

Home-Based Exercise Programs in Heart Failure: A Rapid Review

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All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2–4-week time frames. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (<http://www.gradeworkinggroup.org/index.htm>), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario 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. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario 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.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series*, which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit <http://www.hqontario.ca> for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, Evidence Development and Standards and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards 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 may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: <http://www.hqontario.ca/evidence/publications-and-ohnac-recommendations>.

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List of Abbreviations

AMSTAR	Assessment of Multiple Systematic Reviews
CHF	Congestive heart failure
CI	Confidence interval(s)
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
MWT	Minute walk test
RCT	Randomized controlled trial
QOL	Quality of life
VO₂	Oxygen uptake

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

To determine the effectiveness of home-based exercise programs for patients with heart failure versus the following:

- supervised centre-based (or hospital) exercise programs or
- usual care for exercise capacity and quality of life (QOL).

Clinical Need and Target Population

Description of Disease/Condition

Congestive heart failure (CHF) is a complex syndrome in which abnormal heart function is responsible for the failure of the heart to pump blood at a rate that is necessary for metabolizing tissues. (1)

Ontario Prevalence and Incidence

The number of people with CHF in North America is estimated to exceed 5 million. (2) Between 1997 and 2008, there were 419,551 incident cases of heart failure in Ontario. (3) Congestive heart failure is the most common cause of hospitalization for adults over the age of 65 years. (2)

Technology/Technique

Exercise training for patients with CHF has a positive effect on physical capacity, such as exercise duration and maximal peak oxygen consumption. (4) Studies have also shown an association between exercise programs and increased QOL in patients with heart failure. (5)

Traditionally, centre-based programs usually incorporate group exercise training in a supervised gym environment and can include an educational component. However, they are resource-intensive and have suboptimal participation. Some reasons for lack of participation in centre-based exercise programs are problems with accessibility, a dislike for groups, and work or domestic commitments. (6;7) Home-based exercise training can include aerobic training, such as the use of exercise bikes, outdoor and treadmill walking, and strength training, such as resistive bands or weights, similar to that of centre-based exercise training. Home-based exercise training is usually unsupervised but can include regular contact with research staff. Home-based exercise programs potentially increase participation and bridge the gap on accessibility issues. (8)

Rapid Review

Research Question

What is the effectiveness of home-based exercise programs for patients with heart failure versus the following:

- centre-based exercise programs or
- usual care for patient outcomes?

Research Methods

Literature Search

Search Strategy

A literature search was performed on December 10, 2013, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, and all evidence-based medicine databases for studies published from January 1, 2008, to December 10, 2013. (Appendix 1 provides details of the search strategies.) 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 publications
- published between January 1, 2008, and December 10, 2013
- randomized controlled trials (RCTs), systematic reviews, and meta-analyses

Exclusion Criteria

- patients who have undergone cardiac surgical procedures
- interventions that incorporate both centre- and home-based exercise programs

Outcomes of Interest

- exercise capacity
 - measured by the 6-minute walk test (MWT) and peak VO₂ (oxygen uptake)
- quality of life

Expert Panel

In December 2013, an Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients was struck. Members of the community-based panels included family physicians, physician specialists, community health care administrators, and allied health professionals.

The role of the expert advisory panel was to provide advice on primary CHF patient groupings; to review the evidence, guidance, and publications related to defined CHF patient populations; to identify and

prioritize interventions and areas of community-based care; and to advise on the development of a care pathway model. The role of panel members was to provide advice on the scope of the project, the methods used, and the findings. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the expert panel members.

