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STRUCTURED ABSTRACT

Purpose: To examine the effects of telerehabilitation compared with other treatments for improving physical or functional outcomes in patients with cardiopulmonary diseases.

Methods: A search was undertaken for English language publications from 1990 to August 2013 across four electronic databases and grey literature. Inclusion criteria were: home-based telerehabilitation as a core component; at least two exercise sessions; randomized controlled trials; and reporting of physical or functional outcome measures in adult patients with coronary heart disease, chronic heart failure and chronic respiratory disease. Studies were independently screened by two reviewers and graded by a reviewer according to the Downs and Black checklist. A narrative synthesis of the included studies was undertaken.

Results: 11 studies were analyzed. It appears that telerehabilitation is no different to other treatments in patients with cardiopulmonary diseases, in terms of exercise capacity expressed as distance on the 6 minute walk test and peak oxygen consumption, and quality of life. Telerehabilitation appears to have higher adherence rates compared with center-based exercise. There has been similar or no adverse events reported in telerehabilitation compared with center-based exercise.

Conclusions: While telerehabilitation shows promise in patients with cardiopulmonary diseases, compelling evidence is still limited. There is a need for more detailed, high quality studies and for studies on the use of video-based telerehabilitation.

CONDENSED ABSTRACT

This review aims to examine the effects of telerehabilitation compared with other treatments for improving physical or functional outcomes in patients with cardiopulmonary diseases. Systematic review and grading of quality of literature was undertaken on 11 studies. While telerehabilitation shows promise in patients with cardiopulmonary diseases, compelling evidence is still limited.

INTRODUCTION

Chronic diseases including cardiovascular diseases, cancer, chronic respiratory diseases and diabetes mellitus, are the leading cause of mortality in the world, representing 63% of all global deaths in 2008.[1] In the United States, about half of all adults have one or more chronic diseases.[2] As more than half of all potentially preventable hospitalizations are from chronic diseases,[3] there is an urgent need to improve management of these conditions.

Research over the past two decades has broadened our understanding of the value of exercise in the management of cardiopulmonary diseases. For example, cardiac and pulmonary rehabilitation programs have been shown to be safe and effective,[4] with benefits including enhanced quality of life,[5, 6] increased functional exercise capacity,[7] reduced hospital re-admissions[8, 9] and reduced mortality.[8] Traditionally, exercise for these patient populations has concentrated on supervised and center-based programs,[10] however participation rates remain low.[11]

In an effort to improve participation rates, alternative models of care including home-based telerehabilitation have been explored. Telerehabilitation is defined as the delivery of rehabilitation services via telecommunication technology,[12] including phone, internet and videoconference communications between the patient and healthcare provider. In recent years, telemonitoring (an automated process of data transmission about a patient's health status from home to the respective healthcare setting) has been shown to improve health outcomes in patients with chronic diseases[13] including coronary heart disease (CHD),[14] cystic fibrosis[15] and chronic obstructive pulmonary disease (COPD).[16] Similar success has also been demonstrated in interactive health communication applications for people with chronic diseases, which has been shown to improve users' knowledge, social support, health behaviors and clinical outcomes.[17] It is possible that telerehabilitation may benefit people with cardiopulmonary diseases in similar ways as telemonitoring and interactive health communication applications.

The aim of this systematic review was to present the available literature and determine if telerehabilitation was effective for improving physical or functional outcomes in patients with cardiopulmonary diseases.

METHODS

Electronic databases were searched for relevant studies published between 1990 and August 2013, including OvidMEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Controlled Trials Register and Physiotherapy Evidence Database (PEDro). Grey literature and reference lists from relevant articles were also reviewed to identify additional articles. The search terms used are listed in Table 1, with limits applied as English, adults, clinical trials and publications after 1990.

Studies were included if they had home-based telerehabilitation as a core component (where at least 50% patient-provider contact was delivered by telephone, videoconference or web-based intervention) and encompassed at least two exercise sessions. Other inclusion criteria included the reporting of at least one physical or functional outcome measure in patients with CHD, chronic heart failure (CHF) or chronic respiratory disease.

