

# In-Home Care for Optimizing Chronic Disease Management in the Community: An Evidence-Based Analysis

Health Quality Ontario

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## About Health Quality Ontario

Health Quality Ontario (HQO) is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. HQO works with clinical experts, scientific collaborators and field evaluation partners to develop and publish research that evaluates the effectiveness and cost-effectiveness of health technologies and services in Ontario.

Based on the research conducted by HQO and its partners, the Ontario Health Technology Advisory Committee (OHTAC) — a standing advisory sub-committee of the HQO Board — makes recommendations about the uptake, diffusion, distribution or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders and policy-makers.

This research is published as part of Ontario Health Technology Assessment Series, which is indexed in CINAHL, EMBASE, MEDLINE, and the Centre for Reviews and Dissemination. Corresponding OHTAC recommendations and other associated reports are also published on the HQO website. Visit <http://www.hqontario.ca> for more information.

## About the *Ontario Health Technology Assessment Series*

To conduct its comprehensive analyses, HQO and/or its research partners reviews the available scientific literature, making every effort to consider all relevant national and international research; collaborates with partners across relevant government branches; consults with clinical and other external experts and developers of new health technologies; and solicits any necessary supplemental information.

In addition, HQO collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social, and legal issues relating to the intervention assist in making timely and relevant decisions to optimize patient outcomes.

The public consultation process is available to individuals and organizations wishing to comment on reports and recommendations prior to publication. For more information, please visit: [http://www.hqontario.ca/en/mas/ohtac\\_public\\_engage\\_overview.html](http://www.hqontario.ca/en/mas/ohtac_public_engage_overview.html).

## Disclaimer

This report was prepared by HQO or one of its research partners for the Ontario Health Technology Advisory Committee and developed from analysis, interpretation, and comparison of scientific research. It also incorporates, when available, Ontario data and information provided by experts and applicants to HQO. It is possible that relevant scientific findings may have been reported since completion of the review. This report is current to the date of the literature review specified in the methods section, if available. This analysis may be superseded by an updated publication on the same topic. Please check the HQO website for a list of all publications: [http://www.hqontario.ca/en/mas/mas\\_ohtas\\_mn.html](http://www.hqontario.ca/en/mas/mas_ohtas_mn.html).

# Abstract

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## Background

The emerging attention on in-home care in Canada assumes that chronic disease management will be optimized if it takes place in the community as opposed to the health care setting. Both the patient and the health care system will benefit, the latter in terms of cost savings.

## Objectives

To compare the effectiveness of care delivered in the home (i.e., in-home care) with no home care or with usual care/care received outside of the home (e.g., health care setting).

## Data Sources

A literature search was performed on January 25, 2012, using OVID MEDLINE, OVID MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), the Wiley Cochrane Library, and the Centre for Reviews and Dissemination database, for studies published from January 1, 2006, until January 25, 2012.

## Review Methods

An evidence-based analysis examined whether there is a difference in mortality, hospital utilization, health-related quality of life (HRQOL), functional status, and disease-specific clinical measures for in-home care compared with no home care for heart failure, atrial fibrillation, coronary artery disease, stroke, chronic obstructive pulmonary disease, diabetes, chronic wounds, and chronic disease / multimorbidity. Data was abstracted and analyzed in a pooled analysis using Review Manager. When needed, subgroup analysis was performed to address heterogeneity. The quality of evidence was assessed by GRADE.

## Results

The systematic literature search identified 1,277 citations from which 12 randomized controlled trials met the study criteria. Based on these, a 12% reduced risk for in-home care was shown for the outcome measure of combined events including all-cause mortality and hospitalizations (relative risk [RR]: 0.88; 95% CI: 0.80–0.97). Patients receiving in-home care had an average of 1 less unplanned hospitalization (mean difference [MD]: –1.03; 95% CI: –1.53 to –0.53) and an average of 1 less emergency department (ED) visit (MD: –1.32; 95% CI: –1.87 to –0.77). A beneficial effect of in-home care was also shown on activities of daily living (MD: –0.14; 95% CI: –0.27 to –0.01), including less difficulty dressing above the waist or below the waist, grooming, bathing/showering, toileting, and feeding. These results were based on moderate quality of evidence. Additional beneficial effects of in-home care were shown for HRQOL although this was based on low quality of evidence.

## Limitations

Different characterization of outcome measures across studies prevented the inclusion of all eligible studies for analysis.

## **Conclusions**

In summary, education-based in-home care is effective at improving outcomes of patients with a range of heart disease severity when delivered by nurses during a single home visit or on an ongoing basis. In-home visits by occupational therapists and physical therapists targeting modification of tasks and the home environment improved functional activities for community-living adults with chronic disease.

# Plain Language Summary

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It is assumed that patients with chronic disease will benefit if they are living at home and being looked after at home or in the community. In addition, there may be cost savings to the health care system when care is provided in the community or in the home instead of in hospitals and other health care settings.

This evidence-based analysis examined whether in-home care given by different health care professionals improved patient and health system outcomes. Patients included those with heart failure, atrial fibrillation, coronary artery disease, stroke, chronic obstructive pulmonary disease, diabetes, chronic wounds, and with more than one chronic disease. The results show that in-home care delivered by nurses has a beneficial effect on patients' health outcomes. Patient mortality and/or patient hospitalization were reduced. In-home care also improved patients' activities of daily living when delivered by occupational therapists and physical therapists. In addition, the results showed that in-home care delivered by nurses has a beneficial effect on health system outcomes, reducing the number of unplanned hospitalizations and emergency department visits.

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# List of Abbreviations

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<b>CCAC</b>	Community Care Access Centre
<b>CI</b>	Confidence interval
<b>COPD</b>	Chronic obstructive pulmonary disease
<b>DBP</b>	Diastolic blood pressure
<b>ED</b>	Emergency department
<b>HbA1c</b>	Hemoglobin A1c
<b>HC</b>	Home care
<b>HQO</b>	Health Quality Ontario
<b>HRQOL</b>	Health-related quality of life
<b>LDL</b>	Low density lipoprotein
<b>LOS</b>	Length of stay
<b>MD</b>	Mean difference
<b>MLWHFQ</b>	Minnesota Living With Heart Failure Questionnaire
<b>NPHS</b>	National Population Health Survey
<b>OHTAC</b>	Ontario Health Technology Advisory Committee
<b>RCT</b>	Randomized controlled trial
<b>RR</b>	Relative risk
<b>SBP</b>	Systolic blood pressure
<b>SD</b>	Standard deviation
<b>SE</b>	Standard error
<b>SF-36</b>	Medical Outcomes Study Short Form 36-Item Health Survey
<b>SGRQ</b>	St George's Respiratory Questionnaire
<b>UC</b>	Usual care

# Background

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In July 2011, the Evidence Development and Standards (EDS) branch of Health Quality Ontario (HQO) began developing an evidentiary framework for avoidable hospitalizations. The focus was on adults with at least 1 of the following high-burden chronic conditions: chronic obstructive pulmonary disease (COPD), coronary artery disease (CAD), atrial fibrillation, heart failure, stroke, diabetes, and chronic wounds. This project emerged from a request by the Ministry of Health and Long-Term Care for an evidentiary platform on strategies to reduce avoidable hospitalizations.

After an initial review of research on chronic disease management and hospitalization rates, consultation with experts, and presentation to the Ontario Health Technology Advisory Committee (OHTAC), the review was refocused on optimizing chronic disease management in the outpatient (community) setting to reflect the reality that much of chronic disease management occurs in the community. Inadequate or ineffective care in the outpatient setting is an important factor in adverse outcomes (including hospitalizations) for these populations. While this did not substantially alter the scope or topics for the review, it did focus the reviews on outpatient care. HQO identified the following topics for analysis: discharge planning, in-home care, continuity of care, advanced access scheduling, screening for depression/anxiety, self-management support interventions, specialized nursing practice, and electronic tools for health information exchange. Evidence-based analyses were prepared for each of these topics. In addition, this synthesis incorporates previous EDS work, including *Aging in the Community* (2008) and a review of recent (within the previous 5 years) EDS health technology assessments, to identify technologies that can improve chronic disease management.

HQO partnered with the Programs for Assessment of Technology in Health (PATH) Research Institute and the Toronto Health Economics and Technology Assessment (THETA) Collaborative to evaluate the cost-effectiveness of the selected interventions in Ontario populations with at least 1 of the identified chronic conditions. The economic models used administrative data to identify disease cohorts, incorporate the effect of each intervention, and estimate costs and savings where costing data were available and estimates of effect were significant. For more information on the economic analysis, please contact either Murray Krahn at [murray.krahn@theta.utoronto.ca](mailto:murray.krahn@theta.utoronto.ca) or Ron Goeree at [goereer@mcmaster.ca](mailto:goereer@mcmaster.ca).

HQO also partnered with the Centre for Health Economics and Policy Analysis (CHEPA) to conduct a series of reviews of the qualitative literature on “patient centredness” and “vulnerability” as these concepts relate to the included chronic conditions and interventions under review. For more information on the qualitative reviews, please contact Mita Giacomini at [giacomini@mcmaster.ca](mailto:giacomini@mcmaster.ca).

The Optimizing Chronic Disease Management in the Outpatient (Community) Setting mega-analysis series is made up of the following reports, which can be publicly accessed at <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ohtas-reports-and-ohtac-recommendations>.

- Optimizing Chronic Disease Management in the Outpatient (Community) Setting: An Evidentiary Framework
- Discharge Planning in Chronic Conditions: An Evidence-Based Analysis
- In-Home Care for Optimizing Chronic Disease Management in the Community: An Evidence-Based Analysis
- Continuity of Care: An Evidence-Based Analysis
- Advanced (Open) Access Scheduling for Patients With Chronic Diseases: An Evidence-Based Analysis
- Screening and Management of Depression for Adults With Chronic Diseases: An Evidence-Based Analysis
- Self-Management Support Interventions for Persons With Chronic Diseases: An Evidence-Based Analysis
- Specialized Nursing Practice for Chronic Disease Management in the Primary Care Setting: An Evidence-Based Analysis
- Electronic Tools for Health Information Exchange: An Evidence-Based Analysis
- Health Technologies for the Improvement of Chronic Disease Management: A Review of the Medical Advisory Secretariat Evidence-Based Analyses Between 2006 and 2011
- Optimizing Chronic Disease Management Mega-Analysis: Economic Evaluation
- How Diet Modification Challenges Are Magnified in Vulnerable or Marginalized People With Diabetes and Heart Disease: A Systematic Review and Qualitative Meta-Synthesis
- Chronic Disease Patients' Experiences With Accessing Health Care in Rural and Remote Areas: A Systematic Review and Qualitative Meta-Synthesis
- Patient Experiences of Depression and Anxiety With Chronic Disease: A Systematic Review and Qualitative Meta-Synthesis
- Experiences of Patient-Centredness With Specialized Community-Based Care: A Systematic Review and Qualitative Meta-Synthesis

## Objective of Analysis

The objective of this evidence-based health technology assessment was to determine the effectiveness of in-home care in optimizing chronic disease management in the community. The assumption is that there will be cost savings to the health care system when patient moves from the health care setting to the community or the home. (1)

## Clinical Need and Target Population

Based on the 1994/95 National Population Health Survey (NPHS), 522,900 Canadians aged 18 years or older were receiving formal home care. (2) This number grew to 545,000 in 1996/97. (2) The largest group of individuals receiving home care were the elderly and the chronically ill. However, people with a range of health conditions may receive home care. (2)

In 1995, use of home care services in Ontario increased dramatically with age, from about 50 per 1,000 population in women 65 years and older to more than 250 per 1,000 population in women 85 years and older. Men displayed a similar age-related increase in the use of home care services. (1)

In 2010, 125,724 Ontario seniors aged 65 years or more who had been assessed by the Resident Assessment Instrument Home Care were receiving publicly funded home care on an ongoing basis (i.e., expecting to receive or receiving services for at least 60 days). The majority were female (66.9%), and about 40% were aged 75 years or more. Overall, 38% were married, indicating that about one-third may have the advantage of a spouse as a caregiver. Less than 5% of the clients who received home care were without a family caregiver. Multimorbidity was common, with diabetes (26.4%), Alzheimer disease/dementia (22.7%), stroke (18.4%), chronic obstructive pulmonary disease (COPD) (17.2%), cancer (13.7%), heart failure (12.9%), and psychiatric diseases (12.7%) the most prevalent. (3)

## Canadian Context

Publicly funded home care in Canada is administered by the provincial or territorial government or by regional health authorities. The way home care works in Canada is as follows: a client is referred to receive home care services, at which point a case manager is assigned to the client. The case manager meets with the client and any potential caregiver to conduct an assessment, and then coordinates care, authorizes services, and provides ongoing monitoring and evaluation. Home care service providers typically are a personal support worker and/or a nurse, either public employees and/or agency employees. A personal support worker assists with basic daily living needs whereas a nurse provides clinical care. The home care team may also include occupational therapists, physiotherapists, pharmacists, nurse practitioners, social workers, dietitians, and physicians. A majority of clients (50%–69%) across Canada are receiving home care services provided by personal support workers. (3)

In Ontario, home care services may begin at the time of hospital discharge, with a care coordinator assessing patient need. Alternately, a rapid response nurse may provide an in-home visit within 24 hours of discharge and provide medication reviews and education on symptom and lifestyle management. (*Personal communication, Community Expert, December 3, 2012*).

Home care services are publicly funded in Ontario, Manitoba, Quebec, Prince Edward Island, and the 3 territories. Provincial plans in British Columbia, Alberta, Saskatchewan, New Brunswick, Nova Scotia, and Newfoundland and Labrador cover most services. However, additional fees may be required for some personal and community support services. Community support services include general house cleaning, meal preparation or delivery, or help with running errands. (3)

## Ontario Context

In Ontario, formal home care services are either government-funded or privately paid for. The Community Care Access Centres (CCACs) administers the former, and the case manager determines the type and amount of service delivered. Among Ontarian adults aged 65 years and older, 8% of women and 6% of men received government-funded services. (4) In total, there are 14 CCACs in communities across Ontario that are funded by Local Health Integration Networks through the Ministry of Health and Long-Term Care. CCAC advice and services are covered by the Ontario Health Insurance Plan (OHIP). (5)

The top 5 ranked type of home care services delivered to Ontario residents in fiscal year 2011/2012 by the CCAC were, by number of services delivered

1. Combined personal support and homemaking services (n = 17,557,390)
2. Nursing visits (n = 6,058,730)
3. Case management (n = 2,100,812)
4. Personal services (n = 1,862,877)
5. Occupational therapy (512,784 sessions) (6)

The rank of the remaining type of home care services were as follows:

1. Physiotherapy (443,289 sessions)
2. Nursing shifts (n = 376,905)
3. Speech language therapy (252,038 sessions)
4. Respite (n = 112,596)
5. Homemaking services (n = 72,790)
6. Social work (n = 55,494)
7. Nutrition/dietetic (47,865 sessions)
8. Other services (n = 37,304)
9. Placement services (n = 2,376)
10. Psychology (n = 340)
11. Respiratory services (n=216) (6)

## In-Home Care

The aim of in-home and continuing care is to provide care for acute or chronically ill individuals in the home, in the community, in supportive housing, or in long-term care facilities. In-home and continuing care, delivered to recovering, disabled, or chronically or terminally ill individuals, maintains or improves the health status of individuals in need. (2) Offered are a variety of health services including nursing, personal care, physiotherapy, occupational therapy, speech therapy, social work, dietician services, homemaking, respite care, day programs for Alzheimer disease, Meals on Wheels, and friendly visitor programs, which can maintain or improve the health status of individuals in need. (2)

For the purposes of this evidence-based analysis, in-home care is defined as care predominately in the patient's home. This includes ongoing in-home assessment, case management, and coordination of a range of services provided in the home or in the community that are curative, preventive, or supportive in nature and that aim to enable clients to live at home, thus preventing or delaying the need for long-term care or acute care. Palliative care and rehabilitation are not considered in this analysis. Supportive care includes personal care, meal preparation, and homemaking tasks. (2)

## **In-Home Care as a Component of Multidisciplinary Care**

Multidisciplinary care may constitute an in-home care component. For example, a number of systematic reviews/meta-analyses have examined multidisciplinary care in relation to heart failure. (7-9) Multidisciplinary care was examined as a complex intervention, (8) as part of a disease management program, (9) or in subgroups based on the setting in which the intervention was delivered including the home. (7)

In a systematic review/meta-analysis that examined multidisciplinary care in heart failure by intervention setting including home visits, (7) 12 of the 30 included studies had a home visit component. The search strategy was current as of 2004. Included studies were published between 1993 and 2005. Multidisciplinary interventions were nurse-led programs, medication reviews, medication adherence interventions, patient education, or enhanced monitoring. Home visits were defined as one or more planned visits by a health care professional to educate or improve patient self-management, but excluded visits to take blood samples, set up physiological monitoring, or deliver wound care. Results showed a 20% reduction in all-cause admissions (relative risk [RR]: 0.80; 95% CI: 0.71–0.89), a 38% reduction in heart failure admissions (RR: 0.62; 95% CI: 0.51–0.74), and a nonsignificant 13% reduction in all-cause mortality (RR: 0.87; 95% CI: 0.72–1.06). (7)

Since multidisciplinary care tends to be used synonymously with disease management programs that focus on the continuum of care across health delivery systems, the systematic reviews / meta-analyses that examined multidisciplinary care were not considered for this evidence-based analysis.

