



Self-management program versus usual care for community-dwelling older adults with multimorbidity: A pragmatic randomized controlled trial in Ontario, Canada

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Abstract

Background: Multimorbidity, the co-existence of 2+ (or 3+) chronic diseases in an individual, is an increasingly common global phenomenon leading to reduced quality of life and functional status, and higher healthcare service use and mortality. There is an urgent need to develop and test new models of care that incorporate the components of multimorbidity interventions recommended by international organizations, including care coordination, interdisciplinary teams, and care plans developed with patients that are tailored to their needs and preferences.

Purpose: To determine the effectiveness of a 6-month, community-based, multimorbidity intervention compared to usual home care services for community-dwelling older adults (age 65+ years) with multimorbidity (3+ chronic conditions) that were newly referred to and receiving home care services.

Methods: A pragmatic, parallel, two-arm randomized controlled trial evaluated the intervention, which included in-home visits by an interdisciplinary team, personal support worker visits, and monthly case conferences. The study took place in two sites in central Ontario, Canada. Eligible and consenting participants were randomly allocated to the intervention and control group using a 1:1 ratio. The participants, statistician/analyst, and research assistants collecting assessment data were blinded. The primary outcome was the Physical Component Summary (PCS) score of the 12-Item Short-Form health survey (SF-12). Secondary outcomes included the SF-12 Mental Component Summary (MCS) score, Center for Epidemiological Studies of Depression (CESD-10), Generalized Anxiety Disorder (GAD-7), Self-Efficacy for Managing Chronic Disease, and service use and costs. Analysis of covariance (ANCOVA) tested group differences using multiple imputation to address missing data, and non-parametric methods explored service use and cost differences.

Results: 59 older adults were randomized into the intervention (n = 30) and control (n = 29) groups. At baseline, groups were similar for the primary outcome and number of chronic conditions (mean of 8.6), but the intervention group had lower mental health status. The intervention was cost neutral and no significant group differences were observed for the primary outcome of PCS from SF-12 (mean difference: -4.94; 95% CI: -12.53 to 2.66; p = 0.20) or secondary outcomes.

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Conclusion: We evaluated a 6-month, self-management intervention for older adults with multimorbidity. While the intervention was cost neutral in comparison to usual care, it was not found to improve the PCS from SF-12 or secondary health outcomes. Recruitment and retention challenges were significant obstacles limiting our ability to assess intervention effectiveness. Yet, the intervention was grounded in internationally-endorsed recommendations and implemented in a practice setting (home care) viewed as a key upstream resource fostering independence in older adults. These features collectively support the identification of ways to recruit/retain older adults and test alternative implementation strategies for interventions that are based on sound principles of multimorbidity management.

Keywords

Multimorbidity, older adults, self-management, home care services, community-based care, pragmatic randomized controlled trial

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Introduction

Multimorbidity, defined as the co-existence of 2+ (or 3+) chronic diseases in the same person,^{1,2} is an increasingly common global phenomenon. Worldwide, more than half of older adults (≥ 65 years old) have multimorbidity,³ with high prevalence rates reported in Canada (43%),⁴ the United States (63%),⁵ and the United Kingdom (67%).⁶ Increasing multimorbidity prevalence is driven by an aging population and the rise in global life expectancies.^{7–9} Multimorbidity is associated with negative outcomes such as reduced quality of life and impaired functional status, as well as increased health service use, mortality and caregiver burden.^{10–14}

Most efforts to date to improve the care of older adults with chronic diseases have focused on developing clinical guidelines for single diseases,^{15–17} which often leads to inappropriate polypharmacy, excessive treatment burden, and fragmentation of care.⁸ Older adults have indicated the need to change to a holistic model of care where one healthcare provider coordinates care to support their constellation of conditions.¹⁸ This has led to the release of guiding principles and recommendations from international expert panels recommending components such as a regular comprehensive review of patients' problems, a focus on patient-reported outcomes such as quality of life and functionality, promoting self-management, care coordination and system navigation, and developing individualized care plans.^{19,20}

Currently, there is little evidence regarding the effectiveness of interventions incorporating these components on outcomes in older adults with multimorbidity.⁸ A 2016 Cochrane review of multimorbidity interventions delivered in primary and community settings reported modest treatment effects and only among interventions targeting specific risk factors or functional difficulties, and called for more pragmatic trials.²¹ Around the same time, a review by the National Institute for Health and Clinical Excellence (NICE) reached similar conclusions and released guidelines that care plans for older adults with multimorbidity use a holistic approach, be

established in collaboration with patients, and be tailored to patients' needs and preferences (<https://www.nice.org.uk/guidance/ng56/chapter/Recommendations>).

Some studies of multimorbidity interventions have been published since these 2016 reviews, including the largest investigation to date—the 3D trial.⁸ This trial randomized adults with multimorbidity (3+ chronic conditions) to usual care or a 6-month intervention incorporating patient-centered care strategies and international recommendations on multimorbidity management. The primary outcome in the 3D trial was quality of life after 15 months.⁸ The 3D trial and studies in their update to the 2016 reviews showed little or no meaningful impact to quality of life.⁸ However, the 3D trial and several others have shown improvements in the patients' experience of patient-centered care. Moreover, the 3D trial process evaluation identified inadequate intervention fidelity and provider training on patient engagement as factors contributing to their modest results.²² A 2018 scoping review further contributed by identifying the patient/professional/organizational elements (e.g., face-to-face clinical assessments, tailored interventions, provider education/meetings) that were included in effective multimorbidity interventions.²³ Since all interventions in the scoping review were complex and involved between four and eight elements, it was not possible to isolate one component to link to the success of the intervention.²⁴

There remains an urgent need to continue to assess new models of care that incorporate the key components recommended in international guidelines and employ measures to ensure competency and fidelity in the delivery of the intervention. The Canadian home care sector is an ideal location for a multimorbidity intervention because of its potential to significantly reduce acute care services, allow older adults to remain in their homes longer, and delay long-term care (LTC) admissions.^{25,26} The sector provides care to an estimated 1 million Canadians at any given time, the majority (82%) of which are older adults²⁷ and many have multimorbidity.²⁸ The purpose of this study is to report the

results of a pragmatic RCT that tested a 6-month, community-based, patient-centered, self-management intervention for community-dwelling older adults with multimorbidity using home care services. We incorporated methods to monitor intervention fidelity and evaluated the intervention using outcomes important to patients, clinicians and policy makers. Interviews were conducted with providers to obtain their views on implementing the intervention and participant benefits. Provider-related behavioral/professional outcomes were also evaluated, are not reported here as these are being published separately.

Methods

The information provided below was prepared in accordance with the CONSORT reporting guidelines for randomized controlled trials (RCTs) (See CONSORT checklist—Appendix Supplemental Table A1).

Study design

A two-arm RCT study design was used. The trial was designed to be pragmatic, in order to inform decision-making by providing a treatment effect predictive of what would occur in real-world practice.²⁹ The Pragmatic Explanatory Continuum Indicator Summary-2 tool³⁰ guided the selection of pragmatic features, including recruiting clients that were representative of the population presenting in clinical practice, intervention delivery by real-world clinical practice providers, flexibility in customizing the intervention to meet patients' unique needs and preferences, selection of patient-relevant outcomes, and intention-to-treat (ITT) analysis. To avoid contamination, providers delivered the intervention or usual care, but not both.

