Reviewer's report

Title: Effectiveness of manual chest physiotherapy techniques in the management of exacerbations of chronic obstructive pulmonary disease (MATREX): a randomised controlled equivalence trial.

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Reviewer: Kylie Hill

Reviewer's report:

This manuscript reports on the results of a large study that examined the effect of manual chest physiotherapy techniques in patients hospitalised with an acute exacerbation on disease-specific health-related quality of life, six months following randomisation.

This study would have been an enormous, difficult and time consuming undertaking. Certainly studies that investigate the role of physiotherapy treatments during an acute exacerbation are necessary and important.

Nevertheless, I strongly suspect that the design has a fatal flaw (see below) and this must be discussed and acknowledged.

- Major Compulsory Revisions

Introduction

The purpose of an equivalence study is to demonstrate that a new (or experimental) treatment is as effective as one with established effectiveness. In order to do this, there must be convincing prior evidence that the control or standard therapy group (in this case, instruction regarding ACBT) is effective compared with placebo or no treatment. Therefore, the most important issue to be addressed in the Introduction, is that ‘ACBT instruction’, is, in fact, effective (at improving health-related quality of life at 6 months). To my knowledge, there is no study demonstrating this and therefore, I believe that this study has simply demonstrated that two ineffective treatments, are equally ineffective. The authors allude to this in the Discussion (by commenting on the need for further research regarding the effectiveness of ACBT), but it is critical to acknowledge this a major flaw in this study.

The rationale for selecting health-related quality of life as the primary outcome needs strengthening. I appreciate that the SGRQ is a standardised patient-orientated outcome, but in the Introduction, the authors state that MCP are done with the goal of ‘improving V/Q ratios and lung function’. Therefore, it would seem that measures which reflect V/Q ratios and lung function would have been more appropriate as the primary outcomes. Are improvements in health-related quality of life really the most important goal of MCP applied in during a hospital admission?
The other aspect that needs strengthening is the rationale for the length of follow-up. I appreciate that earlier work has not examined long-term effectiveness of MCP, but I would have thought that the outcome of interest with regards of long-term effectiveness of MCP would be exacerbation frequency, antibiotic use or maybe healthcare utilisation. Why did the authors expect MCP to confer benefits in health-related quality of life 6 months following randomisation?

Methods

Following the work by Gallon in the 1990s (and very early work by Campbell demonstrating a decrease in FEV1 with percussion), there is a general consensus that MCP, especially percussion, should only be offered to patients characterised by mucus hypersecretion (i.e. # 30 mls per day). Can the authors strengthen their rationale for why mucus hypersecretion was not an inclusion criteria?

Under ‘statistical analysis’ – you use the term ‘non-superiority’ (which I am not certain is appropriate). Was the trial designed as an equivalence study, or a non-inferiority trial (i.e. powered for two-tailed vs. one-tailed analysis)?

Why was an effect size chosen for the power calculations and not the MCID for the SGRQ?

When you explain how the effect size was calculated, I am not clear how the data from the control group was used (mean difference in what?)

Who collected the outcome measures – were they blinded to the aims of the study and group allocation?

Results

It is important that the within-group results (for both the no MCP and the MCP groups) are reported. Did either group achieve a significant improvement in the SGRQ? If not, both interventions were ineffective and this must be stated clearly.

The data pertaining to saturation are interesting. However, I think it is important to know how many desaturated by an amount that is likely to be important (and is more than the measurement error of most oximeters). Can you please provide data on how many desaturated by # 4% to a level # 90% (i.e. criteria often cited in UK guidelines)?

Under the subheading ‘MCP treatment’ – I am unclear what you mean by’ Shortness of breath reported by patients was accompanied by varying degrees of reduced oxygen saturation’. Can you please re-phrase this? Did all patients report shortness of breath?

How many in each group were re-admitted over the six months follow up period?

I noticed in Table 1 – for the variable ‘Deviations from MCP treatment protocol’ – you have 248 (38%) for ‘one position only’ – was there an expectation to treat in
more than one position?