## **Alternate In-Home Care Strategies**

A number of health care strategies involve an in-home care component. However, many are out-of-scope and therefore are not part of this evidence-based analysis. They include the following:

- Early supported discharge. Patients after stroke conventionally receive much of their rehabilitation in hospital. Services have been developed that offer patients an early discharge from hospital with more rehabilitation at home. (10)
- Transitional care. Also known as integrated care or disease management programs, transitional care focuses on improving the experience of patients when they are discharged from acute hospital care to other types of care. Transitional care may include home visits as part of the coordinated service. It aims to address the needs of the 20% of patients who experience an adverse clinical event within 30 days of the discharge from hospital. (11)
- Hospital-at-home. Hospitalizations result in a high demand on hospital resources and high health care costs. Hospital-at-home is a safe alternative to hospitalization in, for example, acute exacerbation of COPD where patients admitted to hospital may be discharged on the fourth day of admission to receive care at home provided by specialized respiratory nurses. (12)
- Home-based rehabilitation as an alternative to hospital-based programs for pulmonary rehabilitation in patients with COPD, for example, expands the recognition, application, and accessibility of pulmonary rehabilitation for these patients. (13) Similar considerations exist for patients undergoing cardiac rehabilitation. Hospital-based cardiac rehabilitation attracts those who prefer supervision during exercise, need the camaraderie of a group, are willing to make travel arrangements, and believe they lack self-discipline. Home-based cardiac rehabilitation attracts the more self-disciplined patients who believe that rehabilitation should fit in with their lives rather than their lives fitting in with the rehabilitation. The patients who prefer home-based care also dislike group therapy and express practical concerns such as travel or transportation to group hospital therapy. (14)

# Evidence-Based Analysis

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## Research Question

To compare the effectiveness of care delivered in the home (i.e., in-home care) with no home care or with usual care / care received outside of the home (e.g., a health care setting).

## Literature Search

### *Search Strategy*

A literature search was performed on January 25, 2012, using OVID MEDLINE, OVID MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), the Wiley Cochrane Library, and the Centre for Reviews and Dissemination database for studies published from January 1, 2006, until January 25, 2012. The start date for the literature search was selected based on scoping of the literature and identification of a number of systematic reviews that had already been completed at that time (see Results). Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

## Inclusion Criteria

English language full-text reports

- published between January 1, 2006, and January 25, 2012
- randomized controlled trials (RCTs), systematic reviews, meta-analyses, health technology assessments
- adults aged  $\geq 18$  years
- at least one in-home care visit had to have occurred
- in-home care provided by any type of health or medical professional or social assistance provider
- studies on multidisciplinary care when findings for home visits were presented separately

## Exclusion Criteria

- studies using telemonitoring or telemedicine to deliver in-home care
- telephone-based follow-up service or patients using self-management strategies alone
- studies on hospice care, end-of-life care, or palliative care delivered in the home
- studies comparing different delivery models of in-home care
- studies on the effectiveness of transitional care, early supportive discharge, hospital-at-home, or rehabilitation

## Outcomes of Interest

- hospital utilization (admissions, readmissions, length of stay [LOS], emergency department [ED] utilization, admissions to long-term care facilities)
- survival/mortality

- health-related quality of life (HRQOL) / functional status
- disease-specific clinical measures / physiological measures
- patient satisfaction

## Statistical Analysis

A meta-analysis was performed using Review Manager Version 5. (15) For continuous data a mean difference was calculated, and for dichotomous data a risk ratio was calculated for RCTs. A fixed effect model was used unless significant heterogeneity was observed (e.g.,  $P \leq 0.10$ ), and then a random effects model was used to address significant heterogeneity. When heterogeneity was not accounted for using a random effects model, a post-hoc subgroup analysis was considered. For continuous variables with mean baseline and mean follow-up data, a change value was calculated (if not presented in the original paper) as the difference between the 2 mean values (e.g., follow-up minus baseline). To allow for analysis and account for the change value, a corresponding standard deviation (SD) was calculated using 3 parameters: baseline SD, follow-up SD, and a correlation coefficient. The correlation coefficient represents the strength of the relationship between the 2 SDs. A correlation coefficient of 0.5 was used for this analysis. For all other continuous variables, a mean difference was calculated based on values at follow-up. Graphical display of the forest plots was also examined. A *P* value of less than 0.05 was considered statistically significant. *P* values in the text have been rounded to 3 decimal places. When the data were available, a subgroup analysis by disease category was performed.

## Quality of Evidence

The quality of the body of evidence for each outcome was examined according to the GRADE Working Group criteria. (16) The overall quality was determined to be very low, low, moderate, or high using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that RCTs are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—are then taken into account. Limitations or serious limitations in these areas result in downgrading the quality of evidence. Finally, 3 main factors are considered that may raise the quality of evidence: large magnitude of effect, dose response gradient, and accounting for all residual confounding. (16) For more detailed information, please refer to the latest series of GRADE articles. (16)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

<b>High</b>	Very confident that the true effect lies close to that of the estimate of the effect
<b>Moderate</b>	Moderately confident in the effect estimate—the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
<b>Low</b>	Confidence in the effect estimate is limited—the true effect may be substantially different from the estimate of the effect
<b>Very Low</b>	Very little confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect

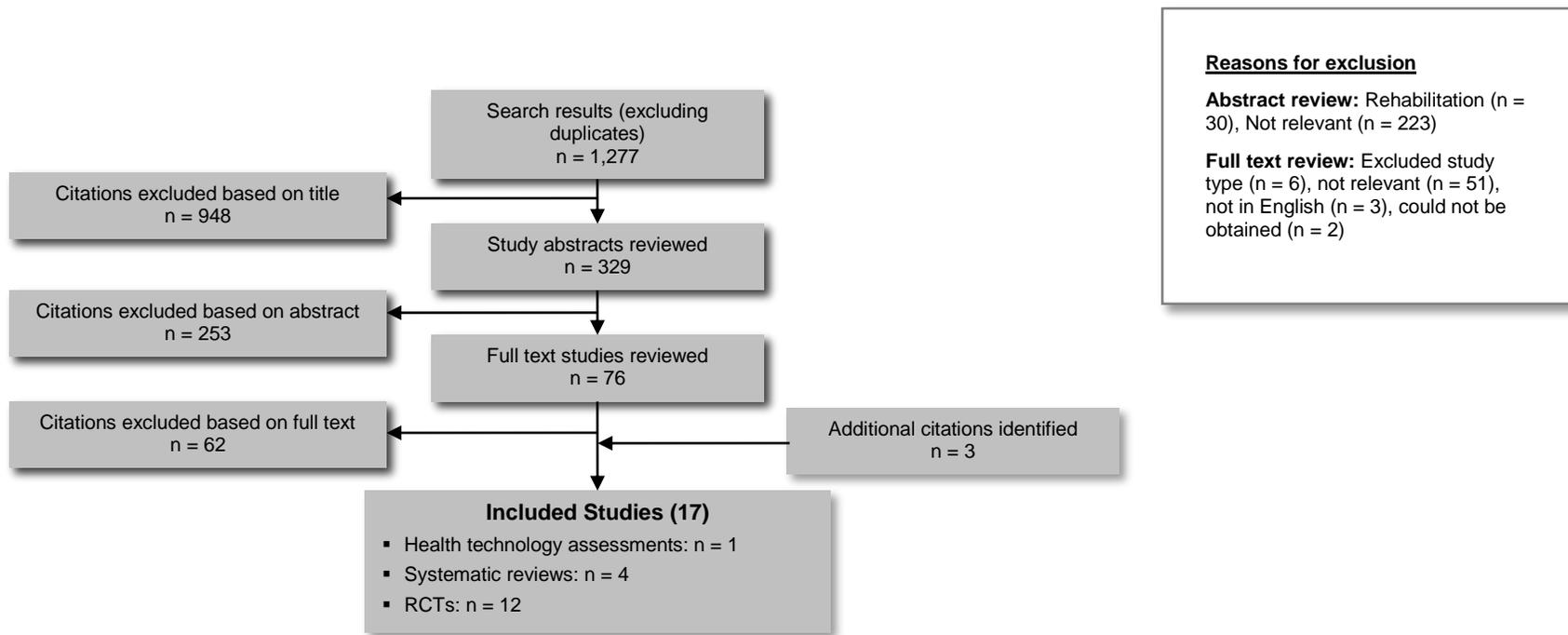
## Results of Evidence-Based Analysis

The database search yielded 1,277 citations published between January 1, 2006, and January 25, 2012 (with duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment. Figure 1 shows the breakdown of when and for what reason citations were excluded from the analysis.

Seventeen studies (1 health technology assessment, 4 systematic reviews, 12 RCTs) met the inclusion criteria. The reference lists of the included studies were manually searched to identify any other potentially relevant studies, and 2 other RCTs were identified. One additional systematic review was identified from a review of MEDLINE. These were also included in this analysis.

Aside from the 17 studies analyzed in this evidence-based analysis, a clinical RCT conducted in Ontario, Canada, was also assessed for inclusion in this analysis. This RCT compared the effectiveness of community leg ulcer clinics with home care for treating patients with leg ulcers. (17) In-home care was considered usual care and care in community leg ulcer clinics was considered the intervention. Because of the reverse comparison, this study was excluded from this evidence-based analysis.

In addition, an RCT that used home-based care for heart failure patients was brought to the attention of the researcher; however, its date of publication was outside of the literature search dates. There was some agreement between our results and those of this study. (18)



**Figure 1: Citation Flow Chart**

For each included study, the study design was identified and is summarized below in Table 1, which is a modified version of a hierarchy of study design by Goodman. (19)

**Table 1: Body of Evidence Examined According to Study Design**

Study Design	Number of Eligible Studies
<b>RCT Studies</b>	
Systematic review of RCTs	5 <sup>a</sup>
Large RCT <sup>b</sup>	9
Small RCT	3
<b>Observational Studies</b>	
Systematic review of non-RCTs with contemporaneous controls	-
Non-RCT with non-contemporaneous controls	-
Systematic review of non-RCTs with historical controls	-
Non-RCT with historical controls	-
Database, registry, or cross-sectional study	-
Case series	-
Retrospective review, modelling	-
Studies presented at an international conference	-
Expert opinion	-
<b>Total</b>	<b>17</b>

Abbreviation: RCT, randomized controlled trial.

<sup>a</sup>Two systematic reviews included only RCTs; (20;21) 2 systematic reviews included RCTs in addition to other study designs (22;23) with only the information on RCTs used for this evidence-based analysis; one health technology assessment of RCTs. (24)

<sup>b</sup>Large RCTs ≥ 150 subjects.

## Health Technology Assessments

### *Heart Failure*

A health technology assessment conducted by the Tufts-New England Medical Centre Evidence-Based Practice Centre under contract to the Agency for Healthcare Research and Quality in the United States compared the effectiveness of interventions that support postdischarge care with that of usual care in heart failure patients to prevent hospital readmission. (24) The magnitude of all-cause hospital readmissions was the primary outcome, whereas all-cause mortality, length of hospital stay, cost, quality of life, and a combined endpoint of mortality and readmissions were examined as secondary outcomes. The articles searched were published from 1990 to 2007. The 1990 search date was chosen as a starting point because that was the year when the medical management of heart failure started to advance rapidly, bringing about changes in practice patterns. RCTs were included if the population of interest was made up of heart failure patients and if the mean age of the population was 50 years or older. A number of interventions were examined, including home visits. These were defined as being done by “a member of the multidisciplinary heart failure team who visited the patient at home to assess clinical stability and provide care to optimize health.” The comparison group was defined as usual care, routine care, or standard care, which included non-structured care (e.g., discharge instructions, information on next appointment). A meta-analysis was performed based on the intervention of home visit (e.g., the setting where the intervention was initiated after an index hospitalization). Included were 37 studies that provided information on hospital readmissions and 30 studies that provided quantitative data for the intervention and control group. Among these were 4 studies on home visits. The meta-analysis of these 4 studies showed a statistically significant reduced risk of hospital readmission in the intervention group receiving

home visits compared with the usual care group (RR: 0.82; 95% CI: 0.69–0.97). The remaining outcomes were not analyzed by intervention setting. The results were based on good to poor quality of evidence according to a 3-level customized grading scheme (i.e., good as the highest quality). The studies included in the meta-analysis were published from 1998 to 2002. The home visits were nurse-led, and in 2 of the 4 studies, there was mention of home services provided in the control group. The authors concluded that interventions that used home visits reduced the risk of hospital readmissions.

There were no health technology assessments identified for the remaining chronic conditions of interest: stroke, coronary artery disease, atrial fibrillation, COPD, diabetes, or chronic wound care.

## **Systematic Reviews**

### ***COPD***

A systematic review examined the effectiveness of in-home care provided for COPD patients by respiratory health care worker programs. Outcomes were mortality, hospitalizations, HRQOL, lung function, and exercise tolerance. (20) Inclusion criteria allowed for RCTs with at least 3 months of follow-up, a home visit as intervention, and COPD defined according to standard criteria. Home visits were defined as a visit to the patient's home by a respiratory nurse or respiratory health worker to facilitate health care, educate, provide social support, identify deteriorations, and reinforce correct use of inhaler therapy. The control group received routine care without access to a respiratory nurse / health care worker. The search was current as of 2009. The results of the meta-analysis of the 9 RCTs identified showed a beneficial effect of home visits by a respiratory nurse on HRQOL assessed using St George's Respiratory Questionnaire (SGRQ; mean difference [MD]: -2.60; 95% CI: -4.81 to -0.39; 4 studies). There was no effect of home visits on mortality (5 studies), hospitalizations (5 studies), or exercise tolerance (2 studies). Data for a meta-analysis of lung function, ED visits, and general practitioner or family doctor visits were insufficient. The evidence was based on heterogeneous quality of evidence ranging from low (e.g., not possible to implement blinding) to high. The authors concluded that in-home care provided by respiratory health care worker programs for COPD improved HRQOL though heterogeneous data precluded conclusions about the other outcomes.

An integrative systematic review examined nursing care provided by nurse clinics in the chronic phase of COPD. (22) A nurse clinic was defined as a respiratory nurse with advanced respiratory competence and a primary role in delivering formalized service within a multidisciplinary team. The search included RCTs and other study designs published from 1996 and 2006. Studies on acute services were excluded. No meta-analysis was performed. From the 20 articles identified (reporting on 16 studies in total), 4 themes emerged, 1 of which was home-based respiratory care. This theme was covered in 9 articles, of which 6 were RCTs. The authors found no difference in hospitalizations except in 2 studies that showed a significant reduction in hospital admissions and readmissions and ED use. There was no difference for HRQOL and mortality. There was some suggestion of improved disease-related knowledge and patient satisfaction. For these studies, the service provided included health assessment, teaching disease facts, disease management, breathing technique and medications, advice on activities of daily living (ADL), healthy lifestyle, symptom awareness, the management of exacerbations, information on service referrals and telephone contact with health professionals. A majority of studies examining home-based respiratory care used an RCT design; however, 3 of the 9 studies were a non-RCT design. For the RCTs included, the control groups were described as usual care or standard protocols, booklets about COPD, following recommendations by physicians; a control group of 1 RCT included home visits by physicians. Because the authors summarized their data for heterogeneous study designs, it is difficult to interpret their results on health care resources, HRQOL, and mortality. Therefore, the contribution of RCT findings to the outcome measures is not clear. The authors concluded that the chronic management of COPD has been mainly conceptualized as home-based respiratory care; they could not conclude whether advanced nursing is more effective than usual care.