Participants and setting

The study took place in two geographical sites within the Community Care Access Center (CCAC) located in central Ontario, Canada. At the time of the study, CCACs were regional centers responsible for arranging all government-funded home care services for people living in their home within the region. CCACs were responsible for deciding who receives care, the level of care, and how long care should be delivered (<https://www.ontario.ca/page/home-care-seniors>). A recruiter who worked in the CCAC contacted potential clients by phone to confirm that they met the following eligibility criteria:

- 65 years of age and older;
- newly referred to and receiving home care services;
- at least three chronic conditions (see Appendix Supplemental Table A2 for full list of chronic conditions; participants were asked to report all conditions confirmed by a doctor or for which prescription medications were being taken);
- able to speak English or have access to a translator;

- community-dwelling within the CCAC catchment area and not planning to move in the next 6 months; and
- mentally competent (based on a Short Portable Mental Status Questionnaire score ≥ 5) to provide informed consent, either independently or by a substitute decision maker.

Recruiters invited eligible participants to take part in the study. They forwarded the contact information for interested clients to the research coordinator at McMaster University. A research assistant from McMaster University obtained written informed consent prior to conducting a baseline study interview at the participant's home.

Intervention

The intervention was adapted from two previous community-based self-management interventions for older adults co-developed by the Aging, Community and Health Research Unit (ACHRU). While the previous interventions targeted older adults with two vascular conditions—diabetes³¹ and stroke³²—they included a major focus on all chronic conditions rather than simply the index conditions, thus serving as a strong foundation for the multimorbidity intervention tested in this trial. The links between vascular conditions, chronic disease and multimorbidity have been recognized, with calls for vascular medicine to use a broader lens that takes multimorbidity into account.³³ There was also strong feedback from participants and providers in these studies that a more holistic approach was needed that considered the suite of conditions facing participants as well as broader determinants (e.g., lifestyle, social and economic conditions). These prior interventions included virtually all of the key elements recommended in international guidelines for managing multimorbidity.^{19,20,23} The MRC framework for complex interventions was used in developing the prior interventions, which highlighted the importance of theoretical and empirical evidence.²⁴ The interventions were grounded in Bandura's Social Cognitive Theory,³⁴ where the aim was to build self-efficacy in order to improve self-management of health conditions and associated risk factors. Importantly they were informed by a range of stakeholders including patients, caregivers, family physicians, and decision-makers from local and provincial health authorities. All stakeholders worked as a team to identify service gaps, which often centered on needs related to multimorbidity and the burden arising from care fragmentation. Service gaps in turn informed the core components of the interventions and areas to tailor. The involvement of multiple provider agencies was critical to designing the interventions to ensure that all viewpoints were considered. Further details on the development of these interventions is provided in the published papers.^{31,32,35}

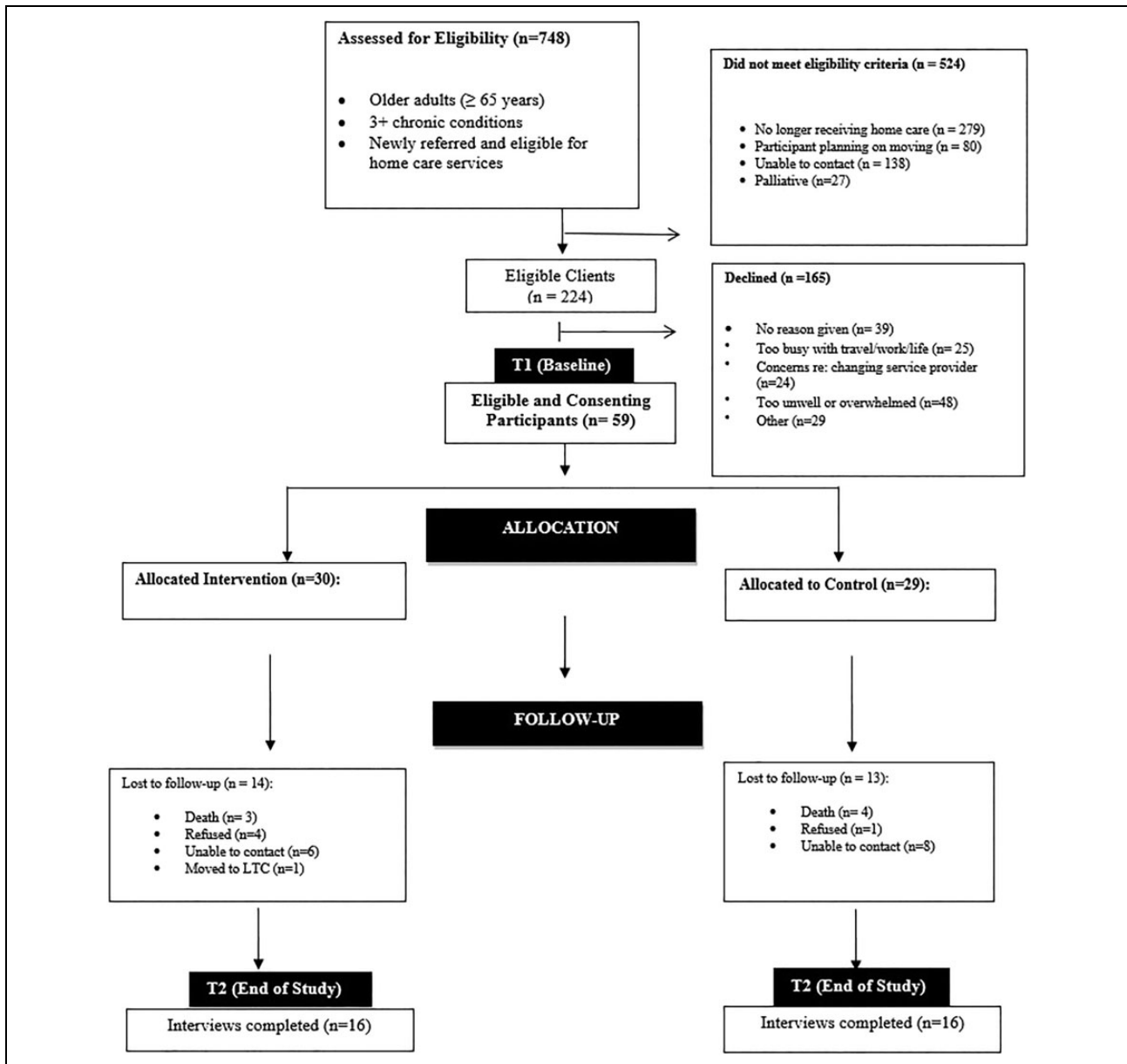


Figure 1. Study flow diagram.

The logic model for the multimorbidity intervention is provided in Supplemental Figure 1 of the Appendix. We highlight its key elements and active ingredients below, and describe the intervention in accordance with the Tidier (Template for Intervention Description and Replication) guidelines (see Tidier Checklist—Appendix Supplemental Table A3).

The multimorbidity intervention was delivered in addition to usual care by an interprofessional team consisting of a Care Coordinator (CC), Registered Nurse (RN), Physiotherapist (PT), Occupational Therapist (OT), and Personal Support Worker (PSW), and consisted of four main components:

- (1) **In-home visits:** The protocol required participants to receive a minimum of one in-home visit from the CC and three in-home visits from the PT or OT.

The schedule, team composition and care plan for the remaining in-home visits were tailored to client needs and preferences and required to fall within the maximum budget for each participant. The maximum budget for participants was calculated based on the costs associated with two CC visits, two RN visits, three PT/OT visits, and three PSW visits. Participants could choose between different provider services, e.g. one in-home visit by an OT could be substituted with one in-home visit by a PT or two visits by an RN. Trained PSWs followed the same visit schedule as per usual care (see Control Group below). Providers functioned as a unified team and used a common set of standardized screening tools, e.g. tools to assess multimorbidity

risk factors, cognition and mental health; medication reviews (comparison of prescribed medications to the Beers List); Safety Checklists completed by PSWs to capture and enable early communication among the team of issues relating to clients' overall wellbeing and changes in clients' status. Providers used a patient-as-partner approach, where they worked alongside clients and their informal/family caregivers to set goals that informed the care plan and select provider services suited to their needs. The in-home visits were critical in enabling providers to assess the full spectrum of health determinants, engage patients and caregivers in the care plan, and tailor the care plan to individual patient needs and priorities.

