



Centre for Clinical Effectiveness

Enhancing patient outcomes through clinical application of the best available evidence

EVIDENCE CENTRE
CRITICAL APPRAISAL
Series 2002: Intervention

Outpatient multidisciplinary pulmonary rehabilitation program for patients with chronic respiratory conditions

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June 2002

SUMMARY STATEMENT

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Abdulwadud, OA. (2002). Outpatient multidisciplinary pulmonary rehabilitation program for patients with chronic respiratory conditions. (The Centre for Clinical Effectiveness), Available: <http://www.med.monash.edu.au/healthservices/cce>

[Accessed:Access date...]

Form Version - B.2002.01.15.1

REQUEST

Outpatient multidisciplinary pulmonary rehabilitation program for patients with chronic respiratory conditions.

REQUESTED BY

Barbara Walker, Director of Physiotherapy, Department of Physiotherapy, Clayton

METHODOLOGY

Search Strategy

The Centre for Clinical Effectiveness defines the 'best available evidence' as that research we can identify that is least susceptible to bias. We determine this according to pre-defined National Health and Medical Research Council (NHMRC, 2000) criteria (see Appendix 1).

First, we search for systematic reviews, evidence based clinical practice guidelines, health technology assessments and randomised controlled trials. If we identify sound, relevant material of this type, the search stops. Otherwise, our search strategy broadens to include studies that are more prone to bias, less generalisable or have other methodological difficulties. We include case-control and longitudinal cohort studies in our critical appraisal reports. While we cite observational and case series studies, and narrative reviews and consensus statements, in our reports we do not critically appraise them. Such studies can produce accurate results but they are generally too prone to bias to allow determination of their validity beyond their immediate setting.

Details of Evidence Request

Subjects/conditions:	Adult patients with chronic respiratory conditions
Intervention:	Outpatient multidisciplinary pulmonary rehabilitation program
Comparison:	Usual care (standard medical management)
Outcomes:	Readmission, length of stay, ED presentation, change in knowledge about disease, respiratory function, exercise endurance, quality of life, use of hospital services.

Search terms

(see Appendix 2 for exact search strategy)

Patients:	Obstructive Lung Diseases, COPD, COAD.
Intervention:	Patient care team, multidisciplinary
Other:	Rehabilitation

Resources Searched

We searched the following databases and Internet websites:

The Cochrane Library (CD-ROM) Issue 2, 2002
Medline (OVID) – 1966 to April week 1 2002
PreMedline (OVID) – April 24, 2002
CINAHL (OVID) – 1982 to March week 5 2002
Current contents (OVID) – 1993 week 27 to 2002 week 17
Australasian Medical Index – April 2002
Centre for Evidence based Physiotherapy (PEDro)

Refinements, Searching & Reporting Constraints

Our electronic searching was performed on the 30 April 2002. The search was restricted to adults and studies that evaluated multidisciplinary outpatient rehabilitation program. Our search was also restricted to high level studies (systematic reviews, meta-analyses, and randomised controlled trials) published in English in the last 3 years. Studies that evaluated the cost effectiveness of pulmonary rehabilitation program were excluded.

RESULTS

From our sources we identified 5 articles related to the request and was categorised as follows:

Table 1: Study designs of articles retrieved by search:

Study design	Number
Systematic reviews or meta-analyses	0
Evidence-based clinical guidelines	0
Randomised Controlled trials	5
Pseudo-randomised controlled trials	0
Level IV evidence	Excluded
Total	5

This left five randomised controlled trials for appraisal. Based on our refinements, searching and reporting constraints we are reasonably confident these articles represent the most relevant findings published to date.

EVIDENCE SUMMARIES

Format

Evidence summaries are presented as spreadsheets attached to this report. Each spreadsheet contains the article citation, details of the study design, patient description, scientific validity of the article, results, and pertinent remarks from the authors and Centre for Clinical Effectiveness reviewer.