Quality of Evidence

The Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool was used to assess the methodologic quality of systematic reviews. (9)

The quality of the body of evidence for each outcome was examined according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. (10) The overall quality was determined to be high, moderate, low, or very low 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—were then taken into account. Limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 main factors that can raise the quality of evidence were considered: large magnitude of effect, dose-response gradient, and accounting for all residual confounding factors. (10) For more detailed information, please refer to the latest series of GRADE articles. (10)

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

High	High confidence in the effect estimate—the true effect lies close to the estimate of the effect
Moderate	Moderate confidence in the effect estimate—the true effect is likely to be close to the estimate of the effect, but may be substantially different
Low	Low confidence in the effect estimate—the true effect may be substantially different from the estimate of the effect
Very Low	Very low confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect

Results of Rapid Review

The database search yielded 610 citations published between January 1, 2008, and December 10, 2013 (with duplicates removed). Articles were excluded on the basis of information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

Two systematic reviews met the inclusion criteria. The systematic review used in this review by Chien et al (11) examined effectiveness of home-based exercise programs compared with usual activity in patients with heart failure on exercise capacity, QOL, and adverse events. This systematic review scored moderately on the AMSTAR scale with 8 of a possible 11 points. Some limitations included no search of grey literature, no assessment of publication bias, not considering the methodologic quality of the studies

in the conclusion, and no statement of conflict of interest. The systematic review by Hwang and Marwick (12) that was not included in this review examined effectiveness of home-based exercise programs compared with usual medical care on exercise capacity in patients with heart failure. This systematic review scored poorly on the AMSTAR scale with 4 of a possible 11 points. Some limitations included only one reviewer, no search of grey literature, no assessment of publication bias, no list of excluded studies, no assessment of the methodologic quality of the primary studies, not considering the methodologic quality of the studies in the conclusion, and no statement of conflict of interest.

There were consistencies across all primary studies included in the Chien et al (11) review. All the exercise programs within the studies incorporated a combination of aerobic exercise (walking or cycling) and resistance training. Also, the control groups of all studies maintained usual care with one exception (home-based electrical stimulation).

The effect of home-based exercise training on peak VO₂ was examined by pooling data from 4 studies with 248 participants using a random effects model (Figure 1). There was no difference for peak VO₂ between those participating in home-based exercise training and usual activity (0.55, 95% confidence interval [CI]: -0.03 to 1.14). The effect of home-based exercise training on 6 MWT was examined by pooling data from 4 studies with 256 participants using a random effects model (Figure 2). Home-based exercise training increased 6 MWT distance compared with usual activity (44.09, 95% CI: 4.57– 83.61). The effect of home-based exercise training on QOL was examined by pooling data from 2 studies with 78 participants (Figure 3). The third study, by Oka et al, (13) did not use the same measure for QOL and therefore was not included in the analysis. There was no difference for QOL between those participating in home-based exercise training and usual activity (13.29, 95% CI: -10.98 to 37.57).

Some limitations of this review included 3 studies examining 2 weeks of hospital-based exercise training before home-based exercise and 2 studies examining 3 months of supervised exercise training before home-based exercise. Only 5 RCTs participated solely in home-based exercise programs. Second, the exercise programs examined in the primary studies had different time and frequencies of exercise duration. Third, the studies included had very small sample sizes with no studies exceeding 100 participants. Last, those in the control groups presumed normal activity (usual care), which did not consist of an exercise program in a supervised setting, so no true comparison of home versus centre-based exercise can be done. The descriptions of the studies are presented in Table 1.