### **Multimorbidity**

A systematic review examined comprehensive geriatric assessment interventions and the effect on ED use. (23) The interventions were defined based on the setting where they were implemented, including the outpatient setting of home care. The interventions were grouped into 5 general categories. The search strategy was current as of 2004 and included RCTs as well as other types of study designs. Inclusion criteria allowed for studies including the frail elderly, with their potential for multiple comorbidities, and patients 60 years of age or older. No meta-analysis was performed due to the heterogeneity of the studies. Identified were 26 studies, including 16 RCTs, that used a variety of intervention settings; 4 studies used in-home care as the intervention setting. Of these 4 studies, only 1 was considered eligible based on criteria established for this evidence-based analysis (e.g., RCT study, appropriate intervention type). This RCT, which was conducted in Italy, showed a reduced time to first ED use (hazard ratio: 0.64;  $P < 0.025$ ). (25) The nature of the intervention in this study was case management—a case manager such as a nurse or social worker coordinated community services including home support, nursing care, and meals on wheels—with the control group described as usual care. (25) However, closer examination showed that both the intervention and the comparison groups included elements of home care. (25) The authors stated that the main difference between the intervention and the comparison groups was the element of case management and care planning present in the intervention group. Although the control group were able to receive the in-home care established in the community, it was considered fragmented. Overall, the authors of this systematic review concluded that interventions initiated in the outpatient setting reduced ED use whereas hospital-based interventions had less of an effect on ED use. (23)

A qualitative systematic review examined the effectiveness of home-based health promotion provided by professional nurses on patient outcomes. (21) Patient outcomes included mortality, admissions, health status, functional status, use of health and social services, and cost. The search strategy was current as of 2003, and inclusion criteria allowed for studies that used an RCT design and for community-living adults aged 65 years and older. The home-based care component included ongoing home visits or telephone contacts. Excluded studies were therapeutic or rehabilitative, involved hospital-at-home care or patients who had been discharged from the hospital. Identified were 12 RCTs. Only 2 studies included individuals in the control group receiving usual in-home care services. The intervention group received a diverse range of in-home care services including education on nutrition, exercise, stress management, substance abuse, emotional and social functions, instrumental activities of daily living (IADL), accessing health care, supportive physical and psychosocial nursing care, functional assessment, and integrated and interdisciplinary case management, to name a few. The nurses' role included preventive care (e.g., early identification and management of health problems) and health promotion strategies (e.g., health education, goal setting). There were between 1.9 and 14.1 visits, and they lasted from 0.5 to 2 hours. The results showed favourable and significant effects for the intervention group of home-based nursing care for mortality (4 of 11 studies), functional status (4 of 8 studies), level of depression (1 of 4 studies), hospital admissions (5 of 9 studies), nursing home use (5 of 10 studies), and use of other health and social services (6 of 9 studies). Methodological limitations of included studies were randomization, blinding of outcome assessors, and incomplete follow-up. Other limitations were lack of detailed information on the content of the intervention (e.g., frequency of visits for some studies, and duration of visits) and control group (e.g., primary care, usual home care, or geriatric clinic), which specific subgroups of older individuals would most likely benefit from the intervention, and lack of information on depression and social support. The authors concluded that, despite overall positive results, it is not clear how the nursing role makes a difference in patient outcomes.

No eligible systematic reviews were identified for the remaining chronic conditions of interest: heart failure, stroke, coronary artery disease, atrial fibrillation, diabetes, or chronic wound care.

## **Randomized Controlled Trials**

The systematic literature search found 12 RCTs eligible for this evidence-based analysis (Tables A2–A5).

### ***Description of Studies***

Of the 12 identified RCTs, 1 study was on diabetes, (26) 6 on heart failure, (27-32) 1 on COPD, (33) 1 on stroke, (34) and 3 on multimorbid chronic disease. (35-37) The sample sizes ranged from fewer than 150 subjects (28;30;33), 150 subjects or more, (26;27;29;31;32;34-37) up to even larger RCTs with more than 300 subjects. (27;36;37) The length of follow-up ranged from 1 to 3 months in 1 study (33) to 10 years in another. (32) There were 4 studies with outcome data at 6 months of follow-up (26;27;34;37) and 4 studies lasting between 1 and 2 years. (28;29;31;35) For the 6 studies on heart failure, the majority of patients were classified at study entry as New York Heart Association (NYHA) functional status class II in 2 studies, (28;30) class II/III in 1 study, (32) class III/IV in 1 study, (27) and class IV in 1 study. (29) The information was unknown for 1 study. (31) The in-home care intervention was delivered by nursing professionals in 5 studies, (28-31;34) by nursing professionals plus a pharmacist in 2 studies, (32;35) by community health workers in 1 study, (26) and allied health professionals including community pharmacists in 4 studies. (27;33;36;37) Half of the studies (6 of 12) were designed with 1 or a few scheduled in-home care visits. (27;28;30-33) Four studies scheduled ongoing in-home care visits, (26;29;36;37) and 2 provided in-home care visits as needed. (34;35) The contact time during the in-home care visit ranged from a minimum of 20 to 30 minutes (33) to a maximum of 2 hours. (28;30;34) A majority of studies (10 of 12) were designed to deliver an in-home care intervention that educated patients on disease facts, lifestyle modification, and medication use. (26-35) Two studies focused on the home environment and task performance. (36;37)

### ***Diabetes***

A randomized controlled clinical trial conducted in Detroit, United States, examined whether a culturally defined diabetes self-management home-based intervention administered by community health workers improved physiological measures in comparison with usual care in patients with type 2 diabetes. (26) Outcomes included hemoglobin A1c (HbA1c), systolic blood pressure (SBP), diastolic blood pressure (DBP), and low density lipoprotein (LDL) cholesterol, among others. (26) Primary or secondary outcomes were not explicitly stated but glycemic control was emphasized and therefore taken as the primary outcome. Eligible patients were identified from medical records, were at least 18 years of age with a physician-confirmed diagnosis of type 2 diabetes, and were self-identified as African American or Latino/Hispanic. Excluded were individuals with diabetes-related complications. Randomization was stratified by race/ethnicity and health care site. Allocation concealment was not stated. Interventionists were not blinded, although the data analysts were. Physiological measures were determined from medical records at baseline and at the 6-month follow-up. Analysis was described as an intent-to-treat. However, for the analysis on physiological measures, there were between 51 and 56 patients in the intervention group and between 55 and 65 patients in the control group, a reduction from the original 84 in the intervention group and 99 in the control group. There were no baseline differences, except for mean age (home care [HC]: 50; 95% CI: 47–52 vs. usual care [UC]: 55; 95% CI: 53–57 year;  $P = 0.02$ ). The baseline and 6-month follow-up measures and change were presented as adjusted means.

### ***Heart Failure***

A randomized controlled clinical trial conducted in Barcelona, Spain, examined the effectiveness of a single home-based educational intervention compared with that of usual care in patients with heart failure. (28) The primary outcomes included number of unplanned hospitalizations, visits to the ED due to heart failure, and all-cause mortality. The secondary outcome relevant to this evidence-based analysis was HRQOL. Patients were eligible for inclusion if they displayed heart failure according to the Framingham criteria, had class II to IV NYHA function, and had left ventricular ejection fraction of less than 45% on echocardiography. The study did not include patients with dementia or neoplastic disease or with a

previous acute coronary syndrome or who were taking dobutamine, lived out of the geographic region, were not community living, or were without a telephone. Patients were randomized using a table of random numbers before hospital discharge. Allocation concealment was not mentioned. The physicians involved in assessment and follow-up were blinded to group assignment. Relevant primary outcomes were assessed at 6 and 24 months by 1 physician reviewing medical records. Quality of life was measured using the Medical Outcomes Study Short Form 36-Item Health Survey (SF-36), a generic health questionnaire, and the Minnesota Living with Heart Failure Questionnaire (MLWHFQ). Quality of life was ascertained at baseline by personal interview and at follow-up by telephone interview. Other baseline data were ascertained before hospital discharge. The discharging physician was blinded to group assignment. The analysis did not mention intent-to-treat. There were no baseline differences. The sample size for examining the SF-36 and MLWHFQ was reduced.

A randomized controlled clinical trial conducted in Barcelona, Spain, examined the effectiveness of a home-based intensive intervention program in comparison with usual care in heart failure patients. (29) The primary outcome was combined all-cause mortality and hospitalizations due to worsening of heart failure. The secondary outcomes relevant to this evidence-based analysis were cardiovascular death, hospitalizations due to cardiovascular disease, quality of life, and patient satisfaction. Eligible individuals were hospitalized for suspected heart failure according to the Framingham criteria and had a diagnosis of heart failure at discharge in the first or second diagnostic position. Exclusion criteria included concomitant illness and a survival prognosis of less than 1 year, a cognitive deficit, not residing in the geographic region, and clinical trial involvement in the preceding 3 months. Randomization was determined from a central data management site using a random generator and stratified by hospital. Allocation concealment was not mentioned. A standardized questionnaire ascertained information on baseline data. HRQOL was determined by the MLWHFQ. Hospital admissions and discharges were ascertained from record services. Clinical outcomes were classified by a committee blinded to group assignment. Personnel ascertaining information on HRQOL measures were aware of assignment status. Follow-up was 1 year. There was a baseline difference in the number of patients with COPD as a comorbidity (HC: 34% vs. UC: 20.1%;  $P = 0.01$ ), with no other baseline differences. The analysis stated an intent-to-treat analysis. There was a reduced sample size for examining MLWHFQ.

A randomized controlled clinical trial conducted in Thailand examined the effectiveness of a home-based program on symptom alleviation and well-being in comparison with usual care in heart failure patients. (30) The primary outcome was not stated. Symptom alleviation was not considered relevant to this evidence-based analysis. Eligible patients were at least 40 years of age, with functional class II NYHA criteria, stable medication use, ability to verbally communicate, living within the designated geographic area, and not living alone. Exclusion criteria were not stated, but criteria for dropping out included the presence of severe symptoms and complications from heart or comorbid diseases. Patients were randomized but other specific details were not stated, including information on allocation concealment. At baseline and follow-up at 8 and 12 weeks, a researcher measured well-being in the home for both the intervention and the control group. There was no mention of blinding or of an intent-to-treat analysis. There were no baseline differences.

A randomized controlled clinical trial conducted in the United Kingdom examined the effectiveness of a home-based intervention delivered by community pharmacists to heart failure patients. (27) The primary outcome was unplanned hospitalizations. The secondary outcomes were all-cause mortality and HRQOL (e.g., EuroQoL and MLWHFQ). Eligible patients were over 18 years of age, were admitted to emergency departments with heart failure, and were taking 2 or more drugs at the time of discharge. Patients were excluded if living in long-term care facilities, on the waiting list for surgery for heart disease, or with a terminal malignancy. Randomization was computer generated, and patients were stratified by the NYHA class and recruitment site. Allocation concealment was achieved using a third party telephone randomization process. An intent-to-treat analysis was specified. Blinding was not mentioned. Follow-up

was 6 months. There were no baseline differences except for social class and use of a drug adherence aid, with the intervention group less likely to be from a non-manual labour social class (HC: 44.1% vs. UC: 54.7%; *P* value not specified) but more likely to use some form of drug adherence aid (HC: 26.5% vs. 15.5%; *P* value not specified). Post-randomization exclusions occurred in the intervention and control groups (HC: n = 20; UC: n = 26 post-randomization exclusions).

A randomized controlled clinical trial conducted in Spain compared the clinical effectiveness of a home-based education program with that of usual care in heart failure patients. (31) The primary outcome was combined unplanned hospitalizations and all-cause mortality. Secondary outcomes were unplanned hospitalizations, all-cause mortality, LOS, and ED use. Only ED visits were examined in the first 6 months of follow-up. Eligible patients did not have severe cognitive deficits, COPD, a psychiatric illness, or other terminal disease. They lived in the geographic area and had family support. Randomization was prepared by a central site and stratified by service location of recruitment. Assignment was performed by the process of closed envelopes. The randomization sequence was concealed until after assignment. Attending personnel involved outside of in-home care were unaware of patient assignment. Follow-up was up to 12 months and data were ascertained by telephone and review of clinical records. Analysis was intent-to-treat. There was no baseline differences on factors considered to be of interest.

A randomized controlled clinical trial conducted in Australia compared the clinical effectiveness of a nurse-led home-based intervention with that of usual care in heart failure patients. (32) The primary outcome was combined unplanned hospitalizations and all-cause mortality. A secondary outcome was all-cause mortality, as described in a previous publication. (38) Eligible patients were at least 55 years of age, had cardiologist-diagnosed heart failure, a history of at least 1 hospital admission for acute heart failure, functional impairment according to NYHA class II, III, or IV, and impaired left ventricular systolic function ( $\leq 55\%$  ejection fraction). Exclusion criteria were a terminal malignancy or planned cardiac surgery. Randomization occurred using a blinded computerized protocol. There was no mention of allocation concealment. Baseline data were determined through patient interviews or medical record reviews before discharge. Follow-up was a minimum of 7.5 years, and data on hospital activity and mortality were ascertained from a computerized medical record system and death registry. Outcomes were ascertained in a blinded manner. Analysis was intent-to-treat. Baseline differences noted were that the intervention group were more likely to have had a prior acute myocardial infarction (HC: 55% vs. UC: 50%; *P* value not shown), left bundle-branch block (HC: 32% vs. UC: 21%; *P* value not shown), and a higher blood urea concentration (data not shown).

### ***COPD***

A randomized controlled clinical trial conducted in Louisiana, United States, compared the effectiveness of educational support either through a home visit or reading material compared with that of usual care in patients with COPD. (33) This evidence-based analysis examined only the effects of home visits. The primary outcome was HRQOL measured by SGRQ. (Secondary outcomes, for example, health knowledge, were not relevant to this evidence-based analysis.) Individuals were 18 years or older and had spirometry-confirmed, physician-diagnosed moderate to severe COPD. Having a Grade 4 reading literacy was also considered an eligibility criterion. Exclusion criteria included congestive heart failure, asthma, and severe cognitive impairment. Randomization was performed by randomly drawn letter cards. Allocation concealment was not mentioned. Personnel were not blinded to group assignment. Length of follow-up was about 30 to 90 days (*Personal communication, Clinical Expert, April 24, 2012*). There was no mention of an intent-to-treat analysis. There were no baseline differences between the intervention and the control group.

### ***Stroke***

A randomized controlled clinical trial conducted in Ohio, United States, compared the effectiveness of comprehensive postdischarge care management with that of organized stroke department care without postdischarge care. (34) The primary outcome was based on 5 domains including elements of neuromotor function, days spent in an institution, quality of life, management of risk, and stroke knowledge and lifestyle modification. Relevant individual outcomes for this evidence-based analysis were all-cause mortality, mean length of hospital stay, quality of life measured by the stroke-specific scale, and physiological outcomes, all secondary outcomes. Patients were eligible if they had a confirmed ischemic stroke, National Institutes of Health Stroke Scale score of 1 or more, were discharged home, lived in the geographic region, had no other dominating illness, spoke English, and did not have an endarterectomy planned. Randomization was generated by the study biostatistician, and group assignment was performed by a research assistant using the sealed envelope method. Length of follow-up was 6 months. Outcome measures relevant to this evidence-based analysis were ascertained by medical record review or at the home visit. Additional information ascertained at the home visit by a research nurse was blinded to patient assignment. Telephone interviews were also conducted. An intent-to-treat analysis was noted. There were no baseline differences except for the percentage of patients with diabetes as a comorbidity being higher in the intervention group (HC: 42% vs. UC: 29%; *P* value not shown) and the mean number of hospital days in the prior year being higher for the control group (HC: 0.6, standard error (SE): 0.3 vs. UC: 2.1, SE: 0.3; *P* value not shown).

### ***Multimorbidity***

A randomized controlled clinical trial conducted in a rural village near Ottawa, Canada, examined the effectiveness of the Anticipatory and Preventive Team Care (ATPCare) program on quality of care for chronic disease management. (35) The ATPCare program was designed as an in-home care intervention. The primary outcome was not relevant to this evidence-based analysis. Relevant outcomes included ED visits and all-cause hospitalizations. Eligible individuals were at least 50 years of age, enrolled in the Family Health Network, and at risk of functional decline, physical deterioration, and need of emergency services. Individuals were excluded if they displayed cognitive impairment, language, or cultural barriers, were expected to live less than 6 months, and were not residing in the geographical area for the study period. A central system assigned concealed random treatment allocation. Length of follow-up was up to 18 months. Health care utilization information was ascertained from an outcome questionnaire and verified by chart audit of electronic medical records by personnel blinded to group assignment. An intent-to-treat analysis was noted. There were no baseline differences except for age, with the intervention group younger than the control group (HC: 69.6 vs. UC: 72.8 years, *P* = 0.018). (39;40)

A randomized controlled clinical trial conducted in Philadelphia, United States, compared the effectiveness of a home-based program that reduces declining abilities in chronically ill elderly individuals with that of usual care. (36) The primary outcome for this study was mortality; however, this study was an extension of previous work by the same investigators who had examined functional difficulties as the primary outcome at the 6-month follow-up. (37) Eligible individuals for both studies were community living, ambulatory, at least 70 years of age, English speaking, cognitively intact, and reporting 1 or more functional difficulties. There was no mention of exclusions. Randomization was generated by the project statistician and prepared using double, opaque envelopes. Randomization was performed by race and living arrangement. Length of follow-up was between 2.5 and 5.25 years for the outcome of mortality, depending on when the baseline interviews were conducted. Length of follow-up was 6 months for the primary outcome of functional difficulties. The National Death Index records were used to determine mortality. Trained interviewers were blinded to group assignment. An intent-to-treat analysis was mentioned but it was not clear how this was used when examining functional difficulties. There were no baseline differences.

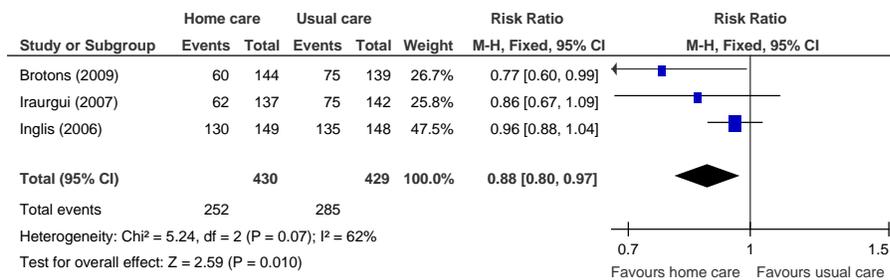
## Meta-Analysis

An analysis was performed to address the research question on the effectiveness of care delivered in the home (i.e., in-home care) compared with no home care or usual care / care received outside of the home (e.g., health care setting). Studies with data in a format suitable for analysis are shown below for the outcomes of combined events of all-cause mortality and hospitalizations, all-cause mortality, cardiovascular-specific mortality, unplanned hospitalizations, heart failure-specific hospitalizations, LOS, ED visits, HRQOL, and functional difficulties. When data were available, the analysis was performed by disease subgroup.

