

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

<b>Submission date</b> 11/05/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/06/2009	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 02/12/2010	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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## 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 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)

**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?
<a href="#">Protocol article</a>		01/11/2005		Yes	No
<a href="#">Results article</a>	results	23/02/2010		Yes	No