Studies were excluded on the following criteria: the age of participants <18 years; no human involvement; published in non-English language; published before 1990; not a randomized controlled trial; or mixed model intervention with combined center-based and telerehabilitation interventions. Studies investigating the reliability or effectiveness of home monitoring equipment which did not encompass an exercise component were excluded. Other exclusion criteria included conference and abstract presentations.

Titles and abstracts of potential papers were extracted so that reviewers were blinded to authors and journals. These titles and abstracts were independently screened by two reviewers (RH and JB) to identify relevant studies. Conflict was resolved after discussion between two reviewers and any unresolved disagreements were arbitrated by a third reviewer (TR). When two or more studies clearly resulted in multiple publications, the study with the longest follow-up and largest sample was included. Full copies of relevant papers were retrieved and screened by two reviewers (RH and JB) according to the inclusion and exclusion criteria. In the event of missing or ambiguous data, authors of relevant papers were contacted to determine eligibility status and seek missing data. Data were extracted for analysis, pertaining to study design, subject numbers, study population, study outcomes, as well as description of the program and technology used in the delivery of telerehabilitation. This data extraction process was undertaken by a reviewer (RH) and re-confirmed by the same reviewer after a fortnight period to ensure the accuracy of data extraction.

The Downs and Black[18] checklist was used by a reviewer (RH) to determine methodological quality of included studies. Studies were assessed against 27 items, which evaluated reporting, external validity, bias, confounding and power. As per previous methodology,[19] item 27 relating to power calculation was dichotomized to answer yes or no. Possible total scores range from 0 to 28. This checklist has been shown to have high internal consistency, good test-retest and inter-rater reliability, and good face and criterion validity.[18] To ensure reliability of the scoring process, the reviewer (RH) benchmarked against a published systematic review[15] for three papers and achieved greater than 80% consistency in scoring.

Quantitative analysis of included studies was performed using The Mix Program, version 1.7.[20] This analysis provided the mean weighted difference of change observed between the telerehabilitation and control groups, as well as 95% confidence intervals (CI) for all continuous data. For each outcome, heterogeneity was evaluated by applying the Cochran Q test.[21] In the absence of heterogeneity, the reviewers intended to use a fixed effects model in the meta-analysis. If substantial heterogeneity ($P < 0.05$) was detected, the reviewers investigated potential underlying factors and used a random effects model with cautious interpretation. Results were considered significant when $P < 0.05$. A narrative synthesis of the included articles was undertaken. This refers to a process in which a narrative approach where the findings are summarized and explained in words, is used to synthesize evidence extracted from multiple studies.[22] Results were tabulated and presented as forest plots.

This systematic review is registered with the international prospective register of systematic reviews (PROSPERO registration number: CRD42014008680) and based on the preferred reporting items for systematic reviews and meta-analysis: the

PRISMA statement.[23]

RESULTS

The search yielded 389 potentially relevant papers. After duplication removal and record screening of abstract and title, 39 full-text papers were retrieved. Of these, 11 papers were retained for final analysis. The flow chart on study selection is presented in Figure 1.

Due to the small number of studies, a meta-analysis was unable to be performed and a narrative synthesis is presented. Included studies are shown in Table 2 and a quality appraisal in Appendix A. The majority of studies scored well on the Downs and Black[18] checklist. Scores ranged from seven to 24 out of 28. In all studies, it was difficult to achieve subject blinding due to the nature of the telerehabilitation intervention. Assessor blinding, concealed allocation and adequate power were also inconsistently reported. External validity was generally poorly reported, with most studies providing insufficient information on generalizablility of study results. For instance, some studies only recruited male patients[24] with mild to moderate disease severity.[25]

Five included studies involved patients with CHD, four with CHF and two with respiratory diseases. A total of 908 individuals with cardiopulmonary diseases were involved across all studies and the proportion of males was 73.8%. The mean age (SD) of participants in the telerehabilitation group was 58.1 (6.1) and 59.3 (5.2) years in the control group. All studies reported no significant baseline differences between the telerehabilitation and control group in terms of age, gender, disease severity and pharmacotherapy.

