

SPRINT Study: active and smoke-free women

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| Submission date 27/01/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 22/06/2010 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 08/05/2013 | Condition category 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

TOSC1

Study information

Scientific Title

Randomised controlled trial for evaluating a brief counselling intervention on physical activity and smoking cessation to smoking women undergoing to the National Health System Cervical Cancer Screening Program (NHS-CCS-Prog) in Tuscany (Florence area), Piedmont (Turin), Emilia-Romagna (Cesena), and Lombardy (Mantua) regions

Acronym

SPRINT Study

Study objectives

1. To verify whether the smoking cessation counselling intervention delivered to women randomly assigned to the "smoking" intervention arm, could increase the one-year cessation rate, in comparison to that recorded in women randomly assigned to the control arm
2. To verify whether the counselling interventions on smoking cessation and physical activity delivered to women randomly assigned to the "smoking and physical activity" intervention arm, could increase the one-year cessation rate, in comparison to that recorded in women randomly assigned to the control arm, or to the "smoking" intervention arm

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Local Health Authority of Florence, Italy, approved on the 5th May 2009

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Smoking cessation in adults (women)

Interventions

The smoking cessation intervention in the "smoking" and in the "smoking and physical activity" arms is tailored according to the DiClemente-Prochaska stage of change on smoking behaviour. The stage of motivational change of each participating woman is obtained from the study questionnaire that participants have to fill in while waiting for the Pap test. The counselling

intervention corresponds to the first two phases of the brief intervention for smoking cessation ("Ask" and "Advice"). It takes about 2 - 3 minutes.

The physical activity intervention in the "smoking and physical activity" arm is tailored according to the DiClemente-Prochaska stage of change regarding physical activity. The stage of motivational change of each participating woman is obtained from the study questionnaire, that participants have to fill in while waiting for the Pap test. The counselling on physical activity is a brief intervention, and takes about 4 - 5 minutes.

The smoking cessation and physical activity interventions are delivered by trained midwives during the Pap-test examination, that takes about 15 - 20 minutes per attending woman.

Participating women have also to fill in an informed consent attached to the study questionnaire they have to fill in while waiting for the Pap test.

A self-help booklet on physical activity and smoking cessation is provided to all participants to the study.

A telephone follow-up of all participants is scheduled after six months and one year from the intervention, in order to evaluate how many women quit smoking after the intervention.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Six-month smoking cessation rate

Secondary outcome measures

Stages of motivational change according to the DiClemente-Prochaska Transtheoretical Model of Change, measured before the interventions and after 6 months with a structured questionnaire delivered to participants to the study

Overall study start date

01/09/2009

Completion date

30/11/2011

Eligibility

Key inclusion criteria

1. Smoking women aged 25 - 64 years old
2. Attending the NHS-CCS-Prog Consulting Rooms located in Florence, Turin, Cesena, and Mantua areas

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

1,350 smoking women

Key exclusion criteria

1. Non-smoking and former smoking women aged 25 - 64 years old
2. Women aged less than 25 years old or more than 64

Date of first enrolment

01/09/2009

Date of final enrolment

30/11/2011

Locations**Countries of recruitment**

Italy

Study participating centre

Cancer Prevention and Research Institute

Florence

Italy

50135

Sponsor information**Organisation**

Ministry of Health, Rome (Italy)

Sponsor details

Viale Giorgio Ribotta 5

Rome

Italy

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m.distefano@sanita.it

Sponsor type

Government

Website

<http://www.ministerosalute.it/index.jsp>

ROR

<https://ror.org/00789fa95>

Funder(s)

Funder type

Government

Funder Name

Ministry of Health, Rome (Italy) - Lombardy Region

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 | 05/09/2012 | | Yes | No |