat analysis). Repeated measures ANOVA was used to compare the change in mean scores between the two groups over the 6-month follow-up period. Analysis of covariance (with pre-intervention scores as covariates) was also used to compare the groups, in order to control for differences in pre-intervention functioning. The service utilization data, summarized as dollar values were skewed, and thus, comparisons were also done using the non-parametric Kruskall-Wallis analysis of variance (Browne, Arpin, Corey, Fitch, & Gafni, 1990).

Descriptive Statistics
Study Environment

The study was conducted under the auspices of the CCAC of Halton, a partner agency with McMaster University, SLRU on Health and Social Service Utilization. The CCAC of Halton is the tenth largest CCAC in Ontario when measured by population served. Halton is one of the fastest growing areas in Canada, and is comprised of the City of Burlington, the Towns of Halton Hills, Milton and Oakville. Between April 1, 2001 and March 31, 2002, the CCAC of Halton delivered a total of 662,924 units of service, consisting of nursing hours (26.5%), personal support hours (65.7%), and rehabilitation hours (7.79%). During this same time period, the CCAC of Halton served a total of 10,710 clients, of which 60% were over the age of 65 years (CCAC of Halton, 2001/2002).

As in Table 3, the characteristics of the environment were examined for the fiscal year prior to and upon completion of the study (1999-2000 compared to 2002-2003). The most notable change over the course of the study was related to the number of clients 75 years and older accessing personal support services through the CCAC. Noteworthy, is that there was a 16.5% reduction in the number of clients 75 years and older accessing personal support services, and a 38.25% reduction in the number of personal support hours provided in 2002-03 compared to 1999-2000. In addition, over the course of the study, access to other professional CCAC services reduced by 10% for clients accessing personal support services.

These data are reflective of provincial changes in policy that occurred during the study period in an attempt to address the continual growth in the demand for home care services, the increasing cost of providing the services and the complexity of services needed by the community within the same funding levels as 2000/2001 (CCAC of Halton, 2001/02). This change in policy impaired access to CCAC services for study participants in both groups, often
resulting in service delays or reductions in service. Therefore, any use of services will be an underestimate of service use for both groups.

Representativeness

Representativeness of Elderly Subjects

All individuals 75 years and older and eligible for personal support services through the CCAC of Halton, were screened for eligibility for the study. Between February 2001 and December 2002 (23 months), 1,119 individuals 75 years and older and eligible for personal support services were screened for eligibility for the study. Once screened, the eligibility criteria for the study were applicable to 51.7% (n = 579) of the CCAC population. The most common reason for ineligibility was that individuals were also eligible for nursing services through the CCAC. Of 579 eligible clients, 288 subsequently entered the study. The flow of the elderly population through the study is illustrated in Figure 14.

Of 288 eligible and consenting frail elderly CCAC clients who were randomly allocated at baseline to receive proactive RN health promotion and preventive care or not, 242 or 84.0% were retained in the 6 month follow-up period. A total of 46 frail elderly CCAC clients were lost to follow-up at 6 months. Reasons for lost to follow-up for the 288 clients randomized to receive RN health promotion and preventive care or usual care included death (37%), missed (28%), and refusal to participate (26%). Participants who were missed were either not located or too ill to participate. Three subjects failed the Short Portable Mental Status Questionnaire and did not have an available proxy respondent, and one subject moved outside of the Halton Region. The baseline characteristics of study completers (n = 242) compared to those lost to follow-up (n = 46) are displayed in Tables 4 to 8. Differences between study completers and those lost to follow up at baseline are summarized in Figure 15.
In Table 4, study completers in the 6-month follow-up analysis (n = 242) were compared to those who were lost to follow-up (n = 46) on their demographic, social and clinical characteristics at baseline, to assess if dropping out affected the representativeness of the respondent group on important study variables. If case dropout events rendered the groups non-comparable in any way, adjustments for these imbalances at baseline would need to be made when testing the hypothesis of differences associated with a 6-month exposure to a proactive RN health promotion intervention.

The demographic and social and clinical profile of study completers versus those lost to follow-up is similar with the exception of gender. A greater proportion of completers were female (76.9%) compared to those lost to follow-up (63.0%, p = 0.048). Four of the 288 eligible and consenting frail elderly CCAC clients were unable to complete the Short Portable Mental Status Questionnaire, three did not respond to the question regarding education, and one person was unable to complete the CES-D due to poor physical health, therefore, they were not included in the analysis.

The results of the chi-square test showed that completers were similar to those lost to follow-up in their average age (83.82 years), the 90.8% who were intellectually intact (<5 errors on the SPMSQ), the 31.4% who were married, and the 68.6% who were either widowed, single, separated or divorced. Similarities also existed in the 82.2% who lived in a house or apartment, the 17.8% who lived in a Retirement Home, and the 87.2% who reported an income of less than $40,000 per year. Completers were similar to those lost to follow-up in the 77.3% who were Canadian ethnic identity, and the 22.7% who were from other ethnic backgrounds. Completers were also similar to those lost to follow-up in the 51.7% who reported that they receive help from their informal support network, the 61.6% who identified this individual as their spouse,
and the 34.4% who identified this individual as either their child, sibling, or friend. Similarities also existed in the 33.1% that had more than High School education. In addition, completers were the same to those lost to follow-up in the 86.0% of frail elderly subjects who were able to respond to the questionnaires themselves.

Clinically, completers were similar to those lost to follow-up in severity of illness indicators which included the 52.4% who had at least one other illness, the 25.6% who were depressed as indicated by a score of \( \geq 21 \) on the CES-D, and the mean number of medications they were taking daily (7.29 medications). Completers were also similar to those lost to follow-up in their reported primary diagnosis:

1. 26.0% had injuries, falls, or fractures;
2. 19.8% had cardiovascular problems;
3. 16.1% had musculoskeletal problems, including arthritis;
4. 12.0% had neurological problems, including dementia;
5. 11.6% reported weakness or frailty.

Other diagnoses included respiratory (6.2%), genitourinary (2.1%), gastrointestinal (2.1%), cancer (1.2%), and other (2.8%).

As in Table 5, study completers (n = 242) were similar to those lost to follow-up (n = 46) in their health related quality of life and function scores on the SF-36 Health Survey in the areas of physical functioning, pain, vitality, and social functioning. Completers in comparison to those lost to follow-up reported higher scores (indicating a higher level of functioning) in the areas of role limitations related to physical problems (27.17 vs. 13.45, where \( t = 3.054, p = 0.003 \)), general health perception (56.84 vs. 43.43, where \( t = 3.539, p < 0.001 \)), role limitations related to emotional problems (78.27 vs. 56.3, where \( t = 3.397, p = 0.001 \)), mental health functioning
(69.68 vs. 59.13, where \( t = 2.367, p = 0.021 \)), overall physical health functioning (37.69 vs. 28.24, where \( t = 3.421, p = 0.001 \)), and overall mental health functioning (57.41 vs. 47.46, where \( t = 2.615, p = 0.01 \)). As in Table 6, completers in comparison to those lost to follow up, reported lower scores on the CES-D indicating lower levels of depressive symptoms (14.78 vs. 20.16, where \( t = -3.245, p = 0.001 \)). However, completers were similar to those lost to follow-up in their perceived level of social support (see Table 6). As in Table 7, completers were similar to those lost to follow up in their coping ability, with the exception of problem-solving. Completers in comparison to those lost to follow up, reported a higher score on the problem-solving foci of coping, indicating a higher level of coping ability in this area (\( p = 0.041 \)).

Finally, as in Table 8, completers in comparison to those lost to follow up, were lower users of family physicians or walk-in clinics (\( p = 0.01 \)), and physiotherapists (\( p = 0.017 \)). In summary, it appears that we retained, in this 6-month follow-up, a slightly higher functioning population of frail elderly home care clients.

*Representativeness of Caregivers*

Figure 14 illustrates that of the 288 eligible and consenting elderly CCAC clients who were randomly allocated at baseline to receive proactive RN health promotion or not, 171 or 59.3% had an available, eligible and consenting caregiver. Caregivers were allocated to the same group as their elderly relative/friend. Of 171 eligible and consenting caregivers at baseline, 116 or 67.8% were retained in the 6 month follow up period. A total of 55 caregivers were lost to follow up at 6 months. Reasons for lost to follow up for the 171 caregivers randomized with their elderly client/friend to receive RN health promotion or not included death of caregiver or client (29.1%), missed (32.7%), and refusal to participate (38.2%). Participants who were missed were either not located or too ill to participate. The baseline characteristics of caregivers who
completed the study \( n = 116 \) compared to those lost to follow-up \( n = 55 \) are displayed in Tables 9 to 11. Differences between caregiver completers and those lost to follow-up at baseline are summarized in Figure 15.

In Table 9, caregiver completers in the 6-month follow-up analysis \( n = 116 \) were compared to those who were lost to follow-up \( n = 55 \) on their demographic, social and clinical characteristics at baseline, to assess if dropping out affected the representativeness of the respondent group on important study variables. Two of the 171 eligible and consenting caregivers did not respond to the Short Portable Mental Status Questionnaire, thirteen caregivers did not respond to the question regarding income, and five did not complete the CES-D, therefore, they were not included in the analysis. The reasons for non completion are unknown.

The results of the chi-square test showed that caregiver completers were similar to those lost to follow-up in the 46.5% who were 70 years of age and older, the 43.1% who were 39 to 59 years of age, and the 70.7% who were female. Similarities also existed in the 100% who were intellectually intact \( (< 5 \) errors on the SPMSQ), the 51.7% who were the elderly client’s spouse and the 43.1% who were the elderly client’s son or daughter. Completers were similar to those lost to follow-up in the 48.5% who were retired, the 34.5% who were working either full-time or part-time, the 44.0% who had more than High School Education and the 67.3% who reported an income of less than $40,000 per year. Similarities also existed in the 83.6% who were Canadian ethnic identity, and the 16.4% who were from other ethnic backgrounds.

Clinically, completers were similar to those lost to follow-up in the 16.7% who exhibited depressive symptoms as indicated by a score of \( \geq 21 \) on the CES-D, the 40.5% who reported taking four or more prescription medications daily, and the 12.9% who reported a hospital admission in the past 6 months. Completers were also similar to those lost to follow-up in their
health related quality of life and function scores as measured by the SF-36 Health Survey. These outcomes included role functioning related to physical health, role functioning related to emotional health and social functioning. However, completers reported taking a higher mean number of prescription medications daily (4.22) compared to those lost to follow-up (3.60) (t = 4.814, p = 0.03).

As in Table 10, caregiver completers (n=116) were similar to those lost to follow-up (n=55) in the level of burden associated with providing care, with the exception of the level of burden of providing care on the caregiver’s schedule. Caregiver completers reported a higher level of burden of providing care on their schedule compared to those lost to follow up (t=2.341, p = 0.02). Finally, as in Table 11, caregiver completers were similar to those lost to follow-up in the 13% who utilized at least one publicly funded home care service for themselves, i.e. nursing, homemaking, physiotherapy, occupational therapy, social work, or nutritionists. However, caregiver completers in comparison to those lost to follow up, were higher users of physiotherapists (p = 0.028), and lower users of private pay homemakers (p = 0.036). In summary, the 116 caregivers participating in the 6-month follow up, were representative of the 171 caregivers who were randomized at baseline in their clinical, demographic, and social characteristics, health related quality of life and functioning, level of burden and expenditure of use of services.