Program duration of included studies ranged from eight to 36 weeks; frequency ranged from one to five sessions per week. Six studies used aerobic training and the remaining five studies used combined aerobic and strength training. The majority of included studies used phone communications between the patient and healthcare provider. Most included telerehabilitation studies encompassed the recommended core components of cardiac rehabilitation programs, including baseline assessment, nutritional counseling, risk factor management, psychological intervention, physical activity counseling and exercise training.[26]

Primary outcome measures included physical or functional measures such as distance on the six minute walk test (6MWD) in meters and peak oxygen consumption (VO_2peak) in milliliters per kilogram of body mass per minute (mL/kg/min). In one study,[27] VO_2peak was reported in metabolic equivalent of task (MET) and this was converted to mL/kg/min during analysis. Secondary clinical outcome measures included: quality of life; clinical process measures such as adherence rates and proportion of adverse events; and costs.

6MWD

There are conflicting results on the effects of telerehabilitation on 6MWD. As demonstrated in Figure 2, there was no significant difference in post-program 6MWD between telerehabilitation and no intervention group in patients with CHF.[28] It is unclear if other recommended core components of cardiac rehabilitation program were incorporated in this telerehabilitation program. However when considering the amount of improvement compared with baseline, Chien et al[28] found a significant difference between telerehabilitation and no intervention group of 21 m (95% CI, 7-36). This is supported by another study on the effects of pulmonary rehabilitation, which also found an improvement of 40.6 m in telerehabilitation compared with a deterioration of 27.3 m in no intervention group.[29]

Similar results were reported when comparing telerehabilitation with center-based programs in patients with CHF.[30] Interestingly in this study by Piotrowicz et al,[30] the amount of 6MWD improvement compared with baseline was significantly greater in the center-based than telerehabilitation group. In contrast for patients with COPD, there was no significant difference in the 6MWD improvement between center-based and telerehabilitation exercise, at completion and 1 year follow-up.[31]

VO_2peak

There are also inconsistent results on the effects of telerehabilitation on VO_2peak. Two studies found no significant difference in post-program VO_2peak between telerehabilitation and no intervention in patients with cardiac conditions (see Figure 3).[27, 32] Conversely, some studies found a significant improvement in VO_2peak following telerehabilitation for patients with cardiac conditions, whereas no intervention group showed a decline.[25, 33] Factors contributing to this discrepancy remain unclear. However, an overall 30% drop-out rate was observed in one study,[32] compared to 10% in another study.[33] Studies which compared telerehabilitation and center-based exercise, found no significant difference in VO_2peak between groups of patients with cardiac conditions.[30, 34]

Quality of life

Some studies used a generic tool to assess quality of life,[25, 30, 34] while others used a disease-specific tool.[28, 29, 32, 33] In general, it appears the telerehabilitation group improved significantly from baseline in quality of life for patients with cardiac[25, 28, 32, 33] and respiratory conditions.[29, 31] For example, when considering the amount of improvement in quality of life compared with baseline, the difference between telerehabilitation and no intervention was seven points on the 105-point Minnesota living with heart failure questionnaire (95% CI, 1-12).[28] However, there was no difference between telerehabilitation and center-based exercise in patients with CHF.[30] Interestingly, telerehabilitation demonstrated a significantly greater improvement in physical composite score on the Short Form-36 and perceived social support than center-based exercise group after coronary artery bypass surgery.[34] This is consistent with a pulmonary rehabilitation study by Maltais et al,[31] which found both telerehabilitation and center-based exercise, were associated with statistically and clinically significant improvements in the Chronic Respiratory Questionnaire dyspnea score post-program. The improvement reached the minimum clinically important difference in telerehabilitation and not in center-based exercise at 1 year.[31]

Adherence

Some studies reported adherence as the number of times exercised per week, while others presented the data as proportion of sessions attended. Most studies measured adherence via self-reported activity logbooks and phone follow-ups. In general, telerehabilitation appears to have higher adherence rates than center-based exercise.[24, 30, 34] For example, in a study by Arthur et al,[34] patients in the telerehabilitation group self-reported exercising an average number of 6.5 times per week, compared with 3.7

times in a center-based group. Similarly in a study by Piotrowicz et al,[30] all patients in a telerehabilitation group completed the exercise program, whereas 79% completed a center-based program. It appears that adherence slowly declined over time, and higher adherence was observed for endurance compared with resistance exercise.[32]

Adverse events

Some studies reported no exercise-related adverse events in the telerehabilitation group,[25, 27, 28, 32, 33] while others have reported comparable adverse events between telerehabilitation and center-based exercise.[30, 31] Reported adverse events in small numbers of participants include hypertension, new arrhythmia (including atrial fibrillation, premature ventricular contractions and supraventricular contractions), angina[24, 35] and exacerbation of COPD.[31] This may reflect increased monitoring used at home, rather than the exercise.

Healthcare utilization

Only one study reported cost as an outcome. In a low-cost telerehabilitation program without electrocardiogram monitoring in Brazil, the cost per patient was US$502.71 for three months.[25] Cost for the no intervention group was not reported.

Muscle strength

There is very limited evidence regarding effects of telerehabilitation on muscle strength. Muscle strength and endurance was preserved or even improved with telerehabilitation in patients with CHF, whereas there was a small decline in no intervention group.[33]

DISCUSSION

The aim of this systematic review was to examine the effects of telerehabilitation in patients with cardiopulmonary diseases. The majority of included studies were not primarily designed to examine the effects of real-time telerehabilitation, but rather to assess effects of home-based exercise delivered by phone communications. There is currently a lack of video-based telerehabilitation programs for patients with cardiopulmonary diseases.

Telerehabilitation is generally associated with an improvement compared with baseline, in terms of exercise capacity (6MWD and VO_2peak) and quality of life in patients with cardiopulmonary diseases. The literature suggests that the outcomes from a telerehabilitation delivered program are not different to center-based programs, for 6MWD,[31] VO_2peak[30, 34] and quality of life.[30] However there are some discrepancies between studies and factors contributing to inconsistent VO_2peak results remain unclear. Exercise intensity, exercise mode, program duration, phone communications and initial period of familiarization appear to be similar across reviewed studies. However, there appears to be a difference in drop-out rate where 30% was observed in one study[32] compared to 10% in another study.[33] Another possible reason for lack of group difference is one study focused on the effects of maintenance exercise after completion of a center-based cardiac rehabilitation program.[27]

Telerehabilitation also appears to be at least as effective as center-based exercise in terms of other outcomes. For instance telerehabilitation is associated with higher adherence rates compared with center-based exercise.[24, 30, 34] Although there is no difference between telerehabilitation and center-based exercise in the number of adverse events, careful patient selection and close monitoring in the early phase is important to minimize adverse events in telerehabilitation.[30]

The use of telecommunication technologies in the delivery of exercise rehabilitation programs for patients with cardiopulmonary diseases are emerging. Innovative telerehabilitation studies in patients with COPD[36] and CHD[37] may shed further light on the effects of telerehabilitation compared with traditional center-based exercise.

Implications for clinical practice

Telerehabilitation appears to be a feasible alternative to traditional center-based exercise for patients with cardiopulmonary diseases, and there are various recommendations for successful delivery of these programs. Some recommendations include risk stratification, observation of exercise contraindications, education, consideration of concomitant device therapy such as cardiac resynchronization therapy, individualized training and presence of an accompanying person during exercise.[38] Monitoring such as transtelephonic exercise monitoring has been used in some studies,[24, 35] however continuous electrocardiographic monitoring is not necessarily required for low to moderate risk patients, and is unable to reduce cardiovascular events.[39] Some studies advocate an initial home visit to identify exercise barriers within the home setting and to develop strategies to overcome these barriers.[27] Regular contact with health professionals such as phone contact can also be useful to identify changes in medical status, provide reinforcement for self-management behaviors and promote exercise adherence.[25, 34] Similarly, follow-up assessments with the health professional may motivate patients to maintain their exercise levels.[27] Activity logs can be used to provide self-reported exercise adherence[27] which can be verified through objective tools.[32] It is unclear which of these recommendations are most effective in contributing to the success of telerehabilitation.

Implications for research

As this is a relatively new area of research, there are few studies in each disease area and the majority used phone-based telerehabilitation. The feasibility of delivering video-based telerehabilitation in this patient group should be investigated. Future studies should strengthen the methodological quality through the use of assessor blinding, concealed allocation and adequate power. External validity should be addressed to enhance generalizability of results. Future research should report both within-group improvements from baseline, as well as between-group differences between telerehabilitation and center-based exercise, to enable clinicians to easily identify the most effective intervention.

Limitations

This systematic review has some limitations. Search criteria were limited to randomized controlled trials published in English, which could predispose to publication bias. Another limitation is the exclusion of studies which did not report a physical or functional outcome measure. The control group was also not limited to one type, making comparison with telerehabilitation difficult. Some control groups received education and no active exercise interventions, while others received center-based exercise.

CONCLUSION

Telerehabilitation appears to be effective in patients with cardiopulmonary diseases. However with only a small number of studies reporting outcomes on physical or functional measures, clinical processes and costs, and with some conflicting findings emerging, compelling evidence supporting broad implementation of telerehabilitation is still limited. There is also a need for studies which include video-based telerehabilitation. Telerehabilitation appears to be a promising alternative to traditional center-based exercise, depending on patient preference, which may help to increase program uptake.

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CONTRIBUTIONS OF AUTHORS

RH conducted the search for studies and selected included studies; assessed study quality; extracted, entered and analyzed data; interpreted results and wrote the review. JB selected included studies and edited the draft review. NM, AM and TR were consulted on studies for inclusion and edited the draft review. All authors conceived the review.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Studies with MET as outcome measures were originally intended to be presented, but have been incorporated into outcomes expressed as VO_2peak. The scope of the review has been reduced from chronic diseases to cardiopulmonary diseases since registration of the protocol.

Table 1. Search terms.

A combination of search terms in the following three categories was used, with limits applied as English, all adults, clinical trials and publications after 1990.

Category	Search terms
1	Cardiovascular disease, cardiac, heart failure, cardiac failure, CHF, CCF, coronary heart disease, cardiomyopathy, lung disease, pulmonary disease, pulmonary condition, asthma, cystic fibrosis, chronic obstructive pulmonary disease, COPD, chronic disease OR chronic condition.
2	Telemedicine, ehealt*, Tele*, e-health OR Health technology.
3	Exercise, rehabilitation, physiotherapy OR physical therapy.

1, 2 AND 3.

Table 2. Characteristics of included studies.

Authors	Year	Quality score (/28)	Study design	Patient characteristics	Study location	Delivery of interventions	Telerehabilitation exercise	Other telerehabilitation components
Arthur et al.[34]	2002	24	RCT	CHD	Canada	Phone	24/52, 5 session/week and 60-70 min/session. Aerobic (walking at 60-70% VO_2peak).	Similar access to nutritional counseling, risk factor management and psychological intervention.
Brubaker et al.[27]	2000	24	RCT	CHD	USA	Phone	36/52, 3-5 session/week and 30-40 min/session. Aerobic (cycling or walking at 50-75% HRR).	Similar access to baseline assessment, nutritional counseling, risk factor management and psychological intervention prior to enrolment.
Chien et al.[28]	2012	20	RCT	CHF	Asia	Phone	8/52, 3 session/week and 30 min/session. Combined aerobic (unclear walking intensity) and strength.	Unclear if access was available for other non-exercise interventions.
Maltais et al.[31]	2008	27	RCT	Respiratory	Canada	Phone	8/52, 3 session/week and 55-70 min/session. Combined aerobic (cycling at 60-80% maximum work rate) and strength.	Similar access to a 4/52 self-management education program (breathless management, energy conservation, action plan, medication, psychological intervention and physical activity) prior to exercise training.
Oh[29]	2003	16	RCT	Respiratory	Asia	Phone	8/52, unclear exercise frequency, dose and intensity. Combined aerobic and strength. Inspiratory muscle training also included.	Similar access to education on pathophysiology, treatment options, medication, energy conservation, bronchial hygiene and nutritional counseling.
Oka et al.[32]	2000	20	RCT	CHF	USA	Phone	12/52, 3 session/week and 40-60 min/session. Combined aerobic (walking at 70% HR_{max}) and strength (75% 1RM).	Unclear if access was available for other non-exercise interventions.
Piotrowicz et al.[30]	2010	23	RCT	CHF	Europe	Phone and ECG	8/52, 3 session/week and 20-45 min/session. Aerobic (walking in telerehabilitation group and cycling in control group at 40-70% HRR and 11 RPE).	Similar access to psychological intervention and education.
Salvetti et	2008	21	RCT	CHD	Brazil	Phone	12/52, 3 session/week and	Access to education on risk factor

