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Effects of home healthcare for adults with chronic respiratory diseases and post-COVID-19 syndrome on hospital bed turnover rate: a protocol of systematic review with meta-analysis

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ABSTRACT

Introduction Chronic respiratory diseases (CRDs) have a high prevalence, morbidity and mortality worldwide. After the COVID-19 pandemic, the number of patients readmitted after hospital discharge increased. For some populations, early hospital discharge and home healthcare may reduce health costs in patients treated at home when compared with those hospitalised. This study aims to systematically review the effectiveness of home healthcare for patients with CRDs and post-COVID-19 syndrome.

Methods and analysis We will search on MEDLINE, CENTRAL, Embase and PsycINFO. We will include randomised controlled trials (RCTs) and non-RCT studies reported in full text and abstracts. No language restriction will be applied. We will include studies related to adults with a diagnosis of CRDs or post-COVID-19 syndrome that compared in-patient hospital care with any home healthcare. We will exclude studies with participants with neurological, mental diseases, cancer or pregnant women. Two review authors will screen abstracts and select the eligible studies. To investigate the risk of bias, we will use the Cochrane 'Risk of Bias' tool for RCT, and the Risk of Bias In Non-randomised Studies-of Interventions for non-RCT. We will use the five Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) considerations to assess the quality of the evidence. Patients and the public will be involved in the preparation, execution and implementation phases of the review.

Ethics and dissemination No ethical approval is required because only published data will be analysed. The publication of the results in peer-reviewed journals and at relevant conferences will guide the direction of future research in the field and healthcare practice. The results will also be disseminated in plain language on social media to disseminate the knowledge to society and the public interested in the topic.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study aims to compare the forms of delivery of effective interventions concerning relevant outcomes for people with chronic respiratory diseases.
⇒ We will use a rigorous, guideline-based methodology to support the systematic review.
⇒ The search strategy was developed by an experienced librarian; the search will be performed in notable databases, and no language restrictions will be applied in the search for primary studies.
⇒ The certainty of systematic review evidence may be limited depending on the availability and quality of evidence found.

INTRODUCTION

Chronic respiratory diseases (CRDs) affect airways and other lung structures. Symptoms such as wheezing, shortness of breath, chest tightness and cough are common in these conditions.[1] The CRDs are among the most common non-communicable diseases worldwide,[2] and present a high prevalence, morbidity and mortality. Chronic obstructive pulmonary disease (COPD) and asthma are notable examples of CRDs that contribute to worldwide mortality rates and healthcare costs,[3] which affect millions of people and represent the majority of treatment costs related to exacerbations and hospitalisations.[4] Since the coronavirus pandemic arise, post-COVID-19 syndrome became another common cause of hospitalisation.[5]

The National Institute for Health and Care Excellence[5] clinical practice guideline defines post-COVID-19 syndrome as a heterogeneous condition that includes severe hospitalisation, and it is characterised by persistent clinical signs and symptoms that appear while or after suffering COVID-19, persist for more than 12 weeks and cannot be explained by

an alternative diagnosis. Evidence shows that one-third of patients who were discharged from the hospital after COVID-19 acute treatment were readmitted and more than 1 patient in 10 died.[6]

For patients with CRDs who need special care, early hospital discharge associated with home healthcare may reduce health costs when compared with those hospitalised.[7] For some populations, home healthcare seems to be safe and feasible,[8 9] and may improve clinical outcomes such as reducing hospital readmission and improving communication between patients and healthcare workers.[10] Despite increasing interest in early hospital discharge, evidence comparing the hospital-based and home-based treatment is lacking.[11]

Thus, this study aims to systematically review the literature to assess the effectiveness of home healthcare for patients with CRDs or post-COVID-19 syndrome, compared with hospital-based care.

Objectives

To determine the effectiveness of managing CRD and post-COVID-19 syndrome patients with home healthcare compared with in-patient hospital care.

METHODS AND ANALYSIS

Registration

This study is registered in the PROSPERO international prospective register of systematic reviews (CRD42022342917). This systematic review protocol will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols Statement (PRISMA),[12] the PRISMA 2020 statement[13] and the Cochrane Handbook for Systematic Reviews of Interventions.[14]

Eligibility criteria

Types of studies

We will include randomised controlled trials (RCTs) and non-RCT. We will include studies reported in full text or abstract and we will exclude unpublished data.

Types of participants

We will include adults (older than 18 years) with a diagnosis of CRD (eg, COPD, asthma, occupational lung diseases, pulmonary hypertension, cystic fibrosis and bronchiectasis) or post-COVID-19 syndrome. We will exclude participants with neurological, mental diseases, cancer or pregnant women.

Types of interventions

Intervention: adults with CRD or post-COVID-19 syndrome who have been assigned to treatment comprising home healthcare.

Comparison: control group receiving in-patient hospital care, health education or alternatively, no active control group.

We will include studies comparing any home healthcare (eg, interdisciplinary home rehabilitation, home-based maintenance telerehabilitation, medication administration at home) with in-patient hospital care.