Representativeness of Elderly CCAC Study Participants to CCAC of Halton Clients

The geographical area of residence and the living arrangement of the 288 clients randomly allocated at baseline was compared to the geographical area and living arrangement of all clients eligible for personal support services through the CCAC of Halton during the study period. These 288 clients were similar to all CCAC clients eligible for personal support services
in the 58.6% who lived in Burlington, the 29.2% who lived in Oakville, the 11.5% who lived in North Halton (Georgetown, Acton, Halton Hills, Campbellville, Milton), and the 46.9% who lived alone (see Table 12). Data was not available to make a statement regarding the representativeness of the caregivers of the elderly CCAC study participants to CCAC of Halton caregivers.

Therefore, the sample was representative of CCAC of Halton clients with respect to living arrangements and regional representation.

*Description and Dose of the Study Intervention*

For the purpose of this study, dosage refers to the frequency and duration with which an intervention is given to produce the expected changes in outcomes (Sechrest et al., 1983). Frequency refers to the number of times the home visits and telephone contacts are performed over the 6 month follow up. Duration refers to the total length of time the intervention is to be implemented for the expected effects to take place (Scott & Sechrest, 1989). The dose or frequency of the intervention was based on the study protocol combined with client needs, and the nurses clinical experience and expertise. Engagement rate in this study is equivalent to the frequency of the intervention and was defined as at least one home visit or telephone contact for treatment.

A visiting nurse engaged 84.7% of those frail elderly participants who were randomly allocated to the RN health promotion intervention at baseline (n = 144). The mean duration of the intervention was 4.25 months. Subjects randomized to the RN health promotion group received an average of 3.94 home visits and 1.81 telephone contacts over the 6-month follow-up. More than half of the sample (57.6%) who were randomly assigned to receive the intervention at baseline (n=144) received 4 or more home visits, and 60.4% completed the 6 month intervention.
Notably, 90.8% of the sample randomized to the nursing group received care from the same nurse throughout the entire intervention period.

Elements of the intervention were tracked for compliance with implementation as indicated in Table 13. Overall, compliance with the intervention was high with some exceptions:

(1) Only slightly more than half (60%) of the study participants received a nursing visit within 1 week of sending the referral to the nursing agency. This was due to difficulties contacting participants, as well as workload issues for those nurses providing the intervention, and

(2) Only one half (49.2%) of the nurses had contact with the personal support worker (via home visit or telephone contact) at least once over the 6 month intervention. This was likely due to the changes in policy that occurred over the study period which impaired access to personal support services for study participants in both groups, often resulting in service delays or reductions in service.

A total of 22 out of 144 (15.3%) frail elderly CCAC clients randomized to the nursing group were not engaged by the study nurse. Reasons for lack of engagement for these 22 clients randomized to receive RN health promotion and preventive care included refusal to participate (31.8%), nurse not assigned (18.2%), hospitalized prior to first nursing visit (18.2%), missed (13.6%), and death (9.1%). One client was placed in a long-term care facility prior to the first nursing visit and two clients became ineligible for the study when nursing was put in during randomization.

A visiting nurse engaged 65.1% of the available caregivers (n=86) of those elderly participants who were randomly allocated to the RN health promotion intervention at baseline. Caregivers of subjects randomized to the RN health promotion group received an average of 1.47
home visits and 0.92 telephone contacts over the 6-month follow-up. The majority of the sample of caregivers (87.2%) (n=86) received 0 to 3 home visits, 10.5% received 4 to 6 visits and 2.3% received 7 or more visits over the 6 month follow up period. Thus, a potential limitation of the study may be that caregivers received a relatively low dose of the study nurse intervention. This may explain why only 36% of caregivers randomized to the nursing group completed the CES-D depression screening tool. Therefore, any differences found will be an underestimate of the real differences.

_Elderly Study Participants_

The study population of 242 consenting CCAC clients presented as a fairly elderly group. Over half of the sample (64.5%) were over 80 years of age with a mean age of 83.82 years. There were a significantly higher proportion of women (76.9%) compared to men (23.1%). The majority of individuals were widowed, separated, divorced or single (65.7%) and almost half the sample (48.3%) lived alone. Over half of the sample (51.7%) reported that they received help from their informal support network. Noteworthy, is that at baseline, 93.4% of the sample reported that they were limited a lot in moderate activities of daily living, and 80.5% were limited to some degree in bathing or dressing. Over half of the sample (57.7%) reported that their health was fair to poor and 72.3% indicated that they had difficulty performing work or other activities most of the time or all of the time. Over half of the sample (52.4%) had more than one illness and one quarter of the sample (25.6%) exhibited depressive symptoms. Over one quarter (26.0%) of the study participants had experienced an injury, fall, or fracture, and 35.9% reported cardiovascular or musculoskeletal problems. Over half of the sample (63.6%) reported a hospital admission in the previous 6 months, and 86.4% reported taking four or more prescription medications daily. However, the majority of the study participants were
intellectually intact (90.8%), and 86.0% were able to respond to the questionnaires by themselves.

A proxy respondent was utilized for 14.0% of the total study population due to limitations in cognition, physical health or language. A total of 19 telephone interviews were conducted in place of a personal in-home interview for data collection (2 at baseline and 17 at 6 months).

**Caregiver Participants**

A total of 116 or 47.9% of the study population of 242 elderly study participants had an available and consenting caregiver. The study population of 116 available and consenting caregivers of eligible study clients were predominantly:

- Women (70.7%)
- 60 years of age and over (56.7%), averaging 66.2 years of age (SD=13.48)
- Elderly clients’ son or daughter (51.7%) or client’s spouse (43.10%)
- Retired (49.10%) or still working in some capacity (33.6%)

Noteworthy, is that 16.7% of the sample exhibited depressive symptoms, and 30% indicated that their health has gotten worse since they assumed this caregiver role. One third of the sample reported that they had difficulty performing work or other activities (33.6%), and cut down on the amount of time spent on work or other activities some of the time or all of the time as a result of their physical health (35.3%). Approximately, one third of the sample (30.4%) reported that they cut down on the amount of time spent on work or other activities some of the time or all of the time as a result of emotional problems, i.e. feeling depressed or anxious. Over one third of the sample (38.8%), reported that their physical health or emotional problems interfered with their normal social activities moderately to extremely. A relatively small
percentage of caregivers (12.9%) reported a hospital admission in the past 6 months, used at least one home care service (13%), and 41.4% reported taking four or more prescription medications daily. Notably, 40.5% of the caregivers are 75 years of age or older, suggesting that a significant proportion of elderly study clients are being cared for by individuals who are elderly as well and facing issues related to later life themselves.

Overall, this study population of 116 caregivers reported that caregiving impacted moderately on the level of individual self-esteem, which represents a sense of value and worth, and impacted at a moderately high level on the individual’s schedule; interrupting usual activities, causing elimination of some activities and interfering with relaxation time. Almost one quarter (23.0%) of the caregivers indicated that they are the sole caregiver, apparently receiving no support from other family members. Yet, the vast majority of caregivers (95.6%) indicated that caregiving was very important to them.

A total of 39 telephone interviews were conducted with caregivers in place of a personal in-home interview for data collection (29 at baseline and 10 at 6 months).

Primary Research Questions: General Effectiveness of Intervention

Comparability

Comparability of Frail Elderly CCAC Clients

Even though randomization was used as a means of ensuring comparable groups at the onset of the study, dropout events after randomization may have rendered study groups non-equivalent on characteristics known to affect the outcome. The baseline characteristics of frail elderly CCAC clients participating in the 6 month follow-up for each of the two study groups are displayed in Tables 14 to 18. Three of the 242 study participants were unable to complete the
Short Portable Mental Status Questionnaire due to poor physical health, therefore, they were not included in the analysis. Differences between groups at baseline are summarized in Figure 16.

Respondents to the 6 month follow-up in the two study groups were similar on most clinical, demographic and social characteristics (Table 14), physical and social functioning (Table 15), level of perceived social support (Table 16), per person direct annual expenditures of use of services (Table 17), and coping style (Table 18) at baseline (T1). However, fewer respondents in the nursing group took 10 or more prescription medications daily (22.5%) compared to those in the usual care group (34.4%, t = 6.317, p = 0.042) (Table 14 and Figure 16). Respondents in the nursing group reported lower scores (indicating a lower level of functioning) in the areas of role functioning related to emotional health (73.19 vs. 83.27, t = -2.628, p = 0.009), mental health functioning (64.14 vs. 74.74, t = -3.818, p = <.001), and overall mental health functioning (54.08 vs. 60.68, t = -2.673, p = 0.008) when compared to the usual care group (Table 15 and Figure 16). In addition, respondents in the nursing group, on average, reported more depressive symptoms than the usual care group (t = 2.355, p = 0.019) (Table 16 and Figure 16), although these five differences, summarized in Figure 16, could be due to chance when in a situation of multiple testing. It would appear that the respondents in the nursing group, who participated in the 6 month follow-up, were somewhat more disadvantaged than those in the usual care group with respect to mental health functioning. However, the use of analysis of covariance using the baseline mental health summary scores and the CES-D depression scores as the covariates in testing the hypotheses will adjust for the imbalances at the onset of the trial.

Comparability of Caregivers

The baseline characteristics of caregivers of elderly CCAC clients participating in the 6 month follow-up for each of the two study groups are displayed in Tables 19 to 21. One of the
caregivers did not complete the Short Portable Mental Status Questionnaire, 9 did not respond to the question regarding income, and 2 did not complete the CES-D, therefore, they were not included in the analysis. Caregiver respondents at the 6 month follow up in the two study groups were similar on all clinical, demographic and social characteristics (Table 19), level of caregiver burden (Table 20), and per person direct annual expenditures of use of services (Table 21). Thus, any 6-month differences between groups of clients or caregivers cannot be attributed to differences in baseline caregiver characteristics.

Research Questions

Elderly CCAC Clients

Primary Research Question: Effectiveness of Proactive RN Health Promotion and Preventive Care on Functional Health Status and Related Quality of Life

Health related quality of life and function outcomes as measured by the SF-36 Health Survey were compared over time from baseline (pre-randomization) (T1) and 6 months (post-randomization) (T2) with the 242 valid and completed cases. Pre-intervention scores were entered as covariates, in order to control for differences in pre-intervention functioning. Scores for the two MCS and PCS summary measures and each of the eight scales were calculated in this study.