- (2) **Monthly case conferences:** providers developed a plan of care in collaboration with the client and their informal/family caregiver. The progress made toward achieving the goals of the plan of care were discussed in monthly case conferences involving the interprofessional team, and the PSW supervisor. At a minimum, each participant was discussed at three case conferences over the 6-month intervention period. The case conferences were critical in formalizing the interprofessional collaboration process and ensuring the early identification and response to participant issues and status changes.
- (3) **Case management:** CCs were responsible for ongoing case management during the 6-month intervention, which involved system navigation and facilitating participant access to appropriate health and social services. This also involved alerts sent to family physicians for concerns relating to prescribed medications, cognition (delirium, dementia), and/or mental health (depression). Case management was accomplished via regular communication between the CC, participant and providers and involved ongoing assessment and advocacy for services to meet the needs of participants and caregivers. System navigation and communication with physicians were critical elements serving to raise awareness of and integrate services across the health and social sectors.

Four strategies were embedded in all intervention components. The first was a *strengths-based approach*, which enabled the client to address challenges and achieve personal goals through the enhancement of self-efficacy building on strengths and abilities, rather than deficits and weaknesses.³⁶ The second strategy was a *holistic care approach focused on prevention and health promotion*, which involved developing a care plan to manage the suite of conditions facing the client to prevent onset or worsening of chronic conditions.³⁷ Care planning emphasized patient-centered outcomes, culturally appropriate

resources, and preferred processes of receiving care.¹⁸ This approach resulted in a care plan that accounted for the factors that impact the client's self-management of multimorbidity (e.g., access to care, social determinants of health such as transportation, income, and social supports). The third strategy was *engaging informal caregivers*, which involved actively consulting them in all aspects of the care of the clients and supporting them in their caregiving role.^{23,38} Support services coordinated by the interventionists considered the caregiver's strengths and challenges, and actively sought direction from clients and caregivers to develop and fulfill a plan of care. The fourth strategy was *interprofessional collaboration and communication*, which emphasized a process of communication and decision-making that valued the separate and shared knowledge of different home care providers, clients and their primary caregivers to provide optimal client care and optimize the scopes of practice of the members of the team.

Control group (usual home care services)

Participants enrolled in both arms of this study received usual care as per CCAC care guidelines, which included follow-up by the CCAC care coordinator to assess the client's eligibility for home care services, arranging and coordinating professional and non-professional home support services, providing information and referral to community agencies, and evaluating the plan of care on an ongoing basis. Table 1 provides a detailed comparison of the intervention with usual care. A number of key differences are apparent in comparing the intervention and usual home care services—communication with family physicians, team-based care and multimorbidity. Communication with physicians was key because they are currently not involved in the direct delivery of home care services. The intervention supported team-based care through training on interprofessional collaboration and monthly case conferences, instead of the single provider visit approach used in usual home care services. Importantly, case conferences included the unregulated care providers (PSWs via involvement of PSW supervisors), who are not typically involved in care planning for home care clients. The intervention also focused on multimorbidity and emphasized a holistic, long-term approach to care planning. This discouraged use of the single-disease model and short-term acute care focus that dominates home care and most health sectors.³⁹

Intervention training and fidelity

The following evidence-based strategies⁴¹ were used to monitor the intervention and enhance implementation fidelity:

- (1) **Training/Educational Workshops:** The investigators held a training session for the providers (CC, RN, OT, PT, PSW) before implementation of the

Table 1. Multimorbidity intervention versus usual home care services.

Characteristics	Multimorbidity intervention	Usual home care
Team-based care	Dedicated interprofessional (IP) teams of home care providers (Care Coordinator, Registered Nurse, Physiotherapist, Occupational Therapist, Personal Support Worker). Home care providers received training in best practices for the prevention and management of multimorbidity, team-based care, strengths-based practice, strategies to promote self-management, patient-centered care, and caregiver assessment and support strategies.	No dedicated IP teams.
Patient- and family-centered care	Providers use a patient-as-partner approach, where they work alongside patients and their family caregivers to set goals that informed an individualized care plan that is tailored to patient needs and preferences.	Care is often provider-centered rather than patient-centered.
Team communication and collaboration	Monthly IP case conferences to discuss patient goals and plan of care over 6-month intervention period.	Case conferences occur on an ad hoc basis with selected home care providers.
Personal support worker involvement in the team	Personal support workers are full members of the IP team and received training in multimorbidity, team-based care, and strengths-based practice. The Observe, Coach, Assist, and Report (OCAR) framework was used to enhance IP collaboration that is inclusive of the PSW. ⁴⁰	Personal support workers are not formally integrated into IP home care teams.
Prevention and management of multimorbidity	Focus of the intervention is on the prevention and management of multimorbidity, care coordination to support their multiple chronic conditions, and a holistic, long-term approach to care planning. This includes regular screening and assessment of multimorbidity risk factors using validated tools. This also includes consideration of broader determinants of health (e.g., lifestyle, social and economic factors).	Most home care interventions focus on the management of single diseases. Moreover, with scarce resources, home care is increasingly focused on acute, short-term medical needs.
Support for Self-Management	Use of a strengths-based approach to promote self-management and behavioral change. Provision of monthly in-home visits by IP team over 6-month intervention period.	With scarce resources, home care is increasingly focused on acute, short-term medical needs versus a long-term approach focused on prevention, health promotion.
Support for family caregivers	Focus of the intervention is on both patients and their family caregivers. Caregiver assessment and support was an integral component of the intervention.	Eligibility for home care services is based on patient's functional/medical needs, not the needs of family caregivers. Screening of family caregivers for caregiver distress and the provision of support and health promotion services for caregivers is not a part of routine home care practice.
Collaboration with primary care physician	Formal mechanisms for communication with the patient's primary care physician using medication, dementia, delirium, and depression alerts.	No formal mechanism for communication between home care providers and primary care physician.
Care Coordination	Care Coordinator role expanded to include leading the IP team, ongoing case management and facilitate access to health and social services over the 6-month intervention period.	Care coordinator role is to assess patient's eligibility for home care services, arranging and coordinating home care services, provide information and referral to community agencies, and monitor service delivery through in-home assessments with patients.

intervention at the study sites. Training at the sites occurred over 2 days. Each session was supported with role-appropriate training manuals. The training focused on intervention components and acceptable ways to tailor them, guidance on interprofessional collaboration, education and role-playing to develop skills in motivational interviewing, promoting self-management, best practices for the

prevention and management of multimorbidity, and caregiver assessment and support strategies. Examples of acceptable ways to tailor the intervention included: the number and approximate timing of in-home visits, provider team composition, and goals/activities/timeline outlined in the care plan, (2) *Monthly Implementation Meetings*: The Principal Investigator (PI) and Research Coordinator

conducted monthly meetings with the providers to discuss the progress of the study, provide feedback and education, and discuss challenges and potential solutions related to implementation of the intervention. Through this strategy, the research team supported the providers who were implementing the intervention and gave them protected time to reflect on the intervention, share lessons learned, and support one another's learning.

