Non-pharmacological management interventions for COPD: an overview of Cochrane systematic reviews (Protocol)

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Non-pharmacological management interventions for COPD: an overview of Cochrane systematic reviews

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To a) summarise the evidence, b) identify gaps in the evidence base and c) describe elements of non-pharmacological, non-surgical and non-device interventions for the management of COPD using a standardised taxonomy for disease management adapted from the American Heart Association (Krumholz 2006).

BACKGROUND

Description of the condition

Chronic obstructive pulmonary disease (COPD) is the fourth most common cause of death internationally and accounts for 3.5% of total years lost due to disability (World Health Organisation 2004). This highly burdensome condition impacts on 80 million people and their families globally. It is characterised by non-reversible airflow limitation in conjunction with progressive debilitating symptoms and systemic effects (Global Initiative for COPD (GOLD) 2010). Increases in bio-fuel use and smoking, particularly in developing countries, are set to increase the prevalence of COPD globally by 30% by 2030 (Buist 2007; Mannino 2002; World Health Organisation 2004).

Despite optimisation of pharmacological treatments such as inhaled medications, a large proportion of individuals with COPD

continue to have inadequately managed symptoms and unmet psychosocial needs (Bausewein 2008; Disler 2012; Effing 2007). Comprehensive approaches to disease management that engage "multiple therapies into a patient-centred plan of care" (Make 2003) are necessary to meet these healthcare needs (Craig 2008; Make 2003; Monninkhof 2003).

Description of the interventions

Key non-pharmacological interventions such as pulmonary rehabilitation and self-management programmes are central to COPD management and are highlighted in international COPD management guidelines (ATS/ERS 2011; Global Initiative for COPD (GOLD) 2010; National Institute for Clinical Excellence 2012). Chronic diseases such as COPD require a comprehensive approach to disease management (Make 2003), potentially incorporating a range of diverse non-pharmacological, non-device and non-sur-

gical intervention strategies. The intervention strategies discussed in this overview, and defined below are: pulmonary rehabilitation; self-management programs; action plans as an integrated strategy and management guideline; telehealthcare; and outreach programs (ATS/ERS 2011; Bausewein 2008; Effing 2007; Global Initiative for COPD (GOLD) 2010; Kruis 2011; Lacasse 2006; Make 2003; McLean 2011; World Health Organisation 2004).

Pulmonary rehabilitation

Pulmonary rehabilitation focuses on building exercise capacity, disease and nutritional education, and psychological coaching. (ATS/ERS 2011; Celli 2004; Global Initiative for COPD (GOLD) 2010; National Institute for Clinical Excellence 2012; Nici 2006). Pulmonary rehabilitation is defined as "an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Integrated into the individualized treatment of the patient, pulmonary rehabilitation is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systemic manifestations of the disease."(ATS/ERS 2011).

Self-management programs

Self-management programs are defined as "any formalized patient education programme aimed at teaching skills needed to carry out medical regimens specific to the disease, guide health behaviour change, and provide emotional support for patients to control their disease and live functional lives" (Effing 2007). Patients with COPD experience high symptom burden and poor health-related quality of life, and are required to manage their condition over extended periods (Bourbeau 2003). Evidence suggests that self-management education programs that target skills to assist patients in coping are likely to reduce hospital admissions in patients with COPD, but there is heterogeneity in current studies (Effing 2007).

Action plans as part of an integrated strategy and management guideline

Action plans are defined as "the use of guidelines which outline self-initiated interventions (such as changing medication regime or visiting the general practitioner or hospital) which are undertaken appropriately in response to alterations in the state of the patients' COPD (e.g. increase in breathlessness, increased amount or purulence of sputum) that suggest the commencement of an exacerbation" (Turnock 2005). Patients who receive early intervention for exacerbations of COPD symptoms are shown to recover sooner and experience better quality of life with ongoing optimal management (Wilkinson 2004). Action plans have been

shown to be effective in early intervention in asthma management; however the evidence for their efficacy in COPD has been limited (Gallefoss 1999; Turnock 2005).

Telehealthcare

Telehealthcare is a rapidly expanding field in healthcare and chronic disease management (Inglis 2010; McLean 2011). Telehealthcare in COPD is described by a recent Cochrane Review as "using technology such as telephones, video cameras and the Internet to allow people to stay at home and communicate with a nurse or doctor when they have a period of increased breathlessness" (McLean 2011). Considering the housebound status of people with advanced COPD and the frequency with which patients access acute health services as the disease progresses, telehealthcare has particular applicability in this population (McLean 2011). Telehealthcare has great potential in the resource-limited future of modern health care.