The study by Gray et al (35;40) with useable information for hospitalizations and ED visits was excluded from this evidence-based analysis because the information for hospitalizations was based on all-cause hospitalizations, rather than unplanned hospitalizations as in the other 2 studies, and ED visits were based on the assumption that every deceased patient had 1 ED visit, which was different from the other included study. (35;40) One study had information on patient satisfaction but was not included in the analysis since it did not use a validated questionnaire. (29)

The interpretation of the results differs based on the outcome measure. For consistency, a beneficial effect of in-home care appears on the left-hand side of the plots. Results are presented as a risk ratio for RCTs with dichotomous data, as a mean difference at follow-up for continuous data, or as a mean difference based on change values for the HRQOL outcomes (i.e., SF-36, MLWHFQ, SGRQ). When the sample size differed between baseline and follow-up for HRQOL measures, to be conservative the smaller of the 2 sample sizes was used. (27-29)

The outcomes were examined and are displayed in Figures 2–16 below.



**Figure 2: Combined All-Cause Mortality and Readmissions/Hospitalizations<sup>a,b,c,d,\*</sup>**

Abbreviations: CI, confidence interval; M-H, Mantel-Haenzel.

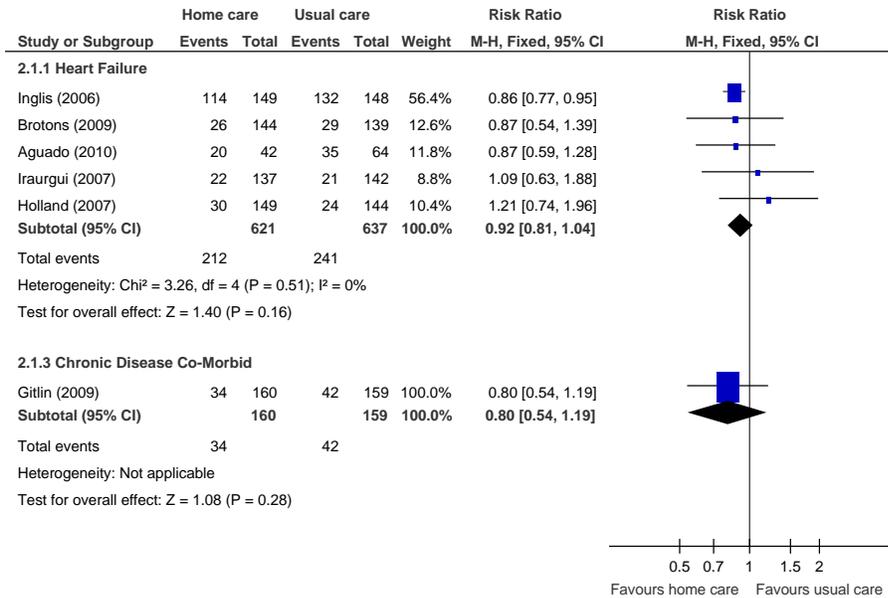
<sup>a</sup>Defined as all-cause mortality and hospital readmission due to worsening of heart failure; (29) all-cause mortality and unplanned hospitalizations; (31) all-cause mortality and unplanned hospitalizations. (32)

<sup>b</sup>Heart failure patients in all 3 studies. (29;31;32)

<sup>c</sup>Primary outcome in all 3 studies. (29;31;32)

<sup>d</sup>First-ever hospitalization in 2 studies. (29;31)

<sup>†</sup>Iraurgi is used throughout the text as a shortened form of the name Aldamiz-Echevarria Iraurgi.

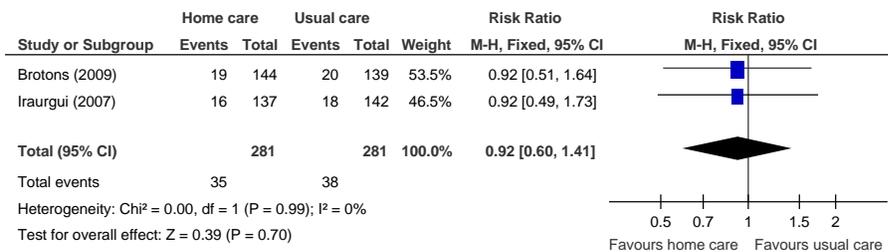


**Figure 3: All-Cause Mortality<sup>a,b</sup>**

Abbreviations: CI, confidence interval; M-H, Mantel-Haenzel.

<sup>a</sup>Analysis included 5 studies on heart failure patients. (27-29;31;32) 1 study on chronic disease comorbid patients. (36)

<sup>b</sup>Primary outcome in 1 study. (28)

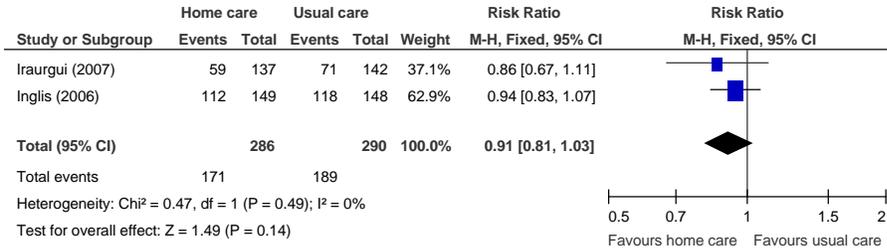


**Figure 4: Cardiovascular-Specific Mortality<sup>a,b,\*</sup>**

Abbreviations: CI, confidence interval; M-H, Mantel-Haenzel.

<sup>a</sup>Heart failure patients in both studies. (29;31)

<sup>b</sup>Not identified as a primary outcome in any study.



**Figure 5: Unplanned Readmissions/Hospitalizations<sup>a,b,c,d</sup>**

Abbreviations: CI, confidence interval; M-H, Mantel-Haenzel.

<sup>a</sup>Cumulative incidence and number of events.

<sup>b</sup>Heart failure patients in both studies. (31;32)

<sup>c</sup>Not identified as a primary outcome in any study.

<sup>d</sup>First-ever hospitalization in 1 study. (31)



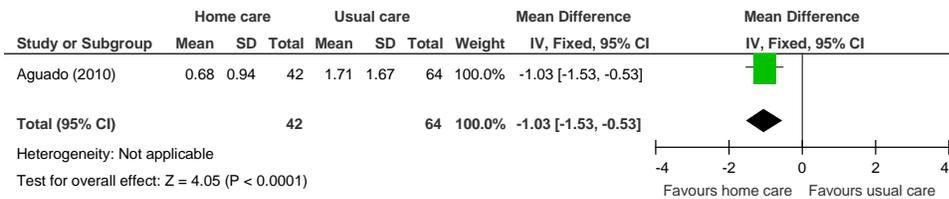
**Figure 6: Heart Failure-Specific Readmissions/Hospitalizations<sup>a,b,c</sup>**

Abbreviations: CI, confidence interval; M-H, Mantel Haenzel.

<sup>a</sup>Number of occasions.

<sup>b</sup>Heart failure patients in both studies. (29;31)

<sup>c</sup>Not identified as a primary outcome in any study.



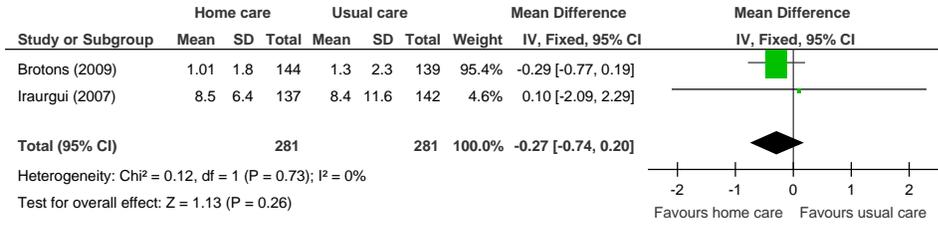
**Figure 7: Mean Number of Unplanned Readmissions/Hospitalizations<sup>a,b,c</sup>**

Abbreviations: CI, confidence interval; SD, standard deviation.

<sup>a</sup>Number of events.

<sup>b</sup>Heart failure patients (28;31)

<sup>c</sup>Primary outcome in 1 study. (28)



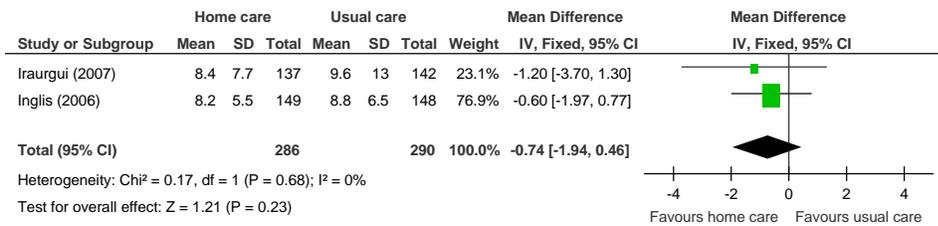
**Figure 8: Mean Number of Heart Failure-Specific Readmissions/Hospitalizations<sup>a,b,c,\*</sup>**

Abbreviations: CI, confidence interval; SD, standard deviation.

<sup>a</sup>Number of events.

<sup>b</sup>Heart failure patients in both studies. (29;31)

<sup>c</sup>Not identified as a primary outcome in any study.



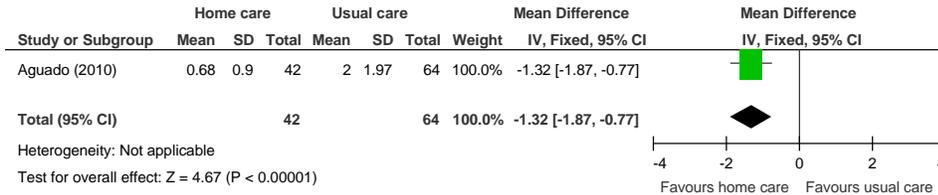
**Figure 9: Mean Length of Hospital Stay<sup>a,b,c</sup>**

Abbreviations: CI, confidence interval; SD, standard deviation.

<sup>a</sup>Days.

<sup>b</sup>Heart failure patients in both studies. (31;32)

<sup>c</sup>Not identified as a primary outcome in any study.



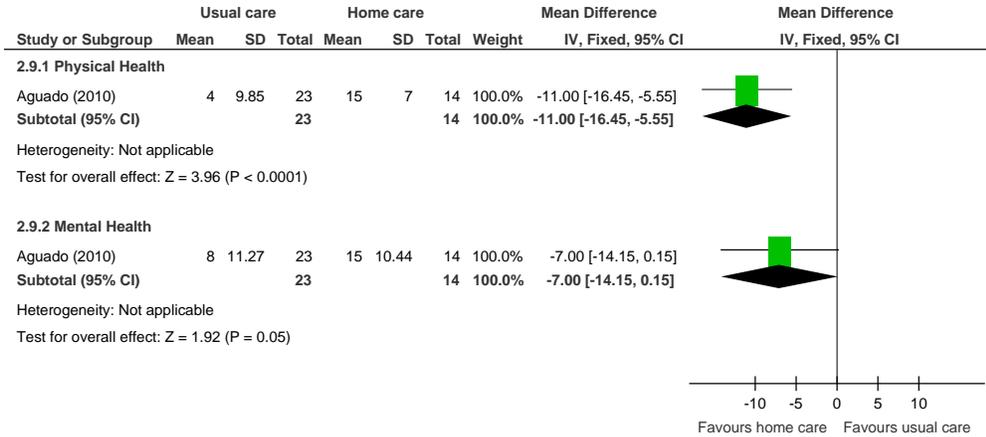
**Figure 10: Mean Number of Emergency Department Visits<sup>a,b,c</sup>**

Abbreviations: CI, confidence interval; SD, standard deviation.

<sup>a</sup>Number of events.

<sup>b</sup>Heart failure patients in 1 study. (28)

<sup>c</sup>Not identified as a primary outcome.



**Figure 11: General Well-Being (assessed using SF-36)<sup>a,b,c,d,e,f,g</sup>**

Abbreviations: CI, confidence interval; MCID, minimal clinically important difference; SD, standard deviation; SF-36, Medical Outcomes Study Short Form 36-Item Health Survey.

<sup>a</sup>Heart failure patients. (28)

<sup>b</sup>Not identified as a primary outcome.

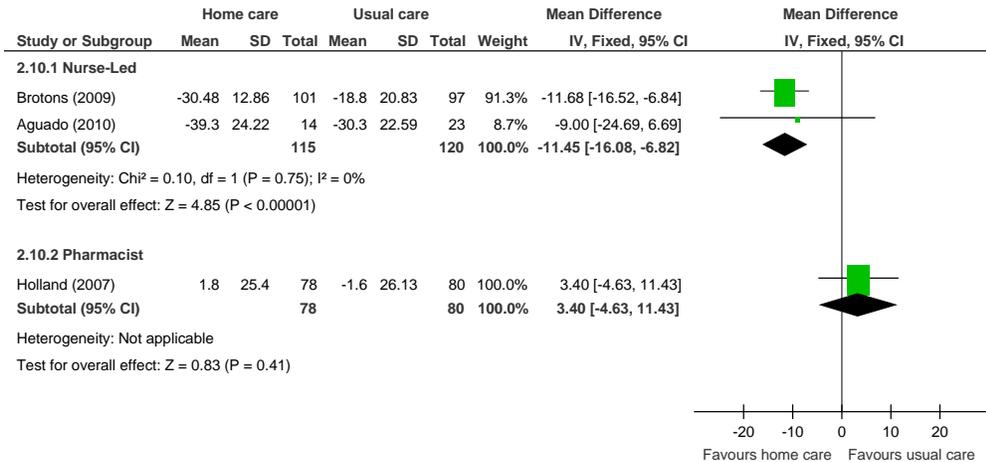
<sup>c</sup>Change from baseline, with a positive value indicating an improvement as higher scores are favoured.

<sup>d</sup>Range for physical MCID: 10-40 points.

<sup>e</sup>Range for mental MCID: 15-37.5 points.

<sup>f</sup>Physical component scale includes physical functioning, role-physical, bodily pain, and general health.

<sup>g</sup>Mental component scale includes vitality, social functioning, role-emotional, and mental health.



**Figure 12: Heart Failure-Specific Well-Being (MLWHFQ)<sup>a,b,c,d,e</sup>**

Abbreviations: CI, confidence interval; SD, standard deviation; MCID, minimal clinically important difference; MLWHFQ, Minnesota Living With Heart Failure Questionnaire.

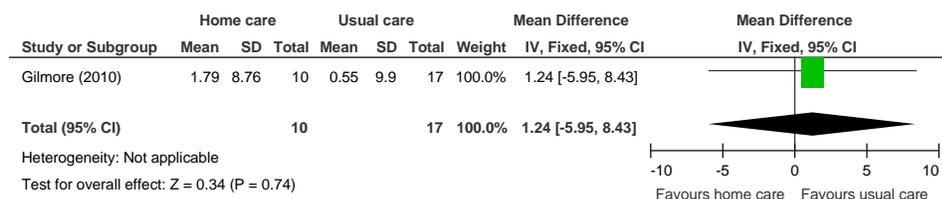
<sup>a</sup>Heart failure patients. (27-29)

<sup>b</sup>Not identified as a primary outcome.

<sup>c</sup>Change from baseline, with a negative value indicating an improvement as lower scores are favoured.

<sup>d</sup>Includes questions on symptoms and signs, physical activity, social interaction, sexual activity, work, and emotions.

<sup>e</sup>MCID is 5 points.



**Figure 13: COPD-Specific Well-Being (SGRQ)<sup>a,b,c,d,e</sup>**

Abbreviations: CI, confidence interval; COPD, chronic obstructive pulmonary disease; MCID, minimal clinically important difference; SD, standard deviation; SGRQ, St George's Respiratory Questionnaire.

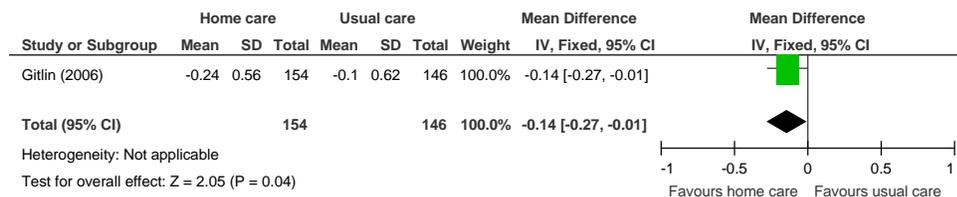
<sup>a</sup>COPD patients. (33)

<sup>b</sup>Primary outcome in study. (33)

<sup>c</sup>Change from baseline, with a negative value indicating an improvement as lower scores are favoured.

<sup>d</sup>Includes symptoms, activity, and impacts.

