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SMOKE study: evaluation of the effectiveness of an intensive SmokeStopTherapy in an outpatient clinic setting for patients with chronic obstructive pulmonary disease

Submission date
12/09/2005

Recruitment status
No longer recruiting

Registration date
12/09/2005

Overall study status
Completed

Last Edited
03/07/2009

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR103; Dutch Asthma Foundation: 3.4.01.67.

Study information

Scientific Title

Study objectives
1. The SmokeStopTherapy (SST) is twice as effective than the minimal intervention strategy for lung patients (LMIS) 12 months after the start of the intervention based on validated continuous abstinence rates in patients with chronic obstructive pulmonary disease (COPD)
2. After one year the SST is more cost-effective than the LMIS
3. The secondary aim was to investigate the prospective determinants of smoking cessation in patients with COPD within the two separate smoking cessation programmes. Based on the ASE model, it was expected that Attitude, Social Support and Self-efficacy would be important predictors within both interventions.

Ethics approval required
Old ethics approval format

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

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
1. Control group: minimal intervention strategy for lung patients (LMIS) - the LMIS consists of individual counselling and telephone contacts which could be combined with pharmacological support at the patients own expense
2. Experimental group: SmokeStopTherapy (SST) - the SST consists of both individual and group

counselling, telephone contacts and bupropion free of charge. Additionally, patients can re-enter the individual sessions after they experienced a lapse within three months after the start of the intervention (recycling) to prevent a total relapse.

Other sponsor's for this trial are:
1. Medisch Spectrum Twente, P.O. Box 50000, 7500 KA, Enschede, The Netherlands
2. Slotervaart Hospital, P.O. Box 90440, 1006 BK, Amsterdam, The Netherlands
3. Catharina Hospital, P.O. Box 1350, 5602 ZA, Eindhoven, The Netherlands

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Biochemically validated (salivary cotinine) continuous abstinence rate (defined as validated abstinence at six months and twelve months after the start of the intervention)
2. Biochemically validated point prevalence abstinence rate at 12 months after the start of SmokeStopTherapy (point prevalence)

Secondary outcome measures
1. Quality of life, measured by the St. Georges's Respiratory Questionnaire
2. Lung function (FEV1, inspired vital capacity [IVC], FEV1/IVC, FEV1% predicted)
3. The frequency and severity of exacerbations. The following severity-scale will be used:
3.1. Mild exacerbation: increased use of pulmonary medication by more than two occasions within a 24 hour period on three or more consecutive days, compared to the stable situation
3.2. Moderately severe exacerbation:
3.2.1. Treatment with antibiotics and/or oral steroids
3.2.2. Evidence of a chest infection
3.2.3. An increase in symptoms and increased use of pulmonary medication by more than four occasions within a 24 hour period on three or more consecutive days, compared to the stable situation
3.3. Severe exacerbation: requirement of emergency hospital treatment/hospital admission
4. Disease-specific symptoms: breathlessness, coughing, sputum production and sputum colour. Symptom scores will be used to indicate the severity of the symptoms
5. Additional secondary data for economic evaluation (cost-effectiveness):
5.1. Number of visits at the outpatient clinic
5.2. Number of hospital-admissions and admission-days
5.3. Number of visits to the emergency room
5.4. Days lost of work
5.5. Medication costs (from pharmacy records)
5.6. Euroqol 5D

Overall study start date
15/02/2002

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Outpatients of Medisch Spectrum Twente (Enschede), Slotervaart hospital (Amsterdam), or Catharina hospital (Eindhoven)
2. Current smoker
3. Motivated to quit smoking
4. Aged 40 - 75 years (1961-1826)
5. Clinically treated COPD. Moderate COPD (% predicted forced expiratory volume in one second [FEV1] = 50 - 69) or severe COPD (% predicted FEV1 less than or equal to 50 as defined by the American Thoracic Society (ATS) criteria

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
234

Key exclusion criteria
1. Hypersensitivity for elements of Bupropion SR
2. (Past history of) serious psychiatric co-morbidity
3. Liver cirrhosis/alcoholism
4. (Past history of) epilepsy/fits
5. Tumour in the central nervous system
6. Quitting the use of alcohol and/or benzodiazepines during the course of the study
7. (Past history of) diabetes
8. Eating disorder(s)
9. Usage of monoamine oxidase inhibitors (MAO-inhibitors)
10. A serious other disease with a low survival rate
11. Not able to understand, read or write Dutch
12. Women who are pregnant, breastfeeding or intending to conceive during the course of the study
13. Participant of the COPE study in the Medisch Spectrum Twente

Date of first enrolment
15/02/2002

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Research Coordinator
Enschede
Netherlands
7500 KA

Sponsor information

Organisation
Netherlands Asthma Foundation (Netherlands)

Sponsor details
Speelkamp 28
Leusden
Netherlands
3831 PE

Sponsor type
Charity

ROR
https://ror.org/04gmab760

Funder(s)

Funder type
Industry

Funder Name
Comprehensive Cancer Centre (Netherlands)

Funder Name
GlaxoSmithKline (Netherlands)

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Stedendriehoek Twente (IKST) (Netherlands)

Funder Name
Netherlands Asthma Foundation (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/05/2007		Yes	No