REFERENCES

ARTICLES CRITICALLY APPRAISED FOR THIS REPORT

1. Green, R. H., S. J. Singh, et al. (2001). "A randomised controlled trial of four weeks versus seven weeks of pulmonary rehabilitation in chronic obstructive pulmonary disease." *Thorax* **56**(2): 143-5.
2. Griffiths, T. L., M. L. Burr, et al. (2000). "Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomised controlled trial" *Lancet* **355**(9201): 362-8.
3. Foglio, K., L. Bianchi, et al. (2001). "Is it really useful to repeat outpatient pulmonary rehabilitation programs in patients with chronic airway obstruction? A 2-year controlled study." *Chest* **119**(6): 1696-704.
4. Guell, R., P. Casan, et al. (2000). "Long-term effects of outpatient rehabilitation of COPD - A randomized trial." *Chest* **117**(4): 976-983.
5. Troosters, T., R. Gosselink, et al. (2000). "Short- and long-term effects of outpatient rehabilitation in patients with chronic obstructive pulmonary disease: A randomized trial." *American Journal of Medicine* **109**(3): 207-212.

APPENDIX 1

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Levels Of Evidence

Based on "How to use the evidence: assessment and application of scientific evidence" (National Health & Medical Research Council, Canberra, 2000):

Level I	Evidence obtained from a systematic review (or meta-analysis) of all relevant randomised controlled trials.
Level II	Evidence obtained from at least one randomised controlled trial.
Level III	-1 Evidence obtained from pseudo-randomised controlled trials (alternate allocation or some other method).
	-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies or interrupted time series with a control group.
	-3 Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group.
Level IV	Evidence obtained from case series, either post-test or pretest/post-test.

APPENDIX 2

Search strategy (Search terms for Medline database)

1. exp Lung Diseases, Obstructive/.
2. lung disease obstructive.tw.
3. (obstructive pulmonary or lung disease\$ or respiratory disease\$ or respiratory condition\$).tw
4. chronic.tw.
5. 3 and 4
6. exp Respiratory Tract Diseases/ or respiratory tract disease\$.mp.
7. Asthma.tw.
8. exp Bronchitis/
9. Bronchitis.tw.
10. exp Emphysema/
11. Emphysema.tw.
12. (COPD or COAD).tw.
13. exp Pulmonary Fibrosis/ or pulmonary fibrosis.mp.
14. 1 or 2 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15. exp Patient Care Team/
16. patient care team.tw.
17. team.tw.
18. (health care or healthcare or medical or multidisciplinary).tw.
19. 17 and 18
20. 15 or 16 or 19
21. exp Rehabilitation/
22. Rehabilitation.tw
23. 21 or 22
24. 20 and 23
25. 14 and 24
26. limit 25 to (human and English language and all adult <19 plus years> and yr=2000-2002)