Authors	Year	Quality score (/28)	Study design	Patient characteristics	Study location	Delivery of interventions	Telerehabilitation exercise	Other telerehabilitation components
al.[25]							30 min/session. Aerobic (walking at 60-80% HR_{max}).	management and exercise. Unclear if control group had access to similar education.
Servantes et al.[33]	2011	25	RCT	CHF	Brazil	Phone	12/52, 3-4 session/week and 50-65 min/session. Combined aerobic (walking at ±10 HR within anaerobic threshold) and strength (30-40% of 1RM and 12-16 repetitions).	Access to education on risk factor management and exercise. Unclear if control group had access to similar education.
Sparks et al.[24]	1993	16	RCT	CHD	USA	Phone and ECG	12/52, 3 session/week and 60 min/session. Aerobic (cycling at 60-75% maximum HRR).	Similar access to nutrition, medication and physical activity counseling.
Squires et al.[35]	1991	7	? Quasi-experimental with control group	CHD	USA	Phone and ECG	1 to 3 session/week and 30-50 min/session. Aerobic. Unclear about exercise intensity.	Unclear if access was available for other non-exercise interventions.

Abbreviations: CHD, coronary heart disease; CHF, chronic heart failure; ECG, electrocardiograph; HR, heart rate; HR_{max}, maximum heart rate; HRR, heart rate reserve; min, minute; RCT, randomized controlled trial; RM, repetition maximum; RPE, rate of perceived exertion; USA, United States of America; VO_2peak, peak oxygen consumption.

Figure 1. PRISMA flow chart on the results of literature search.