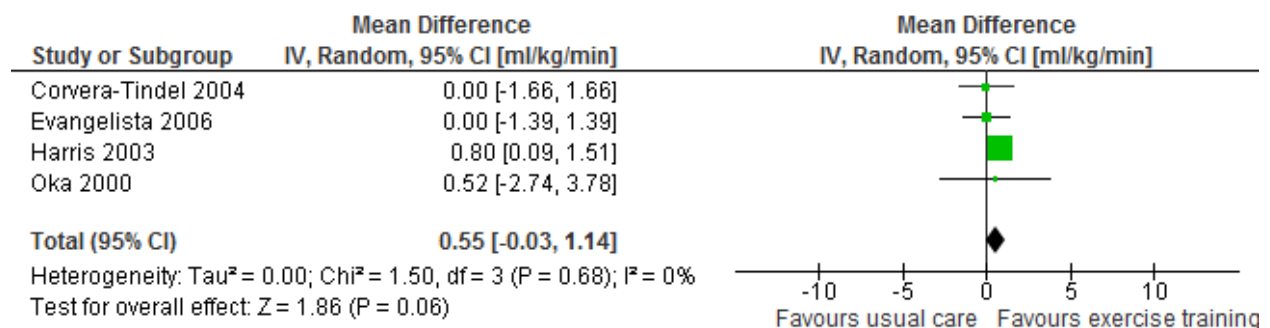


Figure 1: Effect of Home-Based Exercise Programs on Peak Oxygen Uptake

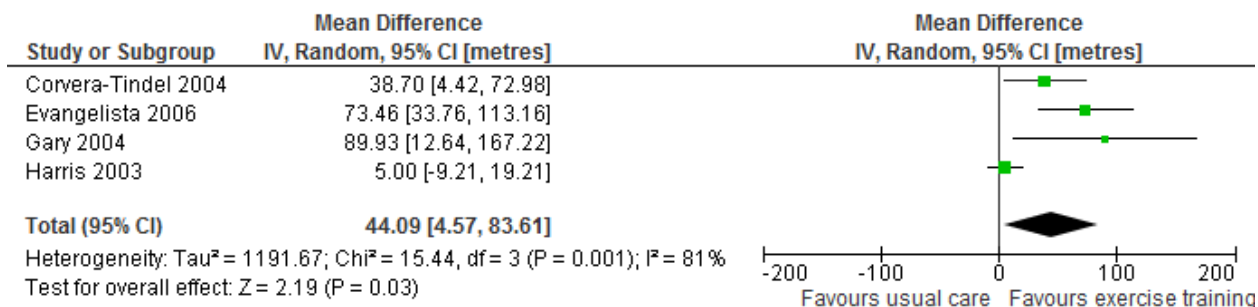


Figure 2: Effect of Home-Based Exercise Programs on the 6-Minute Walk Test

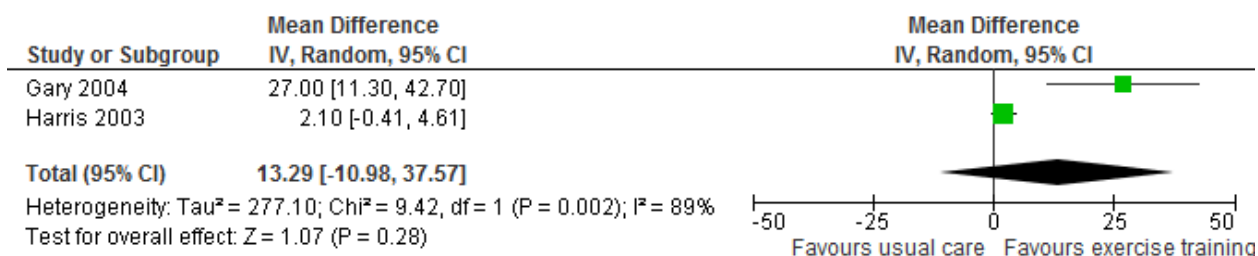


Figure 3: Effect of Home-Based Exercise Programs on Quality of Life

Table 1: Randomized Controlled Trials in Chien et al Review

Author, Year	Participants (n)	Outcome	Exercise Training		Result	
			Intervention	Control	Outcomes	Other
Corvera-Tindel et al (14)	HF secondary to IHD and non-IHD, NYHA II–IV, EF 24.7%–29.1%, Age = 61–63 yr (n = 79)	Peak VO ₂ (mL/kg/min) 6 MWT (ft)	12-wk home walking exercise with intensity at 40%–65% max HR, 60 min/d, 5 d/wk	Usual care	Peak VO ₂ did not differ between intervention and control groups over time (14.3 ± 3.7 to 15.3 ± 3.8 vs. 14.2 ± 3.4 to 15.2 ± 4.1, <i>P</i> = 0.70) 6 MWT was improved in the intervention group compared with the control group (1,219.0 ± 241.5 to 1,337.1 ± 272.2 vs. 1,273.2 ± 249.2 to 1,263.9 ± 254.5, <i>P</i> = 0.008)	Global rating of dyspnea and fatigue symptoms was reduced in the intervention group compared with the control group (3.2 ± 0.10 vs. 3.7 ± 0.8, <i>P</i> = 0.03)
Evangelista et al (15)	Advanced HF, BMI ≥ 27 (measured in kg/m ²), NYHA II–IV, EF ≤ 40%, Age = 53–55 yr (n = 99)	Peak VO ₂ (mL/kg/min) 6 MWT (ft)	6-month home walking program with intensity at 60% max HR, 45 min, combined with resistance exercise, ≥4 times/week	Usual care	Peak VO ₂ and 6 MWT did not differ between intervention and control groups (14 ± 3 to 14 ± 4 vs. 13 ± 3 to 13 ± 4, <i>P</i> = 0.72, and 1,379 ± 338 to 1,577 ± 404 vs. 1,331 ± 231 to 1,288 ± 320, <i>P</i> = 0.51)	Depression and anxiety scores did not differ between intervention and control groups (14.0 ± 7.6 to 7.2 ± 3.4 vs. 16.2 ± 5.3 to 9.0 ± 3.9, <i>P</i> = 0.82, and 7.0 ± 4.1 to 7.2 ± 4.2 vs. 8.6 ± 4.0 to 8.5 ± 4.1, <i>P</i> = 0.69)