Overall, this study population of 242 consenting CCAC clients reported poor health related quality of life and function scores on the SF-36 Health Survey in comparison with published norms for a general Canadian population of females ≥ 75 years (Hopman et al., 2000). Table 22 provides a comparison of the total mean scores obtained by the study participants
compared to normative data (for females aged 75 and over) to give a sense of where individuals fell in relation to the general population at baseline. Results from the SF-36 health survey indicated that study participants (n = 242) scored below the mean of the general population of Canadian women $\geq 75$ years on all of the SF-36 dimensions of health related quality of life with the exception of the mental health component summary score at baseline. With the exception of role functioning related to emotional health, these differences in mean scores were statistically significant (p < 0.01). Noteworthy, is that the health of the study participants compared to the general population was particularly compromised in the areas of physical functioning (19.4 vs. 55.5), social functioning (48.24 vs. 82.2), energy/vitality (31.28 vs. 58.9), and role functioning related to physical health (27.17 vs. 59.5). These data provide a meaningful picture of the health related quality of life and function of the study participants at baseline.

At 6 months, even though study participants (n= 242) had improved scores in all of the SF-36 dimensions of quality of life, they still scored below the mean of the general population for the majority of the dimensions with the exception of role functioning related to emotional health, and overall physical and mental health functioning. As in Table 23, these differences in mean scores between the study completers and published norms were statistically significant (p < 0.01).

The mean scores and standard deviation for the two summary measures and each of the scales in the SF-36 at baseline (Time 1) and 6-months (Time 2) were compared between the two groups as illustrated in Table 24. The mean change scores (delta for individual participants) from baseline to 6 months (T1-T2) for the eight SF-36 scale scores and the physical (PCS) and mental health component (MCS) summary scores were analysed (using repeat measures ANOVA) to understand individual improvements over time. Improvements in SF-36 scores
were calculated accounting for baseline scores (T1-T2, divided by T1). As in Table 24, analysis of covariance (ANCOVA) was also calculated using Time 1 (pre-intervention) scores as a covariate, to compare the values at the 6-month follow-up, in order to control for differences in pre-intervention functioning. One of the 242 study completers was unable to complete the general health perception subscale, and two were unable to complete the mental health subscale due to poor physical health, therefore, they were not included in the analysis for this outcome measure. A mean change score difference of > 5 between the groups was considered clinically important.

At 6 months, both the usual care and the nursing group had improved in individual change scores on the PCS, MCS, and the subscale scores, with the exception of role functioning related to emotional health and the mental health subscale scores in the usual care group which decreased by 4.92% and 1.32% respectively. However, there were greater improvements in individual change scores for participants receiving the RN intervention compared to the usual care group within six of the eight SF-36 scales and the overall summary scores for mental and physical health.

At the 6-month follow-up, there was a statistically significant and clinically important percentage improvement in the summary score for mental health for the nursing group (20.4%) vs. a 7.4% improvement in the usual care group (F = -2.632, p = 0.009) (see Table 24) (See Figure 17). When analysis of covariance (ANCOVA) was calculated using the Time 1 (pre-intervention) mental component summary and the CES-D scores as covariates, in order to control for differences in pre-intervention functioning, there was a statistically significant difference between groups (F = 4.227, p = 0.041).
Within the subscales that contribute to the physical health component summary in the SF-36, the most noteworthy improvement was in the subscale score relating to physical functioning. Physical functioning is defined as the capacity to perform physical activities normal for people in good health, such as self-care activities (bathing, dressing), activities related to mobility (getting around indoors, outdoors and in the community), and physical activities (walking, bending, lifting, climbing stairs, and running) (Ware, 1993). As illustrated in Table 24 and Figure 18, there was a clinically important percentage improvement in physical functioning in the nursing group (61.7%) versus a 34.7% improvement in the usual care group. A mean change score difference of 5.39 between the groups is clinically important. However, due to the large standard deviation, the power to detect the difference of 5.39 was less than 50% and not statistically significant (F = -1.851, p = 0.065).

There was also a clinically important percentage improvement in role functioning related to physical health for the nursing group compared to the usual care group. Role functioning can be defined as the degree to which an individual performs, or has the capacity to perform, activities typical for a specified age and social responsibilities (Sherbourne et al., 1992). An advantage of the SF-36 is that it distinguishes between physical and mental causes of role limitations, which are often missed with other instruments (Ware & Sherbourne, 1992). As illustrated in Table 24 and Figure 19, the subscale score for role functioning related to physical health more than doubled in the nursing group (106%) compared to an 83.2% improvement in the usual care group. A mean change score difference of 6.26 between the groups is clinically important. However, due to the large standard deviation, the power to detect the difference of 6.26 was less than 50% and not statistically significant (F = -1.023, p = 0.307).
As expected, improvements in the subscale scores contributing to overall physical health in the nursing group resulted in notable improvements in two of the subscales contributing to the mental health component summary measure: role functioning related to emotional health and mental health functioning. As illustrated in Table 24 and Figure 20, there was a statistically significant and clinically important percentage improvement in role functioning related to emotional health for the nursing group (13.76%) versus a 0.5% drop in the usual care group (F = -2.462, p = 0.015). Role functioning is defined as the degree to which an individual performs or has the capacity to perform activities typical for a specified age and social responsibility (Sherbourne et al., 1992). This subscale of the SF-36 refers to emotional causes of role limitations. This 10.48 difference in mean change scores between the groups is clinically important.

As illustrated in Table 24, there was also a statistically significant and clinically important percentage improvement in mental health functioning for the nursing group (10.09%) vs. a 1.32% drop in the usual care group (F = -2.859, p = 0.005). Mental health is assessed by exploring psychological distress and well being as they pertain to feeling happy, peaceful, anxious, depressed or blue (Sherbourne et al., 1992). The SF-36 includes measures for anxiety, depression, loss of behavioural or emotional control, and psychological well being (Ware & Sherbourne, 1992). This 7.46 difference in mean change scores between the groups is clinically important.

Because the two summary scales take into account the correlations among the eight scales, they help to clarify that the study intervention resulted in improvements in both physical and mental health. However, the major improvement at the 6-month follow-up was concentrated in the mental dimension of health. The importance of these findings is illustrated in studies of
empirical validity of the SF-36 - that is, scales that relate highest to the physical component are most responsive to treatments that change physical morbidity, whereas scales that relate highest to the mental component respond most to therapies that target mental health (Ware & Gandek, 1998).

*Secondary Research Question: Proactive RN Health Promotion and Preventive Care on Health and Social Service Expenditures and Utilization*

Service utilization outcomes as measured by the Health and Social Services Utilization Inventory (Browne et al., 2001) were compared over time from baseline (pre-randomization) (T1) and 6 months (post-randomization) (T2) with the 242 valid and completed cases. To calculate annual utilization measures, the various spans of time are extended to yield an annual rate of utilization per category of health service and multiplied times the current unit charges for each service to yield a measure of expenditures for health and social service. Unit charges or costs for each service, as outlined in Table 25, were based on averages for Ontario, Canada, as reported by Browne et al. (2001) and CCAC of Halton rates for the study period (February 2001-June 30, 2003) (C. Harvey, personal communication, 2001). When study participants were unwilling to report their range of income on the demographic questionnaire, their income was estimated based on their response to the question regarding the amount of income received through government cheques in the past 6 months. The other few missing responses at 6 months were assigned the baseline (T1) value for that service in the analysis.

A unit of homemaking service is equivalent to one hour and the length of a homemaking visit/shift can vary between 15 minutes and 12 hours. A limitation of the study was missing data regarding the length of the homemaking visits. Therefore, for the purpose of this analysis, one homemaking visit, as reported by participants, was assumed to be equivalent to one service hour.
Thus, the total direct cost of homemaking service utilization for both groups may not be a true estimate of the real cost.

At 6 months, 53 or 21.9% of the 242 study completers were residing in a Retirement Home, and 8 or 3.3% were residing in a long-term care facility. A limitation of the study was missing data related to the number of days in a retirement home and long-term care facility over the 6 months of the study. Therefore, the cost associated with living in a retirement home or long-term care facility were not included in the analysis. Thus, the total direct cost of health and social service utilization for both groups will be an underestimate of the real cost from a societal perspective.

As illustrated in Table 26, the mean costs and standard deviation for health and social service utilization at baseline (T1) and 6 months (T2) were compared between the two groups with the 242 valid and completed cases. The total annualized direct utilization cost of health and social services was high for both groups. At Time 2, the average total per person direct cost of health and social services (including hospitalization) for both groups was $18,178.37. As expected with this frail elderly home care population, the majority of the costs were related to acute hospital stays (64.02%) and medications (13.81%). However, only 23.6% (n=57) of the participants reported one or more hospital admissions over the 6 months of the study. In other words, 23.6% of the study population contributed to 100% of the cost for acute hospitalization. Another interesting finding was that on average, participants reported an average use of 50.2 hours of personal support services over 1 year or 1.05 hours per week, and personal support services accounted for only 6.4% of the total per person direct cost of health and social services (including hospitalization) for both groups. In this frail and functionally limited study
population, this finding probably reflects the reality of reduced access to home care services rather than a lack of need.

The main finding is that there was no statistical difference between the RN and the usual care group in total annual per person direct expenditures (including hospitalization). Even when the cost of the RN health promotion intervention was added to the total cost, it was no more expensive to augment usual care with nursing visits ($\chi^2 = -0.026, p = 0.979$), for a group of frail elderly CCAC clients who were more disadvantaged to begin with (see Figure 21). The finding that RN health promotion can improve health outcomes at no additional cost to society as a whole is both economically and administratively important in a system of national health insurance.

While the intervention and control group did not differ significantly in the use of health and social services, the pattern of service utilization is noteworthy. Out of the 30 items in the Health and Social Service Utilization Inventory, the main cost differences between the two groups was found in five items which included: utilization of medications, physiotherapy, use of supplies, aids or devices, use of acute hospitalization, and visiting nursing services. As expected, the RN health promotion group had a higher statistically significant utilization of visiting nursing services ($324.28$) vs. usual care ($73.10$) ($\chi^2 = -8.104, p < 0.001$).

Also as expected, those participants receiving RN health promotion and preventive care were slightly higher users of family physicians, emergency room, psychiatrists, psychologists, occupational therapists, social workers, nutritionists, public health nurses, chiropractor, homemakers, meals on wheels, and parking costs compared to the usual care group. Noteworthy, is that after 6 months; participants in the nursing group were higher users of acute hospitalization, with 27.5% reporting one or more hospital admissions compared to 19.7% in the
usual care group. As part of the RN intervention, participants would have been appropriately referred to these services based on their needs. However, these differences in mean utilization were not statistically significant.

Higher expenditures of use of these services were offset by a lower statistically significant utilization of medications in the nursing group ($2,412.76) versus usual care ($2,605.60, p = 0.036). There was a statistically significant difference in the mean number of medications taken in the past two days in the nursing group (6.69 medications) versus the usual care group (8.18 medications) (t = -2.903, p = 0.004). Therefore, the lower expenditures of use of medications in the nursing group is not due to differences in the type of medications taken. There was also a significantly lower use of physiotherapy in the nursing group ($336.87) versus the usual care group ($592.49) and supplies or aids ($273.92) versus the usual care group ($531.97). There was also a slightly lower use of physician specialist, other health care providers/services, ambulance services, laboratory tests, and mileage in the nursing group compared to the usual care group. However, these differences were not statistically significant. A total of 8 study participants entered a long-term care facility during the 6 months of the study (4 in the nursing group and 4 in the usual care group).