- (3) *Reminders*: The PI and Research Coordinator provided regular updates on the study to the providers, including successes and areas for improvement related to the intervention.
- (4) *Audit and feedback*: The providers were asked to keep logs of intervention-specific activities that were carried out (i.e., home visits, case conferences, safety checklists). At 1-month intervals, the PI and Research Coordinator conducted audits of the study-related documentation to assess fidelity by reviewing the extent to which the providers adhered to delivering the components of the intervention. The research team monitored in-home visits to ensure that participants received within the minimum and maximum number, and case conference records to verify that they were done monthly and to determine provider/participant attendance. More prescriptive auditing of intervention delivery (e.g., monitoring topics covered in in-home visits, referrals made) was avoided to remain consistent with the goals of a pragmatic trial where the aim is to train providers on the intervention but allow flexibility in the delivery of the components as would normally occur in routine care.³⁰ A comprehensive audit and feedback system has been shown to be effective when combined with education, outreach visits, or reminders.⁴²

Randomization

Eligible and consenting participants were randomly allocated to the intervention and control group using a 1:1 ratio. A biostatistician not involved in recruitment generated group allocations using stratified permuted block randomization. Random number sequences were input into a centralized web-based service (RedCap) that allocated clients (within site) to the two groups according to sequence.

Six-month change in outcome measures

We examined a variety of patient-reported outcome measures (i.e., PROMs). Health-related quality of life (HRQoL) was selected as the primary outcome, consistent with the overall goal of our intervention and approach for managing multimorbidity recommended by NICE (<https://www.nice.org.uk/guidance/NG56/chapter/Recommendations#principles-of-an-approach-to-care-that-takes-account-of-multimorbidity>). Additionally, HRQoL is a common outcome used in care planning for chronic conditions⁴³ and one highly relevant to patients with multimorbidity.⁴⁴ We used the 12-item Medical Outcomes Study Short-Form Health Survey (SF-12) to measure HRQoL,⁴⁵ which offers two HRQoL measures—the Physical Component Summary (PCS) and Mental Component Summary (MCS) score. We specifically selected the PCS as the primary outcome, which captures physical functioning, and ranges from 0 to 100 with higher scores representing better physical functioning. We also collected data on the following secondary outcomes:

(1) Mental functioning measured by the MCS from the SF-12. MCS scores range from 0 to 100, with higher scores representing better mental functioning.

(2) Depressive symptoms measured using the Center for Epidemiologic Studies Depression Scale (CESD-10).⁴⁶ CESD-10 scores range from 0 to 30, with higher scores representing more depressive symptoms.

(3) Anxiety measured using the Generalized Anxiety Disorder Scale (GAD-7).⁴⁷ GAD-7 scores range from 0 to 21, with higher scores representing higher levels of anxiety.

(4) Self-efficacy measured using the Self-Efficacy for Managing Chronic Disease Scale.⁴⁸ The scale score ranges from 1 to 10, with higher scores representing higher levels of self-efficacy.

(5) Healthcare and social service use and cost. Service use was measured using the Health and Social Services Utilization Inventory (HSSUI),⁴⁹ which is a reliable and valid self-report questionnaire that measures the use of health and social services.^{50,51} Inquiries are restricted to the reliable duration of recall: 6 months for recalling a hospital, emergency department (ED), or physician visit and 2 days for use of prescription medications. Service costs were determined by multiplying service use by the unit cost for the service to obtain total service cost. A societal perspective was assumed in identifying and costing services, to ensure that costs for all stakeholders were considered thus informing the broad allocation of resources in the public interest.⁵² Intervention costs (i.e., costs for providers to attend in-home visits and case conferences, including transportation/mileage) were included in the costs for participants in the intervention group. Unit costs were obtained from a provincial database providing the costs of all services paid for by the publicly-funded provincial health care system.⁵³

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- (2) Depressive symptoms measured using the Center for Epidemiologic Studies Depression Scale (CESD-10).⁴⁶ CESD-10 scores range from 0 to 30, with higher scores representing more depressive symptoms.
- (3) Anxiety measured using the Generalized Anxiety Disorder Scale (GAD-7).⁴⁷ GAD-7 scores range from 0 to 21, with higher scores representing higher levels of anxiety.
- (4) Self-efficacy measured using the Self-Efficacy for Managing Chronic Disease Scale.⁴⁸ The scale score ranges from 1 to 10, with higher scores representing higher levels of self-efficacy.
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Guidelines were available for judging clinical significance for only some study measures. SF-12 developers

suggest a minimally important difference (MID) of 2–3 for interpreting group mean summary score differences (PCS, MCS) and warn against comparing subdomain scores.⁵⁴ Recently, Toussaint et al.⁵⁵ suggested a four-point decrease as the MID for the GAD-7 for a population with major depression, which can serve as a rough guideline for judging group differences in our study. The CESD-10 does not have an established MID.⁵⁶

Trained research assistants obtained outcome data at baseline and 6 months (i.e., at the end of the intervention). Inter-rater reliability was established prior to data collection. At baseline, we also collected sociodemographic data and medical history.

Blinding

Efforts were made to blind participants by not advising them of whether they were receiving the intervention or usual care. Because of the nature of the intervention, it was not feasible to blind providers. To reduce bias, the statistician and research assistants collecting assessment data were blinded.

Sample size

The sample size was calculated based on the PCS from the SF-12. As noted above, a difference of 2–3 points in mean scores between groups is considered a minimally important difference.⁵⁴ For this study, an effect size of 0.50 was assumed (mean difference = 5, standard deviation = 10), which represents a moderate effect size shown to hold across a wide range of chronic conditions and HRQoL outcome measures.⁵⁷ The required sample size was estimated to be 160 (80 per group), including an allowance of an additional 20% to offset drop-outs (two-tailed alpha = 0.05; power = 80%; effect size = 0.5).

Statistical analysis

Descriptive data were presented as means and standard deviations for continuous variables and numbers and percentages for categorical variables. Analysis of covariance (ANCOVA) was used to test the differences in outcome variables between the intervention and control groups at 6 months. Separate ANCOVA models were run for each outcome, with the 6-month outcome as the dependent variable, group (intervention, control) as the independent variable, and the baseline outcome value as the covariate. Multiple imputation (MI) was used in the primary analysis, because this is considered the best method for addressing the most common and realistic missing data patterns seen in RCTs⁵⁸ and has been shown to perform better than alternative methods such as maximum likelihood with small samples.⁵⁹ We used joint multiple imputation (J-MI), which has been recently shown to perform well in samples like ours (small, arbitrary missingness pattern), and compared the results using different methods of implementing J-MI in SAS. The ANCOVA model was run on five

imputations, and overall parameter estimates were obtained by pooling the results from the imputations. A complete case analysis using only clients with complete outcome data was also performed as a sensitivity analysis to test the robustness of the results to the method chosen in the primary analysis (J-MI) for handling missing data.⁵⁸ Resulting confidence intervals for SF-12 outcomes were evaluated using recent recommendations to distinguish between negative and inconclusive findings by comparing the confidence limits to the MID.⁶⁰ We could only do this on the SF-12 outcomes, because MIDs were not available for the other outcomes.

Acute care service use, such as emergency department (ED) visits and hospitalizations, are the most expensive healthcare services in many jurisdictions. The intervention aimed to enhance self-management and independence, potentially enabling participants to remain in their homes longer, thus we expected acute care service use to be lower in this group. Differences in the use of acute care services were explored using a variety of methods. Chi-square and/or Fisher's exact test (for small expected frequencies) were used to determine group differences in use of acute care services (number of participants, number of visits). McNemar's test was used to determine whether there was a difference in the proportion of emergency department visits and hospitalizations prior to baseline compared to the intervention period for the intervention and control groups.

To compare the cost of health service use between the intervention and control groups, differences between median costs for service use 6-months prior to baseline and the 6-month intervention were calculated and non-parametric methods (Mann-Whitney U test) were used to evaluate group differences for the change in cost for each service and for total service cost. Non-parametric methods were used because cost data are often substantially positively skewed (as in this study) and are traditionally handled using non-parametric methods.^{61,62}

SAS Version 9.4 was used for all statistical analyses. A two-tailed alpha of 0.05 was used for all inferential statistics.