Types of outcome measures

Primary outcomes

1. Mortality (eg, measured by a health professional or researcher).
2. Length of stay in hospital and home healthcare (eg, number of days).
3. Health-related quality of life (eg, measured using any validated patient-reported outcome instrument such as Health-Related Quality of Life; Short form 36 health survey questionnaire).

Secondary outcomes

1. Self-efficacy (eg, measured using validated patient-reported outcome instrument such as General Self-Efficacy Scale; Self-efficacy for exercise scale).
2. Adherence (eg, measured using a validated patient-reported outcome instrument; measured by a health professional or as reported by trialists).
3. Functional status (eg, measured using field exercise tests such as the Six-Minute Walk Test, or Shuttle Walk Test).
4. Readmissions to the hospital (eg, exacerbations rates, hospitalisation rates).
5. Patient satisfaction (eg, patient self-report; or measured using any validated patient-reported outcome instrument).
6. Costs (eg, as reposted by trialists).
7. Adverse events (eg, number of people with any undesired outcome due to the intervention).

We will report outcomes using the following time points:

1. Immediate.
2. Short term (up to 3 months from).
3. Long term (more than 3 months).

We will report outcomes using the following time points:

1. Immediate (immediately after the intervention).
2. Short term (up to 3 months after intervention).
3. Long term (more than 3 months).

Information sources

Search strategy

1. We will identify studies by searching the following databases and trial registries:
2. MEDLINE Ovid SP 1946 to date.
3. Embase Ovid SP 1974 to date.
4. CINAHL.
5. Cochrane Central Register of Controlled Trials (CENTRAL), via the Cochrane Register of Studies, all years to date.
6. World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch).

US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov).

The proposed MEDLINE search strategy is listed in online supplemental material 1. This will be adapted for use in the other databases.

All the search sources will be explored from their inception to the present, without restricting due to year of publication or language. We will handsearch for conference abstracts and grey literature.

Searching other resources

We will search for retractions from included studies and list of references of primary studies.

Data collection and analysis

Selection of studies

We will use the Mendeley tool (https://www.mendeley.com) to import the results and remove the duplicates. We will export the reference list to the Rayyan QCRI systematic review web-based application (https://rayyan.qcri.org).[15] Two review authors (SL and JVdSB) will screen the titles and abstracts of the search results and classify them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. The authors (SL and JVdSB) will independently screen the full text of all eligible studies and report the reason for exclusion of all ineligible studies. Disagreements will be resolved by a third person (KMPPdM). Duplicate reports of the same study will be collated and considered as the unit of interest in the review.

Data extraction and management

Two review authors (SL and JVdSB) will extract data for all included studies using a pre-piloted (piloted by GC) form which included the following study characteristics:

1. Methods: study design, total duration of the study, details of any 'run-in' period, number of study centres and location, study setting, withdrawals, and date of the study.
2. Participants: N, mean age, age range, gender, disease severity, diagnosis criteria, baseline lung function, smoking history, inclusion and exclusion criteria.
3. Interventions: intervention, comparison, duration of intervention, frequency of intervention, method of delivery.
4. Outcomes: primary and secondary outcomes specified and collected, and time points reported.
5. Notes: study funding and notable conflicts of interest of trial authors.

Extraction data from included studies will be done independently by two reviewers (SL and JVdSB). The outcomes not reported will be signalised in the 'Characteristics of included studies'. A third author will solve the disagreements. The data will be transferred to the Revman Review Manager.[14] We will double-check the data, and a second review author (GC) will spot-check study characteristics for accuracy against the study report.

Assessment of risk of bias in included studies

Two review authors (TAS and KSM) will independently assess the risk of bias for each study using tools, outlined in the Cochrane Handbook for Systematic Reviews of Interventions,[16] for RCT, version two of the Cochrane 'Risk of Bias' tool or the Risk of Bias In Non-randomised Studies-of Interventions, for non-randomised studies of interventions. We will resolve any disagreements by discussion or by involving another author (GC). We will assess the risk of bias according to the following domains:

For RCT:

1. Bias arising from the randomisation process.
2. Bias due to deviations from intended interventions.
3. Bias due to missing outcome data.
4. Bias in measurement of the outcome.
5. Bias in the selection of the reported result.

For non-RCT:

1. Preintervention (covering confounding and selection of participants in the study).
2. At intervention (classification of the interventions themselves).
3. Postintervention (biases due to deviations from intended interventions, missing data, measurement of outcomes and selection of the reported result).

We will judge each potential source of bias as 'high', 'low' or 'some concerns' for RCT. For non-RCT, we will classify as 'low', 'moderate', 'serious', 'critical' and 'no information'. We will provide a quote from the study report together with a justification for our judgement in the 'risk of bias' table. We will summarise the risk of biased judgments across different studies for each of the domains listed. For the risk will consider as blinding separately for different key outcomes where necessary (eg, for unblinded outcome assessment, the risk of bias for all-cause mortality may be very different from for patient-reported outcomes). We will take into account the risk of bias for the studies that contribute to that outcome, when considering treatment effects.

Assessment of bias in conducting the systematic review

This review will be conducted according to the published protocol, and any differences between this protocol and the review will be justified and reported in the 'differences between protocol and review'.