**Secondary Research Question: Proactive RN Health Promotion and Preventive Care on Mental Health, Perceived Social Support, and Coping Ability**

**Mental Health (Level of Depression)**

Mental status (level of depression) outcomes, as measured by the Centre for Epidemiological Studies in Depression Scale (CES-D), was compared over time from baseline (pre-randomization) (T1) and 6 months (T2) with 228 valid and completed cases. Fourteen of the 242 study completers were unable to respond to the CES-D questionnaire due to poor
physical health, and/or a proxy respondent unable to answer and, therefore, they were not included in the analysis for this outcome measure. Based on a review of the literature, the investigator chose a cut-off score of ≥ 21/60 to distinguish between depressed and non-depressed elderly CCAC clients.

The mean score and standard deviation for the total CES-D score at baseline (T1) and 6 months (T2) were compared between the two groups as illustrated in Table 27. The mean change scores (delta for individual participants) from baseline to 6 months (T1-T2) for the total CES-D score was analysed (using repeat measures ANOVA) to understand individual improvements over time. Improvements in the mean score for the CES-D were calculated and accounted for baseline scores (T1-T2, divided by T1). As in Table 27, analysis of covariance (ANCOVA) was also calculated, to compare the values at the 6-month follow-up, using Time 1 (pre-intervention) scores as a covariate in order to control for differences in pre-intervention functioning.

As expected, with improvements in physical and mental functioning in both groups, there was a concomitant reduction in individual CES-D change scores at 6 months in both groups, indicating a lower level of depression. Noteworthy, is that there was a statistically significant and clinically important percentage reduction in the CES-D depression score in the nursing group (23.9%) versus a 8.79 % reduction in the usual care group (F = 2.298, p = 0.022) (Table 27 and Figure 22). This 1.72 difference in mean change scores between the groups is clinically important. The groups were also compared using a cut-off score of ≥ 21 to distinguish between depressed and non-depressed participants. There was a clinically and statistically significant percentage increase in the number of clients who improved and became non-depressed in the nursing group over the 6 months (16.8%) versus the usual care group (11.3%) (x^2 = 13.618, p =
0.001) (See Figure 23). These findings provide further support for the effectiveness of the study intervention on improving mental health for a frail elderly population.

*Perceived Social Support*

Perceived social support outcomes, as measured by the Personal Resource Questionnaire (PRQ85) – Part Two, were compared over time from baseline (pre-randomization) (T1) and 6 months (post-randomization) (T2) with 225 valid and completed cases as illustrated in Table 27. The mean change scores (delta for individual participants) from baseline to 6 months (T1-T2) for the total PRQ85 score was analysed (using repeat measures ANOVA) to understand individual improvements over time. Improvements in the mean score for the PRQ85 were calculated and accounted for baseline scores (T1-T2, divided by T1). Analysis of covariance (ANCOVA) was calculated using Time 1 (pre-intervention) scores as a covariate to compare the values at follow-up in order to control for differences in pre-intervention functioning. Seventeen of the 225 study completers were unable to respond to the PRQ85 questionnaire due to poor physical health and/or a proxy respondent unable to answer and, therefore, they were not included in the analysis for this outcome.

At 6 months, the level of perceived social support was high in both groups. However, there was a small statistically significant percentage increase in the level of perceived social support in the nursing group (2.43%) versus a 0.82% reduction in the usual care group (F = -2.646, p = 0.009) (see Figure 24).

*Coping Style*

Coping style outcomes, as measured by the Coping Questionnaire (Moos et al., 1985) was compared over time from baseline (pre-randomization) (T1) and 6 months (T2) with the valid and completed cases. At 6 months, seventeen of the 242 study completers were unable to
respond to the active behavioural coping, avoidance coping, information seeking, affective regulation, and emotional discharge subscales in the questionnaire and, therefore, they were not included in the analysis for this outcome. Nineteen of the 242 study completers were unable to respond to the cognitive coping subscale, twenty one were unable to respond to the problem solving subscale, and twenty four were unable to respond to the logical analysis subscale of the questionnaire, and, therefore, they were not included in the analysis for this outcome. Missing responses were related to poor physical health and/or a proxy respondent unable to answer.

The mean score and standard deviation for each of the three methods of coping (active cognitive coping, active behavioural coping, avoidance coping), and each of the five foci of coping (problem solving, logical analysis, emotional distress, affective regulation, and information seeking) at baseline (T1) and 6 months (T2) were compared between the two groups as illustrated in Table 28 - the greater the score on each of the subscales, the higher the level of use of each particular coping style. The change score (delta for individual participants) from baseline to 6 months (T1-T2) for each of the subscales were analysed (using repeat measures ANOVA) to understand individual improvements over time. Changes in the mean scores were calculated and accounted for baseline scores (T1-T2, divided by T1). As in Table 28, analysis of covariance was calculated using pre-intervention scores as covariates.

As seen in Table 28, all types of coping styles were used to some extent in handling current stressors. However, subjects were more likely to utilize active cognitive coping and behavioural coping styles than avoidance coping styles. They were also more likely to seek information and guidance and use problem-solving styles than use affective regulation, emotional discharge and logical analysis coping styles. At 6 months, there was no statistically significant or clinically important difference in coping styles between the two groups.
Effectiveness of Proactive RN Health Promotion and Preventive Care on Functional Health Status and Related Quality of Life

Health related quality of life and function outcomes, as measured by selected scales in the SF-36 Health Survey, were compared over time from baseline (pre-randomization) (T1) and 6 months (post-randomization) (T2) with the 116 valid and completed cases. The SF-36 scales that were measured in this study include: role functioning related to physical health, role functioning related to emotional health, and social functioning.

Table 29 provides a comparison of the total mean scores for each of the eight scales and two summary measures in the SF-36 at baseline compared to normative data (by age group) to give a sense of where caregivers fell in relation to the general population at baseline (Hopman et al. 2000). Noteworthy, is that at baseline, all caregiver participants (n=116) scored below the mean of the general population in social functioning. Social functioning of the caregiver participants compared to the general population was particularly compromised for individuals aged 45 to 54 years (n= 23) (63.04 vs. 84.3, p = 0.02), and 75 years and up (n=47) (63.83 vs. 82.2, p < 0.01); this represents 60.3% of the total sample.

The mean scores and standard deviation for each of the scales in the SF-36 at baseline (T1) and 6-months (T2) were compared between the two groups as illustrated in Table 30. The mean change scores (delta for individual participants) from baseline to 6 months (T1-T2) for the three SF-36 scale scores were analysed (using repeat measures ANOVA) to understand individual improvements over time. Improvements in SF-36 scores were calculated accounting for baseline scores (T1-T2, divided by T1). As in Table 30, analysis of covariance (ANCOVA) was also calculated using Time 1 (pre-intervention) scores as a covariate in order to control for
differences in pre-intervention functioning. A mean change score difference of >5 between the groups was considered clinically important.

At 6 months, caregivers in both the usual care and the nursing group had improved in individual change scores in each of the SF-36 scales. However, there were greater improvements in individual change scores in relation to role functioning related to physical health and social functioning for caregivers receiving the RN intervention compared to the usual care group. At the 6-month follow-up, there was a clinically important percent improvement in social functioning in the nursing group (23.7%) vs. a 5.9% improvement in the usual care group. Social functioning can be defined as the degree to which health problems (physical and emotional), interfere with normal social activities (Sherbourne et al., 1992). A mean change score difference of 11.31 between groups is clinically important. However, due to the large standard deviation, the power to detect the difference of 6.26 was less than 50% and not statistically significant (F = -1.41, p = 0.161).

Mental status (level of depression) outcomes, as measured by the Centre for Epidemiologic Studies in Depression Scale (CES-D) was compared over time from baseline (pre-randomization) (T1) and 6 months (T2) with the 109 valid and completed cases. The mean scores and standard deviation for the total CES-D score at baseline (T1) and 6-months (T2) were compared between the two groups as illustrated in Table 30. The mean change scores (delta for individual participants) from baseline to 6 months (T1-T2) for the total CES-D score was analysed (using repeat measures ANOVA) to understand individual improvements over time. Improvements in the mean score for the CES-D were calculated accounting for baseline scores (T1-T2, divided by T1). As in Table 30, analysis of covariance (ANCOVA) was also calculated
using Time 1 (pre-intervention) scores as a covariate in order to control for differences in pre-intervention functioning.

As illustrated in Table 30, there was a percentage reduction in the CES-D depression score in the nursing group (13.2%) versus an 8.3% increase in the usual care group. However, this 2.38 difference in mean change scores between the groups was not statistically significant (F=0.941, p = 0.349) nor clinically important. The groups were compared using a cut-off score of ≥ 21 to distinguish between depressed and non-depressed participants. At 6 months, there was a 7.7% increase in the number of caregivers who became depressed in the usual care group compared to a 1.5% decrease in the nursing group. Although this difference was not statistically significant (x² = 0.819, p = 0.365), it suggests a favourable trend.

**Effectiveness of Proactive RN Health Promotion and Preventive Care on Level of Caregiver Burden**

Caregiver burden as measured by the Caregiver Reaction Assessment Scale (CRA) (Given et al. 1992) was compared over time from baseline (pre-randomization) (T1) and 6 months (post-randomization) (T2) with the 116 valid and completed cases (Table 31). The mean scores and standard deviation for each of the subscales in the CRA at baseline (T1) and 6-months (T2) were compared between the two groups as illustrated in Table 31. The mean change scores (delta for individual participants) from baseline to 6 months (T1-T2) for the five subscale scores were analysed (using repeat measures ANOVA) to understand individual improvements over time. Improvements in CRA scores were calculated accounting for baseline scores (T1-T2, divided by T1). As in Table 31, analysis of covariance (ANCOVA) was also calculated using Time 1 (pre-intervention) scores as a covariate in order to control for differences in pre-
intervention functioning. A mean change score difference of >5 between the groups was considered clinically important.

At 6 months, both the usual care and the nursing group had improved individual change scores within each of the subscales (indicating a reduction in the level of burden associated with caregiving), with the exception of the family support subscale score in the usual care group which increased by 11.4% vs. a slight (0.9%) improvement in the nursing group. The family support subscale measures the extent to which family supports and works together with the caregiver. It assesses the caregiver’s perception of being “dumped on” or abandoned (Given et al. 1992). However, this 1.14 difference in mean change scores between the two groups was not statistically significant (F=1.446, p = 0.151) nor clinically important. At the 6-month follow-up, there was no statistically significant or clinically important difference in the mean change scores for level of caregiver burden between the two groups.