Qualitative data and related analyses

Qualitative data from focus group interviews with providers were used to obtain feedback on the barriers and facilitators to delivering the intervention and the perceived benefits of the intervention to participants. A qualitative descriptive design was used, which is appropriate for obtaining an account of an experience that is low-inference and remains close to the words of the focus group participants.^{63,64} Focus group interviews were conducted at each site at 6 months (post intervention). Interview questions asked providers about their likes/dislikes regarding the intervention, how it fit within their practice, and the perceived benefits to participants. A total of five focus group interviews were held, with the number of participants ranging from three to eight. The interviews were conducted

by the RC and a trained graduate student. All interviews were audio-recorded and transcribed verbatim (interview guides available upon request). A conceptual content analysis was used to analyze the focus group data.^{65,66} This approach aligns with our study design⁶⁷ and stays close to the data without use of preconceived categories in order to capture the experiences as described by the participants.⁶⁵ A trained graduate student completed the analysis. An initial review of the transcripts was undertaken to identify key potential themes. This was followed by a more detailed review of the transcripts; the themes were revised accordingly. The full list of themes was then synthesized to draw overall conclusions regarding barriers, facilitators and perceived intervention benefits.

Ethics

Institutional ethics approval was obtained from the Hamilton Integrated Research Ethics Board (#14-542). Written informed consent was obtained from participants before their study involvement.

Results

The study flow chart is shown in Figure 1. Recruitment was lengthy and spanned 1-1/2 years (January 2016–July 2017), due to the significant recruitment challenges (see Discussion). A total of 748 clients were assessed for eligibility, with 524 (70%) not meeting the eligibility criteria and over half of these having been discharged from the CCAC prior to contact from the study recruiter ($n = 279$, 53%). Of the 244 eligible clients, 59 (24%) consented (none requiring a substitute decision-maker) and entered the study with 30 randomly assigned to the intervention group and 29 to the control group. Of the 59 enrolled participants, 32 successfully completed the 6-month follow-up, resulting in a retention rate of 54% (32/59). Reasons for loss to follow-up are shown in Figure 1.

Table 2 provides the baseline characteristics of the participants in each group ($n = 59$). Relative to the control group, participants in the intervention group were on average more inclined to be male, younger, married, and of lower income and to have fewer chronic conditions, medications, and falls. All participants had at least 3 chronic conditions (per eligibility criteria), with an average of 8.6 and 8.7 conditions in the intervention and control groups respectively. The top conditions in both groups were cardiovascular, diabetes, arthritis, and vision and hearing disorders. Similarly, participants reported taking many prescription medications (an average of 7.7 and 8.8 in the intervention and control groups respectively). While participants in the two groups were similar on average regarding physical functioning (PCS from SF-12), the intervention group had lower mental functioning (MCS from SF-12) and had more depressive symptoms and anxiety and lower self-efficacy.

Table 2. Baseline characteristics of trial participants ($n = 59$).

Characteristic	Intervention group ($n = 30$)	Control group ($n = 29$)
Sex, n (%)		
Female, n (%)	13 (43)	16 (55)
Male, n (%)	17 (57)	13 (45)
Age in years, n (%)		
65–69	3 (10)	2 (7)
70–74	8 (27)	6 (21)
75+	19 (63)	21 (72)
Marital Status, n (%)		
Married, living together	15 (50)	13 (45)
Widowed, divorced, separated	15 (50)	16 (55)
Annual Income (\$CAD), n (%)		
\$0 to \$39,999	15 (50)	12 (41)
\$40,000+	3 (10)	3 (10)
Missing	12 (40)	14 (48)
Number of chronic conditions, mean (SD)	8.63 (4.71)	8.72 (4.33)
Top chronic conditions, n (%)		
Cardiovascular	27 (90)	27 (93)
Kidney & Urogenital	18 (60)	16 (55)
Arthritis	17 (57)	18 (62)
Gastrointestinal	16 (53)	13 (45)
Endocrine (diabetes, thyroid)	16 (53)	19 (66)
Hearing and Vision	16 (53)	20 (69)
Number of prescription medications, mean & SD	7.72 (2.81)	8.79 (3.45)
Fall within last 12 months		
Yes	16 (53)	17 (61)
No	14 (47)	11 (39)
HRQoL—Physical Functioning ^a , mean (SD)	28.14 (6.67)	28.74 (11.15)
HRQoL—Mental Functioning ^b , mean (SD)	45.30 (13.77)	53.40 (13.46)
Depressive Symptoms ^c , mean & SD	11.67 (7.77)	8.07 (5.11)
Anxiety ^d , mean (SD)	5.90 (6.41)	2.86 (4.36)
Self-Efficacy ^e , mean (SD)	5.37 (2.81)	6.53 (2.27)

^aMeasured by Physical Component Summary Score (PCS) of SF-12 survey, scale range 0–100.

^bMeasured by Mental Component Summary Score (MCS) of SF-12 survey, scale range 0–100.

^cMeasured by Center for Epidemiologic Studies Depression 10-Item Scale (CESD-10), scale range 0–30.

^dMeasured by Generalized Anxiety Disorder 7-Item Scale (GAD-7), scale range 0–21.

^eMeasured by Self Efficacy for Managing Chronic Disease 6-Item Scale, scale range 0–10.

Feasibility of implementing the intervention

Of the 30 intervention group participants, 20 (67%) received at least one in-home visit. Fourteen participants were lost to follow-up, four (29%) of which decided against the intervention because they did not want to change from

their usual home care providers to the providers delivering the intervention. Among the participants that completed the intervention ($n = 16$), all received at least one visit from the Care Coordinator, with three participants receiving two CC visits. All but one participant received at least one visit from a RN, with most (12) receiving three RN visits. All participants also received either three PT visits or three OT visits (none received visits from both). All but one participant (who received one PSW visit) received at least six PSW visits, with two participants receiving eight PSW visits. Overall, these statistics reflect a high engagement rate with various intervention components among the participants that completed the intervention. The intervention was also delivered with fidelity and in accordance with the protocol. For example, the minimum number of in-home visits were received by all participants that completed the intervention, providers were highly engaged with the strategies embedded into the intervention components (e.g., strengths-based approach, holistic care, interprofessional collaboration), and consistent efforts were made by providers to partner with patients and caregivers in developing and implementing care plans.

Focus group interviews with providers yielded further insights into the high engagement rates, feasibility of delivering the intervention, and perceived benefits. The team-meetings and impact on communication were cited often by providers as a significant benefit in helping to understand the roles of each discipline and to stay on the same page in working with clients. One provider described them as “*helpful because we discuss the client in detail, with enthusiasm, and from a social point of view as well. So, I found that was very helpful to help you approach the client.*” Provider collaboration is rare in usual care, with one provider noting “*It’s [the intervention] more team building. I mean we don’t have many meetings. So this really got us to meet, and actually just talk*”; and another provider said “*I think that was actually my favourite part of the process. Is that, everyone who would normally not be speaking to each other, was actually talking to each other. So we were all on the same page about what the concerns were, and all working together towards that same goal or set of goals.*” The intervention improved communication according to one provider: “*I think, we had, a better communication. Like, we were, motivated to get back to each other even faster because of the team effort. Umm, and, one of our clients had many chronic conditions which lead to involving a whole other team. So I don’t think that whole transition would have happened as quickly, and with as much of a benefit for the family, umm, without, the communication that way.*”