Discussion

I would argue that first statement under the subheading ‘MCP treatment protocol’ is not correct. There have been at least two systematic reviews recently published that evaluate the role of ‘chest physiotherapy’ in the management of an acute exacerbation and both conclude that the evidence is strongest for positive pressure devices (i.e. PEP like devices), not MCP. Therefore, I would be interested to know why the authors think that their MCP treatment was based on ‘best available research evidence’.

The paragraph with the subheading ‘MCP versus ACBT’ needs re-visiting. In addition to stating that ACBT is a popular treatment choice, the authors must review the evidence for this treatment. The statement ‘Our results suggest that a short teaching session on ACBT might be equally effective in terms of QOL after six months as several sessions of ACBT performed with support from the physiotherapist’ is misleading (I suspect neither were effective). Can this be re-worded?

The authors must include a paragraph that summarises the limitations of their study. If neither group conferred an improvement in quality of life, the authors must be transparent that this study has not confirmed equivalence of two effective treatments, but in fact, has shown equivalence of two ineffective treatments.

• Minor Essential Revisions

Abstract

Last line under ‘Methods’ – please change ‘This study is registered’ to ‘This study was registered’. Also please state which registry was used.

Under ‘Results’, is the word ‘evaluable’ needed? Please make it clear that the 95% CI pertains to that for an effect size, not the actual units of the SGRQ.

There are some redundant sentences. For example, the authors state that the study looked at quality of life six months following intervention three times – (i) end of Background, (ii) last paragraph under ‘design and patients’ and (iii) under ‘outcome measures’ – this needs stating only once.

Introduction

It would be useful to clarify if the authors actually expected a difference between the groups and why (or why not). It would be useful to move the paragraph that summarises the study objectives from the Methods section to the end of the Introduction.

Methods

Was there any contact with the participants between discharge and follow-up?
Last line of the paragraph under the subheading ‘outcome measures’ – please change ‘trail’ to ‘trial’.

Results

Under ‘Efficacy Analyses’ – can you please clarify that the mean differences were calculated as no MCP – MCP

Discussion

The opening statement of the Discussion is confusing. For readers who are not familiar with how the SGRQ is scored, it sounds as though the patients in this study had better quality of life than others. Can this be re-worded?

Other

References: The authors need to check their use of references. As an example, the paper by Cecins et al is cited to support the statement that “Sputum volume ...is recommended as an indicator of the physiological impact of MCP” – but this study was not in COPD, used sputum weight not volume as its outcome measure, and did not investigate MCP – so does not support this statement.

The manuscript refers to both a consort diagram (last line of first paragraph under sub-heading ‘procedures’) and Figure 1 (first line of Results) – neither of which were available at the time of review. Were these uploaded?

Regarding the Tables, can the authors please carefully consider how many decimal points it is appropriate to use when expressing their data. In most instances, it would not be appropriate to use more than one decimal point.

Table 2 – the abbreviations JPH, NNUH etc – I assume that these represent the hospitals? It would be better to have these listed as Site 1, Site 2 etc.

There are some inconsistencies in formatting throughout the manuscript – e.g. for some subheadings the authors have capitalised the first letter of each word and for others, they haven’t. This happens again in the Tables.

Reference 24 is not formatted correctly (e.g. single spaced)

• Discretionary Revisions

In the Abstract – consider replacing the term ‘chest clearance’ with ‘airway clearance’

Consider re-phrasing the statement ‘Chronic obstructive pulmonary disease (COPD) is characterised by exacerbations during which....’ to ‘Chronic obstructive pulmonary disease (COPD) is characterised by exacerbations, some of which result in increased cough....(not all exacerbations are characterised by excessive sputum production – some are characterised more by dyspnea and fatigue).
In the Introduction, where the authors state ‘However, systematic reviews of clinical trials…’ the references supporting this statement are not all systematic reviews. The authors might want to consider citing some of the very recent systematic reviews that have been done in the area of ‘chest physiotherapy’ for patients during an acute exacerbation (there are plenty of them).

In the Discussion, in addition to the paper by Yohannes et al, the authors might want to cite the paper by Harth et al that examined practice patterns of physiotherapists who treat patients hospitalised with an acute exacerbation across Canada.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests