NKR10 Rehabilitering af KOL. Rehabilitation program with or without relatives

Characteristics of studies

Characteristics of included studies

Marques 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *COPD severity (GOLD/MRC scale)*: 67 (22.4) FEV1, % predicted ● *Male (%)*: 81.8 % ● *Age (range)*: 68.8 (7.3) age, year Intervention 2 ● *COPD severity (GOLD/MRC scale)*: ● *Male (%)*: ● *Age (range)*: Control ● *COPD severity (GOLD/MRC scale)*: 74.3 (21.7) FEV1, % predicted ● *Male (%)*: 50 % ● *Age (range)*: 65.9 (13.4) age, year Overall ● *COPD severity (GOLD/MRC scale)*: ● *Male (%)*: ● *Age (range)*: **Included criteria:** Patients were considered eligible for the study if they (1) were diagnosed with COPD according to the GOLD (Global Initia-tive for Chronic Obstructive Lung Disease) criteria; (2) had a family member 18 years old who provided physical and/or supportive care, without receiving any payment; and (3) were able to provide informed consent to participate in the study. **Excluded criteria:** Patients were excluded if they had exacerbations or hospital admissions 1 month prior to the study, severe neurologic/musculoskeletal conditions, and/or unstable cardiovascular disease. Dyads were excluded if one of them presented severe psychiatric conditions or inability to understand and cooperate or if one of them refused to participate. **Pretreatment:** There were no significant differences between com-pleters and dropouts regarding any of the sociodemo-graphic, clinical, or psychologic baseline characteristics.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Family-based pulmonary rehabilitation ● *Length (weeks)*: 12 weeks ● *Longest follow-up (after end of treatment)*: After end of treatment Intervention 2 ● *Description*: ● *Length (weeks)*: ● *Longest follow-up (after end of treatment)*: Control ● *Description*: Conventional pulmonary rehabilitation ● *Length (weeks)*: 12 weeks ● *Longest follow-up (after end of treatment)*: After end of treatment
Outcomes	*Quality of life, SD* ● **Outcome type**: ContinuousOutcome *ADL, SD* ● **Outcome type**: ContinuousOutcome *Dropout, n* ● **Outcome type**: DichotomousOutcome *Quality of life, SD (longest follow-up)* ● **Outcome type**: ContinuousOutcome *ADL, SD (longest follow-up)* ● **Outcome type**: ContinuousOutcome *Anxiety, SD (longest follow-up)* ● **Outcome type**: ContinuousOutcome *Depression, SD (longest follow-up)* ● **Outcome type**: ContinuousOutcome
Identification	**Sponsorship source:** Th is work was supported by Portuguese National Funds through FCT-Foundation for Science and Technology [Grant RIPD/CIF/109502/2009]. **Country:** Portugal

	Setting: three primary care centers **Comments:** ClinicalTrials.gov; No.: NCT02048306 **Authors name:** Alda Marques **Institution:** School of Health Sciences, University of Aveiro (ESSUA **Email:** amarques@ua.pt **Address:** School of Health Sciences, University of Aveiro (ESSUA), Agras do Crasto-Campus Universitário de Santiago, Edifício 30, 3810-193 Aveiro, Portugal
Notes	*Henriette Callesen* on 28/11/2017 01:15 **Outcomes** Quality of life: SGRQ total score after end of treatmentDropout: not directly estimated. Based on calculation of total adherence

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was performed by a computer-generated schedule in random blocks of three."
Allocation concealment (selection bias)	Low risk	Quote: "Th e allocation sequence was kept in sealed opaque envelopes by a researcher who was not involved in data collection."
Blinding of participants and personnel (performance bias)	Unclear risk	Quote: "Participants were only told that they were entering a PR program that involved the family and that, depend- ing on group allocation, the involvement of the family member would diff er." Judgement Comment: Unclear if personnel was blinded
Blinding of outcome assessment (detection bias)	High risk	Quote: "disease impacted on the out- come. It was also not possible to blind the outcome assessor, which could have influenced the results. Finally, long-term follow-up was not" Quote: "Th is was a single-blinded, randomized controlled trial." Judgement Comment: This was single-blinded. In the study it is mentioned that only participants were blinded.
Incomplete outcome data (attrition bias)	Low risk	No apparent other sources of bias
Selective reporting (reporting bias)	High risk	Judgement Comment: The protocol refers to outcome concerning depression and anxiety. Yet this is not reported in the study.Taken from the protocol:Secondary outcome measures:Change in psychological well-being (depression, anxiety and stress) [Time Frame: Before, immediately after, 3 and 6 months after the intervention]Depression Anxiety Stress Scales are designed to measure the 3 related negative emotional states of depression, anxiety and stress. Higher scores indicate a worst psychological outcome.
Other bias	Low risk	No apparent other sources of bias