The important contribution of PSWs on the team, who are typically excluded from care planning, was highlighted, with one provider saying “*We have the PSW coming in the meeting as well, and I really liked that . . . during those meetings, they actually have a say and express what they think about the client and also the caregiver. And, honestly, they are so much more knowledgeable, because they are*

there all the time, every week. We are only there 2 or 3 times in total, they are actually there 2 or 3 times per week.” In response to one provider referring to PSW’s as an “*untapped information system that we don’t access,*” another said “*I think that was my biggest lesson learned coming out of this. Just how important they are . . . that was really such a light bulb to see how important these PSW are to their patient. And if that’s the case, then from our perspective of case management anyway, we at least should be tapping into that more. That’s where the success is going to be. To include them in their care planning.*”

Providers valued the strengths-based approach, linking it to client empowerment, self-management, and moving beyond episodic acute-care. One provider said “*I do like the strengths base approach. Us service providers usually focus on the problem, or issue that needs to be dealt with in the treatment plan. Whereas in this model, there is a patient empowerment piece. Which is good, especially when we need to deal with a permanent disability. So we need to help the patients address the negatives and tap on the positives to recover. Which is very good. It’s a different way of thinking.*” Evidence of the value of the strength-based approach is the change to current practice noted by one provider: “*So, when I do home visits now, I use the strengths based assessment. When I visit now, when I am speaking to the patients, umm, I try and look at it from their point of view, and let them direct where things are going. Instead of dictation, because it’s in us to take over right? So, you know, allowing the patients to kind of lead where things are going and set the goals.*”

The main barrier cited by providers was the small number of study participants, which resulted in poor provider attendance at case conferences (repetitive since the same participants were discussed each month).

Intervention effectiveness

Table 3 provides the ANCOVA results based on multiple imputation (J-MI) with the results pooled across five imputed data sets and compares this to the results from complete case analysis. There was no evidence of a significant difference between study groups in the primary outcome, PCS, with a mean difference of -4.94 (95% CI: -12.53 to 2.66 , $p = 0.20$). No significant differences between groups were seen for the secondary outcomes. The results were similar across the three different methods of achieving J-MI in SAS (data not shown). The complete case was consistent with these results; although a significant difference was seen in the SF-12 general health domain, developers warn against comparing subdomain scores (noted above).

Acute care service use and costs of service use

Figure 2(a) and (b) show the change from 6 months prior to baseline to the end of the 6-month intervention period in the

Table 3. Outcomes (baseline, 6 months) and between group differences (results for multiple imputation and complete case).

Outcome	Multiple imputation (n = 59)		Complete case (n = 32)	
	Mean difference (95% CI) ^a	p Value ^b	Mean difference (95% CI) ^a	p Value ^b
SF-12: Physical Function	-3.93 (-8.52 to 0.67)	0.09	-1.66 (-6.41 to 3.08)	0.48
Role Physical	-2.87 (-9.46 to 3.72)	0.38	-4.50 (-10.22 to 1.22)	0.12
Bodily Pain	-6.20 (-18.68 to 6.27)	0.32	-3.30 (-13.59 to 6.99)	0.52
General Health	3.86 (-6.23 to 13.94)	0.43	8.72 (2.30 to 15.14)	0.01
Vitality	1.69 (-5.62 to 8.99)	0.65	0.14 (-6.75 to 7.03)	0.97
Social Function	-4.28 (-15.29 to 6.73)	0.44	-8.30 (-18.35 to 1.75)	0.10
Role Emotion	5.60 (-4.62 to 15.82)	0.26	4.09 (-3.07 to 11.25)	0.25
Mental Health	2.62 (-6.65 to 11.88)	0.56	3.58 (-2.40 to 9.57)	0.23
PCS	-4.94 (-12.53 to 2.66)	0.20	-2.91 (-9.66 to 3.84)	0.39
MCS	4.91 (-2.00 to 11.81)	0.16	3.19 (-3.06 to 9.43)	0.31
CESD-10 ^c	-1.57 (-4.71 to 1.58)	0.32	-3.07 (-6.48 to 0.33)	0.08
GAD-7 ^d	0.22 (-1.11 to 1.55)	0.74	0.43 (-1.28 to 2.14)	0.61
Self-Efficacy ^e	-0.13 (-1.06 to 0.81)	0.79	0.26 (-1.04 to 1.57)	0.68

^aIntervention mean – control mean. Estimate from ANCOVA model, adjusted for baseline outcome value.

^bp Value for t statistic of parameter estimate in ANCOVA model.

^cCenter for Epidemiologic Studies Depression 10-Item Scale (CESD-10).

^dGeneralized Anxiety Disorder 7-Item Scale (GAD-7).

^eSelf efficacy measured using Stanford Self Efficacy for Managing Chronic Disease 6-Item Scale.

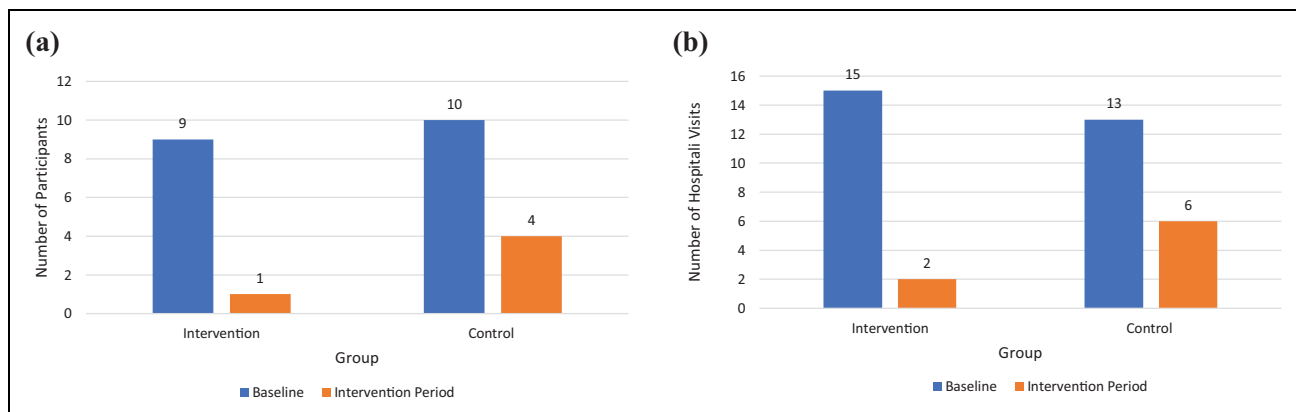


Figure 2. (a) Number of participants with hospitalization 6 months prior to baseline vs 6-month intervention period (n = 32 complete cases, 16 in each group). (b) Number hospitalizations 6 months prior to baseline vs 6-month intervention period (n = 32 complete cases, 16 in each group).

number of participants with a hospitalization and number of hospitalizations for both groups. Figure 3(a) and (b) show the parallel data for ED visits. These figures show that there was a decline in the number of participants with an acute care episode and in the number of episodes in both the intervention and control groups. Chi-square and/or Fisher's exact tests did not indicate a statistically significant difference between the groups on these outcomes, due to declines being seen in both groups and small numbers.

Tables 4a and 4b show hospitalizations in the 6 months prior to baseline and 6-month intervention period for the intervention and control groups respectively. The McNemar test showed a significant difference for the intervention group ($p = 0.01$), indicating that the proportion of hospitalizations during the period 6 months prior to baseline (0.56) was significantly higher compared to the proportion

of hospitalizations during the 6-month intervention period (0.06). No significant difference was seen for the control group ($p = 0.08$).

Tables 5a and 5b show ED visits in the 6 months prior to baseline and 6-month intervention period for the intervention and control groups respectively. The McNemar test showed no significant difference for the intervention group ($p = 0.27$), whereas a significant difference was found for the control group ($p = 0.02$) indicating that the proportion of ED visits during the period 6 months prior to baseline (0.81) was significantly higher compared to the proportion of ED visits during the 6-month intervention period (0.25).