Outreach programs

Outreach programs are those interventions that "comprise home visits by a respiratory nurse or similar respiratory health worker, to facilitate health care, provide education, provide social support, identify respiratory deteriorations promptly and reinforce correct technique with inhaler therapy" (Wong 2012). Delivery of care in the community targets those patients who are housebound or frequently reliant on acute services in the advanced stages of COPD. Outreach programs strive to maintain optimal management of disease and assist patients in self-management behaviours, as well as regular monitoring and early intervention in condition deterioration. A recent Cochrane systematic review found that this type of intervention does improve health -elated quality of life; however the current studies are heterogeneous in their approach (Wong 2012).

Why it is important to do this overview

Chronic diseases such as COPD require a comprehensive and multi-dimensional approach to disease management that incorporates a range of integrated intervention components, for example exercise rehabilitation with self-management education (Global Initiative for COPD (GOLD) 2010; Make 2003; World Health Organisation 2004).

Many of these discrete interventions are complex in both design and delivery, and require distillation of essential elements: e.g. the type, frequency and level of intervention intensity, as well as description of the workforce type and scope. Using a pre-specified and standardised taxonomy may assist in providing information to health providers and consumers in design of effective and appropriate interventions for COPD management (Krumholz 2006;

Make 2003). Understanding the most efficacious organisation, timing and sequencing of these interventions within a disease management approach, as well as resource requirements for these approaches, are of high interest internationally and will inform policy, healthcare decisions and future research (Disler 2012; Effing 2007; Krumholz 2006; Make 2003).

This overview will summarise evidence for non-pharmacological, non-surgical, non-device programs for the management of COPD, highlight the current gaps in knowledge, provide recommendations for how best to report outcomes for these complex interventions and inform future program improvement and design. Specifically, we will investigate the evidence for pulmonary rehabilitation, self-management programs, action plans as part of an integrated strategy and management guideline, telehealthcare and outreach programs.

OBJECTIVES

To a) summarise the evidence, b) identify gaps in the evidence base and c) describe elements of non-pharmacological, non-surgical and non-device interventions for the management of COPD using a standardised taxonomy for disease management adapted from the American Heart Association (Krumholz 2006).

METHODS

Criteria for considering reviews for inclusion

Types of reviews

We will include reviews published in the *Cochrane Database of Systematic Reviews* (CDSR) that examine non-pharmacological, nonsurgical, or non-device strategies for the management of COPD. This overview seeks to assess the evidence published in the original Cochrane systematic reviews and will not seek to update these reviews. However, specific information about intervention components may be sought from trial reports and individual researchers.

Types of participants

People with a clinical diagnosis of COPD according to the definitions in the original reviews.

Types of interventions

We will include non-pharmacological, non-surgical, non-device intervention strategies for the management of COPD within a comprehensive and multifaceted approach, specifically: pulmonary rehabilitation; self-management programs; action plans as an integrated strategy and management guideline; telehealth-care; and outreach programs. We will exclude reviews of surgical treatments and treatment devices as outside of the scope of this overview, for example non-invasive ventilation, continuous positive airway pressure and lung volume reduction surgery will not be included.

Types of outcome

The following outcomes will be discussed and reported if present within the included Cochrane systematic reviews:

Primary outcomes

- Health-related quality of life (any validated measure)
- All cause hospital admissions
- All cause emergency department presentations

Secondary outcomes

- Patient-reported breathlessness (any validated measure)
- Functional capacity (any validated measure)

Search methods for identification of reviews

We will search the *Cochrane Database of Systematic Reviews* on The *Cochrane Library* (latest issue) using the search strategy in Appendix 1. We will not apply date or language restrictions. All protocols for ongoing reviews will be noted in the 'Studies awaiting assessment' section for possible inclusion in future updates of this overview.

Data collection and analysis

Selection of reviews

Two authors (RTD, PMD) independently will assess Cochrane systematic reviews as being 'for exclusion', 'for inclusion', or 'potentially eligible' on the basis of title and abstract. We will locate full texts for Cochrane reviews judged as 'eligible' or 'potentially eligible' and two independent authors (RTD, PMD) will judge their suitability for inclusion against the inclusion criteria. In the instance of disagreement a third review author will adjudicate.