Gary et al (16)	HF secondary to IHD and non-IHD, NYHA II–III, EF 54%–57%, Age = 67–69 yr (n = 32)	6 MWT (ft) QOL (MHFQ)	12-wk home walking program with intensity at 40%–60% max HR, 40 min/d, 3 d/wk, 12 weekly home visits with education program	Usual care and 12 weekly home visits with education program only	6 MWT was improved in the intervention compared with the control group (840 ± 366 to 1,043 ± 317 vs. 824 ± 367 to 732 ± 408, <i>P</i> = 0.002) QOL improved in the intervention group compared with the control group at 12 weeks (41 ± 26 to 24 ± 18 vs. 27 ± 18 to 28 ± 22, <i>P</i> = 0.002) and 3-month follow-up (24 ± 18 to 19 ± 18 vs. 28 ± 22 to 32 ± 27, <i>P</i> = 0.01)	Depression scores improved in the intervention compared with the control group at 12 weeks (6 ± 4 to 4 ± 4 vs. 5 ± 3 to 7 ± 5, <i>P</i> = 0.012) and 3-month follow-up (4 ± 4 to 4 ± 4 ^a vs. 7 ± 5 to 7 ± 5, ^a <i>P</i> = 0.009)
Harris et al (17)	HF secondary to DCM and IHD, NYHA II–III, EF 28.3%–32.0%, age = 61–63 yr (n = 46)	Peak VO ₂ (mL/kg/min) 6 MWT (m) QOL (MHFQ)	6-wk home bicycle exercise with intensity at 70% max HR, 30 min/d, 5 d/wk	Functional electrical stimulator, no specific exercise	Peak VO ₂ did not improve in either the intervention or control group (19.0 ± 1.14 to 19.8 ± 1.10, <i>P</i> = 0.276, vs. 18.6 ± 1.27 to 18.6 ± 1.07) 6 MWT improved in both the intervention and control group (495 ± 24 to 540 ± 23, <i>P</i> < 0.001 vs. 491 ± 26 to 531 ± 25, <i>P</i> < 0.001) QOL improved for both groups on average (32.7 ± 3.16 to 28.4 ± 2.91, <i>P</i> = 0.024), but no improvement was seen independently in the intervention or control group (36.3 ± 4.21 to 31.0 ± 3.66, <i>P</i> = 0.105, vs. 28.7 ± 4.70 to 25.5 ± 4.61, <i>P</i> = 0.094)	
Oka et al (13)	Mixed HF, NYHA II–III, EF 22.3%–24.9%, Age = unknown (n = 40)	Peak VO ₂ (mL/kg/min) QOL (CHFQ)	12-wk aerobic walking with intensity at 70% max HR, 40–60 min/d, 3 d/wk Resistance training = 75% 1RM, 30–40 min/d, 2 d/wk	Usual care	Peak VO ₂ did not differ between intervention and control groups over time (18.37 ± 4.0 to 18.89 ± 4.69 vs. 19.00 ± 3.75 to 19.00 ± 3.82) QOL improved on the mastery (23.0 ± 4.2 to 25.6 ± 3.1 vs. 21.1 ± 4.1 to 21.3 ± 5.1, <i>P</i> = 0.04) and emotion (38.8 ± 4.8 to 42.1 ± 4.8 vs. 35.7 ± 6.6 to 33.2 ± 8.7, <i>P</i> = 0.02) subscales in the intervention group compared with the control group	