Table 6 provides a comparison of health and social service costs for the intervention and control groups. The median cost of the intervention was \$CAD 1,180.16 (interquartile range \$CAD 1,172.66–2,013.46) per study

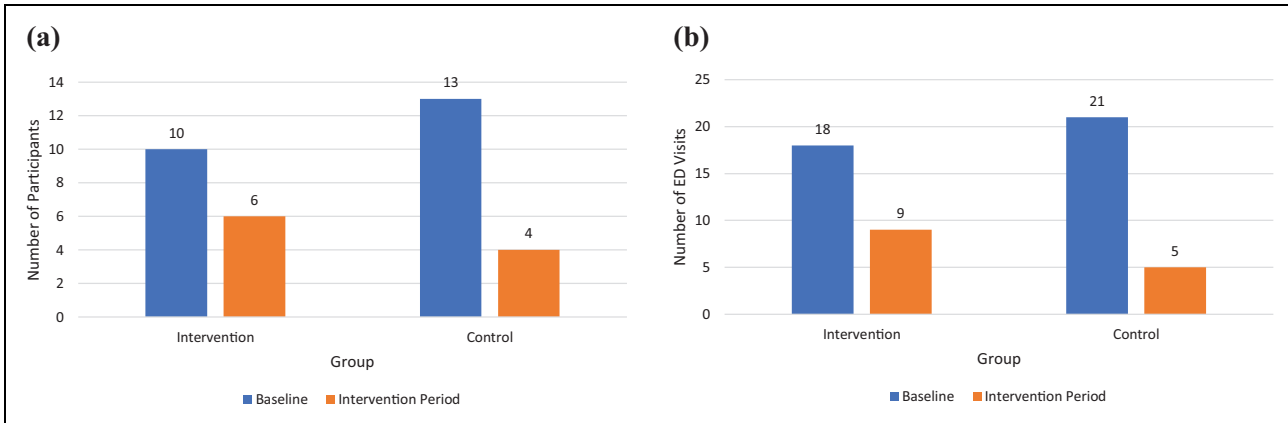


Figure 3. (a) Number of participants with ED visits 6 months prior to baseline vs 6-month intervention period ($n = 32$ complete cases, 16 in each group). (b) Number of ED visits 6 months prior to baseline vs 6-month intervention period ($n = 32$ complete cases, 16 in each group).

Table 4a. Intervention group comparison of hospitalizations 6 months before baseline versus 6 months after baseline ($n = 16$ complete cases).^a

	I + hospitalization in 6 months after baseline	No hospitalization in 6 months after baseline	Row totals
I + hospitalization in 6 months before baseline	1	8	9
No hospitalization in 6 months before baseline	0	7	7
Column totals	1	15	16

^aMcNemar test showed a significant difference (p value = 0.01, $\alpha = 0.05$), indicating that the proportion of hospitalizations during the period 6 months prior to baseline (0.56) was significantly higher (statistically) compared to the proportion of hospitalizations during the 6-month intervention period (0.06).

Table 4b. Control group comparison of hospitalizations 6 months before baseline versus 6 months after baseline ($n = 16$ complete cases).^a

	I + hospitalization in 6 months after baseline	No hospitalization in 6 months after baseline	Row totals
I + hospitalization in 6 months before baseline	3	7	10
No hospitalization in 6 months before baseline	1	5	6
Column totals	4	12	16

^aMcNemar test showed no a significant difference (p value = 0.08, $\alpha = 0.05$), indicating that the proportion of hospitalizations during the period 6 months prior to baseline (0.63) did not significantly differ (statistically) from the proportion of hospitalizations during the 6-month intervention period (0.25).

participant, with a mean cost of \$CAD 1,532.70 (SD = \$CAD 481.27). The only service cost showing a statistically-significant difference between the two groups was the Home Care & Outpatient service costs, which was expected as the costs of the intervention were included in these costs (for the intervention group). However, despite inclusion of the intervention costs, there was no statistically-significant difference between groups in the change in total costs from baseline to 6 months.

Discussion

We evaluated a 6-month, self-management intervention for older adults with multimorbidity that included the key elements recommended by international organizations for multimorbidity interventions. The intervention was cost neutral in comparison to usual care, but was not associated with a significant difference in the primary outcome—physical functioning (PCS from SF-12)—or the secondary

Table 5a. Intervention group comparison of emergency department visits 6 months before baseline versus 6 month after baseline (n = 16 complete cases).^a

	I + ED visits in 6 months after baseline	No ED visits in 6 months after baseline	Row totals
I + ED visits in 6 months before baseline	4	6	10
No ED visits in 6 months before baseline	2	4	6
Column totals	6	10	16

^aMcNemar test showed no a significant difference (p value = 0.27, $\alpha = 0.05$), indicating that the proportion of ED visits during the period 6 months prior to baseline (0.63) did not differ significantly (statistically) from the proportion of hospitalizations during the 6-month intervention period (0.38).

Table 5b. Control group comparison of emergency department visits 6 months prior to baseline versus 6 month intervention period (n = 16 complete cases).^a

	I + ED visits in 6 months after baseline	No ED visits in 6 months after baseline	Row totals
I + ED visits in 6 months before baseline	3	10	13
No ED visits in 6 months before baseline	1	2	3
Column totals	4	12	16

^aMcNemar test showed a significant difference (p value = 0.02, $\alpha = 0.05$), indicating that the proportion of ED visits during the period 6 months prior to baseline (0.81) was significantly higher (statistically) compared to the proportion of ED visits during the 6-month intervention period (0.25).

outcomes (mental functioning, mental health, self-efficacy).

Our trial had several strengths. It was rigorously done, consistent with recommended standards for RCTs and inclusive of measures to ensure intervention fidelity. The trial employed many pragmatic criteria to allow an estimate of the effects that would be seen in a real-world setting.³⁰ The intervention was evaluated using patient-oriented outcomes that span core categories recently identified in a consensus study on multimorbidity research⁶⁸ and relevant to clients, clinicians and policy makers.⁶⁹ Our patient-as-partner approach to the intervention was grounded in the principles of collaboration, including both shared-decision making and assigning primacy to patients' needs, goals and preferences.

The trial also faced several challenges, the main one being recruitment and retention of study participants. Only 24% of those eligible to participate in the study agreed to participate, and 53% of enrolled participants completed the 6-month interviews (see Figure 1). Our recruitment and retention rates are typical of trials in this population^{8,70} and were seen in earlier work that informed this intervention.³² Recruitment challenges are a significant and realistic barrier to studying this vulnerable population. Our study faced additional challenges, including loss of many potential participants (n = 279) due to discharge from the CCAC prior to contact from the recruiter, and eligible participants refusing the intervention due to a reluctance to switch home care providers (n = 28). However, the provider change for intervention participants was a study-related issue, and

premature discharge from home care would be minimized in a system focused on chronic disease management rather than the current episodic, acute care.⁷¹

The recruitment and retention challenges in this study impacted the sample size, which was well below the 160 needed to detect an effect for the primary outcome. The effect of the small sample size can be seen in the wide confidence intervals for the mean differences for all outcomes (see Table 2). Yet, there are hopeful signs in the statistical results. The mental functioning (MCS) confidence interval could be regarded as inconclusive 60 given an upper limit (11.81) well above the MID (suggesting the intervention could outperform usual care) and lower limit (-2.00) not reaching the MID (suggesting that usual care is unlikely to outperform the intervention). The results for acute care service use show promise as well, with declines in utilization seen for the intervention (and control) group.