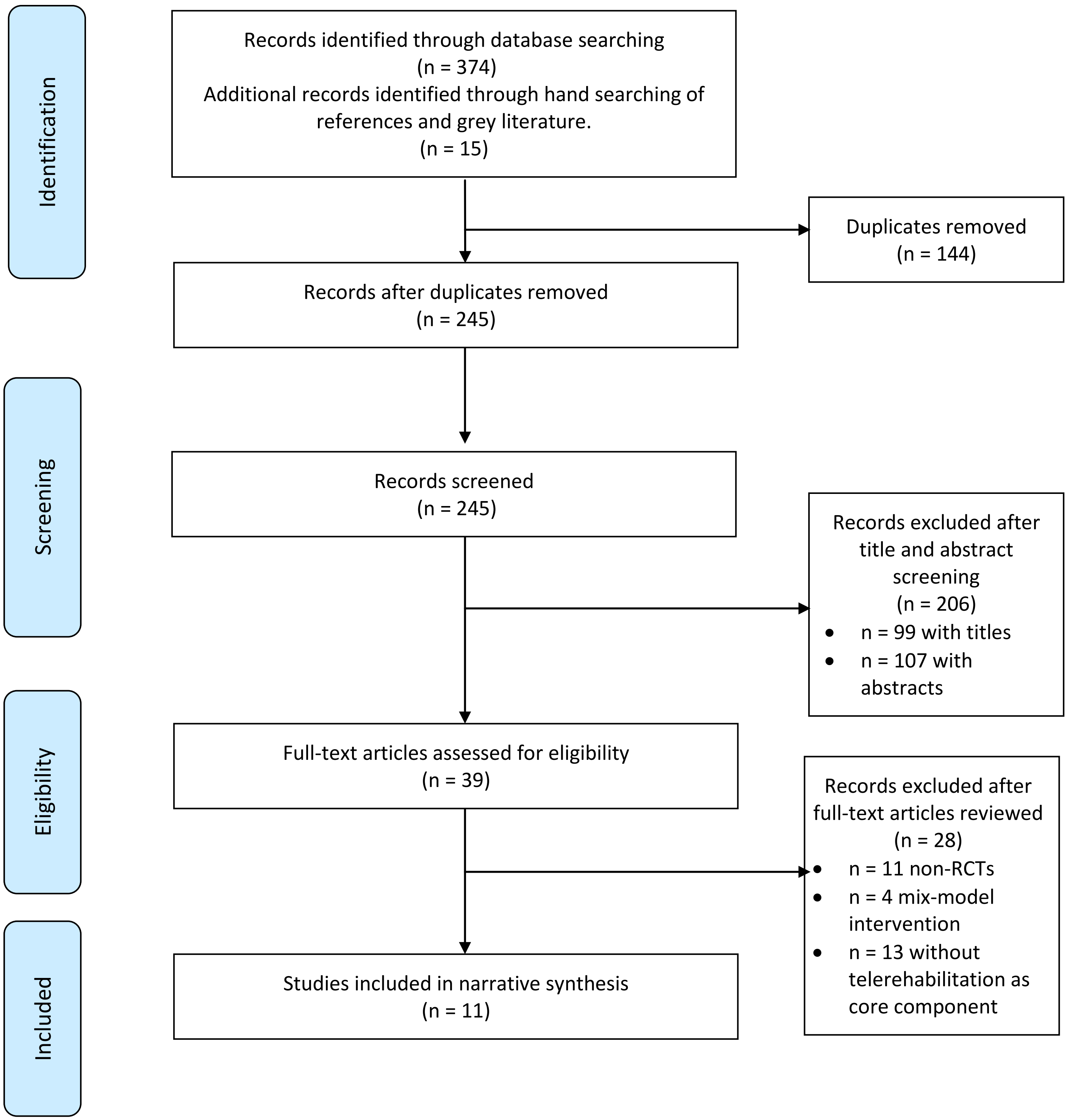
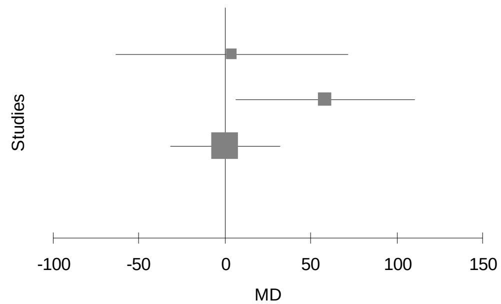


Figure 2. Forest plot of the mean difference in post-program six minute walk test distance (in meters).

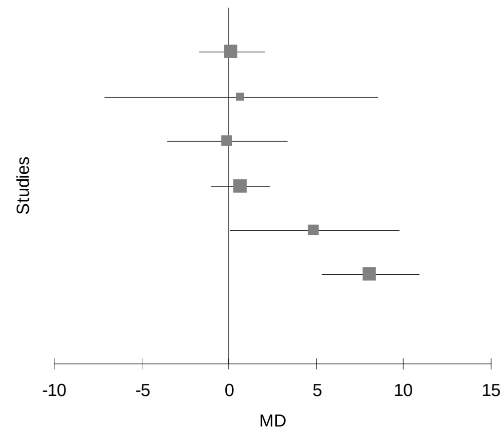
Study	Year	Telerehab n/Mean/SD	Control n/Mean/SD	Weight (%)	Mean difference with 95% CI
Chien et al.	2011	24/433/145	27/429/93	14.00%	4 (-63.79 to 71.79)
Oh	2003	15/391.31/68.63	8/332.78/55.93	23.00%	58.53 (6.49 to 110.57)
Piotrowicz et al.	2010	75/462/91	56/462/92	63.00%	0 (-31.7 to 31.7)



Abbreviations: CI, confidence interval; MD, mean difference; n, number of subjects; SD, standard deviation.

