

# Respiratory Therapy Services in Home Care for Individuals With Chronic Obstructive Pulmonary Disease (COPD): A Rapid Review

Health Quality Ontario

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Evidence Development and Standards Branch at Health Quality Ontario

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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.

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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 (<u>http://www.gradeworkinggroup.org/index.htm</u>), 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.

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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.

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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.

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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: <a href="http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations">http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.</a>

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# **List of Abbreviations**

CCAC	Community Care Access Centre
COPD	Chronic obstructive pulmonary disease
СР	Cardiopulmonary
CRE	Certified respiratory educator
ED	Emergency department
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
HQO	Health Quality Ontario
HRQOL	Health-related quality of life
OHTAC	Ontario Health Technology Advisory Committee
PR	Pulmonary rehabilitation
RCT	Randomized controlled trial
RT	Respiratory therapist
SGRQ	St. George's Respiratory Questionnaire
SR	Systematic review

# 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.

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## **Objective of Analysis**

The objective of this analysis was to determine the effectiveness of respiratory services provided in the home or community by respiratory therapists (RTs) in reducing health care utilization and improving patient outcomes.

### **Clinical Need and Target Population**

Respiratory therapy services comprise a variety of interventions that are related to airway management and maintenance of lung health. These include oxygen therapy, ventilation, tracheostomy care, medication management, and teaching and support of inhaler-use technique. An RT's scope of practice covers caring for cardiopulmonary (CP) conditions and making use of the advanced technology that may be required as part of CP care. (1) RTs provide rehabilitation services, administer inhaled medications, teach patients how to manage their illness, and educate patients and professionals on critical topics such as smoking cessation. (1) They can perform spirometry testing in pulmonary rehabilitation programs, arterial blood gas procurement, and oxygen management—core competencies and skills that are specific to the RT profession. (Personal communication, Expert Consultation, March 10, 2014)

In Ontario, RTs work predominantly in hospitals, especially in high-intensity areas such as intensive care units, emergency departments (EDs), and operating rooms. (1) However, RTs also work in clinic or outpatient settings, for instance in pulmonary rehabilitation programs, and even in patients' homes. In 2009, respiratory therapy was added as a specialized professional service that could be provided through Community Care Access Centres (CCACs) to eligible patients in the home, group settings, or long-term care facilities. (2) Through the Ministry of Health and Long-Term Care's Home Oxygen Program, eligible patients can be funded fully or partially to receive RT home visits for home oxygen, which is usually indicated during end-stage disease. (3) At present, only a few CCACs include RTs within their scope of home care services, outside of home oxygen support.

# **Rapid Review**

## **Research Questions**

What is the effectiveness of respiratory services in the home and/or community provided by respiratory therapists post-discharge, especially for those with respiratory disease?

### **Research Methods**

#### **Literature Search**

#### Search Strategy

A literature search was performed on February 14, 2014, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), and EBM Reviews, for studies published from January 1, 2009, to February 14, 2014. (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, 2009, and February 14, 2014
- observational studies, randomized controlled trials (RCTs), systematic reviews, and metaanalyses
- reporting on services provided in the home or community setting by an RT

#### **Exclusion Criteria**

- reporting on the effectiveness of specific respiratory interventions (e.g., long-term oxygen therapy, ventilator management, artificial respiration)
- reporting on respiratory services provided by any other health care provider (e.g., nurse, physiotherapist, occupational therapist)
- case reports, editorials, commentaries, conference abstracts, guidelines

#### **Outcomes of Interest**

- ED visits, hospital admissions or readmissions
- health-related quality of life (HRQOL)
- intervals between exacerbations

## **Expert Panel**

In November 2013, an Expert Advisory Panel on Post-Acute Community-Based Care for COPD Patients was struck. Members of the panel included physicians, personnel from the Ministry of Health and Long-Term Care, and representatives from community care organizations.