Footnotes

Characteristics of excluded studies

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

Summary of findings tables

Additional tables

References to studies

Included studies

Marques 2015

Marques, Alda; Jacome, Cristina; Cruz, Joana; Gabriel, Raquel; Brooks, Dina; Figueiredo, Daniela. Family-based psychosocial support and education as part of pulmonary rehabilitation in COPD: a randomized controlled trial. Chest 2015;147(3):662-72. [DOI: https://dx.doi.org/10.1378/chest.14-1488]

Excluded studies

Studies awaiting classification

Ongoing studies

Other references

Additional references

Other published versions of this review

Classification pending references

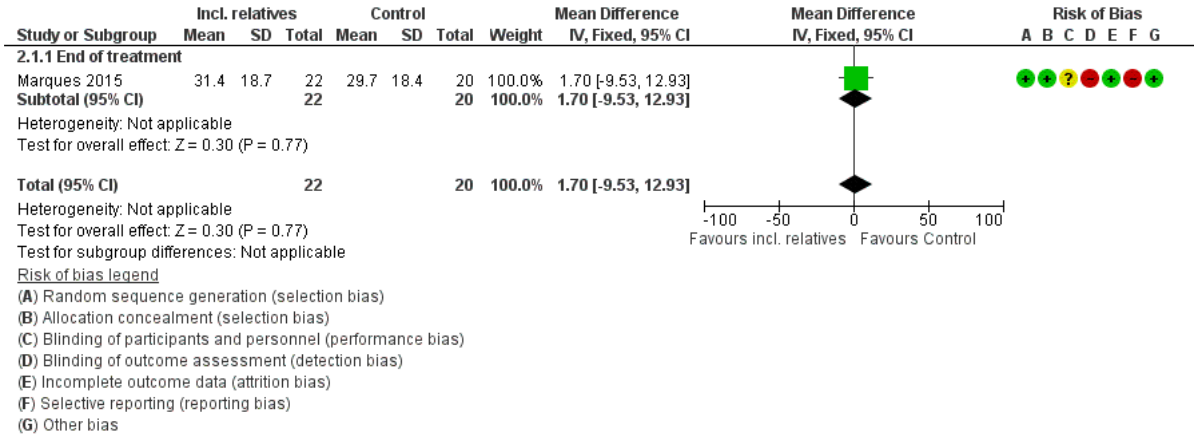
Data and analyses

2 Rehabilitation with relatives versus control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Quality of life, End of treatment	1	42	Mean Difference (IV, Fixed, 95% CI)	1.70 [-9.53, 12.93]
2.1.1 End of treatment	1	42	Mean Difference (IV, Fixed, 95% CI)	1.70 [-9.53, 12.93]
2.7 Dropout, End of treatment	1	56	Risk Ratio (IV, Fixed, 95% CI)	0.75 [0.30, 1.88]
2.7.1 End of treatment	1	56	Risk Ratio (IV, Fixed, 95% CI)	0.75 [0.30, 1.88]

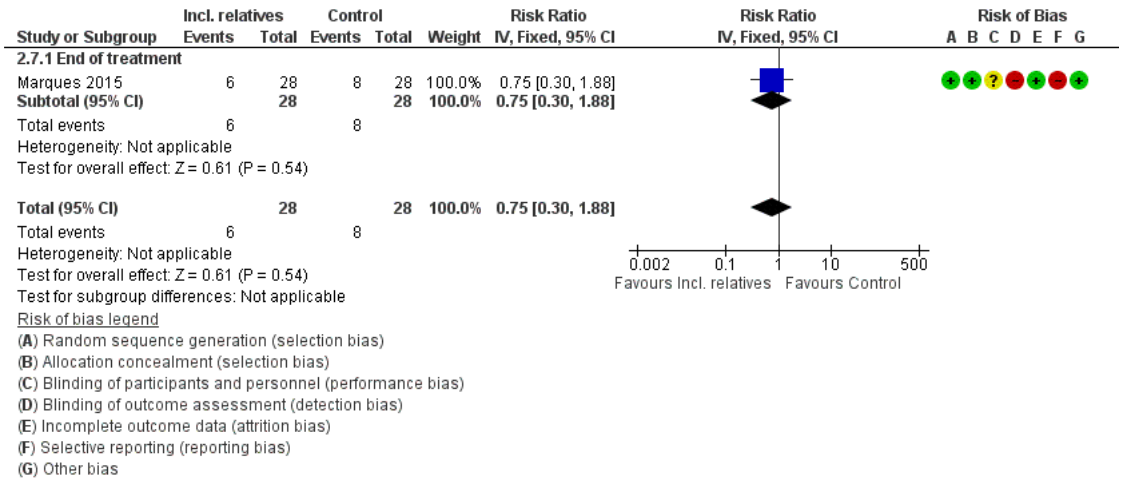
Figures

Figure 1 (Analysis 2.1)



Forest plot of comparison: 2 Rehabilitation with relatives versus control, outcome: 2.1 Quality of life, End of treatment.

Figure 2 (Analysis 2.7)



Forest plot of comparison: 2 Rehabilitation with relatives versus control, outcome: 2.7 Dropout, End of treatment.