*Proactive RN Health Promotion and Preventive Care on Service Expenditures and Utilization*

Service utilization outcomes as measured by the Health and Social Services Utilization Inventory (Browne et al., 2001) were compared over time from baseline (pre-randomization) (T1) and 6 months (post-randomization) (T2) with the 114 valid and completed cases (Table 32). Two caregivers did respond to the health and social service utilization inventory at the 6 month follow up and, therefore, they were not included in the analysis for this outcome measure. To calculate annual utilization measures, the various spans of time are extended to yield an annual rate of utilization per category of health service and multiplied times the current unit charges for each service to yield a measure of expenditures for health and social service. Unit charges or costs for each service, as outlined in Table 25, were based on averages for Ontario, Canada, as
reported by Browne et al. (2001) and CCAC of Halton rates for the study period (February 2001-

The main finding is that there was no statistically significant difference between the RN
and the usual care group in caregiver’s total annual per person direct expenditures (including
hospitalization). Even when the cost of an RN health promotion intervention was added to the
total cost, it was no more expensive to augment usual care with nursing visits ($x^2 = -0.198, p =
0.843) for a group of caregivers, 16.7% of whom are depressed, 35.3% of whom are functionally
limited related to their physical health, and 60.3% who were limited in terms of social
functioning.

At 6 months, the average total per person annual direct cost of service utilization
(including hospitalization) for both groups was relatively low ($3,183.10) (Table 32) compared
to the average utilization reported by the elderly client participants ($18,178.37). The majority of
the costs were related to medications (33.1%) and acute hospital stays (31.0%). However, only
5.8% (n=10) of the caregiver participants reported one or more hospital admission over the 6
months of the study. At 6 months, only 11% (n=13) of the 116 caregiver completers reported use
of any home care service for themselves over the past 6 months.

While the intervention and control group did not differ significantly in the use of health
and social services, the pattern of service utilization is noteworthy. Out of the 30 items in the
Health and Social Service Utilization Inventory, the main cost differences between the two
groups was found in three items. Participants in the nursing group reported a higher utilization of
medications ($1,169.42) vs. usual care ($944.04), a higher use of physiotherapy services
($246.03) vs. usual care ($41.77), and a higher use of acute hospitalization ($1049.59) vs. usual
care ($928.95). However, these differences in mean utilization were not statistically significant.
In addition, there was no statistically significant difference between the two groups in the number of participants reporting one of more hospital admissions ($x^2 = 0.955, p = 0.607$).

Also as expected, those participants receiving the RN health promotion intervention were also slightly higher users of emergency room, social workers, nutritionists, laboratory test and other health care providers/services. As part of the RN intervention, participants would have been appropriately referred to these services based on their needs. However, these differences in mean utilization were not statistically significant. Higher expenditures of use of these services were offset by slightly lower use of family physicians, physician specialists, psychologists, occupational therapist, chiropractor, homemaker, ambulance, and supplies, aids or devices. However, these differences in mean utilization were not statistically significant.

In summary, there were no statistically significant differences in caregiver characteristics (clinical, demographic, social, level of burden associated with caregiving, and expenditure of use of services) at 6 months between the two groups. Thus, any 6-month differences between groups of elderly CCAC clients cannot be attributed to differences in caregiver characteristics.

We examined the characteristics of elderly study participants (age, presence of depression, presence of co-morbid conditions, living arrangement, cognitive status, coping style, level of perceived social support, presence of a caregiver, level of homemaking service utilization), using a regression approach, to explain the improvement in the SF-36 mental health component summary score. As illustrated in Table 33, living alone, presence of depression (CES-D $\geq 21$), and availability of an informal caregiver explains 48.7% of the variation in the SF-36 mental health component summary score ($p = 0.009$) for both groups using the scores reported at baseline.

*Subgroup Analysis*
We also examined the characteristics of the frail elderly participants (age, depression, living arrangement, availability of an informal caregiver, coping style, cognitive status) which may have interacted with the approach to treatment to explain improvement in the client’s SF-36 mental component summary score. There were no particular types of clients who benefited more from nursing health promotion versus usual home care services. Frail elderly home care clients of all types receiving the nursing health promotion intervention in addition to usual care benefit in terms of improved mental health status.
DISCUSSION

Summary of Results - Elderly Study Participants

*Proactive RN Health Promotion and Preventive Care Intervention*

This is the first Canadian randomized controlled trial with a full economic evaluation that provides evidence for the effectiveness and efficiency of an RN health promotion and preventive care intervention for a general population of frail elderly home care clients eligible for personal support services.

Out of 288 subjects eligible for personal support services and randomized to either usual home care or usual home care plus the RN health promotion and preventive care intervention, 242 (84.0 %) were retained in the 6-month follow-up. Eligible subjects were lost to follow-up as a result of death (37%), missed (not located or physically unable to participate) (28%), or refusal to participate (26%). The 242 frail elderly home care clients (76.9% women) in this study who were retained in the 6-month follow-up reported a higher level of health related quality of life and functioning, a lower level of depressive symptoms, a higher use of problem-solving as a coping style, and a lower use of family physicians and physiotherapists than those lost to follow-up. Thus, a potential limitation of this study may be that study completers had a higher level of quality of life and functioning compared to those who were lost to follow-up, which may have influenced their ability and willingness to participate.

Frail elderly participants were clinically and statistically similar in both experimental and control groups on most baseline variables including gender, age, cognitive status, marital status, living arrangement, ethnic/cultural group, relationship to caregiver, level of education, income, cognitive status, and severity of illness factors. However, participants in the nursing group took fewer medications, reported a lower level of mental health related quality of life and functioning,
and a higher level of depressive symptoms than those in the usual care group. Thus, the respondents in the nursing group, who participated in the 6 month follow-up were more disadvantaged than those in the usual care group with respect to mental health functioning.

This study provides insight and a profile of an elderly home care population assessed as eligible for personal support services. Clinically, the study participants presented as a fairly elderly group, predominantly female (76.9%), with a mean age of 83.8 years. The majority were functionally limited with 93.4% reporting that they were limited to some degree in performing activities of daily living (and fairly ill) with 63.6% reporting a hospital admission in the previous 6 months, 52.4% reporting more than one illness, 25.6% exhibiting depressive symptoms, and 86.4% taking four or more prescription medications daily. The majority of the sample was widowed, separated or single (65.7%), and almost half (48.3%) lived alone. Over half of the sample (51.7%) reported that they received help from their informal support network. The health of the study participants, as reported on the SF-36 health survey, was particularly compromised in the areas of physical functioning, role functioning related to physical health, social functioning, and energy/vitality, compared to published norms (Ware, 1993).

A visiting nurse engaged 84.7% of those frail elderly participants who were randomly allocated to the RN health promotion and preventive care intervention at baseline. Subjects randomized to the RN group received an average of 3.94 nursing visits and 1.81 telephone contacts over the 6-month follow-up. More than half of the sample (57.6%) received 4 or more home visits, and 60.4% completed the 6 month intervention. Overall, compliance with the intervention by the study nurses was high with the exception of not visiting participants within one week of sending the referral to the nursing agency, and completing at least one home visit with the personal support work. The former was related to missing information, difficulties
contacting participants, as well as workload issues for those nurses providing the intervention. The latter was related to changes in policy that occurred over the study period which impaired access to personal support services for study participants in both groups, often resulting in service delays or reductions in service.

**Functional Health Status and Quality of Life**

Both approaches to care resulted in immediate improvements in functional health status and quality of life at 6 months. However, proactive RN health promotion and preventive care resulted in several clinically and statistically significant improvements in both physical and mental health functioning, compared to usual care. In terms of the physical health component summary in the SF-36, there was a clinically important 61.7% improvement in the physical functioning subscale in the nursing group versus a 34.7% improvement in the usual care group. In addition, the proactive RN intervention had a clinically important 106% improvement in the subscale related to physical role functioning versus a 83.2% improvement in the usual care group. The finding that home based health promotion and preventive care enhances physical functioning amongst older adults is consistent with the literature (Bernabei et al., 1998, Pathy et al., 1992; Stuck et al., 1995; Stuck et al., 2000).

As expected, improvements in physical health in the proactive RN group resulted in several clinically and statistically significant improvements in mental health functioning. With proactive RN health promotion and preventive care there was a clinically and statistically significant improvement in both emotional role functioning (13.7%) and mental health functioning (10.1%) versus a respective 0.5% and 1.3% drop in the usual care group. Improvements in the subscales relating to mental health at the 6-month follow-up were also captured by both a clinically and statistically significance improvement in the summary score for
mental health for the nursing group (20.4%) versus a 7.4% increase in the usual care group. This is the first study to provide strong evidence for the effectiveness of a proactive RN health promotion and preventive care intervention on mental health outcomes. Although Bernabei et al. (1998) also suggested mental health benefits, the intervention was provided by a multidisciplinary geriatric team; thus, it was difficult in this study to isolate the contribution of the RN to any observed change in outcome.

The overall conclusion from this present study results is that proactive RN health promotion and preventive care results in measurable gains in both mental and physical functioning for frail elderly home care clients eligible for personal support services. Of note, is that the major improvement at the 6-month follow-up was concentrated in the mental dimension of health.

### Mental Health, Perceived Social Support and Coping Style

As expected, with an improvement in physical and mental health functioning in both groups, there was a concomitant reduction in the level of depression in both groups. Specifically, there was a clinically and statistically significant percentage reduction in the prevalence of depressive symptoms in the nursing group (23.9%) versus a 8.8% reduction in the usual care group. This finding provides further support for the effectiveness of a proactive nursing intervention on improving mental health for the frail elderly and improved quality of life.

At 6 months, the level of perceived social support was relatively high in both groups. However, there was a small statistically significant percentage increase in the level of perceived social support in the nursing group compared to a small reduction in the usual care group. Respondents in both groups used all types of coping styles to some extent in handling current
stressors. However, at 6 months, there was no statistically significant or clinically important difference in coping styles between the two groups.

**Expenditures for Use of Health and Social Services**

This is the first Canadian study that combines both a strong research design and a comprehensive cost assessment to evaluate the impact of a health promotion and preventive care intervention within the context of home care services.

Not only was a proactive RN health promotion and preventive care intervention more effective but also these benefits were produced at no additional expense to society as a whole. There was no statistically significant difference between the two groups in total annual per person direct expenditures (including the cost of the nursing intervention), for a group of frail elderly CCAC clients who were more disadvantaged to begin with. The finding that RN health promotion can improve health outcomes at no additional cost to society as a whole is both economically and administratively important in a system of national health and social insurance.

As depicted in Figure 6, Birch and Gafni (1996) identified nine possible outcomes of economic evaluation of health programmes. From an economic perspective, the outcome of this study is favourable and illustrates outcome #4, where increased effects are achieved with one approach over another at equivalent expenditures (Birch & Gafni). This is the first study to provide strong evidence for the effectiveness of a proactive RN health promotion and preventive care intervention on the use and costs of a full range of health and social services from a societal perspective. Although other studies of this type have suggested cost benefits, they have been limited to the costs of institutional care such as reduction in nursing home (Bernabei et al., 1998; Stuck et al., 1995; Stuck et al., 2000) and hospital admissions (Bernabei et al., 1998; Hendriksen
et al., 1984; Zimmer et al., 1985), have not addressed the full range of services and were not conducted in a Canadian System of National health insurance.