The role of the expert advisory panel was to provide advice on primary COPD patient groupings; to review the evidence, guidance, and publications related to defined COPD 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 methodology for a rapid review of primary studies includes a risk of bias assessment based on GRADE Working Group criteria (4) to assess quality of evidence. Risk of bias is evaluated based on consideration of allocation concealment, blinding, accounting of patients and outcome events, selective reporting bias, and other limitations.

## **Results of Rapid Review**

The database search yielded 1,465 citations published between January 1, 2009, and February 14, 2014 (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.

One study (5) met the inclusion criteria. The reference list of the included study and health technology assessment websites were hand-searched to identify other relevant studies, and 1 additional citation (6) was found, for a total of 2. Both included studies were randomized controlled trials (RCTs) conducted in the United States.

The 2010 study by Gilmore and colleagues (5) evaluated the effect of educational support on healthrelated quality of life (HRQOL) for community-dwelling patients with a physician-diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD). In this study, 37 patients were randomized via letter cards in blocks of 4 to one of the following interventions: standard care, a COPD educational guide (booklet and video); a home visit by an RT; both the guide and RT home visit. The time period of followup of the study was unclear. Intervention details are shown in Table 1. Health-related quality of life (HRQOL) was measured using a modified version of St. George's Respiratory Questionnaire (SGRQ). (5)

## Table 1: Study Design of RCT Evaluating Educational Strategies for Community-Dwelling Patients With Moderate to Severe COPD

Study Group	Description of Intervention
Standard Care (Group D)	Information on newly prescribed medication use and reinforcement education at physician's request (e.g., review of inhaler techniques, indications for medications)
COPD Educational Guide (Group B)	Educational booklet with chapters on living well, optimizing medication, breathing exercises and techniques, active lifestyle, planning for symptom worsening, and smoking cessation to teach patients and families about COPD and how to better self-manage it; 7-minute video on inhaler technique instruction
RT Home Visit <i>(Group C)</i>	Structured visit to reinforce disease-management education and perform a standardized home evaluation of subject's general health environment, ability to move around the home, layout of movable objects, and access to oxygen and local caregiver assistance resources
COPD Educational Guide + RT Home Visit	Interventions of both Groups B and C (see above for details)
(Group A)	

Abbreviations: COPD, chronic obstructive pulmonary disease; RCT, randomized controlled trial; RT, respiratory therapist. Source: Gilmore et al. (5)

Attrition was high in this study, with 10 of the 37 subjects (27%) lost to follow-up. Thus, results pertain to only the 27 who completed the study. There were no statistically significant differences between any of the groups in HRQOL, although the RT Home Visit group (Group C) observed a minimal improvement that approached statistical significance (P < 0.10) in the activity and symptom domains of the 4-domain SGRQ. Given the small sample size, with group sizes ranging from 10 to 17 patients prior to any loss to follow-up, the study was clearly underpowered to detect differences between groups.

The RCT by Rice and colleagues (6), also published in 2010, assessed the effectiveness of a simple disease-management program led by an RT, compared with usual care. In this RCT, 743 eligible patients at high risk of exacerbation were randomized and completed the study. The effect of this intervention on HRQOL and on the number of all-cause and disease-specific hospital or ED visits was assessed via SGRQ over a 12-month follow-up period. The description of the interventions and results of the study for these outcomes are in Table 2.

Study Group	Number	Description of Intervention	Proportion of Patients with ≥1 ED Visit or Hospital Admission Within 1 Year (rate)	HRQOL After 1 Year
Usual Care	371	Handout containing principles of COPD care and a 24-hour nursing helpline phone number	39.1%	Worsened
			(82.2 per 100,000 patient-years)	(6.4 points)
Disease	372	Single 1- to 1.5-hour group	27.4%*	Worsened
Management		education session with an RT-case manager, <sup>a</sup> action plan including medications and refill prescriptions, RT-case manager contact information and 24-hour helpline phone number, and monthly phone calls from RT to see if action plan medications taken or if patient has questions	(48.4 per 100,000 patient-years)	(1.3 points*)

## Table 2: Summary of RCT Evaluating Disease-Management Program for Community-Dwelling COPD Patients at High Risk for Hospitalization

Abbreviations: COPD, chronic obstructive pulmonary disease; ED, emergency department; HRQOL, health-related quality of life; RCT, randomized controlled trial; RT, respiratory therapist. <sup>a</sup>Education session consisted of COPD information, inhaler technique and medication review and adjustment, smoking cessation, vaccination

counselling, exercise encouragement, and hand hygiene instruction.