<sup>e</sup>MCID is 4 points.



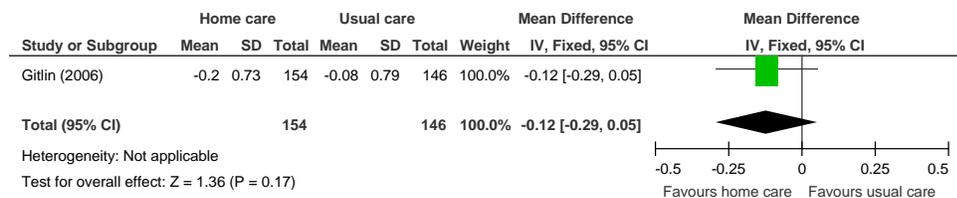
**Figure 14: Activities of Daily Living<sup>a,b,c</sup>**

Abbreviations: CI, confidence interval; SD, standard deviation.

<sup>a</sup>Chronic disease multimorbid patients. (37)

<sup>b</sup>Primary outcome in study. Activities of daily living include difficulty dressing above waist or below waist, grooming, bathing/showering, toileting, and feeding.

<sup>c</sup>Change from baseline, with a negative value indicating an improvement as lower scores are favoured.



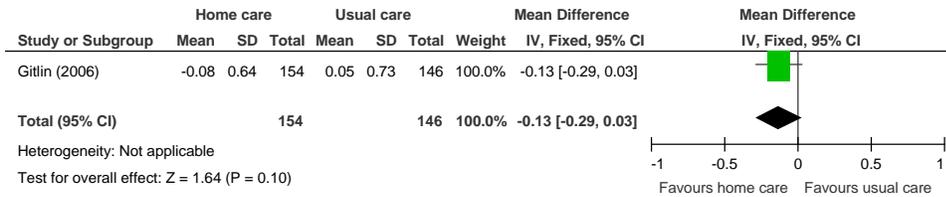
**Figure 15: Mobility<sup>a,b,c</sup>**

Abbreviations: CI, confidence interval; SD, standard deviation.

<sup>a</sup>Chronic disease multimorbid patients. (37)

<sup>b</sup>Primary outcome in study. Mobility includes getting in/out of the car, walking indoors, walking one block, climbing one flight of stairs, moving in/out of a chair, and moving in/out of bed.

<sup>c</sup>Change from baseline, with a negative value indicating an improvement as lower scores are favoured.



**Figure 16: Instrumental Activities of Daily Living<sup>a,b,c</sup>**

Abbreviations: CI, confidence interval; IADL, instrumental activities of daily living; SD, standard deviation.

<sup>a</sup>Chronic disease multimorbid patients. (37)

<sup>b</sup>Primary outcome in study. IADL include light housework, shopping, preparing meals, managing money, telephone use, and taking medications.

<sup>c</sup>Change from baseline, with a negative value indicating an improvement as lower scores are favoured.

## Results of Meta-Analysis

The results of the meta-analysis show a beneficial effect of in-home care compared with usual care, without significant heterogeneity ( $P > 0.10$ ) (where relevant), for the following outcomes:

- Heart failure patients receiving in-home care had, on average, about one less unplanned hospitalization compared with heart failure patients receiving usual care (MD:  $-1.03$ ; 95% CI:  $-1.53$  to  $-0.53$ ;  $P < 0.001$  ( $I^2$ : n/a;  $P = n/a$ ))
- Heart failure patients receiving in-home care had, on average, about one-and-a-half fewer ED visits compared with those receiving usual care (MD:  $-1.32$ ; 95% CI:  $-1.87$  to  $-0.77$ ;  $P < 0.001$  ( $I^2$ : n/a;  $P = n/a$ ))
- Heart failure patients receiving in-home care were more likely to have increased HRQOL compared with those receiving usual care. A statistically significant and clinically relevant effect was shown for physical well-being (MD:  $-11.00$ , 95% CI:  $-16.45$  to  $-5.55$ ;  $P < 0.001$ ), and a statistically significant and clinically relevant effect was shown for nurse-led in-home interventions on HRQOL specific to heart failure (MD:  $-11.45$ ; 95% CI:  $-16.08$  to  $-6.82$ ;  $P < 0.001$ ;  $I^2$ : 0%,  $P = 0.75$ )
- Chronic disease multimorbid patients receiving in-home care were more likely to report less difficulties in ADL compared with patients receiving usual care (MD:  $-0.14$ ; 95% CI:  $-0.27$  to  $-0.01$ ;  $P = 0.04$ ).

In addition,

- Heart failure patients receiving in-home care were 12% less likely to experience an event of the combined of all-cause mortality and hospitalizations compared with those receiving usual care (RR: 0.88; 95% CI: 0.80–0.97;  $P = 0.010$ ;  $I^2$ : 62%;  $P = 0.07$ ). Using a fixed effect model, heterogeneity was borderline. The point estimate remained the same and heterogeneity was not reduced when using a random effects model (RR: 0.88, 95% CI: 0.74–1.05;  $P = 0.15$ ;  $I^2$ : 62%;  $P = 0.07$ ). The confidence interval also widened for a nonstatistically significant beneficial effect of in-home care in the latter.

The results did not show statistically significant effects of in-home care compared with results of usual care for the following outcomes:

- All-cause mortality by disease category
- Cardiovascular-specific mortality
- Heart failure-specific hospitalizations
- Length of hospital stay
- Mental well-being and heart failure-specific HRQOL when in-home care was delivered by community pharmacists
- HRQOL for COPD patients
- Functional difficulties including mobility and IADL

These results were without significant heterogeneity ( $P > 0.10$ ) (where relevant).

## Qualitative Assessment

### *Physiological Outcomes*

Two studies had information on physiological outcomes including HbA1c, SBP, DBP, and lipid levels. (26;34) One study involved diabetes patients, (26) and the other stroke patients. (34) These studies could neither be meta-analyzed together nor individually because the data in the papers were not in a useable format. For HbA1c, the study of diabetes patients showed a beneficial effect of in-home care, (26) and the study on stroke patients did not show a difference between the intervention and the control groups. (34) There were no differences between the intervention and the control groups for SBP, DBP, and lipid levels in both studies. (26;34) Overall, the benefits of in-home care were shown for lowering HbA1c in diabetes patients.

### Summary of the Literature Review

In summary, education-based in-home care is effective at improving patient outcomes when it is delivered by nurses during a single home visit or on an ongoing basis to patients with a range of heart disease severity. In-home visits by occupational therapists and physical therapists targeted at modifying tasks and the home environment improved functional activities for community-living chronic disease adults.

The beneficial effect of in-home care on the combined events of all-cause mortality and hospitalizations was based on 3 studies that included heart failure patients. (29;31;32) The disease severity ranged from NYHA class II to IV in a majority of patients. The nature of the home care intervention was similar although the frequency of the home care visits differed. The length of follow-up was 1 year in 2 studies (29;31) and up to 10 years in the third. (32) Longer follow-up accounted for the higher proportion of events in the longer-term follow-up study. Overall, in-home care has a beneficial effect on the combined events of all-cause mortality and hospitalizations. The GRADE quality of evidence was moderate.

The beneficial effect of in-home care on the mean number of unplanned hospitalizations and ED visits was based on 1 study of heart failure patients. (28) The results showed unplanned hospitalizations down by 1, and ED visits down by a mean of about one-and-a-half. The standard deviations for this study were quite small. The beneficial effect of in-home care on physical well-being, assessed using the SF-36, was also based on this study. Two summary component scales, the physical and mental component scales, which are made up from the 36 questions in the 8 individual domains covered by the questionnaire, (41) were reported. A difference of 11 points is considered within the range of possible values for a minimal clinically important difference. (42) A factor contributing to the success of the in-home care intervention in this 1 study, and hence to the results, may have been the high educational level of a majority of the individuals in the intervention group (63% with a secondary school education). (28) Overall, in-home care has a beneficial effect on lowering hospital utilization and improving HRQOL. The GRADE quality of

evidence was moderate quality for unplanned hospitalizations and ED visits, and low for the physical component of the SF-36.

The lack of a beneficial effect on unplanned hospitalizations, characterized as the number of events, may be due to the heterogeneity in the data provided in the 2 studies, with 1 study apparently considering the number of occasions so that each patient may contribute more than one event (32) and the other study considering only first-ever hospitalizations. (31) Imprecision may have also been a factor considering the sample size calculations. (31;32) The GRADE quality of evidence was low quality for unplanned hospitalizations when characterized as event data.

The lack of an effect on heart failure-specific hospitalizations suggests that the reasons for readmissions are due to different causes or comorbid conditions and not due to the index diagnosis. Imprecision may have also been a factor considering the sample size calculations. (29;31) The GRADE quality of evidence was low quality for heart failure-specific hospitalizations.

The beneficial effect of a nurse-led in-home care intervention on HRQOL in heart failure patients was based on 2 studies that used the MLWHFQ. (28;29) The MLWHFQ is a heart failure-specific questionnaire. It contains 21 questions that ask about symptoms and signs relevant to heart failure, physical activity, social interaction, sexual activity, work, and emotions. The maximum score is 105, with a lower score indicating better HRQOL. (41) A difference of about 12 points is considered to be beyond the specified clinically relevant change score of 5 points. (43) The result was weighted heavily on 1 study in which the nurse-led intervention was provided monthly for the duration of the 1-year study. (29) Also, the heart failure patients in this study were NYHA class IV, which may have been the population with the potential for the largest improvement in HRQOL. Overall, nurse-led in-home care has a beneficial effect on HRQOL; however, the GRADE quality of evidence was considered low quality.

The beneficial effect of in-home care on ADL was based on 1 study. (37) The ADL index is based on the mean perceived difficulty across 6 areas including dressing above the waist, dressing below the waist, grooming, bathing/showering, toileting, and feeding. Difficulty is rated on a score of 1 to 5, with higher scores indicating increased difficulty. A trend for a beneficial effect was shown for the other 2 measures of physical function including mobility and IADL; however, they did not reach statistical significance. Mobility assesses 6 areas including getting in/out of the car, walking indoors, walking one block, climbing one flight of stairs, moving in/out of a chair, and moving in/out bed. The IADL index comprises 6 areas including light housework, shopping, preparing meals, managing money, telephone use, and taking medications. The in-home care intervention of occupational therapists and physical therapists targeting task modifications and home hazards may have been more effective at improving the ADL compared with the other 2 indexes that assess challenges outside of the home and more complex activities. The clinical significance of the difference between comparison groups for ADL is not known. The GRADE quality of evidence was moderate for all 3 functional status measures.

There were no differences between the intervention and the control group for the remaining outcomes. For length of hospital stay, it was not clear whether the data in 1 study referred to the condition under study or if the duration of hospitalization was for another medical reason or referred to overall duration of hospitalization. (32) For all-cause mortality, there was no difference between the intervention and the control groups when studies were analyzed by disease category. For the mental health component of the SF-36, there was no difference between the intervention and the control groups. The mental health component is made up of vitality, social functioning, role-emotional, and mental health domains whereas the physical component is made up of physical functioning, role-physical, bodily pain, and general health domains. Therefore, the mental health component scale may be perceived as more complex, requiring as it does a more substantive intervention than nurse-led in-home care education on disease management to observe improvements.

There was no difference between the intervention and the control groups for pharmacist-led in-home care on heart failure-specific HRQOL. (27) In this 1 study, the lack of ongoing visits may have been the limiting factor although additional study design limitations including post-randomization exclusions may have had an effect. (27) There was no difference between the intervention and the control group for COPD-specific HRQOL measured by SGRQ. (33) The mean difference for the total SGRQ was 1.24 (95% CI: -5.95 to 8.43,  $P = 0.74$ ) while a clinically significant change value is 4 units. (44) The confidence interval crosses the clinically significant threshold; therefore, a lack of precision may have been a limiting factor (HC,  $n = 10$  vs. UC,  $n = 17$  patients).

The GRADE quality of evidence for all outcomes is shown in Appendix 2.

# Conclusions

---

**Based on moderate quality of evidence**, there was a beneficial effect of in-home care:

- on the combined events of all-cause mortality and hospitalizations in heart failure patients;
- on unplanned hospitalizations in heart failure patients;
- on emergency department (ED) visits in heart failure patients;
- on the functional measure of activities of daily living (ADL) in chronic ill multimorbid patients.

**Based on moderate quality of evidence**, there was no difference between in-home care and usual care:

- for all-cause mortality in chronically ill multimorbid patients;
- for the functional measure of mobility in chronically ill multimorbid patients;
- for the functional measure of instrumental activities of daily living (IADL) in chronically ill multimorbid patients.

**Based on low quality of evidence**, there was a beneficial effect:

- of in-home care on the physical component scale of the Medical Outcomes Study Short Form 36-Item Health Survey (SF-36), which assessed health-related quality of life (HRQOL) in heart failure patients;
- of nurse-led in-home care on the heart failure-specific HRQOL in heart failure patients;
- of in-home care on hemoglobin A1c in diabetes patients.

**Based on low quality of evidence**, there was no difference:

- for all-cause mortality in heart failure patients;
- for cardiovascular-specific mortality in heart failure patients;
- for heart failure-specific hospitalizations in heart failure patients;
- for length of hospital stay in heart failure patients;
- between in-home care and usual care for the mental health component of the SF-36 HRQOL in heart failure patients;
- between pharmacist-led in-home care and usual care for heart failure-specific HRQOL in heart failure patients;
- between in-home care and usual care for the physiological measures of systolic blood pressure (SBP), diastolic blood pressure (DBP), and lipid levels in diabetes and stroke patients.

**Based on indeterminate evidence**, there was no difference between in-home care and usual care for chronic obstructive pulmonary disease (COPD)-specific HRQOL.

# Existing Guidelines for Home Care

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While there are no specific guidelines for use of in-home care in Canada, listed below are the client populations and service programs offered by the Toronto Central Community Care Access Centres that deliver home care (*Personal communication, Community Expert, January 7, 2013*). (5)

1. Adult\*
  - Seniors Integrated Care
  - Seniors Enhanced Care (Frail Seniors\*)
  - Community Independence Program (Seniors Independent Living\*)
  - Adult Supportive Care
  - Telehomecare Program
2. Post-acute / Short-term support
  - Rapid Response Program\*
  - Acute and Rehab Transitional Program
3. Child and Family – Long and Short Stay
4. End of Life
5. Urban Health (Mental Health / Homeless)
  - Urban Health Program
  - Intercity Access Program
6. Acquired Brain Injury Program

An asterisk indicates the programs relevant to this evidence-based analysis.

# Glossary

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<b>Advanced practice nurse</b>	Advanced level of clinical nursing practice that includes the <i>clinical nurse</i> and the <i>nurse practitioner</i> .
<b>Ambulatory</b>	Individuals who experience some difficulty with everyday living but who are not totally dependent or homebound or who are receiving services to address functional problems.
<b>Client</b>	The person who is receiving home care services.
<b>Clinical nurse</b>	A nurse that provides clinical guidance and nursing leadership and promotes evidence-based practice to complex care clients.
<b>Disease management</b>	Coordinated multidisciplinary comprehensive care across the care continuum and specifically for chronic disease.
<b>Disease management program</b>	Multidisciplinary programs that target recently hospitalized patients in an effort to optimize their longer-term management, including post-acute discharge care within the community.
<b>Family Health Network</b>	A type of group practice that provides primary care services to rostered patients.
<b>Multidisciplinary care models</b>	Aims to address the needs of individuals from many perspectives, e.g., medical, psychological, behavioural, and financial. Involves a team of many different health professionals who also attempt to bridge patient care from the hospital to other care delivery or the home.
<b>New York Heart Association Functional Classification</b>	Ranks patients' limitations during physical activity, e.g., class I/II: none or mild limitation; class III: moderate limitation; class IV: severe limitation.
<b>Nurse practitioner</b>	Nurses who provide care in rural and remote areas that would otherwise not receive medical care and who possess the skills to diagnosis and manage disease within legislative scope.
<b>Rehabilitation</b>	The physical restoration of a sick or disabled person by therapeutic measures and re-education to participation in the activities of a normal life within the limitations of the person's physical disability.