**Summary of Results - Caregiver Participants**

This is the first randomized controlled trial in a Canadian home care context to evaluate the effects and expense of a nursing health promotion intervention for both frail elderly clients and their informal caregivers. Although Zimmer et al. (1985) suggested benefits to caregivers, these benefits were limited to satisfaction with the level of care. In addition, because the intervention was provided by a physician led interdisciplinary team, it was difficult to isolate the contribution of the RN to any observed change in outcome.

Out of 171 eligible and consenting caregivers of elderly study participants randomized to either usual home care or usual home care plus the RN health promotion intervention, 116 or 67.7% were retained in the 6-month follow-up period. Eligible caregivers were lost to follow-up as a result of death of either themselves or the elderly client (29.1%), missed (not located or physically unable to participate) (32.7%), or refusal to participate (38.2%). Thus, 47.9% of the study population of 242 elderly study participants had an available caregiver who participated in the study at baseline and 6 months. The 116 caregivers who were retained in the 6-month follow-up reported a higher use of prescription medications and physiotherapy services and a higher level of burden in terms of scheduling than those lost to follow-up. Caregiver respondents at the 6 month follow-up in both groups were similar on all clinical, demographic and social characteristics, level of caregiver burden, and per person expenditure of use of services.

This study provides insight and a profile of informal caregivers of frail elderly persons eligible for home care services. Clinically, approximately one out of three caregiver participants reported difficulty performing activities of daily living as a result of their physical health
(33.6%) and emotional problems (30.4%). In addition, one out of three caregivers (38.8%), reported that their physical health or emotional problems interfered with their normal social activities moderately to extremely, and one out of six (16.7%) exhibited depressive symptoms. Noteworthy, is that 40.5% of the caregivers were 75 years of age and older. These findings suggest that a significant proportion of elderly home care clients are being cared for by individuals who are elderly as well and facing issues related to later life themselves. Yet, only one out of 8 (13%) of all caregivers reported using formal home care services, and one quarter (23.0%) indicated that they did not receive support from other informal sources, i.e. family members. So there is probably a substantial subgroup of caregivers who are in need of formal home care services but are not receiving them. Notably, all caregiver participants scored significantly lower than the mean of the general population in terms of social functioning.

A visiting nurse engaged 65.1% of available and consenting caregivers who were randomly allocated at baseline to the RN health promotion intervention. Caregivers of subjects randomized to the RN group received an average of 1.47 home visits and 0.92 telephone contacts over the 6-month follow-up. The majority of the sample of caregivers (87.2%) received 0-3 home visits over the 6-month follow-up period. Thus, a potential limitation of the study may be that caregivers received a relatively low dose of the study intervention.

Functional Health Status and Quality of Life

Both approaches to care resulted in immediate improvements in functional health status and quality of life at 6 months. However, RN health promotion resulted in greater improvements in social functioning (23.7%) vs. a 5.9% in the usual care group. However, this difference was not statistically significant (p = 0.161). Notably, there was a 7.7% increase in the number of caregivers who became depressed in the usual care group compared to a 1.5% decrease in the
nursing group. Although this difference was not statistically significant ($p = 0.365$), it suggests a favourable trend.

*Caregiver Burden*

Both approaches to care resulted in immediate reductions in the level of burden associated with caregiving. However, no significant differences were found between the two groups at the 6-month follow-up.

*Expenditures for Use of Services*

The main finding is that there was no statistically significant difference between the two groups in caregiver’s total annual per person expenditure of use of services. Even when the cost of the RN intervention was added to the total cost, there were no significant differences were found between the two groups at the 6-month follow-up. Higher use of prescription medications, physiotherapy services, acute hospitalization, emergency room, social work, and nutritionists in the nursing group were offset by a lower use of family physicians, physician specialists, psychologist, homemaker, and other health care professionals compared to the usual care group.

In summary, there were no statistically significant differences in caregiver characteristics at 6 months between the two groups. Thus, any 6-month differences between the two groups cannot be attributed to differences in caregiver characteristics.

*Evaluation of a Collaborative Model of Research*

One of the strengths of the project has been the participation of key decision-makers in the development, implementation, and evaluation of the project. This involved collaboration with administrators, managers and front line staff of the participating organizations. In a qualitative study of 25 executive directors of local health service agencies, Anderson, Cosby, Swan, Moore & Broekhoven (1999) reported that a key factor contributing to the use of research
findings by local health service organizations is that the research is relevant to organizational needs, and a mutual commitment to the study has been established. Thus, the establishment of a steering committee and the resources, both financial and human, provided by the agencies involved was critical to the initiation, implementation and completion of the study. The combined perspective of front line staff, management, and researchers helped to identify and address issues related to implementation of the study, while creating unique opportunities for innovation and a sense of commitment to the project goals and completion.

Another key factor contributing to the successful implementation of the study was the scheduling of regular meetings with the investigator and the Registered Nurses providing the study intervention for mutual problem solving and support. Through this forum, opportunities were provided to staff for support, further education and skill enhancement. “Collaboration is not an end in itself but a means to other ends such as improved practice, expanded knowledge, increased productivity, and increased quality of education” (Browne, Arpin, Fitch, & Corey, 1988, p. 76). A useful measure of outcome to assess the effectiveness of collaboration is a positive change in clinical practice (Browne et al., 1988). Several themes emerged from the interactions between the investigator and the study nurses, which suggest that the implementation of this collaborative study had a positive impact on practice:

1. **Developing trusting, caring relationships: Study nurses and frail elderly clients:** This included identifying and sharing strategies for developing a trusting and caring relationship and establishing open communication with frail elderly clients and their caregivers. This issue was critical and time intensive for the nurses in the earlier stage of the intervention. Communication skills and making a good impression during the initial contact were identified as essential because they influence whether or not the nurse is
allowed to enter and/or return to the home. In the community, clients control access to their homes as well as information they are willing to share. The development of a trusting, caring and meaningful relationship with the client is a complex process that occurs over a period of time and is essential for fostering a client centred approach to care (McNaughton, 2000; RNAO, 1999; Trojan & Yonge, 1993).

2. **Acquiring knowledge, skills and attitudes related to mental health promotion**: This included raising awareness of the importance of initial and on-going screening for depression and dementia in the older adult. Together clients and nurses negotiated completion of a standardized depression screening tool and set goals to promote mental health, while facilitating client independence. The nurses acquired essential knowledge, skills and attitudes related to mental health promotion, which included use of a standardized assessment tool to support clinical observations.

3. **Providing a collaborative and interdisciplinary approach to care**: This involved identifying and addressing gaps in the current delivery system in order to promote a client centred and interdisciplinary approach to care. Nurses worked collaboratively with the client’s primary personal support worker, CCAC case manager, family physician, caregiver and/or other home care providers to coordinate the development, implementation, and evaluation of the plan of care. Mechanisms were put into place to foster continuity of care amongst these various organizations.

4. **Acknowledging and describing clinical knowledge**: Nurses acquire clinical knowledge over time; however, it is often difficult to capture (Benner, 1984). One of the side benefits of the interactions between the investigator and the RN’s in this study was that nurses began to recognize and share their clinical knowledge and relate these to positive
client outcomes. The nurses were asked to describe actual client care episodes, including their intentions and interpretations of the events as well as a description of the action and outcomes. The strength of this approach to identifying nursing competencies is twofold: “1) actual performance demands, resources, and constraints are described rather than hypothetical ones, and 2) this method provides a rich description of nursing practice” (Benner, 1984, p. 45). Thus, the meetings provided a forum for peer mentoring, support and learning.

Another benefit of the implementation of this study was the emphasis on health, the determinants of health and health promotion versus the traditional illness oriented approach. This required a significant change in values, emphasizing process related models of care that stand in contrast to the traditional outcome oriented, medical model of care.

Study Implications - Elderly Home Care Populations

*Nursing Practice Implications*

The major clinical benefit of the RN health promotion and preventive care intervention is clearly apparent in measures of quality of life and functioning at no additional cost to society as a whole. The clients in the intervention group had a higher quality of life (defined and measured to include mental health functioning and level of depressive symptoms) and an increased level of perceived social support immediately following the 6 month intervention. The finding that the intervention resulted in an increased level of social support and a reduction in depressive symptoms is significant in that both depression and low social support have been identified as risk factors for functional decline amongst community-dwelling older people (Stuck et al., 1999). This unique study provides evidence for a cost-efficient model of service delivery for frail
elderly home care clients through the use of both health promotion and preventive care strategies combined with an evidence-based approach.

The findings of this study are consistent with McWilliam et al. (1999), in a randomized controlled trial evaluating the effects and expense of a post-discharge health promotion intervention for 288 chronically ill persons 65 years of age and older. McWilliam et al. reported that those who received the intervention had significantly greater quality of life (defined and measured to include level of independence, ability to manage own health, and desire for information) at no additional cost. However, the costs in this study were limited to the cost of hospitalization and use of home care services.

The study findings support and extend the findings of Browne et al. (1999) in a review of 12 studies involving clients in community settings in Southern Ontario, Canada, suffering from a variety of chronic physical and mental health conditions. Browne et al. concluded that it is as, or more effective, and as, or less expensive, in the same year to offer complete and proactive community health services to vulnerable persons living with chronic circumstances than to provide reactive, on-demand, and piecemeal care in a system of national health insurance. For example, Browne et al. (2001a), in a randomized controlled trial, found that proactive co-interventions with sole-support parents were more effective in promoting parent economic adjustment than any intervention alone, including self-directed care. In a sub-analysis of this study, Markle-Reid, Browne, Roberts, Gafni, & Byrne (2002), found that, after 2 years, sole support parents who received a proactive, public health nursing case management intervention were less depressed and better adjusted than those who received the usual self-directed care. Not only was this approach more effective, but also these benefits were produced at no additional
cost to society as a whole, and costs were averted due to a 12% difference in non-use of social assistance in the previous 12 months.

This study provides empirical support for the synergistic and cumulative effects of personal resources and environmental supports on health outcomes and the use of scarce health care resources. Pawson & Tiley (1997) stated that realistic evaluations of multi-faceted community interventions require understanding of contextual factors and the mechanisms by which interventions work in addition to measuring outcomes. The model of vulnerability in this study helps to explain how and why this health promotion and preventive care intervention resulted in improved health outcomes and decreased costs, as well as what contextual components were necessary to its success. The process of bolstering personal resources (physical and mental health functioning) and environmental supports (level of perceived social support), both of which are considered determinants of health, resulted in significant improvements in health status to considerable economic effect (no additional expense). In summary, the model of vulnerability provides a comprehensive theoretical approach for directing the future design and evaluation of an effective and efficient health promotion and preventive care programme. It provides a framework for understanding the factors that contribute to a clients quality of life; many of which lie outside the formal health care system.

A focus on health and health promotion rather than illness and disease prevention requires a fundamental change in values. “To date, research in this area has focused largely on identifying risk factors and preventive care to minimize the risks of chronic diseases and debilitation associated with aging” (McWilliam et al., 1999, p. 27). Education related to health, the determinants of health, and strategies for promoting health must be carried out. “Skill
development efforts need to encompass the valuing of process-related practice approaches not premised on the medical model of care”(McWilliam et al., 1999, p. 38).