\$ Wildcard indicating truncation

<p style="text-align: center;">Evidence Summary Therapy/Intervention</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Outpatient multidisciplinary pulmonary rehabilitation program for patients with chronic respiratory conditions</p> </div>	<p style="text-align: center;">Study 1</p> <p style="text-align: center;">Green, R. H., S. J. Singh, et al. (2001). A randomised controlled trial of four weeks versus seven weeks of pulmonary rehabilitation in chronic obstructive pulmonary disease. <i>Thorax</i> 56(2):143-5</p>	<p style="text-align: center;">Study 2</p> <p style="text-align: center;">Griffiths, T. L., M. L. Burr, et al. (2000). Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomised controlled trial. <i>Lancet</i> 355(9201):362-68.</p>
<p>STUDY DESIGN & NHMRC LEVELS OF EVIDENCE</p>	<p>Level II – Randomised controlled trial</p>	<p>Level II - Randomised controlled trial</p>
<p>DESCRIPTION: Patients (subjects), Intervention, Comparisons, Outcomes, Inclusion & Exclusion Criteria</p>	<p>Setting: United Kingdom Patients (subjects): Adult patients (n=44) with COPD Intervention: Twice weekly outpatient rehabilitation programme for 7-weeks (education, training exercises and practical demonstrations from a range of health care professionals). [n=21, mean (SD) age 68 (9.2) years, 61% men, FEV₁ 1.08 (0.4)] Comparison: Condensed 4-weeks programme [n=23, mean (SD) age 69(8.8) years, 67% men, FEV₁ 1.03(0.3)]</p> <p>Outcomes: Health status and exercise assessments using the Chronic Respiratory (CRQ) and Breathing Problems Questionnaires (BPQ), shuttle walking (SWT) and the treadmill endurance tests. Incl & Excl Criteria: Included patients (n=44) had COPD, FEV₁ <80%, ratio of FEV₁ to forced vital capacity (FVC) <70%, and consistent symptoms. The exclusion criteria weren't stated adequately or clearly.</p>	<p>Setting: United Kingdom Patients (subjects): Adult patients (n=200) with disabling chronic lung disease (84% with COPD). Intervention: Outpatient multidisciplinary rehabilitation programme (3 half days per week for 6 weeks of educational activities; exercise, individually tailed training programmes, and Treadmill training). [n=99, male 61, mean (SD) age 68.2 (8.2) years, smoking 43.5 (31.1) pack years]. Comparison: usual outpatient or primary care follow-up and were later offered the programme [n=101, male 59, mean (SD) age 68.3 (8.1) years, smoking 45.7 (21.9) pack years]. Outcomes: Health service use, walking tolerance & health status. Incl & Excl Criteria: Patients were included if their FEV₁, measured at a time of clinical stability, was less than 60% of predicted with less than 20% reversibility in response to inhaled - agonist. Those with additional, non-obstructive but disabling pulmonary disease, who matched the spirometric criteria, were not specifically excluded. Patients unable to walk, or had severe sensory or cognitive impairment or symptomatic ischaemic heart disease were excluded.</p>
<p>VALIDITY: Methodology, rigour, selection</p>	<p>Randomisation: using concealed envelopes. Blinding: Yes for the exercise tests (a technician was blinded) but not clear for the other outcomes. All patients accounted for: Yes Patients treated equally: Yes Similar groups: No, for shuttle walking test distance & in the CRQ domains of fatigue, emotion and mastery.</p>	<p>Randomisation: using sealed envelopes. Blinding: the technicians doing the walking and questionnaire testing were not aware of the randomisation. All patients accounted for: Yes Patients treated equally: Yes Similar groups: Yes</p>
<p>RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p>	<p>Participation: all patients in both groups completed the program (100% participation rate). Impact of the intervention: Compared to</p>	<p>Participation: Ten patients from the rehabilitation group didn't complete at least 12 of the 18 sessions. Of those who had rehabilitation, only 26 attended at least ten of the weekly patient-run exercise and social meetings. Admission: No difference between the two groups. The length of hospital stay by the rehabilitation group was significantly shorter</p>

	<p>the 4-week course, patients who completed the 7-week programme had greater improvements in all outcome measures.</p> <p>a) total CRQ score (mean difference (95% CI) of difference) -0.61(-0.15 to -1.08), p<0.05),</p> <p>b) CRQ domains of dyspnoea (-0.80 (95% CI -0.13 to -1.48), p<0.05)</p> <p>c) emotion (-0.89 (95% CI -0.33 to -1.45), p<0.005)</p> <p>d) mastery (-0.84 (95% CI -0.10 to -1.58), p<0.05).</p> <p>e) Improvements in exercise assessments: the differences was not statistical significant</p>	<p>than the control group [mean (SD) 10.4 (9.7) vs 21.0 (20.7), p=0.02).</p> <p>Use of primary care facility: The rehabilitation group had more primary-care consultations with the general practitioner than the control group [8.6 (6.8) vs 7.3 (8.3), p=0.033] but fewer primary-care home visits [1.5 (2.8) vs 2.8 (4.6), p=0.037]. The rehabilitation group also showed greater improvements in walking ability and in general and disease-specific health status than control group.</p>
<p>AUTHOR(S) CONCLUSIONS: Limitations, implications for practice and research</p>	<p>"A 7-week course of pulmonary rehabilitation provides greater benefits to patients than a 4-week course in terms of improvements in health status. Larger prospective studies are required to determine the optimal duration of a pulmonary rehabilitation programme."</p>	<p>"For patients chronically disabled by obstructive pulmonary disease, an intensive, multidisciplinary, outpatient programme of rehabilitation is an effective intervention, in the short term and the long term, that decreases use of health services."</p>
<p>OUR COMMENTS: Opportunity for bias, weakness and strength</p>	<p>Potential for bias: Unclear exclusion criteria and small study. Not sure if outcome assessors were all blinded.</p> <p>Weakness/es:</p> <ul style="list-style-type: none"> • Small sample size and didn't perform power calculation before the trial. • The composition of the multidisciplinary team was not clearly stated. <p>Strength/s:</p> <ul style="list-style-type: none"> • Clear research question • Randomised Controlled Trial • Obtained written informed consent • Study approved by ethics committee • To account for baseline differences between the two groups, analysis of covariance model was used. • The authors acknowledged that larger prospective studies are required. 	<p>Potential for bias: Analysis was performed with intention to treat.</p> <p>Strength/s:</p> <ul style="list-style-type: none"> • Randomised controlled trial • Clear research question • Study approved by ethics committee • Patients gave written informed consent • Stated randomisation method • Performed sample size calculation prior to the study • Stated the composition of the multidisciplinary rehabilitation programme (occupational therapy, physiotherapy, dietetic staff, a specialist respiratory nurse and a smoking-cessation counsellor) • All of the analyses were based on intention to treat.

<p style="text-align: center;">Evidence Summary Therapy/Intervention</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Outpatient multidisciplinary pulmonary rehabilitation program for patients with chronic respiratory conditions</p> </div>	<p style="text-align: center;">Study 3</p> <p>Foglio, K., L. Bianchi, et al. (2001). Is it really useful to repeat outpatient pulmonary rehabilitation programs in patients with chronic airway obstruction? A 2-year controlled study. Chest 119(6): 1696-704.</p>	<p style="text-align: center;">Study 4</p> <p>Guell, R., P. Casan, et al. (2000). Long-term effects of outpatient rehabilitation of COPD - A randomized trial. Chest 117(4): 976-983.</p>
<p>STUDY DESIGN & NHMRC LEVELS OF EVIDENCE</p>	<p>Level II – Randomized, controlled clinical study</p>	<p>Level II - a randomized controlled trial</p>
<p>DESCRIPTION: Patients (subjects), Intervention, Comparisons, Outcomes, Inclusion & Exclusion Criteria</p>	<p>Setting: Italy Patients (subjects): Adult patients (n=61) with stable Chronic Airway Obstruction (CAO) who completed an initial 8-week outpatient Pulmonary Rehabilitation Program (PRP1) before 1 year. A second PRP (PRP2) was completed by the first group (group 1) but not by the second group (group 2). One year later, a third PRP (PRP3) was performed by both groups Intervention: Group 1 (n=30) attended 8-weeks PRP (pharmacologic treatment, three sessions per week, of exercise; abdominal, upper-limb, and lower-limb muscle activities; patient & family education; nutritional programs & psychosocial counselling). Comparison: Group 2 (control n=31) Outcomes: Lung function, cycloergometry, walking test, dyspnea, and quality of life (HRQL) before and after PRP2, and before and after PRP3. Also recoded hospitalisations and exacerbations details. Incl & Excl Criteria: Those with stable CAO and free from exacerbations in the 4 weeks prior to entry into the study. Patients with other organ failure or cancer or unable to cooperate were excluded.</p>	<p>Setting: Spain Patients (subjects): Consecutive adult patients (n=60) with moderate to severe COPD (age 65±7 years; FEV1 35 ± 14%, men 100%;) Intervention: Three months of outpatient breathing retraining and chest physiotherapy, 3 months of daily supervised exercise, and 6 months of weekly supervised breathing exercises (n=30). Comparison: control group received standard care (n=30) Outcomes: Lung function, maximum voluntary ventilation, lung volumes, lung diffusing capacity, arterial blood gases, maximum respiratory pressures, exercise tests, heart rate, arterial oxygen saturation, dyspnea, fatigue, emotional function, mastery. Incl & Excl Criteria: stated but not in detail</p>
<p>VALIDITY: Methodology, rigour, selection</p>	<p>Randomisation: Yes. Blinding: Technicians were blinded to a patient's allocation to PRP2 or the control group. All patients accounted for: Yes, but there were dropouts from both groups Patients treated equally: Yes during PRP1 and PRP3. The PRP2 phase was only for the intervention group. Similar groups: Yes</p>	<p>Randomisation: Yes, but not concealed & method wasn't stated. Blinding: Supervisors and technicians who measured outcomes were blinded. All patients accounted for: All 60 patients completed 6 months of follow-up. Between the 6- and 9-month visits, 3 patients in the control group and 1 in the PR group withdrew from the program. Patients treated equally: Yes Similar groups: Yes</p>
<p>RESULTS: Generally favourable or unfavourable, specific</p>	<p>No significant change over time for airway obstruction in either group. After PRP2, exercise tolerance,</p>	<p>Significant differences between the two groups in perception of dyspnea (p<0.0001), in 6-min walking test distance (p<0.0001),</p>