Despite some promising results in our study, questions remain about the effectiveness of multimorbidity interventions and for what outcomes. Current evidence points to issues beyond trial size/rigor and intervention intensity. We are not alone in seeing the lack of impact on HRQoL, noting that the 2016 review 21 and 2018 update 8 found modest effects on HRQoL, and the large 3D trial failed to show an impact on this outcome.⁸ Possible explanations for these modest results include the potential lack of sensitivity in current HRQoL measures for detecting clinically-meaningful change, the need for a longer delivery and/or follow-up period in order to see the benefits, and the difference between patient perceptions of the quality of care

Table 6. Comparison of HSSU costs (6 month costs at baseline vs 6 month intervention period).

Service	Intervention (n = 16)			Control (n = 16)			Non-Parametric Independent Samples Diff Test Wilcoxon Mann Whitney z statistic (p) ^a
	Baseline median (Q1, Q3)	6 month median (Q1, Q3)	Difference in median costs ^c (Q1, Q3)	Baseline median (Q1, Q3)	6 month median (Q1, Q3)	Difference in median costs ^c (Q1, Q3)	
Family Physician	270.20 (154.40, 463.20)	386.00 (198.00, 463.20)	0.00 (-194.00, 203.05)	249.00 (229.00, 347.40)	193.01 (77.20, 386.01)	-77.20 (-124.52, 77.20)	-0.38 (0.71)
Physician Specialist	123.33 (71.65, 204.48)	56.27 (0.00, 168.74)	-78.35 (-184.04, 18.80)	73.71 (20.44, 168.56)	16.05 (0.00, 168.80)	-14.61 (-75.76, 71.65)	1.21 (0.23)
Home Care & Outpatient ^b	50.12 (0.00, 105.62)	1,262.69 (1,001.07, 1,599.73)	1,121.70 (967.96, 1,456.65)	43.12 (0.00, 330.62)	30.62 (0.00, 61.23)	0.00 (-43.12, 61.23)	-3.00 (0.003)
Ambulance & 911	0.00 (0.00, 264.80)	0.00 (0.00, 132.40)	0.00 (-120.00, 0.00)	240.00 (0.00, 372.40)	0.00 (0.00, 120.00)	0.00 (-372.40, 0.00)	-0.34 (0.73)
Emergency Department	239.31 (0.00, 478.62)	0.00 (0.00, 239.31)	-119.66 (-239.31, 0.00)	239.31 (239.31, 478.62)	0.00 (0.00, 119.66)	-239.31 (-478.62, 0.00)	-1.13 (0.26)
Hospital	8,629.50 (0.00, 23,535.00)	0.00 (0.00, 0.00)	-7,845.00 (-21,966.00, 0.00)	7,845.00 (0.00, 32,949.00)	0.00 (0.00, 784.50)	-6,276.00 (-23,535.00, 0.00)	0.21 (0.83)
Equipment	0.00 (0.00, 191.13)	0.00 (0.00, 110.00)	0.00 (-83.48, 0.00)	92.50 (0.00, 209.00)	0.00 (0.00, 22.50)	-57.50 (-160.00, 0.00)	-1.16 (0.25)
Prescription Meds	693.72 (506.65, 1,063.99)	807.12 (275.81, 1,258.93)	2.61 (-183.32, 282.32)	908.78 (405.89, 1,404.53)	658.68 (305.76, 936.39)	-145.01 (-813.36, 31.44)	-1.71 (0.09)
Recreational Services	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	-1.68 (0.09)
Transportation	0.00 (0.00, 42.00)	0.00 (0.00, 4.00)	0.00 (-18.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	1.07 (0.29)
Total Costs	12,448.91 (1,521.59, 27,083.52)	2,998.23 (2,278.48, 3,441.14)	-7,361.41 (-20,964.54, 1,180.02)	9,722.88 (2,569.41, 36,857.12)	1,914.33 (789.62, 6,325.88)	-4,364.80 (-21,596.58, -65.66)	-0.28 (0.78)

^aWilcoxon-Mann-Whitney test is a non-parametric analog to the independent samples t-test. The hypothesis being tested is whether the two medians are equal.

^bIncludes the costs of the intervention for the intervention group (in-home visits, monthly case conferences).

^cA positive median cost difference indicates that median costs were higher at 6 months. A negative median cost difference indicates that median costs were lower at 6 months.

(where effects have been seen) versus the quality of life (where effects have not been seen).⁸ One challenge is that multimorbidity is heterogeneous, which favors the use of generic tools such as the SF-12 or EQ-5D series of instruments over disease-specific ones that are often more responsive to change. Strong cross-effects between mental and physical health have been reported even after controlling for confounding factors,^{72–74} although little is known about the pathways involved.⁷⁵ Another challenge is identifying multimorbidity itself using self-reported data, where under-reporting of conditions like mental health disorders is common.⁷⁶

Questions also remain about the most appropriate setting where multimorbidity interventions should be delivered. Patients with multimorbidity are often managed by primary care physicians,^{6,21} who help in identifying patient needs and navigating the healthcare system.^{77,78} However, the home care setting can play an important role too. Over 82% of home care clients are older adults, the age group with the highest level of multimorbidity.³ The home care sector is vital to supporting the healthcare system by enabling early hospital discharge and allowing older adults to live longer in their homes (<https://www.homecareontario.ca/home-care-reports/other-home-care-publications/aging-seniors>). Our intervention was designed for the home care setting, thus supports these public policy and patient-centered aims. Our inclusion of unregulated workers (PSWs) was novel, as PSWs are rarely involved as decision-making partners on professional home care teams yet they provide the majority of home care services. This aspect of our intervention promotes teamwork, respect among colleagues, and engagement with service delivery. Provider feedback reinforced the value of PSWs in care planning and cited perceived benefits to patients arising from other elements of our intervention, including interprofessional collaboration and communication and the focus on patient-centered/holistic care. Our intervention includes various elements such as care coordination that should lead to less fragmentation and better integration of home care services, ultimately leading to a better patient experience. Resources did not allow us to interview patients to obtain their experiences with the intervention, although providers suggested there may have been improvements in this area. Perhaps patient experience should be valued in its own right since it is one of the triple aims adopted worldwide for health system reform.^{8,79} Fostering a collegial team as we did in our intervention adds a fourth dimension to care delivery, moving to a quadruple aim approach that values improvements to the provider's experience.⁸⁰

The results of our study also point to important areas for future research on multimorbidity interventions, including a better understanding of the interrelationship between mental and physical health and the potential implications for follow-up, consideration of a full range of patient-relevant outcomes including measures of the care experience from the perspective of both patients and providers,

successful strategies to overcome challenges associated with recruiting vulnerable populations of older adults, conducting a process evaluation to better understand implementation challenges, and continued testing of alternative ways of working within existing healthcare systems to implement interventions based on sound principles for managing multimorbidity.

Conclusion

We evaluated a 6-month, self-management intervention for older adults with multimorbidity. While the intervention was cost neutral in comparison to usual care, it was not found to improve the primary outcome (HRQoL) or the secondary health outcomes (mental functioning, mental health, self-efficacy). Recruitment and retention challenges were significant obstacles that limited our ability to assess the effectiveness of the intervention, which was grounded in internationally-endorsed recommendations for managing multimorbidity and implemented in a practice setting (home care) viewed as a key upstream resource that fosters independence and keeps older adults out of hospital. Alongside the cost neutral status of our intervention, these features collectively suggest that it is imperative to continue exploring alternative ways of implementing interventions that are grounded in internationally-endorsed principles for managing multimorbidity.

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Author contributions

KF wrote the original draft of the manuscript and performed all statistical analyses. All authors contributed to study design, discussion and editing. MMR and JP designed the intervention and guidelines for intervention implementation. All authors read and approved the final manuscript.

Declaration of conflicting interests

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Supplemental material

Supplemental material for this article is available online.

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