Measures of treatment effect

We will analyse dichotomous data as OR and continuous data as the mean difference (MD) or standardised MD. If data from rating scales are combined in a meta-analysis, we will ensure they are entered with a consistent direction of effect (eg, lower scores always indicate improvement).

We will undertake meta-analyses only where this is meaningful; that is, if the treatments, participants and the underlying clinical question are similar enough for pooling to make sense.

We will describe biased data, as medians and IQRs for each group). We will include only the relevant arms, where multiple trial arms are reported in a single study. To avoid double-couting when two comparisons are pooled in the same meta-analysis, active arms or halve the control group will be combined.

If adjusted analyses are available (analysis of variance or analysis of covariance), we will use these as a preference in our meta-analyses. If both changes from baseline and endpoint scores are available for continuous data, we will use change from baseline unless there is a low correlation between individual measurements. If a study reports outcomes at multiple time points, we will consider the immediate, short and long term.

We will use intention-to-treat or 'full analysis set' analyses when they are reported (ie, those where data have been imputed for participants who were randomly assigned but did not complete the study) instead of complete or per-protocol analysis.

Unit of analysis issues

We will use participants rather than events for dichotomous outcomes, as the unit of analysis (ie, the number of patients admitted to the hospital, rather than the number of admissions per patient). We will analyse them on this basis if rate ratios are reported in a study.

Dealing with missing data

If missing numerical outcome data exists, we will contact the trial authors or study sponsors to obtain information. When not obtainable, and the missing data are deemed to introduce serious bias, we will consider it when rating the certainty of evidence for affected outcomes.

Assessment of heterogeneity

In each analysis, we will employ the I^2 statistic to assess heterogeneity among the studies in accordance with the guidance provided in the Cochrane Handbook for Systematic Reviews of Interventions.[14] We will apply the χ^2 test, with a p value of 0.10 indicating statistical significance, and the I^2 statistic, with a value greater than 50% representing a substantial level of heterogeneity,[17] we will report it and explore the possible causes by prespecified subgroup analysis.

Assessment of reporting biases

If we include more than 10 studies per outcome/analysis, we will explore potential small studies and publication biases through funnel plots.

Data synthesis

We will use a random-effects model and perform a sensitivity analysis with a fixed-effect model.

Subgroup analysis and investigation of heterogeneity

If possible, we will consider subgroup analyses based on:

1. Degree of disease severity: mild versus moderate-to-severe, based on related clinical practice guidelines (eg, GINA, GOLD).[18 19]
2. Mode of intervention delivery (eg, remote; face to face).

We will use the following outcomes in subgroup analyses:

1. Mortality.
2. Length of stay in hospital and home health care (length of stay >9 days).
3. Readmissions to the hospital.

We will use the formal test for subgroup interactions in Review Manager V.5 (Revman).[20]

Sensitivity analysis

We plan to carry out a sensitivity analysis in which we only include studies with an overall low risk of bias, excluding studies with some concerns and a high risk of bias.

Summary of findings and assessment of the certainty of the evidence

We will create a 'summary of findings' table using seven outcomes at a short-term point: mortality, length of stay in hospital and/or home care, health-related quality of life, adverse events, readmissions to hospital, patient satisfaction and costs.[14] Two authors (GC and SL) will use the five Grading of Recommendations, Assessment, Development, and Evaluations(GRADE) considerations (risk of bias, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of a body of evidence as it relates to the studies that contribute data for the prespecified outcomes. We will use the methods and recommendations described in Section V.8.5 and Chapter 12 of the Cochrane Handbook for Systematic Reviews of Interventions,[21] using GRADEpro software (GRADEpro GDT).[22] We will justify all decisions to downgrade the quality of studies using footnotes and we will make comments to aid the reader's understanding of the review where necessary.

Patient and public involvement

We will perform patient and public involvement (PPI) to improve the quality, relevance and outcomes of this review,[23] using the Guidance for Reporting Involvement of Patients and the Public (short form) for reporting PPI.[24]

Two patients (volunteer one diagnosed with the post-COVID-19 syndrome, and volunteer two with cystic fibrosis) contributed to the judgement of outcomes and time points of this protocol. For the systematic review, patients and the public will support the interpretation of the findings and will plan strategies to disseminate the results.

Ethics and dissemination

This systematic review will assess and provide evidence for the effectiveness of managing CRD and post-COVID-19 syndrome patients with home healthcare compared with in-patient hospital care. No ethical approval is required because only published data and publicly available will be analysed.

The publication of the results in peer-reviewed journals and at relevant conferences may guide the direction of healthcare practice and research. The results will also be published in plain language on social media to disseminate the knowledge to society and the public interested in the topic.

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Contributors SL, KSM, TAS, JVdSB, TZMS, CA, ZG, SA and KSM conceptualised and designed the protocol, drafted the initial manuscript and reviewed the manuscript. SL and TAS developed the search strategy. SL, KMPPdM and GC defined the data extraction process and methodological appraisal of the studies. GC planned statistical analysis. All authors have approved and contributed to the final written manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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