# Acknowledgements

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Kellee Kaulback, BA(H), MIST

## Expert Panel for Health Quality Ontario: Optimizing Chronic Disease Management in the Community (Outpatient) Setting

Name	Title	Organization
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Theresa Agnew	Executive Director	Nurse Practitioners' Association of Ontario
Onil Bhattacharyya	Clinician Scientist	Li Ka Shing Knowledge Institute, St. Michael's Hospital, University of Toronto
Arlene Bierman	Ontario Women's Health Council Chair in Women's Health	Department of Medicine, Keenan Research Centre in the Li Ka Shing Knowledge Institute, St. Michael's Hospital, University of Toronto
Susan Bronskill	Scientist	Institute for Clinical Evaluative Sciences
Catherine Demers	Associate Professor	Division of Cardiology, Department of Medicine, McMaster University
Alba Dicenso	Professor	School of Nursing, McMaster University
Mita Giacomini	Professor	Centre of Health Economics & Policy Analysis, Department of Clinical Epidemiology & Biostatistics
Ron Goeree	Director	Programs for Assessment of Technology in Health (PATH) Research Institute, St. Joseph's Healthcare Hamilton
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Moira Stewart	Director	Centre for Studies in Family Medicine, University of Western Ontario
Walter Wodchis	Associate Professor	Institute of Health Management Policy and Evaluation, University of Toronto

# Appendices

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## Appendix 1: Literature Search Strategies

### Home Care – Final Search Strategy

Database: Ovid MEDLINE(R) <1946 to January Week 3 2012>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <January 25, 2012>, Embase <1980 to 2012 Week 03>

Search Strategy:

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- 137 exp Coronary Artery Disease/ (211925)
- 2 exp Myocardial Infarction/ use mesz (133578)
- 3 exp heart infarction/ use emez (216783)
- 4 (coronary artery disease or cad or heart attack).ti. (44430)
- 5 ((myocardi\* or heart or cardiac or coronary) adj2 (atheroscleros\* or arterioscleros\* or infarct\*)).ti. (149495)
- 6 or/1-5 (539636)
- 7 exp Atrial Fibrillation/ use mesz (28093)
- 8 exp heart atrium fibrillation/ use emez (55436)
- 9 ((atrial or atrium or auricular) adj1 fibrillation\*).ti,ab. (73456)
- 10 or/7-9 (99330)
- 11 exp heart failure/ (300723)
- 12 ((myocardi\* or heart or cardiac) adj2 (failure or decompensation or insufficiency)).ti,ab. (234410)
- 13 11 or 12 (381620)
- 14 exp Stroke/ (177913)
- 15 exp Ischemic Attack, Transient/ use mesz (16370)
- 16 exp transient ischemic attack/ use emez (19656)
- 17 exp stroke patient/ use emez (5632)
- 18 exp brain infarction/ or exp cerebrovascular accident/ use emez (100939)
- 19 (stroke or tia or transient ischemic attack or cerebrovascular apoplexy or cerebrovascular accident or cerebrovascular infarct\* or brain infarct\* or CVA).ti,ab. (281020)
- 20 or/14-19 (391349)
- 21 exp Diabetes Mellitus, Type 2/ use mesz (68223)
- 22 exp non insulin dependent diabetes mellitus/ use emez (101510)
- 23 exp diabetic patient/ use emez (12865)
- 24 (diabetes or diabetic\* or niddm or t2dm).ti,ab. (764490)
- 25 or/21-24 (789402)
- 26 exp Skin Ulcer/ (72029)
- 27 ((pressure or bed or skin) adj2 (ulcer\* or sore\* or wound\*)).ti,ab. (28663)
- 28 (decubitus or bedsore\*).ti,ab. (8526)
- 29 or/26-28 (90720)
- 30 exp Pulmonary Disease, Chronic Obstructive/ use mesz (17049)
- 31 exp chronic obstructive lung disease/ use emez (54703)
- 32 (chronic obstructive adj2 (lung\* or pulmonary or airway\* or airflow or respiratory) adj (disease\* or disorder\*)).ti,ab. (54430)
- 33 (copd or coad).ti,ab. (45643)
- 34 chronic airflow obstruction.ti,ab. (1063)
- 35 exp Emphysema/ (37422)
- 36 exp chronic bronchitis/ use emez (6977)
- 37 ((chronic adj2 bronchitis) or emphysema).ti,ab. (50825)

- 38 or/30-37 (159227)
- 39 exp Chronic Disease/ (340679)
- 40 ((chronic\* adj2 disease\*) or (chronic\* adj2 ill\*)),ti,ab. (219900)
- 41 39 or 40 (506233)
- 42 6 or 10 or 13 or 20 or 25 or 29 or 38 or 41 (2605524)
- 43 exp Home Care Services/ use mesz (36884)
- 44 exp home care/ use emez (46848)
- 45 exp home care agencies/ or exp home health aides/ use mesz (48362)
- 46 exp House Calls/ use mesz (2048)
- 47 ((home or domicil\* or communit\*) adj2 (visit\* or care or caring or caregiver\* or healthcare or assist\* or aid\* or agenc\* or service\* or rehabilitation)),ti,ab. (86989)
- 48 (homecare or homemaker service\* or home nurs\* or meals on wheels).ti,ab. (3972)
- 49 43 or 44 or 45 or 46 or 47 or 48 (143324)
- 50 42 and 49 (17054)
- 51 limit 50 to 42ochran language (14353)
- 52 limit 51 to yr="2006 –Current" (5606)
- 53 limit 52 to (controlled clinical trial or meta analysis or randomized controlled trial) (690)
- 54 exp Technology Assessment, Biomedical/ or exp Evidence-based Medicine/ use mesz (63489)
- 55 exp Biomedical Technology Assessment/ or exp Evidence Based Medicine/ use emez (523373)
- 56 (health technology adj2 assess\$).ti,ab. (3059)
- 57 exp Random Allocation/ or exp Double-Blind Method/ or exp Control Groups/ or exp Placebos/ use mesz (379638)
- 58 Randomized Controlled Trial/ or exp Randomization/ or exp RANDOM SAMPLE/ or Double Blind Procedure/ or exp Triple Blind Procedure/ or exp Control Group/ or exp PLACEBO/ use emez (901804)
- 59 (random\* or RCT).ti,ab. (1255504)
- 60 (placebo\* or sham\*).ti,ab. (414042)
- 61 (control\* adj2 clinical trial\*).ti,ab. (35063)
- 62 meta analysis/ use emez (58594)
- 63 (meta analy\* or metaanaly\* or pooled analysis or (systematic\* adj2 review\*) or published studies or published literature or medline or embase or data synthesis or data extraction or 42ochrane).ti,ab. (252855)
- 64 or/53-63 (2164699)
- 65 52 and 64 (1348)
- 66 remove duplicates from 65 (960)

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**CINAHL**

#	Query	Results
S43	S39 and S42 Limiters – Published Date from: 20060101-20121231; English Language	411
S42	S40 or S41	157006
S41	random* or sham* or rct* or health technology N2 assess* or meta analy* or metaanaly* or pooled analysis or (systematic* N2 review*) or published studies or medline or embase or data synthesis or data extraction or 43ochrane or control* N2 clinical trial*	148913
S40	(MH “Random Assignment”) or (MH “Random Sample+”) or (MH “Meta Analysis”) or (MH “Systematic Review”) or (MH “Double-Blind Studies”) or (MH “Single-Blind Studies”) or (MH “Triple-Blind Studies”) or (MH “Placebos”) or (MH “Control (Research)”)	83970
S39	S33 and S38	6361
S38	S34 or S35 or S36 or S37	66000
S37	homecare OR homemaker service* OR home nurs* OR meals on wheels	9390
S36	((home OR domicil* OR communit*) N2 (visit* OR care OR caring OR caregiver* OR healthcare OR assist* OR aid* OR agenc* OR service* OR rehabilitation))	57389
S35	(MH “Home Health Agencies”) OR (MH “Home Health Care Information Systems”)	4318
S34	(MH “Home Health Aides”) OR (MH “Home Health Care+”)	27543
S33	S5 or S8 or S11 or S15 or S19 or S22 or S27 or S32	223005
S32	S28 or S29 or S30 or S31	71626
S31	chronic* N2 disease* or chronic* N2 ill*	43890
S30	comorbid* OR co-morbid* OR multimorbid* OR multi-morbid* OR (complex* N1 patient*) OR (multiple N2 (condition* OR disease* OR patient*))	30356
S29	(MH “Comorbidity”)	16703
S28	(MH “Chronic Disease”)	23713
S27	S23 or S24 or S25 or S26	8821
S26	chronic N2 bronchitis or emphysema	1823
S25	(MH “Emphysema”)	886
S24	chronic obstructive N2 disease* or chronic obstructive N2 disorder* or copd or coad	7394
S23	(MH “Pulmonary Disease, Chronic Obstructive+”)	5374
S22	S20 or S21	16228
S21	pressure N1 ulcer* or bedsore* or bed N1 sore* or skin N1 ulcer* OR pressure N1 wound* OR decubitus	9608
S20	(MH “Skin Ulcer+”)	14882
S19	S16 or S17 or S18	70413
S18	diabetes or diabetic* or niddm or t2dm	70413
S17	(MH “Diabetic Patients”)	3551
S16	(MH “Diabetes Mellitus, Type 2+”)	18307

S15	S12 or S13 or S14	38366
S14	stroke or tia or transient ischemic attack or cerebrovascular apoplexy or cerebrovascular accident or cerebrovascular infarct* or brain infarct* or CVA	37868
S13	(MH “Cerebral Ischemia, Transient”)	1907
S12	(MH “Stroke”) OR (MH “Stroke Patients”)	25741
S11	S9 OR S10	18910
S10	myocardi*failure OR myocardial decompensation OR myocardial insufficiency OR cardiac failure OR cardiac decompensation or cardiac insufficiency OR heart failure OR heart decompensation OR heart insufficiency	18898
S9	(MH “Heart Failure+”)	14423
S8	S6 OR S7	8118
S7	atrial N1 fibrillation* OR atrium N1 fibrillation* OR auricular N1 fibrillation*	8118
S6	(MH “Atrial Fibrillation”)	6503
S5	S1 OR S2 OR S3 OR S4	30205
S4	TI myocardi* N2 infarct* or TI heart N2 infarct* or TI cardiac N2 infarct* OR TI coronary N2 infarct* or TI arterioscleros* or TI atheroscleros*	9678
S3	coronary artery disease OR cad OR heart attack*	7725
S2	(MH “Myocardial Infarction+”)	19236
S1	(MH “Coronary Arteriosclerosis”)	4653

Wiley Cochrane

ID	Search	Hits
#1	<u>MeSH descriptor <b>Coronary Artery Disease</b> explode all trees</u>	2183
#2	<u>MeSH descriptor <b>Myocardial Infarction</b> explode all trees</u>	7746
#3	<u>(myocardi* or heart or cardiac or coronary) NEAR/2 (atheroscleros* or arterioscleros* or infarct*):ti or (coronary artery disease or cad or heart attack*):ti</u>	8469
#4	<u>MeSH descriptor <b>Atrial Fibrillation</b> explode all trees</u>	2102
#5	<u>(atrial NEAR/2 fibrillation* or atrium NEAR/2 fibrillation* or auricular NEAR/2 fibrillation* ):ti</u>	2310
#6	<u>MeSH descriptor <b>Heart Failure</b> explode all trees</u>	4710
#7	<u>(myocardi* NEAR/2 (failure or decompensation or insufficiency)):ti or (heart NEAR/2 (failure or decompensation or insufficiency)):ti or (cardiac NEAR/2 (failure or decompensation or insufficiency)):ti</u>	5252
#8	<u>MeSH descriptor <b>Stroke</b> explode all trees</u>	3899
#9	<u>MeSH descriptor <b>Ischemic Attack, Transient</b> explode all trees</u>	466
#10	<u>(stroke or tia or transient ischemic attack or cerebrovascular apoplexy or cerebrovascular accident or cerebrovascular infarct* or brain infarct* or CVA):ti</u>	9902
#11	<u>MeSH descriptor <b>Diabetes Mellitus, Type 2</b> explode all trees</u>	6993
#12	<u>(diabetes or diabetic* or niddm or t2dm):ti</u>	16585
#13	<u>MeSH descriptor <b>Skin Ulcer</b> explode all trees</u>	1572
#14	<u>(pressure or bed or skin) NEAR/2 (ulcer* or sore* or wound*):ti</u>	669
#15	<u>(decubitus or bed sore*):ti</u>	98
#16	<u>MeSH descriptor <b>Pulmonary Disease, Chronic Obstructive</b> explode all trees</u>	1754
#17	<u>(chronic obstructive NEAR/2 (lung* or pulmonary or airway* or airflow or respiratory) ):ti</u>	2415
#18	<u>(copd or coad):ti</u>	3319
#19	<u>(chronic airflow obstruction):ti</u>	72
#20	<u>MeSH descriptor <b>Emphysema</b> explode all trees</u>	91
#21	<u>(chronic NEAR/2 bronchitis) or emphysema:ti</u>	1183
#22	<u>MeSH descriptor <b>Chronic Disease</b> explode all trees</u>	9875
#23	<u>(chronic* NEAR/2 disease* or chronic* NEAR/2 ill*):ti</u>	1670
#24	<u>MeSH descriptor <b>Comorbidity</b> explode all trees</u>	1941
#25	<u>(comorbid* OR co-morbid* OR multimorbid* OR multi-morbid* OR (complex* NEXT patient*) OR "patient* with multiple" OR (multiple NEAR/2 (condition* OR disease*))) :ti</u>	649
#26	<u>(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25)</u>	68126
#27	<u>MeSH descriptor <b>Home Care Services</b> explode all trees</u>	1872
#28	<u>MeSH descriptor <b>Home Care Agencies</b> explode all trees</u>	7

#29	<u>MeSH descriptor <b>Home Health Aides</b> explode all trees</u>	17
#30	<u>MeSH descriptor <b>House Calls</b> explode all trees</u>	215
#31	<u>((home or domicil* or communit*) NEAR/2 (care or caring or caregiver* or healthcare or assist* or aid* or agenc* or service* or rehabilitation)):ti or ((home or domicil* or communit*) NEAR/2 (care or caring or caregiver* or healthcare or assist* or aid* or agenc* or service* or rehabilitation)):ab</u>	2169
#32	<u>(homecare or homemaker service*):ti and (homecare or homemaker service*):ab</u>	8
#33	<u>(#27 OR #28 OR #29 OR #30 OR #31 OR #32)</u>	3650
#34	<u>(#26 AND #33), from 2006 to 2012</u>	335

**CRD**

Line	Search	Hits	
<input type="checkbox"/> 1	MeSH DESCRIPTOR coronary artery disease EXPLODE ALL TREES	230	Delete
<input type="checkbox"/> 2	(coronary artery disease or cad or heart attack*):TI	213	Delete
<input type="checkbox"/> 3	((myocardi* or heart or cardiac or coronary) adj2 (atheroscleros* or arterioscleros* or infarct*)):TI	224	Delete
<input type="checkbox"/> 4	MeSH DESCRIPTOR Atrial Fibrillation EXPLODE ALL TREES	225	Delete
<input type="checkbox"/> 5	((atrial or atrium or auricular) adj1 fibrillation*):TI	0	Delete
<input type="checkbox"/> 6	((atrial or atrium or auricular) adj1 fibrillation*):TI	168	Delete
<input type="checkbox"/> 7	MeSH DESCRIPTOR heart failure EXPLODE ALL TREES	418	Delete
<input type="checkbox"/> 8	((myocardi* or heart or cardiac) adj2 (failure or decompensation or insufficiency)):TI	280	Delete
<input type="checkbox"/> 9	MeSH DESCRIPTOR stroke EXPLODE ALL TREES	549	Delete
<input type="checkbox"/> 10	MeSH DESCRIPTOR Ischemic Attack, Transient EXPLODE ALL TREES	32	Delete
<input type="checkbox"/> 11	(stroke or tia or transient ischemic attack or cerebrovascular apoplexy or cerebrovascular accident or cerebrovascular infarct* or brain infarct* or CVA):TI	622	Delete
<input type="checkbox"/> 12	MeSH DESCRIPTOR Diabetes Mellitus, Type 2 EXPLODE ALL TREES	511	Delete
<input type="checkbox"/> 13	(diabetes or diabetic* or niddm or t2dm):TI	1223	Delete
<input type="checkbox"/> 14	MeSH DESCRIPTOR Skin Ulcer EXPLODE ALL TREES	253	Delete
<input type="checkbox"/> 15	((pressure or bed or skin) adj2 (ulcer* or sore* or wound*)):TI	73	Delete
<input type="checkbox"/> 16	(decubitus or bedsore*):TI	0	Delete
<input type="checkbox"/> 17	MeSH DESCRIPTOR Pulmonary Disease, Chronic Obstructive EXPLODE ALL TREES	237	Delete
<input type="checkbox"/> 18	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow or respiratory)):TI	219	Delete
<input type="checkbox"/> 19	(copd or coad):TI	108	Delete

<input type="checkbox"/>	20	(chronic airflow obstruction):TI	0	Delete
<input type="checkbox"/>	21	MeSH DESCRIPTOR Emphysema EXPLODE ALL TREES	10	Delete
<input type="checkbox"/>	22	((chronic adj2 bronchitis) or emphysema):TI	47	Delete
<input type="checkbox"/>	23	MeSH DESCRIPTOR Chronic Disease EXPLODE ALL TREES	687	Delete
<input type="checkbox"/>	24	((chronic* adj2 disease*) or (chronic* adj2 ill*)):TI	252	Delete
<input type="checkbox"/>	25	MeSH DESCRIPTOR Comorbidity EXPLODE ALL TREES	146	Delete
<input type="checkbox"/>	26	(comorbid* OR co-morbid* OR multimorbid* OR multi-morbid* OR (complex* adj1 patient*) OR “patient* with multiple” OR (multiple adj2 (condition* OR disease*)))	22	Delete
<input type="checkbox"/>	27	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26	4656	Delete
<input type="checkbox"/>	28	MeSH DESCRIPTOR home care services EXPLODE ALL TREES	375	Delete
<input type="checkbox"/>	29	MeSH DESCRIPTOR home care agencies EXPLODE ALL TREES	1	Delete
<input type="checkbox"/>	30	MeSH DESCRIPTOR home health aides EXPLODE ALL TREES	2	Delete
<input type="checkbox"/>	31	MeSH DESCRIPTOR house calls EXPLODE ALL TREES	32	Delete
<input type="checkbox"/>	32	((((home or domicil* or communit*) adj2 (visit* or care or caring or caregiver* or healthcare or assist* or aid* or agenc* or service* or rehabilitation)))) FROM 2006 TO 2012	785	Delete
<input type="checkbox"/>	33	#28 OR #29 OR #30 OR #31 OR #32	1057	Delete
<input type="checkbox"/>	34	#27 AND #33	190	Delete
<input type="checkbox"/>	35	#27 AND #33	190	Delete