Data extraction and management

Two review authors (RTD, PMD) will independently extract data from included Cochrane reviews and a third author will check all extracted data for accuracy and consistency. We will collect extracted data using a customised electronic data extraction form. The data extracted will include review objectives, participant information, primary outcome measurements and limitations noted in the review. Quality of included reviews (using AMSTAR) and quality of evidence in included reviews (using GRADE and risk of bias) data will be extracted for assessment of overall methodological quality. In addition, we will extract details of the following elements for discussion: intervention content; delivery personnel; method of communication; intensity and complexity of intervention; setting and environment; and outcome measures (Krumholz 2006; Ryan 2011).

Dealing with missing data

Outcomes will be discussed and reported if present within the included original Cochrane Systematic reviews. If any information from the reviews is unclear or missing, we will access the published reports of the individual trials and contact individual researchers.

Assessment of methodological quality of included reviews

Quality of included reviews

Two review authors (RTD, PMD) will assess the methodological quality of the included reviews independently using the 'assessment of multiple systematic reviews' (AMSTAR) measurement tool (Shea 2009). Disagreements will be resolved by a third author. We will not exclude Cochrane reviews on the basis of methodological quality.

Quality of evidence in included reviews

Two review authors (RTD, PMD) will assess the quality of evidence presented in the included reviews using the GRADE assessment tool and through assessment of risk of bias of the included evidence. We will retrospectively apply the risk of bias tool and GRADE the evidence from trials in individual systematic review where this was not done previously (Higgins 2011).

'Summary of findings' tables

We plan to prepare several summary tables. Summary tables will present data extracted on the characteristics of included reviews; the methodological quality of included reviews (AMSTAR ratings); the quality of evidence in included reviews (GRADE and risk of bias); and a summary of primary outcomes reported in included reviews - by intervention (pulmonary rehabilitation, self-management programs, action plans as part of an integrated approach, telehealthcare, and outreach programs). We will summarise information on the multi-component interventions used in COPD disease management using an adapted standardised disease management taxonomy. This 'elements of multi-component interventions' table will include the following content: intervention content, delivery personnel, method of communication, intensity and complexity of intervention, setting and environment, and outcome measures (Krumholz 2006).

Data synthesis

We do not anticipate that we will be able to perform quantitative data analyses. Therefore we will present a narrative summary of results for the individual reviews and primary outcomes. For future updates of this overview we may perform quantitative data analysis of interventions across reviews for the primary outcomes if data permit.

We will present narrative descriptions of the evidence for non-pharmacological, non-surgical, non-device interventions for COPD using two comparisons: intervention versus placebo, and intervention A versus intervention B (e.g. self-management versus standard care or self-management versus action plans). This descriptive approach to summarising evidence is similar to the successful approaches seen in the Cochrane overviews of pain management for women in labour (Jones 2012) and of consumer-oriented interventions for evidence-based prescribing and medicines use (Ryan 2011).

We plan to adapt and apply a standardised disease management taxonomy to organise the discussion (Table 1). We hope that the use of such a framework will guide discussion and increase the utility of the review for decision-makers by promoting increased understanding of intervention intensity and duration and workforce requirements (Krumholz 2006).

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* Indicates the major publication for the study

ADDITIONAL TABLES

Table 1. Taxonomy of COPD Disease Management (Adapted from the American Heart Association (Krumholz, et al., 2006))

Patient Population	_		Delivery Personnel		Intensity	Complexity	Environ- ment	Outcome measures
 Disease severity Comorbid conditions Non-clinical characteristics 	•	education Medication manage- ment Prescribed exercise Peer Support	1	face: Individual Face to face: Group Telephone: In person Telephone:	Frequency and • periodicity • Follow- up	Sequencing • of components	Inpatient Hospital: Outpatient Community based	 Process measures Quality of life measures Healthcare
	•	Counselling				•	Telehealthcare	

Table 1. Taxonomy of COPD Disease Management (Adapted from the American Heart Association (Krumholz, et al., 2006)) (Continued)

managers			
• Care •	Internet:		
coordinators	Telehealth-		
	care		
	care		

APPENDICES

Appendix I. Search strategy: The Cochrane Library

#1 MeSH descriptor Pulmonary Disease, Chronic Obstructive explode all trees

#2 MeSH descriptor Lung Diseases, Obstructive, this term only

#3 COPD:ti

#4 (obstruct*) near/3 (pulmonary or lung* or airway* or airflow* or bronch* or respirat*):ti

#5 (#1 OR #2 OR #3 OR #4)

[Limited to Cochrane Database of Systematic Reviews]

CONTRIBUTIONS OF AUTHORS

All authors contributed to the development of the title registration, overview of methods, development of selection criteria, decisions on the organising framework and development and writing of the protocol.

DECLARATIONS OF INTEREST

None known

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NOTES

None.