

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

Submission date
11/05/2009

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
17/06/2009

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
02/12/2010

Condition category
Mental and Behavioural Disorders

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Maria Ramos Monserrat

Contact details

Conselleria de Salut i Consum

C/ Cecili Metel 18

Palma

Spain

07003

+34 971176891

mramos@dgsanita.caib.es

Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

Three-arm individually randomised controlled trial

Study type(s)

Other

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(s)

Continued abstinence at 12 months confirmed through CO-oximetry

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Individuals less than 18 years of age
2. Terminal illness
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)

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

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	23/02/2010		Yes	No
Protocol article		01/11/2005		Yes	No