Abbreviations: BMI = body mass index, CHFQ = Chronic Heart Failure Questionnaire, DCM = dilated cardiomyopathy, EF = ejection fraction, HF = heart failure, IHD = ischemic heart disease, MHFQ = Minnesota Heart Failure Questionnaire, 6 MWT = 6-minute walk test, NYHA II–IV = New York Heart Association (Functional Class I–IV), QOL = quality of life.

^aDepression scores did not change from the 12-week to 3-month follow-up visit in the Gary et al article.

Conclusions

Low- to moderate-quality evidence indicates home-based exercise training increases the 6 MWT distance compared with usual activity. However, peak VO₂ and quality of life did not differ between participants who received home-based exercise training and patients who maintained their usual activity levels.

Acknowledgements

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Health Quality Ontario (HQO)'s Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

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Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategies

Search date: December 10, 2013

Databases searched: Ovid MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, All EBM Databases (see below)

Q: What is the effectiveness of home-based exercise programs versus centre-based exercise programs in patients with heart failure on patient outcomes?

Limits: 2008-current; English

Filters: Meta-analyses, systematic reviews, health technology assessments

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to October 2013>, EBM Reviews - ACP Journal Club <1991 to November 2013>, EBM Reviews - Database of Abstracts of Reviews of Effects <4th Quarter 2013>, EBM Reviews - Cochrane Central Register of Controlled Trials <November 2013>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <4th Quarter 2013>, EBM Reviews - NHS Economic Evaluation Database <4th Quarter 2013>, Ovid MEDLINE(R) <1946 to November Week 3 2013>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <December 09, 2013>

Search Strategy:

#	Searches	Results
1	exp Patient Discharge/	19905
2	exp Aftercare/ or exp Convalescence/	10298
3	"Continuity of Patient Care"/ or exp "Recovery of Function"/	49411
4	((patient* adj2 discharge*) or after?care or post medical discharge* or post?discharge* or convalescen*).ti,ab.	37891
5	exp Heart Failure/	93131
6	((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency)).ti,ab.	135925
7	exp Pulmonary Disease, Chronic Obstructive/	26667
8	exp Emphysema/	11099
9	(copd or coad or chronic airflow obstruction* or (chronic adj2 bronchitis) or emphysema).ti,ab.	60068
10	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) adj (disease* or disorder*)).ti,ab.	37815
11	exp Pneumonia/	78260
12	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) adj inflammation*).ti,ab.	147382
13	or/1-12	513261
14	exp Exercise Tolerance/	9966
15	exp Exercise/	127308
16	exp Rehabilitation/	162816
17	exp Rehabilitation Nursing/	1136
18	exp "Physical and Rehabilitation Medicine"/	19975
19	exp Rehabilitation Centers/	12881
20	exp Physical Therapy Modalities/	136983

