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SPRINT Study: active and smoke-free women

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/05/2013	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Screening

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(s)
Six-month smoking cessation rate

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

ROR
https://ror.org/00789fa95

Funder(s)

Funder type
Government

Funder Name
Ministry of Health, Rome (Italy) - Lombardy Region

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				

Results article	05/09/2012	Yes	No