## Appendix 2: GRADE Tables

Table A1: GRADE Evidence Profile for Comparison of In-Home Care and Usual Care: Mortality

No. Of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
<b>All-cause mortality – heart failure patients</b>							
5 (RCTs)	Serious limitations (-1) <sup>a</sup>	No serious limitations	No serious limitations	Serious limitations (-1) <sup>b</sup>	Undetected	n/a	⊕⊕ Low
<b>All-cause mortality – chronic disease</b>							
1 (RCTs)	No serious limitations	No serious limitations	No serious limitations	Serious limitations (-1) <sup>b</sup>	Undetected	n/a	⊕⊕⊕ Moderate
<b>Combined all-cause mortality and hospitalizations</b>							
3 (RCTs)	Serious limitations (-1) <sup>c</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕⊕ Moderate
<b>Cardiovascular-specific mortality</b>							
2 (RCTs)	Serious limitations (-1) <sup>c</sup>	No serious limitations	No serious limitations	Serious limitations (-1) <sup>b</sup>	Undetected	n/a	⊕⊕ Low

**Table A2: GRADE Evidence Profile for Comparison of In-Home Care and Usual Care: Hospital Utilization**

No. Of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
<b>Unplanned hospitalizations</b>							
2 (RCTs)	Serious limitations (-1) <sup>c</sup>	No serious limitations	No serious limitations	Serious limitations (-1) <sup>b</sup>	Undetected	n/a	⊕⊕ Low
<b>Heart failure-specific hospitalizations</b>							
2 (RCTs)	Serious limitations (-1) <sup>c</sup>	No serious limitations	No serious limitations	Serious limitations (-1) <sup>b</sup>	Undetected	n/a	⊕⊕ Low
<b>Mean number of unplanned hospitalizations</b>							
1 (RCTs)	Serious limitations (-1) <sup>c</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕⊕ Moderate
<b>Mean number of heart failure-specific hospitalizations</b>							
2 (RCTs)	Serious limitations (-1) <sup>c</sup>	No serious limitations	No serious limitations	Serious limitations (-1) <sup>b</sup>	Undetected	n/a	⊕⊕ Low
<b>Length of stay</b>							
2 (RCTs)	Serious limitations (-1) <sup>c</sup>	No serious limitations	No serious limitations	Serious limitations (-1) <sup>b</sup>	Undetected	n/a	⊕⊕ Low
<b>Mean number of emergency department visits</b>							
1 (RCT)	Serious limitations (-1) <sup>c</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕⊕ Moderate

**Table A3: GRADE Evidence Profile for Comparison of In-Home Care and Usual Care: Health-Related Quality of Life and Functional Status**

No. Of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
<b>General well-being – physical</b>							
1 (RCT)	Very serious limitations (–2) <sup>d</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕ Low
<b>General well-being – mental</b>							
1 (RCT)	Very serious limitations (–2) <sup>d</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕ Low
<b>Heart failure-specific well-being – nurse-led</b>							
2 (RCTs)	Very serious limitations (–2) <sup>e</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕ Low
<b>Heart failure-specific well-being – pharmacist</b>							
1 (RCT)	Very serious limitations (–2) <sup>f</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕ Low
<b>COPD-specific well-being</b>							
1 (RCT)	Very serious limitations (–2) <sup>g</sup>	No serious limitations	No serious limitations	Very serious limitations (–2) <sup>g</sup>	Undetected	n/a	Indeterminate
<b>Activities of daily living</b>							
1 (RCT)	Serious limitations (–1) <sup>h</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕⊕ Moderate
<b>Mobility</b>							
1 (RCT)	Serious limitations (–1) <sup>h</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕⊕ Moderate
<b>Instrumental activities of daily living</b>							
1 (RCT)	Serious limitations (–1) <sup>h</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕⊕ Moderate

**Table A4: GRADE Evidence Profile for Comparison of In-Home Care and Usual Care: Physiological Measures**

No. Of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
<b>Hemoglobin A1c</b>							
2 (RCTs)	Very serious limitations (-2) <sup>d</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕ Low (Qualitative assessment) <sup>i</sup>
<b>Systolic blood pressure</b>							
2 (RCTs)	Very serious limitations (-2) <sup>d</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕ Low (Qualitative assessment) <sup>i</sup>
<b>Diastolic blood pressure</b>							
2 (RCTs)	Very serious limitations (-2) <sup>d</sup>	<b>No serious limitations</b>	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕ Low (Qualitative assessment) <sup>i</sup>
<b>Lipids (low density lipoprotein and total cholesterol)</b>							
2 (RCTs)	Very serious limitations (-2) <sup>d</sup>	No serious limitations	No serious limitations	No serious limitations	Undetected	n/a	⊕⊕ Low (Qualitative assessment) <sup>i</sup>

Abbreviations: RCT, randomized controlled trial.

<sup>a</sup> Allocation concealment was not identified and post-randomization exclusions may have biased results.

<sup>b</sup> Imprecision based on sample size calculation.

<sup>c</sup> Allocation concealment was not identified.

<sup>d</sup> Allocation concealment was not identified and losses to follow-up may have biased results.

<sup>e</sup> Allocation concealment was not identified, lack of blinding, and losses to follow-up may have biased results.

<sup>f</sup> Lack of blinding and post-randomization exclusions may have biased results.

<sup>g</sup> Lack of blinding and allocation concealment was not identified, imprecision (small sample size and confidence interval crosses threshold).

<sup>h</sup> Losses to follow-up may have biased results.

<sup>i</sup> Unable to meta-analyze results across the 2 studies.

## Appendix 3: Summary Tables

Table A5: Summary of Study Characteristics (N = 12 Studies)

Author, Year	Study Location	Cohort	Study Design	Length of Follow-Up (Length of Intervention <sup>a</sup> )	HC / UC	Losses to Follow-Up (HC / UC)
Spencer et al, 2011 (26)	Medical records, Detroit, USA	T2 DM	Parallel RCT	6 mo (6 mo)	84 / 99	56 / 57 <sup>b</sup>
Aguado et al, 2010 (28)	University hospital, Spain	HF	Parallel RCT	Up to 2 y (n/a)	42 / 64	- <sup>c</sup>
Gilmore et al, 2010 (33)	Outpatient clinic, Louisiana, USA	COPD	FT RCT	1–3 mo (n/a)	10 / 17 <sup>d</sup>	-
Gray et al, 2010 (35)	FHT, Ottawa, Canada	Chronic <sup>e</sup>	Parallel RCT	1–1.5 y (12–18 mo)	120 / 121	-
Allen et al, 2009 (34)	Acute care, Ohio, USA	Stroke <sup>f</sup>	Parallel RCT	6 mo (6 mo)	190 / 190	- <sup>g</sup>
Brotos et al, 2009 (29)	4 hospitals (U+C), Spain	HF	Parallel RCT	1 y (1 y)	144 / 139	144 / 138 <sup>c</sup>
Gitlin et al, 2009 (36)	Community, Philadelphia, USA	Chronic	Parallel RCT	Up to 5.25 y (6 mo)	160 / 159	-
Wongpiriyayothar et al, 2008 (30)	Hospital clinic, Thailand	HF	Parallel RCT	Up to 3 mo (n/a)	48 / 48	48 / 45
Holland et al, 2007 (27)	3 hospitals, UK	HF	Parallel RCT	6 mo (n/a)	169 / 170	148 / 143 <sup>c,h</sup>
Iraurqui et al, 2007 (31)	Tertiary care hospital, Spain	HF	Parallel RCT	1 y (n/a)	137 / 142	-
Gitlin et al, 2006 (37)	Community, Philadelphia, USA	Chronic	Parallel RCT	6 (6 mo)	160 / 159	154 / 146
Inglis et al, 2006 (32)	Tertiary centre, Australia	HF	Parallel RCT	Up to 10 y (n/a) <sup>i</sup>	149 / 148	-

Abbreviations: C, community hospital; chronic, chronic disease; COPD, chronic obstructive pulmonary disease; FHT, Family Health Team; FT, factorial RCT; HbA1c, hemoglobin A1c; HC, home care; HF, heart failure; HRQOL, health-related quality of life; mo, month; RCT, randomized controlled trial; T2 DM, type 2 diabetes mellitus; U, University hospital; UC, usual care; y, year.

<sup>a</sup>Length of intervention information may be indicated by n/a if the HC intervention was a single visit or a few visits (e.g., 2–3 visits), and refers to the application of the intervention and does not refer to longer-term surveillance (e.g., the addition of telephone follow-up).

<sup>b</sup>Reduced sample size for HbA1c, primary outcome. This is the number with complete data at baseline and 6-month follow-up.

<sup>c</sup>Reduced sample size for HRQOL outcome (Aguado et al, 2010 (28), HC: 14 / UC: 23; Brotos et al, 2009 (29), HC: 101 / UC: 97; Holland et al, 2007 (27), HC: 78 / 80).

<sup>d</sup>Study subjects after losses to follow-up.

<sup>e</sup>For this particular study, 4 chronic diseases were specified: coronary artery disease, diabetes, congestive heart failure, COPD.

<sup>f</sup>Ischemic stroke.

<sup>g</sup>Reduced sample size for physiologic measures (HC: 175 / UC: 163).

<sup>h</sup>Post-randomization exclusions (HC: 149 / UC: 144), plus reduced sample size at the end of follow-up (HC: 148 / UC: 143).

<sup>i</sup>Reduced length of follow-up for the primary outcome of combined all-cause mortality and hospitalizations and separately for hospitalizations, median: 4.2 y, range: 3 to 6 y.

**Table A6: Detailed Description of Home Care Intervention (N = 12 Studies)**

Author, Year	Components of Home Care	Type of Providers <sup>a</sup>	Frequency	Duration
Spencer et al, 2011 (26)	Promotion of healthy lifestyle and DM self-management education activities + 1 TC / 2 wks CHWs also provided community DM education classes and escorted PCP clinic visits, in-home care: goal setting, progress support, communication skills, facilitated referrals	CHWs / family health advocates	2 visits / mo	60 min
Aguado et al, 2010 (28)	Education in relevant aspects of disease and self-management Elements of education included patient's habits, understanding of medication, and preventive activities	2 physician-trained nurses	1 visit	2 h
Gilmore et al, 2010 (33)	Educational support for disease management and evaluation of the patient's general health environment Structured assessment form to summarize ADL, medications, and living space; evaluation of the home environment, medication access, and family or personnel assistance	Respiratory therapist	1 visit	20–30 min
Gray et al, 2010 (35)	To ensure disease management and strong social supports + TC Patient care plan priorities based on 5 dimensions of care: disease management, medical review, education and self-care, social support and community integration, psychological issues Providers working with family physicians, educational classes, 22 patients received a telehealth / remote monitoring of clinical factors	3 nurse practitioners, pharmacist	NP for 18 mo, P for 12 mo <sup>b</sup> as needed	1 h for NP
Allen et al, 2009 (34)	Comprehensive assessment, PT as needed, education for lifestyle modification, medication use, social services, education to recognize signs and symptoms of recurrence, self-management + 1 TC / wk (1 <sup>st</sup> mo) and then 1 TC / mo (up to 6 mo)	Advanced practice nurse care manager	Initial visit and then as necessary	1–2 h
Brotans et al, 2009 (29)	Intensive, including disease education, warning symptom recognition, assessment of medication adherence and lifestyle habits, medical history review, functional status and vital sign examination + TC / 15 days Additional information provided prior to hospital discharge, worked with PCP or cardiologist	Nurses	Monthly	40–45 min

Author, Year	Components of Home Care	Type of Providers <sup>a</sup>	Frequency	Duration
Gitlin et al, 2009 (36) and Gitlin et al, 2006 (37)	Aimed to compensate for declining abilities by home environment and task performance modifications during the active phase (6 mo) + 3 TC (OT) during the maintenance phase (6–12 mo) OTs for environmental barriers and support, goal setting, cognitive, behavioural, and environmental strategies; PTs for balance and muscle strength exercises and fall recovery techniques	OT, PT	OT: 4 + 1 TC, plus PT: 1 (active phase), 1 final OT visit (maintenance phase)	OT: 90 min, PT: 90 min
Wongpiriyayothar et al, 2008 (30)	Patient education and plan to enhance patient's symptom monitoring and management skills + 2 TC / weekly Educational booklet also provided, coaching strategies used	Advanced practice nurse	2 visits 1 week apart	1 <sup>st</sup> : 2 h, 2 <sup>nd</sup> : 45–60 min
Holland et al, 2007 (27)	Patient education on disease, medication, healthy lifestyle, signs and symptoms, removed discontinued drugs, educational booklet Worked with PCP and local pharmacist for use of drug adherence aid; community pharmacists were not independent prescribers to modify drug regimen; standardized visit form	17 community pharmacists	2 visits	1 <sup>st</sup> : 72 min 2 <sup>nd</sup> : 50 min
Iraurqui et al, 2007 (31)	Educational program about disease facts and management (symptoms, lifestyle, diet, therapy), with special emphasis Home attention included physician visits and clinical exam, tests and analyses when needed therapeutic review; information manual, TC available for queries	Nurses	3 visits @ 2, 5, 10 days	1 hr
Inglis et al, 2006 (32)	Comprehensive assessment, physical exam, reviewed medication adherence and disease knowledge, assessed social supports, remedial counselling, strategies, and monitoring action + TC at 6 mo (routine and surveillance) Report shared with PCP and cardiologist, community pharmacist contacted to help manage medications	Nurse and P, or cardiac nurse	1 visit	60–90 min

Abbreviations: ADL, activities of daily living; CHW, community health workers; DM, diabetes; HC, home care; h, hours; min, minutes; mo, months; NP, nurse practitioner; OT, occupational therapist; P, pharmacist; PCP, primary care provider; PT, physical therapist; TC, telephone call; wks, weeks.

<sup>a</sup>Type of providers who delivered the in-home care.

<sup>b</sup>Intervention period reduced to 12 months for those recruited last.

**Table A7: Detailed Summary of Study Design Characteristics (N = 12 Studies)**

Author, Year	Study Population	Description of HC / UC	Results	Other Comments
Spencer et al, 2011 (26)	≥ 18 y, physician dx T2 DM, AA or L/H, geographic defined, identified from MR	HC: Culturally defined HB CHW intervention for T2 DM in low income inner city AA and Latinos UC: Contacted once per mo to update contact information	Mean age: 52.5 y; high school graduate: 60%; insulin use: 28% % change from baseline, at 6 mo, HbA1c, HC: n = 56, -0.8 (-1.2, -0.4, <i>P</i> < 0.01) <sup>a</sup> vs. UC: n = 57, 0.0 (-0.4, 0.4, ns) <sup>a</sup> ; LDL, HC: n = 51, -10 (-17, -2, <i>P</i> < 0.05) <sup>a</sup> vs. UC: n = 55, -4 (-12, 4, ns) <sup>a</sup> ; SBP, HC: n = 54, -2 (-6, 2, ns) <sup>a</sup> vs. UC: n = 65, -3 (-6, 1, ns) <sup>a</sup> ; DBP, HC: n = 54, 0 (-3, 3, ns) <sup>a</sup> vs. UC: n = 65, -2 (-5, 1, ns) <sup>a</sup>	Community living, all participants received REACH related to living a healthy lifestyle and diet, and at designated health care facilities; LFU 28/164 (17.1%)
Aguado et al, 2010 (28)	Patients admitted to hospital with systolic HF, class II to IV NYHA and < 45% on EC or in prior 6 mo	HC: HB education visit for discharged HF patients UC: no educational component Both: conventional discharge care and outpatient care by attending physicians	Mean age: 77.6 y; secondary school education: 63%; NYHA class II: 46%; comorbidities, hypertension (59%), DM (39%), COPD (31%), CVA (15%) At 24 mo, all-cause mortality, HC: 20/42 (46.7%) vs. 35/64 (55.4%), <i>P</i> = 0.448; mean (SD) ED visits, HC: 0.68 (0.90) vs. UC: 2.00 (1.97), <i>P</i> = 0.001; mean (SD) unplanned hospitalizations, HC: 0.68 (0.94) vs. UC: 1.71 (1.67), <i>P</i> = 0.003; mean (SD) MLWHFQ score, HC: 11.9 (10.5) vs. UC: 18.3 (16.2); mean (SD) SF-36 physical score, HC: 50 (5) vs. UC: 44 (3); mean (SD) SF-36 mental score, HC: 52 (7) vs. UC: 44 (6)	Intervention 1 week after discharge; LFU for outcome of HRQOL, HC: 28/42 (66.6%) vs. UC: 41/64 (64%), compliance with medication in HB group; 0 LFU for primary study outcomes; reduced SS for HRQOL, HC: 14 and UC: 23
Gilmore et al, 2010 (33)	≥ 18 y, confirmed spirometry, physician dx COPD, moderate to severe by GOLD, ≥ 4 <sup>th</sup> grade reading literacy	HC: HB education visit for moderate to severe COPD UC: clinic visit with no educational component Both: information on medication use, physician initiated patient education related to inhalers and indications for medications	Mean age: 58 y; mean (SD) education: 10.4 (2.5) y; mean (SD) FEV <sub>1</sub> : 45.2% (15.7) At 30–90 days, mean (SD) overall SGRQ change from baseline, HC: 1.79 (8.76) vs. UC: 0.55 (9.9) (ns)	Outpatient pulmonary clinic, designed to examine education support by both a standardized home visit and COPD educational guide, additional information of SGRQ domains, additional information on knowledge and self-efficacy, LFU, 10/37 (27%)