21	(rehabilitat* or (physical* adj (fit* or train* or therap* or activit*)) or ((exercise* or fitness) adj3 (treatment or intervent* or program*)) or (train* adj (strength* or aerobic or exercise*)) or wellness program* or ((pulmonary or lung* or respirat* or cardiac) adj2 (physiotherap* or therap* or rehabilitat*)) or angina plan* or heart manual*).ti,ab.	235554
22	or/14-21	536336
23	Meta Analysis.pt.	52738
24	Meta-Analysis/ use mesz or exp Technology Assessment, Biomedical/ use mesz	61456
25	(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 cochrane).ti,ab.	211340
26	((health technolog* or biomedical technolog*) adj2 assess*).ti,ab.	2746
27	or/23-26	227857
28	13 and 22 and 27	1230
29	limit 28 to (english language and yr="2008 -Current") [Limit not valid in CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained]	773
30	remove duplicates from 29	613

Appendix 2: Evidence Quality Assessment

Table A1: AMSTAR Scores of Systematic Reviews

Author, Year	AMSTAR Score ^a	(1) Provided Study Design	(2) Duplicate Study Selection	(3) Broad Literature Search	(4) Considered Status of Publication	(5) Listed Excluded Studies	(6) Provided Characteristics of Studies	(7) Assessed Scientific Quality	(8) Considered Quality in Report	(9) Methods to Combine Appropriate	(10) Assessed Publication Bias	(11) Stated Conflict of Interest
Hwang et al, 2009 (12)	4	✓	X	✓	X	X	✓	X	X	✓	X	X
Chien et al, 2008 (11)	8	✓	✓	✓	X	✓	✓	✓	✓	✓	X	X

Abbreviations: AMSTAR, Assessment of Multiple Systematic Reviews; RCT, randomized controlled trial.

^aMaximum possible score is 11. Details of AMSTAR score are described in Shea et al. (9)

Table A2: GRADE Evidence Profile for Comparison of Home-Based Exercise Versus Usual Care

Number of Studies (Design)	Risk of Bias ^a	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
6-Minute Walk Test							
4 (RCTs)	No serious limitations	Serious limitations (-1) ^b	Serious limitations (-1) ^c	No serious limitations	Undetected	None	⊕⊕ Low
Peak VO₂							
4 (RCTs)	No serious limitations	No serious limitations	Serious limitations (-1) ^c	No serious limitations	Undetected	None	⊕⊕⊕ Moderate
Quality of Life							
3 (RCTs)	No serious limitations	No serious limitations	Serious limitations (-1) ^c	No serious limitations	Undetected	None	⊕⊕⊕ Moderate

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.

^a See Table A3 for risk of bias details.

^b Heterogeneity in estimates not due to disease severity.

^c Differences in duration and frequency of exercise training.

Table A3: Risk of Bias Among Randomized Controlled Trials for Comparison of Home-Based Exercise Versus Usual Care

Author, Year	Allocation Concealment	Blinding	Complete Accounting of Patients and Outcome Events	Selective Reporting Bias	Other Limitations
Corvera-Tindel et al, 2004 (14)	No limitations	Limitations ^a	No limitations	No limitations	No limitations
Evangelista et al, 2006 (15)	No limitations	Limitations ^a	Limitations ^b	No limitations	No limitations
Gary et al, 2004 (16)	Limitations ^c	No limitations	No limitations	No limitations	No limitations
Harris et al, 2003 (17)	No limitations	No limitations	Limitations ^c	No limitations	No limitations
Oka et al, 2000 (13)	Limitations	No limitations	Limitations ^c	No limitations	No limitations

^a No blinding among research assistants, participants, or data analysts.

^b No intention-to-treat analysis.

^c No allocation concealment.

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