<p>outcomes of interest, estimate of experimental effect and precision if appropriate</p>	<p>dyspnea, and HRQL improved in group 1. Nevertheless, 1 year later, group 1 patients didn't differ from group 2 patients in any outcome parameter, in comparison to before PRP1, only HRQL was still better in both groups 24 months after PRP1. Yearly hospitalizations & exacerbations per patient significantly decreased in both groups in the 2 years following PRP1, when compared to the 2 years prior. Nevertheless, at the 24-month follow-up visit, a further reduction in yearly exacerbations was observed only in group 1 but not in group 2 in comparison to what was observed at the 12-month follow-up visit. The PRP3 resulted in improvement in exercise tolerance in both groups</p>	<p>and in day-to-day dyspnea, fatigue, and emotional function ($p < 0.01$), The improvements were evident at the third month and continued with somewhat diminished magnitude in the second year of follow-up. The PR group experienced a significant ($p < 0.0001$) reduction in exacerbations, but not in the number of hospitalizations. The number of patients needed to treat to achieve significant benefit in health-related quality of life for a 2-year period was approximately three.</p>
<p>AUTHOR(S) CONCLUSIONS: Limitations, implications for practice and research</p>	<p>"In patients with CAO, an outpatient PRP can achieve benefits in HRQL and a decreased number of hospitalizations, which persist for a period of 2 years. Successive, yearly interventions lead to similar short-term gains but don't result in additive long-term physiologic benefits. Further reduction in yearly exacerbations seems to be the main benefit of an additional PRP."</p>	<p>"Outpatient rehabilitation programs can achieve worthwhile benefits that persist for a period of 2 years."</p>
<p>OUR COMMENTS: Opportunity for bias, weakness and strength</p>	<p>Potential for bias: Small study, high number of patients withdrew from the study. Weakness/es:</p> <ul style="list-style-type: none"> • Small sample size • Significant number of dropouts <p>Strength/s:</p> <ul style="list-style-type: none"> • A randomised controlled study • Patients gave informed consent • Study approved by ethics committee • Acknowledged the study limitations • Stated the composition of the multidisciplinary team 	<p>Potential for bias: small study, randomisation wasn't concealed and the method was not described. Weakness/es:</p> <ul style="list-style-type: none"> • Excluded patients with missing data from the analysis. • Didn't perform sample size calculation prior to the study <p>Strength/s:</p> <ul style="list-style-type: none"> • A randomised controlled study • Patients gave informed consent • Study approved by ethics committee • Acknowledged the limitations of their study.

<p style="text-align: center;">Evidence Summary Therapy/Intervention</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Outpatient multidisciplinary pulmonary rehabilitation program for patients with chronic respiratory conditions</p> </div>	<p>Study 5</p> <p>Troosters, T., R. Gosselink, et al. (2000). Short- and long-term effects of outpatient rehabilitation in patients with chronic obstructive pulmonary disease: A randomized trial. <i>American Journal of Medicine</i> 109(3): 207-212.</p>
<p>STUDY DESIGN & NHMRC LEVELS OF EVIDENCE</p>	<p style="text-align: center;">Level II – A randomized trial</p>
<p>DESCRIPTION: Patients (subjects), Intervention, Comparisons, Outcomes, Inclusion & Exclusion Criteria</p>	<p>Setting: Belgium Patients (subjects): Adult patients (n=100) with severe COPD, moderate peripheral and respiratory muscle weakness, impaired functional and maximal exercise capacity. Intervention: Training group-a 6-month outpatient rehabilitation program of exercise training (included cycling, walking, strength training) (n = 50). Comparison: Control group (usual medical care) (n = 50). Outcomes: pulmonary function, 6-minute walking distance, maximal exercise capacity, peripheral and respiratory muscle strength, quality of life, and cost-effectiveness of the program. Incl & Excl Criteria: Patients were included if they were less than 75 years of age, had FEV₁ less than 65% of the predicted value, and had stable clinical condition at inclusion, with no infection or COPD exacerbation in the previous 4 weeks. Patients with other severe medical problems (heart failure, myocardial infarction, cerebrovascular disease, cancer, or orthopedic disorders) were excluded.</p>
<p>VALIDITY: Methodology, rigour, selection</p>	<p>Randomisation: Using sealed envelopes Blinding: Unclear All patients accounted for: Yes, but there were 30 dropouts (refusal, deceased, etc.) Patients treated equally: yes Similar groups: Yes</p>
<p>RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p>	<p>Participation: In the training group 34 patients were evaluated after 6 months, and 26 patients after 18 months of follow-up. In the control group, 28 patients were evaluated at 6 months and 23 after 18 months. Patients in the training group participated in a mean of 46 ± 11 sessions (attendance rate 77% ± 19%). Impact of training: At 6 months, the training group showed improvement in 6-minute walking distance [mean difference (training - control) of 52 m; 95% CI, 15 to 89 m], maximal work load (12 W; 95% CI, 6 to 19 W), maximal oxygen uptake (0.26 liters/min; 95% CI, 0.07 to 0.45 liters/min), quadriceps force (18 Nm; 95% CI, 7 to 29 Nm), inspiratory muscle force (11 cm H₂O; 95% CI, 3 to 20 cm H₂O), and quality of life (14 points; 95% CI, 6 to 21 points; all P <0.05). At 18 months all these differences persisted (P <0.05), except for inspiratory muscle strength. For 6-minute walking distance and quality of life, the differences between the training group and controls at 18 months exceeded the minimal clinically important difference.</p>
<p>AUTHOR(S) CONCLUSIONS: Limitations, implications for practice and research</p>	<p>"Among patients who completed the 6-month program, outpatient training resulted in significant and clinically relevant changes in 6-minute walking distance, maximal exercise performance, peripheral and respiratory muscle strength, and quality of life. Most of these effects persisted 18 months after starting the program."</p>
<p>OUR COMMENTS: Opportunity for bias, weakness and strength</p>	<p>Potential for bias: patients drop out was 31% by 6 months, and 36% by 18 months. Not clear if outcome assessors were blinded. The sample size was also small. Weakness/es:</p>