Elkan et al. (2001), in a review of the literature, recommended that a greater focus be placed on the process of delivering care, including a description of the components of a home visiting intervention. This study supports and extends the literature regarding models for best practice in the provision of proactive services for elderly home care clients. That is, in order to be effective, a preventive care and health promotion intervention must allow for a flexibly driven, client centred, and interdisciplinary approach to care delivery, involve an initial and comprehensive assessment or screening combined with regular home visits (Elkan et al., 2001; Jensen, 1997; Stuck et al., 1993b; Stuck et al., 2002), and provide referral to and coordination of community services (Rubenstein et al., 1991). Several studies suggest that health professionals must really come to know and connect with clients if empowerment is to be achieved (McWilliam et al., 1997). Organizational models of care delivery are needed that support nurses ability to develop continuous, uninterrupted and meaningful relationships with clients.

The results provide evidence for the effectiveness and efficiency of the nurse’s role in mental health promotion of older adults. Screening of the older adult’s mental health status should be considered integral to nursing practice. The findings extend and support recently published nursing best practice guidelines related to assessing mental health status in older adults (RNAO, 2003). The specific recommendations are as follows:

1. Initial and ongoing education related to normal aging and mental health promotion; i.e. screening assessment, and caregiving strategies for dementia and depression.

2. Utilization of a standardized screening tool to objectively identify symptoms of depression and dementia and support clinical observations.
3. Developed mechanisms for referral to specialized services (i.e. family physician, specialized geriatric mental health services and/or other members of the interdisciplinary team) when a nurse determines the client is exhibiting depressive symptoms and/or features of dementia.

4. Opportunities for ongoing professional development and mentorship to educate, support, and reinforce best practice related to assessing older adult’s mental health status.

“Nursing best practice guidelines can be successfully implemented only where there are adequate planning, resources, organizational and administrative support, as well as appropriate facilitation” (RNAO, 2003).

Implementation of best practices for nursing care results in positive changes for clients and nurses alike. Organizations should support the implementation of evidence based best practice guidelines for the promotion of mental health in older adults.

This study provides evidence of the type of functional outcomes that are possible and in which nurses can have a positive influence, including considerable economic benefit. In this study, the RN intervention had a positive impact on both physical and mental health functioning with the major improvement at the 6-month follow-up concentrated in the mental dimension of health. Few studies have demonstrated the use of the SF-36 Health Survey as an outcome measure for evaluating nurses’ contribution to client outcomes (Irvine et al., 2000). This study extends and supports the findings of Irvine et al. (2000) who compared the SF-36 with the Quality of Life Profile: Senior Version (QOLPSV) in a home health setting. Irvine et al. (2000) concluded that the SF-36 was more sensitive to changes over time, and more sensitive to several nursing variables including the client’s health status than the QOLPSV.
Finally, the results of this study provide evidence for the effectiveness of aiming a preventive, health promotion intervention at the general population of elderly home care clients aged 75 and over (eligible for personal support services), without specific selection criteria. This approach is consistent with health promotion, which is aimed at the population at large in its total environment (Stachtchenko & Jenicek, 1990).

**Implications for Policy**

An assumption underlying the shift in function of home care away from maintenance and preventive functions to acute care functions is that reducing access to professional nursing services for preventive functions saves the system money. For the first time, in the context of a national system of health and social insurance, this study demonstrates that this assumption is incorrect and untenable. In fact, it is no more expensive to provide this vulnerable frail elderly home care population with RN health promotion and preventive care than usual reactive home care services thus, making the intervention highly feasible given its clinical benefits. The finding that RN health promotion can improve health outcomes at no additional cost to society as a whole is both economically and administratively important within a system of national health and social insurance. “An intervention which enhances quality of life while not increasing overall costs of health care deserves further attention” (McWilliam et al., 1999, p. 36).

While the intervention and control group did not differ significantly in their total expenditure of use of health and social services, the pattern of service utilization is noteworthy. Compared to the usual care group, participants in the nursing group were higher users of acute hospitalization, family physicians, emergency room, and other health professionals. However, these differences were offset by a lower and more appropriate use of prescription medications, physiotherapy, and supplies or aids in the nursing group versus the usual care group. Therefore,
the additional cost of nursing visits was offset by a lower and more appropriate use of other health and social services compared to the usual care group.

The results of this study provide strong evidence for the effectiveness and efficiency of a visiting nurse in providing health promotion and preventive care within the existing Canadian home care setting compared to the usual on-demand and piecemeal services. The policy implications are significant given the shift in function of home care away from maintenance and preventive functions to acute care function (Anderson & Parent, 2000; Boyle, 2001; CNA, 1998). In the absence of national standards, home care policies, services and their delivery vary greatly within and between provinces/territories and across the country (CHCA, 1999; Coyte & McKeever, 2001; Coyte & Young, 1999; MacAdam, 2000). In addition, there is often no linkage between standards and the quality of care provided. For example, in this study, is usual care the standard we want to create and compare against or is the nursing health promotion model the standard? If the usual home care model is the standard, then are we under servicing vulnerable persons? Questions remain regarding is there enough funding in home care or is it a question of appropriate resource allocation?

The results of this study provide scientific evidence to inform resource allocation decision-making regarding the prioritization and reallocation of home care resources for a growing elderly population in a climate of acute health care resource constraints. Eligibility criteria for home care services are designed to distinguish qualified from non-qualified persons - they are not intended to establish priorities among qualified persons. Case managers are left to their own devices to determine how best to establish priorities within these general criteria (Carefoote, 1998). Re-investment of professional nursing services in preventive functions for chronic and vulnerable elderly home care populations must become a priority. Enhanced quality
of life can be achieved with existing home care resources by simply reorganizing services in a different way.

This is the first study to provide strong evidence for the effectiveness and efficiency of a visiting nurse in mental health promotion for a frail elderly home care population, 25.6% of whom are depressed. Despite the fact that the prevalence of depression among those receiving home care is estimated to be at least twice that among elderly people in general (Banerjee, 1993; Harrison et al., 1990; Ilife et al., 1993), it is rare for home care services to focus on mental health issues - access to home care services depends upon the presence of a physical illness or disability (Parent et al., 2000). Unrecognized, untreated and undertreated mood disorders such as depression increase the risk of functional decline (Murphy, 1982; Stuck et al., 1999) and the use of expensive health care resources (Colenda et al., 1991; Murphy, 1982; Stuck et al., 1999).

Improvements in mental health outcomes for frail elderly home care clients receiving proactive RN health promotion and preventive care, at no additional expense, provides convincing evidence for the prioritization and reallocation of professional nursing services toward mental health promotion for frail elderly home care clients. Home care programmes should collaborate with nursing and other mental health agencies in order to overcome barriers to services access, and provide effective care and support for clients with mental health issues. This includes re-evaluation of the eligibility criteria for home care that is based solely on the presence of physical needs or disability.

These findings add to the accumulating evidence that regardless of age, chronic illness or circumstance, geographic setting or specific intervention, proactive and comprehensive care early in the trajectory is both more effective and no more expensive in a system of national
health insurance (Browne et al., 2001b). The costs of the added intervention pay for themselves in the same year.

The findings from this study also highlight the complex interactions among different levels of care in the health system and the fact that making changes in one part of the health care system may affect other parts of the system. That is, decisions that are made in one part of the system (such as reducing professional nursing services for chronic, frail and vulnerable seniors), to deal with fiscal constraints and a growing elderly population, need to be evaluated for their impact on the larger whole (Hollander & Tessaro, 2001). The focus on short-term (acute care) home care functions is designed to deal with the output (discharge) side of the equation by facilitating reductions in hospital stays at the expense of dealing with the ever-increasing demand for the input (admission) side of the equation (Hollander, 2003). This input side is where preventive home care functions can have a significant impact. The results of this study provide scientific support for a national home care programme that provides a continuum of services including health promotion, prevention, curative, rehabilitation and palliative services (CNA).

The development of policies and the effective delivery of services at the provider level should be evidence-based. Changes in policy need to be evaluated for their impact on the larger whole, considering both health outcomes and costs from a societal perspective. Assumptions underlying current home care policies need to be empirically tested because of the real impact they are having on individuals and their families.

In summary, from a societal point of view, in the context of a national system of national health and social insurance, this study documents that it is immediately more costly to under serve this population of frail elderly home care clients, 93.4% of whom are functionally limited, 52.4% of whom have two or more health conditions and 25.6% of whom are depressed. The
potential for positive outcomes can be achieved for elderly home care clients when society pays for a proactive RN health promotion and preventive care intervention.

Study Implications - Informal Caregivers of Elderly Home Care Clients

The caregiver results have important implications for policy, service delivery and clinical practice. Although the literature on caregiving burden has addressed the emotional and social problems associated with caregiving, small samples, a focus on particular diseases, and a lack of focus on elderly home care recipients limit the applicability of the findings (Canadian Home Care Human Resources Study, 2003; Cochrane et al., 1997). Noteworthy, is that there is a distinct lack of information on the emotional, social and physical problems associated with caregiving amongst informal caregivers of elderly home care clients, and yet they are the largest group of caregivers (Anderson & Parent, 2000).

This study provides unique information about the prevalence of informal caregiving for elderly home care recipients and its associated physical and emotional health problems. In terms of prevalence, almost one half of elderly home care recipients had an identified informal caregiver. The most notable findings were that one in three caregivers indicated that they themselves were frail/disabled and/or needed help, one in six were depressed, over one half reported a loss in social functioning related to their health, and some 40.5% were 75 years of age and older. Low frequency of social contacts, depression, and poor self-perceived health have been identified as key risk factors for functional decline among community-dwelling people (Stuck et al., 1999). These data suggest that a significant proportion of elderly home care recipients are being cared for by individuals who are elderly as well and facing significant issues related to later life themselves; many of which are risk factors for functional decline.
Documentation of the prevalence of caregiving and its associated health problems is critical in that caregivers, rather than professionals, are the main providers of care to older, community dwelling persons with chronic illnesses (Morris et al., 1996). Approximately 80% of community dwelling, functionally impaired elderly individuals receive assistance entirely from informal care providers (Clark, 1996; Ferguson, 1995; National Advisory Council on Aging (NACA), 1999). Clinicians, practitioners and policy makers have acknowledged the sustained energy and commitment that are required by caregivers, and clearly sanction the need to support family caregivers in their role (Ontario Ministry of Health (OMH), 1998; Minister of Long-term Care and Responsibility for Seniors (MLTCRS), 1999; NACA, 1999). This is related to the recognition that without adequate supports in place to enable caregivers to fulfil their roles, the cost of formal health care will rise substantially (CNA, 1998; Health and Welfare Canada, 1991; Levine, 1999; NACA), particularly related to institutionalization (Hu et al., 1986; Weinberger et al., 1993), and potential secondary disability in the primary caregiver (Roberts et al., 1999). Caregivers’ poor health related quality of life has also been associated with the care recipient’s perceived unmet needs and increased depression (Mui, 1995).