\*Statistically significant difference between groups (P < 0.001).

Source: Rice et al. (6)

Over 1 year, a significantly lower proportion of patients in the disease management group had 1 or more ED visit or hospitalization (difference 0.34; 95% confidence interval [CI], 0.15–0.52). There was a statistically significant 41% reduction in the composite ED/hospitalization outcome in the disease management group (rate ratio [RR], 0.59; 95% CI, 0.44–0.75; P < 0.001). When separating the subcomponents of the primary outcome, disease management patients had 30% fewer hospitalizations (P = 0.03) and 50% fewer ED visits (P = 0.001). As seen in Table 2, HRQOL worsened significantly more in the usual care group, a decrease in points on the SGRQ that is considered clinically significant. (7) The authors remark that further study is needed to determine the effect of disease management in conjunction with pulmonary rehabilitation (PR), as the intervention was entirely separate though potentially complementary to PR.

## Limitations

The risk of bias assessment for the studies included in this rapid review can be found in Appendix 2. Specific limitations include high attrition in the study by Gilmore and colleagues (5); and both studies lacked blinding due to the nature of the intervention and had incomplete outcome reporting. In addition, the Gilmore et al study had a very small sample size and was inadequately powered to detect a clinically significant change in HRQOL. Based on an *a priori* power calculation, 18 subjects per group would be required to detect a "very efficacious" effect size with 80% power or a "moderately efficacious" effect size with 50% power. (5)

Neither study reported on the outcome of time interval between exacerbations; the potential impact that the educational strategies investigated by Gilmore and colleagues (5) or the disease-management program tested by Rice and colleagues (6) might have on this remains unknown.

In addition, some characteristics of the studies' samples influence the generalizability of the findings. Rice and colleagues (6) conducted their study at 5 Veterans Affairs medical centres. Therefore, an overwhelming number of participants were male (97.6 to 98.4%). Furthermore, the usual care group was slightly older with superior lung function, though these latter between-group differences were not statistically significant. In the Gilmore et al study (5), participants assigned to the educational guide group had a longer smoking history, and were more likely to be female and less likely to be insured. For generalizability, attention needs to be paid to how representative the study participants are of COPD patients in the community.

# Conclusions

- There were no studies that reported the effect of RT services on the time interval between acute exacerbations.
- Based on the results of a very small RCT with serious limitations due to risk of bias, COPD educational strategies involving an educational guide, RT home visit, or a combination did not have an effect on HRQOL, compared with usual care.
- Based on a large RCT with some limitations due to risk of bias, a community-based COPDspecific disease management program led by an RT reduced ED visits and hospitalizations and led to a smaller decline in HRQOL over a 1-year period, compared with usual care.

# **Expert Consultation**

In addition to the Expert Advisory Panel, a group of experts comprised of RTs and representatives from the Ontario Lung Association was convened to add professional-practice context to the evidence.

The expert consultation identified "specialized respiratory nurses" in the United Kingdom's National Health Service, a designation approximately equivalent to the RT designation that exists in North America. In light of this, the database was re-screened and a meta-analysis of respiratory nurse-led homebased interventions for COPD patients in the community was identified. (8) The analysis included studies from 1987 to 2006 and found benefit for HRQOL and mixed results for hospitalizations, with significant heterogeneity in the latter. Upon examination of the 9 RCTs included in the analysis, only 2 were conducted in the United Kingdom; the others were mostly from the United States, where RT is a distinct professional discipline. Furthermore, in those studies which described the credentials of those providing the intervention, the reported respiratory specialization of the providers varied from 8 hours of training to having attended weekly rounds for 3 months. (8) Based on the information reported in the primary studies and meta-analysis, there was no conclusive evidence that the providers were specialized respiratory nurses nor that they had a comparable skill set to RTs'. Thus, this study was excluded.

In the consultation, the experts emphasized that a specialized respiratory skill set is essential in order to appropriately support COPD patients across the continuum of care. They emphasized that an ongoing relationship with a dedicated health care provider—one who serves as the patient's main contact—is a key component of management for COPD patients. In the post-acute period (e.g., during PR), a high degree of respiratory clinical expertise is essential, such as the expertise developed through an RT's focused training in respiratory disease management and care. This is less essential for longer-term maintenance support. A holistic approach was cited as key throughout the care continuum, including education, self-management support, and psychosocial support. The experts stated that disease management can be appropriately delivered by an RT or by other health professionals provided they are certified in respiratory core competencies—for example, by a certified respiratory educator (CRE). There was agreement among the experts that consideration should be given to enhancing the CRE certification to provide standardized training for all health care professionals involved in pulmonary rehabilitation.

# Acknowledgements

#### **Editorial Staff**

Sue MacLeod

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# Health Quality Ontario's Expert Advisory Panel on Post-Acute Community-Based Care for COPD Patients

Panel Members Affiliation(s)		Appointment(s)	
Co-Chairs			
Dr Chaim Bell	Mount Sinai Hospital University of Toronto	Clinician Scientist Associate Professor	
Lisa Droppo	Ontario Association of Community Care Access Centers (OACCAC)	Chief Care Innovations Officer	
Primary Care			
Dr Kenneth Hook	Ontario College of Family Physicians STAR Family Health Team	Past-President Senior Physician	
Dr Alan Kaplan	Family Physicians Airway Group of Canada	Chair, Family Physicians Airway Group of Canada	
Dr Peter Selby	Department of Family and Community Medicine & Psychiatry and Dalla Lana School of Public Health University of Toronto Ontario Tobacco Research Unit	Associate Professor Principal Investigator	
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Nursing			

Panel Members	Affiliation(s)	Appointment(s)	
Cheryl Lennox	South West Community CCAC, Intensive Home Care Team	Nurse Practitioner-Primary Health Care Certified Respiratory Educator	
Andrea Roberts	Toronto Central CCAC	Rapid Response Transition Nurse	
Mary-Jane Herlihey	ParaMed Home Health Care Ottawa	Clinical Consultant	
	St. Mary's General Hospital	Nurse Practitioner Primary Health Care	
Suzy Young		SWCCAC Intensive Health Care Team	
		Certified Respirator Educator	

# Appendices

## **Appendix 1: Literature Search Strategies**

Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, All EBM

Databases (see below), CINAHL

Limits: 2009-current; English

Filters: Removal of case reports, comments, editorials, letters, conference proceedings

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to December 2013>, EBM Reviews - ACP Journal Club <1991 to January 2014>, EBM Reviews - Database of Abstracts of Reviews of Effects <1st Quarter 2014>, EBM Reviews - Cochrane Central Register of Controlled Trials <January 2014>, EBM Reviews - Cochrane Central Register of Controlled Trials <January 2014>, EBM Reviews - Cochrane Central Register of Controlled Trials <January 2014>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <1st Quarter 2014>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2014>, Ovid MEDLINE(R) <1946 to February Week 1 2014>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <February 13, 2014> Search Strategy:

#	Searches	Results
1	exp Patient Discharge/	19216
2	exp Aftercare/ or exp Convalescence/	10054
3	"Continuity of Patient Care"/ or exp "Recovery of Function"/	46227
4	((patient* adj2 discharge*) or after?care or post medical discharge* or post?discharge* or convalescen*).ti,ab.	36811
5	exp Stroke/	85027
6	exp brain ischemia/ or exp intracranial hemorrhages/	129002
7	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) adj (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or (brain adj2 isch?emia) or (cerebral adj2 isch?emia) or (intracranial adj2 h?emorrhag*) or (brain adj2 h?emorrhag*)).ti,ab.	194865
8	exp Heart Failure/	89257
9	(((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.	130071
10	exp Pulmonary Disease, Chronic Obstructive/	36493
11	exp Emphysema/	10699
12	(copd or coad or chronic airflow obstruction* or (chronic adj2 bronchitis) or emphysema).ti,ab.	56196
13	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) adj (disease* or disorder*)).ti,ab.	34617
14	exp Pneumonia/	74413
15	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) adj inflammation*)).ti,ab.	137241
16	or/1-15	752281
17	*Respiratory Therapy/	3387
18	(((respirat* or inhalation or oxygen) adj2 therap*) or (respirat* adj2 (home or service* or outreach or educator*))).ti,ab.	13646
19	17 or 18	16157
20	16 and 19	3470
21	Case Reports/ or Comment.pt. or Editorial.pt. or Letter.pt. or Congresses.pt.	2852586
22	20 not 21	3087

#### CINAHL

#	Query	Results
<b>S</b> 1	(MH "Patient Discharge+") or (MH "After Care") or (MH "Recovery") or (MH "Continuity of Patient Care+")	45,168
<b>S</b> 2	((patient* N2 discharge*) or aftercare or after care or post medical discharge* or postdischarge* or post discharge* or convalescen*)	29,321
<b>S</b> 3	(MH "Stroke+") or (MH "Cerebral Ischemia+") or (MH "Intracranial Hemorrhage+") or (MH "Stroke Patients")	49,394
S4	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) N1 (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or ((brain or cerebral) N2 (ischemia or ischaemia)) or ((intracranial or brain) N2 (hemorrhag* or haemorrhag*)))	61,592
<b>S</b> 5	(MH "Heart Failure+")	22,458
<b>S</b> 6	((cardia* or heart) N1 (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) N1 (failure or insufficiency))	29,048
<b>S</b> 7	(MH "Pulmonary Disease, Chronic Obstructive+") or (MH "Emphysema+")	11,502
<b>S</b> 8	((chronic obstructive N2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) N1 (disease* or disorder*)) or (copd or coad or chronic airflow obstruction* or (chronic N2 bronchitis) or emphysema))	14,648
<b>S</b> 9	(MH "Pneumonia+")	12,449
<b>S</b> 10	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) N1 inflammation*))	19,458
S11	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10	174,707
S12	((respirat* or inhalation or oxygen) N2 therap*) or (respirat* N2 (home or service* or outreach or educator*))	17,581
<b>S</b> 13	(MM "Respiratory Therapy") OR (MH "Respiratory Therapy Service") OR (MH "Respiratory Therapists")	5,370
S14	S12 OR S13	17,581
S15	S11 AND S14	2,495
S16	S11 AND S14 Limiters - Published Date: 20090101-20141231	1,000

### **Appendix 2: Evidence Quality Assessment**

#### Table A1: Risk of Bias Among RCTs for the Comparison of Respiratory Therapist Interventions Versus Usual Care

Author, Year	Allocation Concealment	Blinding	Complete Accounting of Patients and Outcome Events	Selective Reporting Bias	Other Limitations
Gilmore et al, 2010 (5)	No Limitations	Serious Limitations <sup>a</sup>	Limitations <sup>b</sup>	No limitations	No limitations
Rice et al, 2010 (6)	No limitations	Limitations <sup>a</sup>	Limitations <sup>c</sup>	No limitations	No limitations

<sup>a</sup>No indication of, or only minimal use of, blinding (chart review for primary outcome assessment in Rice et al), although blinding is challenging given the nature of the interventions. Non-blinded participants are of greatest concern for the assessment of health-related quality of life (HRQOL), which is self-reported and is the primary outcome in Gilmore et al (5) and secondary outcome in Rice et al (6).

<sup>b</sup>Loss to follow-up was approximately 27% of those enrolled and randomized, and intention-to-treat principle was not adhered to. It is unclear if attrition differed between study groups.

<sup>c</sup>Response rate for self-reported HRQOL did not differ between groups and was 55% for the usual care group and 60% for the intervention group, resulting in lack of power to draw definitive conclusions.

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