	<ul style="list-style-type: none">• Small study and sample size calculation was not performed prior to the trial.• The composition of the multidisciplinary team was not fully described.• Although 100 patients were randomly assigned to receive either exercise training or usual care, only 70 patients participated in the training and control groups (33 in the control group and 37 in the training group).• The content of the intervention program wasn't comprehensive and focused on exercise training alone.• Authors did not acknowledge the limitations of their study. <p>Strength/s:</p> <ul style="list-style-type: none">• Randomised controlled trial• The local ethics committee approved the study.• Inclusion/exclusion criteria are stated
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EXPLANATION OF TERMINOLOGY USED IN SPREADSHEET

Level of evidence: A hierarchy of study evidence that indicates the degree to which bias has been eliminated in the study design.

Intervention: A therapeutic procedure such as treatment with a pharmaceutical agent, surgery, a dietary supplement, a dietary change or psychotherapy.

Randomisation: A process of allocating participants to treatment or control group within a controlled trial by using a random mechanism, such as coin toss, random number table or computer-generated random numbers. Study subjects have an equal chance of being allocated to an intervention or control group; thus, the two groups are comparable. Randomisation ensures that the results are not biased by the selection of particular types of patients to receive a specific therapy.

Blinding: Blinding or masking is a process used in epidemiological studies and clinical trials in which the observers and the subjects have no knowledge as to which treatment groups subjects are assigned. It is undertaken in order to minimise bias occurring in patient response and outcome measurement.

All patients accounted for: Once patients are randomly allocated to a specific group and withdraw before study conclusion, they have to be accounted for in order to ensure that patients withdrawing from the study are not significantly different from those continuing in the study. The final analysis should be conducted on an intention-to-treat basis, which includes the results of withdrawn patients in the analysis.

Patients treated equally: To be able to attribute any difference in the observed outcome to the intervention, study patients need to be treated equally in every way except for the intervention being evaluated.

Similar groups: Baseline characteristics of patients that are also likely to affect results should be evenly distributed between the intervention and control groups. Following proper randomisation, patients' attributes would be expected to be equally distributed between groups.

Validity:

Of measurement: an expression of the degree to which a measurement measures what it purports to measure; it includes construct and content validity.

Of study: the degree to which the inferences drawn from the study are warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn (internal and external validity, applicability, generalisability).

Potential for bias: Bias is a systematic deviation of a measurement from the 'true' value leading to either an over (or under) estimation of the treatment effect. Bias can originate from many different sources (including allocation of patients, measurement, interpretation, publication and review of data).