Yet, support for elderly caregivers of older persons eligible for home care services has not been identified as an essential component of the basket of services for a publicly funded home care program (Romanow, 2002). One of the implications of the shift away from preventive and maintenance functions to acute home care functions is that more expectations are being placed on informal caregivers (Anderson & Parent, 2000). “And although relatively unknown, silent, and unpaid, they must bear the consequences of the current cost-shifting in the publicly funded system” (Anderson & Parent, 2000, p. 21). This could lead to a negative cost spiral in which further support for caregivers of persons with chronic needs is reduced, leading to greater
demands on acute and long-term care services because caregivers are no longer able to cope at home. The desired result in terms of cost-effectiveness is unlikely to be achieved unless governments begin to attend to the needs of informal caregivers of elderly home care clients. A recent report on home care human resources in Canada, identified the lack of recognition of the role of informal caregivers by governments and the public as a key issue to be addressed within the home care sector (Canadian Home Care Resources Study, 2003).

The finding that RN health promotion results in measurable gains in caregiver’s quality of life, (attributable to improved social functioning and a reduction in depression), at no additional expense, provides convincing evidence for reinvestment of professional nursing services in proactive and early health promotion interventions that target both elderly home care clients and their informal caregivers. This study provides a model for best practice in the provision of caregiver services that includes the following recommendations:

1. Models of care that support the development of continuous, uninterrupted and meaningful relationships with caregivers.

2. Systematic assessments of caregiver’s physical, emotional and social needs in order to proactively identify and address risk factors for functional decline.

3. Utilization of a standardized screening tool to support early identification and management of depression. Clinical depression is usually more disabling than anxiety disorders; its recognition and treatment are particularly important (Kouzis & Eaton, 1994; Hecht & Wittchen, 1988). A recent synthesis of the literature commissioned by Health and Welfare Canada (1991) concluded that proactive and integrated initiatives to treat caregiver depression would be the single most important strategy to overcome barriers to the use of available community services.
4. Individual counseling and education to assist caregivers in making decisions and solving problems related to their own health and their caregiving roles. Efforts to promote caregiver resilience and coping capacity will delay and/or prevent institutionalization of the care recipient (Browne & Roberts, 1999; Meshefedjian, McCusker, Bellevance, & Baumgarten, 1998).

5. Education to assist caregivers in identifying appropriate community services and how to access them.

Noteworthy, is that although one in three caregivers reported that they themselves were frail/disabled and/or needed help, only one in eight were utilizing any kind of formal home care service. The finding that there is not a good match between caregiver needs and use of services has been widely discussed in a growing literature on the use of community services by informal caregivers (Borgatta & Montgomery, 1987; Caserta et al., 1987; Collins, Stommel, Given, & King, 1991; Canadian Study of Health and Aging Working Group, 1994; Markle-Reid & Browne, 2001; Wilkins & Park, 1998). Health promotion interventions for informal caregivers that include referral to formal community services, need to proactively identify and address any barriers to service utilization in order to encourage appropriate utilization, discourage inappropriate utilization, and promote cost-effective care (Aday, 1993; Cox, 1997).

In summary, from a societal point of view, in the context of a national system of health and social insurance, this study documents that it is immediately more costly to under serve this population of informal caregivers of elderly home care clients, 16.7% of whom are depressed, 35.3% of whom are functionally limited related to their physical health, and 60.3% of whom are limited in terms of social functioning. The potential for enhanced health and well-being can be achieved for informal caregivers of elderly home care clients when society pays for proactive
nursing health promotion intervention. “If we assume that the definition of health encompasses both medical and social elements, then the scope of insured home care services under Medicare should be expanded to incorporate a broader array of services” (Anderson & Parent, 2000, p. 22).

Limitations/Generalizability of the Results

There are a number of areas of caution that the reader should take into account when reviewing the report and drawing conclusions. The major limitations of the study related to conducting the study in the “real world” within the usual setting of care with the usual providers. These include the following:

1. **Instrument design weaknesses:** The results of the health and social service utilization inventory may have been affected by missing data related to the length of the homemaking visits and the length of stay in a retirement home or long-term care facility. Thus, the total direct cost of health and social service utilization for both groups will be an underestimate of the real cost from a societal perspective. Proxy interviews were conducted for frail elderly subjects who were unable to participate due to functional limitations. When a proxy respondent was used, the reliability and completeness of self-reported data for subjective health measures such as depression, self-rated health, and perceived social support may have been limited.

   **Strategy:** Compare self-report data from the Health and Social Service Utilization Questionnaire to home care programme records. Home care programme records can provide the total hours of homemaking services, and total number of professional visits (nursing, physiotherapy, occupational therapy, respiratory therapy, and social work).

2. **Non-response bias:** This occurs when those individuals who were retained in the study differ systematically from those who were lost to follow-up. Participants who were retained in the study were a slightly higher functioning population of elderly home care clients than those lost to
follow-up in terms of their reported level of physical and emotional health. For example, 90.8% of the study completers were intellectually intact.

**Strategy:** Identify and implement strategies to enhance recruitment and retention of low functioning community dwelling older persons, specifically older persons with cognitive impairment. Recruitment was completed using predominantly telephone contacts versus in-person contacts. A lower rate of refusal may have been obtained if all clients could have been approached in person regarding participation in the study.

3. **Caregiver Compliance:** High attrition rate (32.2%) and low engagement rate and dosage of the nursing health promotion intervention for caregivers. A low compliance can negatively influence the effectiveness of the intervention and/or reflect an inability to tailor the intervention to the clients’ individual needs (van Haastregt et al., 2000). Thus, any differences found between those caregivers who received the intervention and those who did not will be an underestimate of the real difference.

**Strategy:** Identify and implement deliberate strategies to enhance recruitment and retention of caregivers.

4. **Health Provider Compliance:** Utilization of the CES-D depression screening tool was relatively low: 76% of clients and 36% of caregivers randomized to the nursing group completed the CES-D at least once over the 6-month follow-up. Health provider compliance is another important factor that can influence the effectiveness of a community intervention (Tugwell, Bennett, Sackett, & Haynes, 1985; van Haastregt et al., 2000).

**Strategy:** Promote, monitor and reinforce this aspect of the intervention with the study nurses and project staff.
5. Data is time sensitive and context bound: The data was collected during 1999-2003. During this period, there were major changes and cutbacks in funding for home care which may have influenced the results. Therefore, any use of services will be an underestimate of service use for both groups.

6. Interviewer bias: Not truly possible to blind interviewers to subject assignment at the 6-month follow-up, because information suggesting the presence or absence of nursing involvement could have been mentioned inadvertently by the subject.

7. Other potential confounders: Due to the nature of the intervention (that is, a change in the provision of care), the CCAC Case Managers were not blinded to subject assignment to the RN augmented intervention. Subjects and Family Physicians were aware of the study, which may have influenced the results.

Implications for Future Research

• Document, implement, and evaluate this health promotion study intervention in other contexts, (i.e. different regions and provinces) to establish the generalizability of the results.

• Extend the time frame for follow-up to a minimum of 1 year to better understand the long-term impact of the intervention. In this study, the immediate 6-month gains in health outcomes and costs may have continued - to greater economic effect.

• Develop enhanced tracking strategies to increase follow-up or to achieve follow-up of at least 80% of those subjects and their caregivers randomized to usual care or the RN health promotion intervention.

• Conduct a process evaluation using a qualitative study design in order to further explain how, and why, this health promotion intervention was effective. For example, did the
study intervention have a positive influence on autonomy, empowerment and/or decision-making abilities? Develop different or new scales and measurement approaches to determine fully the outcomes of health promotion. Traditional outcome oriented measures of health may not capture the more process-oriented notion of health (McWilliam et al., 1999).

Conclusion

In conclusion, under the current home care delivery system, this study demonstrates that it is more effective and less expensive to provide proactive RN health promotion and preventive care to a general population of frail seniors living with chronic circumstances and their informal caregivers than to provide professional services on a reactive and piecemeal basis. Re-investment of professional nursing services in health promotion and preventive care for chronic and vulnerable elderly home care populations must become a priority. The results of this study provide scientific evidence to support policy decisions regarding the prioritization and reallocation of home care resources for chronic elderly home care populations in a climate of acute health care resource constraints.
ENDNOTES

1 Community based services refers to services provided in the home, community or long-term care institution that are paid for with public or private funds. These services include homemaking, personal care support services, in-home nursing services, adult day programs, and/or caregiver support services (OMHLTC, 1998).

2 Resource allocation can be defined as the distribution of resources among competing programs or persons (McKneally et al., 1997).

3 Preventive care (or health protection) is “behaviour motivated by a desire to actively avoid illness, detect it early, or maintain functioning within the constraints of illness” (Pender et al., p. 7). Any intervention may be classified as preventive if it reduces the chance that a disease or disorder will affect an individual, if it interrupts or slows the progress of the disorder or if it reduces disability (Stachtchenko & Jenicek, 1990).

4 Health promotion is the process of enabling individuals and communities to increase control over the determinants of health and thereby improve their health (Epp, 1986). Health promotion is “behaviour motivated by the desire to increase well-being and actualize human health potential” (Pender et al., 2002, p. 7).

5 Usual home care services under the current home care delivery system consisted of:

- Standard case management services including intake eligibility assessments, and regular ongoing eligibility assessments by a CCAC Case Manager.
- Newly referred to and eligible for personal support services through the CCAC.
- Newly referred to and eligible for other professional home care services with the exception of nursing (RN level) services.
Clients are eligible for personal support if: the client is assessed as requiring assistance with personal care. Personal care may be provided either by a caregiver that lives inside or outside of the home or a personal support worker contracted by the CCAC. Clients who live in rest/retirement homes are entitled to receiving personal support services if they meet the eligibility criteria (CCAC, 1998). Effective August 2001, services were restricted to personal care only; assistance with housekeeping was no longer provided. Service levels were capped at 60 hours for regular clients and 80 hours for palliatives. This change in policy was in response to restrictions on funding levels for the CCAC’s in Ontario for the 2001-02 fiscal year (CCAC of Halton, August 2001).

The term personal support workers will be used throughout the paper to describe those who provide personal support services as defined by the OMHLTC Act (1998). The following are personal support services:

- Personal hygiene activities.
- Routine personal activities of living.
- Providing prescribed equipment, supplies or other goods.
- Services prescribed as personal support services.

Primary prevention: Activities that decrease the probability of occurrence of specific illness or dysfunction in an individual, family, group, or community and reduce incidence of new cases of disorder in the population by combating harmful forces that operate in the community and by strengthening the capacity of people to withstand these forces (Murray & Zentner, 1997).

Secondary prevention: Early diagnosis and treatment of the pathogenic process, thereby shortening disease duration and severity and enabling the person to return to normal function as quickly as possible (Murray & Zentner, 1997).
Tertiary prevention: Restoring the individual to optimal functioning through rehabilitation and within the constraints of the problem when an abnormality or disability is fixed, stable or irreversible (Murray & Zentner, 1997).
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