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The efficacy and cost-effectiveness of confrontational counselling for smoking cessation in smokers with previously undiagnosed COPD: a randomised controlled trial

Submission date 28/04/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/04/2006	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 15/06/2010	**Condition category** Respiratory	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Daniel Kotz

Contact details
University Maastricht (UM)
CAPHRI Research Institute
Department of General Practice
P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 3882893
d.kotz@hag.unimaas.nl

Additional identifiers

Protocol serial number
NTR627

Study information

Scientific Title

Acronym
COSMO

Study objectives
Confrontation with the results from spirometry as part of counselling for smoking cessation in smokers with not earlier diagnosed mild to moderate COPD is effective with regard to prolonged abstinence from smoking during a period of 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tobacco addiction, chronic obstructive pulmonary disease (COPD)

Interventions
Intervention groups:
1. Confrontational counselling delivered by a pulmonary nurse and pharmacotherapy
2. Health education and promotion delivered by a pulmonary nurse and pharmacotherapy
3. 'Care as usual' delivered by the general practitioner

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome of this study is biochemically validated prolonged abstinence from smoking during a period of 12 months. A smoker is defined as prolonged abstinent if he/she is a non-smoker (no cigarette smoked during the preceding seven days), at the end of the

intervention (day 50), and at the follow-up visits after 6 months (day 197) and 12 months (day 380). Non-smoking is verified by urine cotinine. Participants with a cotinine-value of >50 ng/ml are regarded as smokers as well as participants who are lost to follow-up.

Key secondary outcome(s)
1. Point prevalence of non-smokers (no cigarette smoked during the preceding seven days) at the end of the intervention period and at 6- and 12-month follow-up
2. Self-reported number of quit attempts and temporary or complete relapse
3. Attitudes, social norms and self-efficacy with regard to smoking cessation
4. Lung function (FEV1 post-bronchodilatory and FEV1/FVC) at baseline and at 12-month follow-up
5. Anthropometry: physical height and weight at baseline, at the end of the intervention period and at 6- and 12-month follow-up
6. Perceived specific health-related complaints (impairments and functional disabilities in everyday life)
7. Health-related quality of life
8. Mental health (fear, depression)
9. Smoking related cognitions (risk perception, health concerns, self-exempting beliefs)
10. Number of unplanned visits to the general practitioner or specialized physician due to respiratory complaints and the number, severity and frequency of exacerbations (self-reported and/or reported by the general practitioner or specialist)

Completion date
01/02/2008

Eligibility

Key inclusion criteria
1. Age between 35 through 70 years
2. Smoker with a smoking history of >10 pack years of cigarettes
3. Motivated to stop smoking
4. One or more of the following symptoms are present: cough, progressive persistent shortness of breath (worse during exercise or respiratory infections) or sputum production
5. Bronchus obstruction detected by spirometry: FEV1/FVC-ratio <70% and postbronchodilatory FEV1 >50% predicted (= mild or moderate COPD/GOLD I or II)
6. Competent enough in speaking the Dutch language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Known by the general practitioner or in the second-line medical care with the diagnosis asthma or COPD (e.g. chronic bronchitis, lung emphysema)
2. Spirometry performed during the preceding 12 months
3. FEV1 <50% predicted (= severe or very severe COPD/GOLD III or IV)
4. Contraindications for the intake of the medication such as an acute myocardial infarction and hypersensitiveness for nortriptyline
5. Current use of antidepressants
6. Quit smoking attempt(s) using nortriptyline or bupropion during the preceding 6 months
7. Co-morbidity: hypersensitiveness towards nortriptyline, tuberculosis, porfyrine, epilepsy, Parkinson's disease, glaucoma, bronchial carcinoma or any other live threatening disease

Date of first enrolment
01/02/2004

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Maastricht (UM)
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation
University Maastricht (UM), CAPHRI Research Institute (The Netherlands)

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
University/education

Funder Name

University Hospital Maastricht (AZM) (Netherlands)

Funder Name
Partners in Care Solutions (PICASSO) (Netherlands)

Funder Name
Dutch Asthma Foundation (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2010		Yes	No