Figure 3. Forest plot of the mean difference in post-program peak oxygen consumption (in mL/kg/min).

Study	Year	Telerehab n/Mean/SD	Control n/Mean/SD	Weight (%)	Mean difference with 95% CI
Arthur et al.	2002	120/18.26/7.51	122/18.1/7.19	21.00%	0.16 (-1.7 to 2.01)
Brubaker et al.	2000	16/32.55/10.5	15/31.85/11.55	8.00%	0.7 (-7.09 to 8.49)
Oka et al.	2000	12/18.89/4.69	12/19/3.82	17.00%	-0.11 (-3.53 to 3.31)
Piotrowicz et al.	2010	75/19.7/5.2	56/19/4.6	21.00%	0.7 (-0.98 to 2.38)
Salvetti et al.	2008	19/31.7/8.1	20/26.8/7.2	14.00%	4.9 (0.08 to 9.72)
Servantes et al.	2011	17/20.9/4.2	11/12.8/3.2	19.00%	8.1 (5.35 to 10.85)



Abbreviations: CI, confidence interval; MD, mean difference; n, number of subjects; SD, standard deviation.

Appendix A. Methodological quality of included studies.

Items on Downs and Black check list	Arthur et al.[34]	Brubaker et al.[27]	Chien et al.[28]	Maltais et al.[31]	Oh[29]	Oka et al.[32]	Piotrowicz et al.[30]	Salvetti et al.[25]	Servantes et al.[33]	Sparks et al.[24]	Squires et al.[35]
1. Hypothesis/aims	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2. Identify main outcomes	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
3. Patient characteristics	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
4. Description of intervention	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
5. List of confounders	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	partially
6. Description of main finding	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
7. Estimates of data variability	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N
8. Adverse events	N	Y	Y	Y	N	Y	Y	Y	Y	N	Y
9. Lost to follow-up	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N
10. Probability values	Y	N	N	Y	Y	Y	Y	Y	Y	N	N
11. Representative sample - potential	U/A	Y	U/A	Y	U/A	U/A	Y	N	Y	N	U/A
12. Representative sample - actual	U/A	Y	U/A	Y	U/A	U/A	Y	U/A	Y	U/A	N
13. Treatment location representative of usual	Y	Y	Y	Y	Y	Y	U/A	U/A	Y	Y	U/A
14. Subject blinding	N	N	N	N	N	N	N	N	N	N	N
15. Assessor blinding	Y	Y	U/A	Y	U/A	U/A	U/A	U/A	Y	U/A	U/A
16. Data dredging	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
17. Analysis adjusted for follow-up	Y	Y	Y	Y	U/A	Y	Y	Y	Y	Y	U/A
18. Appropriate statistical tests	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	U/A
19. Reliable intervention compliance	Y	Y	U/A	Y	U/A	Y	Y	Y	Y	Y	Y
20. Accurate outcome measures	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	U/A
21. Intervention and control from same population	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
22. Recruitment over common period	Y	Y	U/A	Y	U/A	U/A	Y	Y	Y	U/A	U/A
23. Randomized	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	U/A
24. Concealed allocation	Y	N	U/A	Y	U/A	U/A	U/A	Y	Y	U/A	U/A
25. Adjustment for confounders	Y	Y	Y	Y	U/A	U/A	Y	U/A	N	U/A	U/A
26. Considered loss to follow-up	Y	Y	Y	Y	U/A	N	Y	Y	Y	Y	Y
27. Adequate power	Y	N	Y	Y	N	N	N	N	N	N	N
Total score	24	24	20	27	16	20	23	21	25	16	7

Abbreviations: N, no; Y, yes; U/A, unable to determine.

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