Author, Year	Study Population	Description of HC / UC	Results	Other Comments
Gray et al, 2010 (35)	≥ 50 y, at risk of functional decline, physical deterioration, or needing emergency services	HC: HB team care program (APTCare) UC: usual medical care Both: PCP visits	Mean age: 72 y; high school education or higher: 61%; mean number of chronic conditions <sup>b</sup> , HC: 2.7 vs. UC: 2.4 (without SDs) Mean (95% CI) ED visits, HC: 7.84 (6.9–8.8) vs. UC: 7.81 (6.9–8.7); mean (95% CI) all-cause hospitalizations, HC: 0.40 (0.3–0.5) vs. 0.46 (0.3–0.6) (without SDs)	Community living, primary outcome: composite of quality of care for 4 chronic conditions of CAD, DM, HF, COPD (152 of 241 (63.1%) had 1 of 4 chronic conditions), mean LFU: 14.3 mo, additional information on appointments with physicians and day surgeries; ED visits: deceased patients were assumed to have each had 1 ED visit
Allen et al, 2009 (34)	Ischemic stroke dx, NIHSS ≥ 1, discharged home, geographic region, no other dominant illness, English speaking, no planned endarterectomy	HC: comprehensive care management UC: organized stroke department care Both: UC and enhanced discharge planning	Mean age: 68 y; diabetes: 36%; mean number of comorbidities: 0.7 At 6 mo, all-cause mortality, HC: 9/190 (4.5%) vs. UC: 7/190 (3.5%) (ns); mean LOS, HC: 1.6 vs. UC: 1.4 <sup>a</sup> days; mean HRQOL total score, HC: 196 vs. UC: 199; % HbA1c > 6.5%, HC: 28.3 vs. 22.8; % SBP > 140 mm Hg, HC: 31.5 vs. UC: 30.0; % DBP > 90 mm Hg, HC: 5.6 vs. UC: 5.2; % total CHL > 180 mg/dL, HC: 35.4 vs. UC: 30.8	Intervention within 1 week of discharge; outcomes selected to reflect the process of care management – 5 domains; no SDs for HRQOL and physiological measures; HC: 175 / UC: 163 for physiological outcomes
Brotans et al, 2009 (29)	Hospitalized for suspected HF per Framingham, HF dx at hospital discharge in 1st or 2nd position (any age)	HC: intensive HB care UC: referred to PCP and/or cardiologist	Mean (SD) age: 76.3 (8.2) y; NYHA class IV at hospitalizations, 51%; comorbidities, hypertension (76%), DM (42%), COPD (27%), with baseline differences for COPD At 1 y, combined, HC: 60/144 (41.7%) vs. UC: 75/138 (54.3%), <i>P</i> = 0.043; all-cause mortality, HC: 26/144 (18.1%) vs. 29/138 (21%) (ns); CVD mortality, HC: 19/144 (13.2%) vs. UC: 20/138 (14.5%); HF hospitalizations, HC: 52/144 (36.1%) vs. UC: 62/138 (44.9%) (ns); mean HF hospitalizations, HC: 1.01 vs. UC: 1.30 (ns) (without SDs); mean (SD) MLWHFQ score, HC: 18.57 (13.1) vs. UC: 31.11 (23.9), <i>P</i> < 0.001	Monthly visits after discharge; reduced sample size for HRQOL: 198 (70.2%); additional information on patient satisfaction and adherence to treatment; combined: hospitalization due to worsening of HF

Author, Year	Study Population	Description of HC / UC	Results	Other Comments
Gitlin et al, 2009 (36) and Gitlin et al, 2006 (37)	Community-living adults, ambulatory, ≥ 70 y, cognitively intact, ≥ 1 functional difficulties, English speaking	HC: ABLE program UC: Home safety education booklet at study end	Mean age: 79 y; less than a high school education: 31%, high school education: 32.3%, more than a high school education: 36.7%; comorbidities, hypertension (71%), CVD (39%), DM (23%) Up to 5.25 y, all-cause mortality, HC: 34/160 (21.3%) vs. UC: 42/159 (26.4%) At 6 mo, ADL, HC: 1.58 (0.54) vs. UC: 1.66 (0.63), $P = 0.03^a$ ; mobility, HC: 2.35 (0.72) vs. UC: 2.41 (0.80), $P = 0.15$ ; IADL, HC: 1.97 (0.69) vs. UC: 2.07 (0.77), $P = 0.04$ [HC: n = 154 / UC: n = 146]	Risk groups created by mortality risk, ↑ scores indicate ↑ risk, mean of 7 health conditions, additional information on 6 and 12 mo measures of fear of falling, functional self-efficacy, home hazards, and control-oriented strategies
Wongpiriyayothar et al, 2008 (30)	HF, ≥ 40 y, class II NYHA, stable medication use, ability to communicate, geographic area, not living alone	HC: HB program on symptom alleviation and well-being UC: HF booklet at end of study follow-up Both: received care from hospital health care providers	Mean age: 60 y; finished primary school: 89% At 12 weeks, mean SF-36 physical score, HC: 78.3 vs. UC: 60.4, $P < 0.001$ ; mean SF-36 mental score, HC: 77.7 vs. UC: 58.6, $P < 0.001$ (without SDs)	Intervention within 1 week of outpatient visit; not clear what is the primary outcome; additional information on symptom severity, as described in the text: many patients had comorbid diseases and > 1 CVD dx, no baseline info on NYHA
Holland et al, 2007 (27)	HF, > 18 y, taking ≥ 2 drugs	HC: HB community pharmacist-led UC: usual care	Mean age: 77 y; NYHA class III, HC: 34.9% vs. UC: 32.6%; NYHA class IV, HC: 32.2% vs. UC: 34% At 6 mo, all-cause mortality, 30/149 (20.1%) vs. UC: 24/144 (16.6%), $P = 0.54$ ; mean (SD) MLWHFQ score, HC: 47.7 (26.3), n = 78 vs. UC: 44.5 (27.9), n = 80 ( $P = 0.32$ )	Intervention within 2 weeks of discharge, post-randomization exclusions (HC: 20, UC: 26), additional information on EQ-5D and drug adherence

Author, Year	Study Population	Description of HC / UC	Results	Other Comments
Iraurqui et al, 2007 (31)	HF, no COPD, severe cognitive deficits, psychiatric, or terminal disease, family support, geographic area	HC: HB educational program UC: PCP Both: PCP	Mean age: 75.8 y; primary schooling or less: 89%; comorbidities, hypertension (68%), DM (36%)  At 1 y, combined CI, HC: 62/137 (45.3%) vs. 75/142 (52.8%), $P = 0.232$ ; all-cause mortality CI, HC: 22/137 (16.1%) vs. 21/142 (14.8%), $P = 0.769$ ; CVD mortality, HC: 16/137 (11.7%) vs. UC: 18/142 (12.7%) (ns); unplanned hospitalization CI, HC: 59/137 (43.1%) vs. UC: 71/142 (50%), $P = 0.280$ ; mean (SD) hospitalizations, HC: 8.6 (7.2) vs. UC: 10.1 (12.9) (ns); mean (SD) HF hospitalizations, HC: 8.5 (6.4) vs. UC: 8.4 (11.6); mean (SD) LOS, HC: 8.4 (7.7) vs. UC: 9.6 (13) days (ns); ED visits, HC: 59/137 (43.1%) vs. UC: 57/142 (40.1%) (ns); HF ED visits, HC: 7/137 (5.1%) vs. 10/142 (7%) (ns)	Intervention up to 15 days later; subgroup analysis with emphasis on non-adherers
Inglis et al, 2006 (32)	$\geq 55$ y, HF dx, class II, III, IV NYHA, impaired systolic function ( $\leq 55\%$ ), hx $\geq 1$ admission for acute HF <sup>c</sup>	HC: HB care UC: PCP and outpatient care Both: postdischarge planning, PCP, outpatient cardiology review	Mean age: 75 y; NYHA class II, HC: 47% vs. UC: 44%; NYHA class III, HC: 45% vs. UC: 45%; comorbidities, hypertension (58%), COPD (36%), DM (29%)  At 7.5 y, all-cause mortality, HC: 114/149 (76.5%) vs. 132/148 (89.1%), $P = 0.0006$ ; up to 10 y, mean (SD) LOS, HC: 8.2 (5.5) vs. UC: 8.8 (6.5) days (ns)  At a median of 4.2 y, combined, HC: 130/149 (87%) vs. UC: 135/148 (91%); unplanned hospitalizations, HC: 112/149 (75%) vs. UC: 118/148 (80%) (ns)	Minimum follow-up of 7.5 y, and up to 10 y, mean Charlson index score, HC: 2.9 (1.4) vs. UC: 2.8 (1.4), additional outcome information (e.g., median, event-free, hospital survival)

Abbreviations: AA, African American; ABLE, Advancing Better Living for Elders; ADL, Activities of Daily Living; APTCare, Anticipatory and Preventive Team Care; CHW, community health workers; COPD, chronic obstructive pulmonary disease; CHL, cholesterol; CVD, cardiovascular disease; DBP, diastolic blood pressure; EC, echocardiography; dx, diagnosed; DM, diabetes mellitus; ED, emergency department; EQ-5D, EuroQoL; FEV<sub>1</sub>, forced expiratory volume in 1 second; GOLD, Global Initiative for Chronic Obstructive Lung Disease; HB, home-based; HbA1c, hemoglobin A1c; HC, home care; HF, heart failure; HRQOL, health-related quality of life; hx, history; IADL, Instrumental Activities of Daily Living; LFU, length of follow-up; L/H, Latino/Hispanic; LOS, length of stay; mo, months; MLWHFQ, Minnesota Living With Heart Failure Questionnaire; MR, medical records; ns, nonsignificant; NIHSS, National Institutes of Health Stroke Scale; NYHA, New York Heart Association; PCP, primary care physician; QoL, quality of life; REACH, Racial and Ethnic Approaches to Community Health; SBP, systolic blood pressure; SD, standard deviation; SF-36, Medical Outcomes Study Short Form Health Survey; SGRQ, St George's Respiratory Questionnaire; SS, sample size; T2 DM, type 2 diabetes mellitus; UC, usual care; y, years.

<sup>a</sup>Adjusted for covariates.

<sup>b</sup>Chronic conditions included diabetes, congestive heart failure, chronic anxiety, depression, or other mental illnesses, chronic obstructive pulmonary disease, coronary artery disease, neurologic conditions, hypertension, anemia, arthritis or back problems, cancer, asthma, cerebrovascular disease, ischemic heart disease, atrial fibrillation, peripheral vascular disease.

<sup>c</sup>Acute HF defined as pulmonary congestion/edema and acute dyspnea at rest.

**Table A8: Summary of Study Outcomes (Primary and Secondary) by Chronic Disease Population for Included Studies (N = 12 Studies)**

Author, Year	Clinical						Other				
	Combined <sup>a</sup>	All-cause Mortality	HF Mortality	All-cause HP	HF HP	LOS	ED Visits	HF ED Visits	HrQOL	Disease-specific	Functional status
<b>Heart Failure</b>											
Aguado et al, 2010 (28)		✓ <sup>b</sup>		✓ <sup>b</sup>			✓	✓ <sup>b</sup>	✓		
Brotans et al, 2009 (29)	✓ <sup>b</sup>	✓	✓		✓				✓		
Wongpiriyayothar et al, 2008 <sup>c</sup> (30)									✓		
Holland et al, 2007 (27)		✓		✓ <sup>b</sup>					✓		
Iraurqui et al, 2007 (31)	✓ <sup>b</sup>	✓	✓	✓	✓	✓	✓				
Inglis et al, 2006 (32)	✓ <sup>b</sup>	✓		✓		✓	✓				
<b>Stroke</b>											
Allen et al, 2009 <sup>d</sup> (34)		✓				✓			✓	✓	
<b>COPD</b>											
Gilmore et al, 2010 (33)									✓ <sup>b</sup>		
<b>T2 DM</b>											
Spencer et al, 2011 (26)										✓ <sup>b</sup>	
<b>Chronic</b>											
Gray et al, 2010 <sup>d</sup> (35)				✓			✓				
Gitlin et al, 2009 <sup>e</sup> (36)		✓									
Gitlin et al, 2006 (37)											✓ <sup>b</sup>

Abbreviations: COPD, chronic obstructive pulmonary disease; ED, emergency department; HF, heart failure; HP, hospitalizations; HRQOL, health-related quality of life; LOS, length of stay; T2 DM, type 2 diabetes mellitus.

<sup>a</sup>Combined outcome of unplanned all-cause hospitalizations and all-cause mortality, except for Brotans (2009), (29) which included hospitalizations due to worsening of heart failure.

<sup>b</sup>Primary outcome(s). Sample size calculation based on hospitalizations for Aguado et al, 2010 (28).

<sup>c</sup>Primary outcome is not known.

<sup>d</sup>Primary outcome was not relevant to this evidence-based analysis.

<sup>e</sup>Primary outcome was based on a previous analysis of functional difficulties, self-efficacy, and fear of falling at 6 and 12 months.

**Table A9: Risk of Bias for 12 Randomized Controlled Trials for the Comparison of Home Care versus Usual Care**

Author, Year	Allocation Concealment <sup>a</sup>	Blinding <sup>b</sup>	Complete Accounting of Patients and Outcome Events <sup>c</sup>	Selective Reporting Bias	Other Limitations
Spencer et al, 2011 (26)	Limitations	No limitations	Limitations	-	SSC?
Aguado et al, 2010 (28)	Limitations	No limitations	No limitations/Limitations	-	-
Gilmore et al, 2010 (33)	Limitations	Limitations	No limitations	-	-
Gray et al, 2010 (35)	No limitations	Limitations	No limitations	-	-
Allen et al, 2009 (34)	No limitations	No limitations	No limitations/Limitations	-	Baseline difference <sup>d</sup>
Brotos et al, 2009 (29)	Limitations	No limitations/Limitations	No limitations/Limitations	-	Baseline difference <sup>d</sup>
Gitlin et al, 2009 (36)	No limitations	No Limitations	No limitations	-	SSC <sup>e</sup>
Wongpiriyaythar et al, 2008 (30)	Limitations	Limitations	No Limitations	-	Primary outcome?
Holland et al, 2007 (27)	No limitations	No limitations/Limitations	Limitations <sup>f</sup>	-	-
Iraurqui et al, 2007 (31)	No limitations	No limitations	No Limitations	-	-
Gitlin et al, 2006 (37)	No limitations	No limitations	Limitations	-	-
Inglis et al, 2006 (32)	Limitations	No limitations	No limitations	-	Baseline differences <sup>d</sup>

Abbreviations: CHL, cholesterol; DBP, diastolic blood pressure; HbA1c, hemoglobin A1c; HRQOL, health-related quality of life; LDL, low density lipoprotein; SBP, systolic blood pressure; SSC, sample size calculation.

<sup>a</sup>Absence of information.

<sup>b</sup>Spencer et al, 2011 (26), abstraction of HbA1c from medical records was not performed by personnel unaware of group assignment; Brotos et al, 2009 (29), no limitations for primary clinical outcomes, possible limitations for secondary outcome, HRQOL; Holland et al, 2007 (27), lack of blinding is a limitation for HRQOL outcome but not for mortality outcome; Gitlin et al, 2009 (36), no limitations for mortality outcome.

<sup>c</sup>Complete accounting of patients refers to losses to follow-up being described, and for outcome events, having performed an intent-to-treat analysis. Losses to follow-up may have biased results [HbA1c, SBP, DBP, LDL: Spencer et al, 2011 (26); HRQOL: Aguado et al, 2010 (28), Brotos et al, 2009 (29); HbA1c, SBP, DBP, total CHL: Allen et al, 2009 (34)].

<sup>d</sup>Baseline differences: Allen et al, 2009 (34), in terms of percent with diabetes and mean hospital days in previous year; Brotos et al, 2009 (29), in terms of COPD; Inglis et al, 2006 (32), in terms of prior acute myocardial infarction, left bundle-branch block, and blood urea concentration.

<sup>e</sup>Sample size calculation based on a previous study of the same patients, with the primary outcomes of the previous study not included in the current study.

<sup>f</sup>Post-randomization exclusions is a source of bias.

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