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Effectiveness of intensive group and individual interventions against smoking in primary health care settings

Submission date
11/05/2009

Recruitment status
No longer recruiting

Registration date
17/06/2009

Overall study status
Completed

Last Edited
02/12/2010

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI03/1648

Study information

Scientific Title
Effectiveness of intensive group and individual interventions against smoking in primary health care settings: a three-arm individually randomised controlled trial

Study objectives
In primary health care settings, an intensive group intervention against smoking is more effective than an intensive individual intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Balearic Islands Ethical Board approved on the 26th February 2003 (ref: PI031648)
2. Mallorca Primary Health Care Research Board approved on the 27th February 2003 (ref: PI031648)

Study design
Three-arm individually randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Smoking

Interventions
The participants were randomly allocated to the following three arms:
Arm 1: Intensive group intervention
Arm 2: Intensive individual intervention
Arm 3: Usual minimal intervention

Intensive interventions (both group and individual):
Consisted of counselling, psychological support and standardised follow-up. Pharmacological treatment with nicotine derivatives or bupropion was also offered as an option at the physician's judgment.

Usual minimal intervention:
Brief counselling. Pharmacological treatment was also offered as an option at the physician's judgement.

The total duration of interventions was variable. In individual intensive intervention, the protocol recommended 20 minutes for the first visit and 10 minutes for the following. In group intensive intervention, the protocol recommended around 1 hour for all visits. In practice, more time was devoted, especially in group intervention. In usual minimal intervention, no recommendations were given.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Continued abstinence at 12 months confirmed through CO-oximetry

Secondary outcome measures
1. Self-reported continued abstinence at 12 months
2. Point abstinence at 12 months confirmed through CO-oximetry
3. Point self-reported abstinence at 12 months

Overall study start date
01/01/2004

Completion date
01/01/2006

Eligibility

Key inclusion criteria
People (both male and female) who smoked and who were in the preparatory phase in accordance with Prochaska's and Di Clemente's transtheoretical model of health behaviour.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
597

Key exclusion criteria

1. Individuals less than 18 years of age
2. Terminal ilness
3. Certain mental health conditions (dementia and schizophrenia)

Date of first enrolment
01/01/2004

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
Spain

Study participating centre
Conselleria de Salut i Consum
Palma
Spain
07003

Sponsor information

Organisation
Ministry of Health and Consumer Affairs (Spain)

Sponsor details
Instituto de Salud Carlos III
C/ Sinesio Delgado 6
Madrid.
Spain
28029

Sponsor type
Government

Website
http://www.isciii.es

ROR
https://ror.org/00y6q9n79

Funder(s)

Funder type
Government

Funder Name
Ministry of Health and Consumer Affairs (Spain) - Health Research Fund

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?
Protocol article		01/11/2005		Yes	No
Results article	results	23/02/2010		Yes	No