

Evaluation of a nursing intervention for smoking cessation in cardiac patients: a pilot randomised study

Submission date 01/10/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/10/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/11/2022	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

GRIISIQ

Study information

Scientific Title

Preliminary evaluation of a nursing intervention to support smoking cessation in patients hospitalised for a cardiac problem: a pilot study [Évaluation préliminaire d'une intervention infirmière de soutien à la cessation tabagique chez des patients hospitalisés pour un problème cardiaque: une étude pilote]

Acronym

SO LIVE-1

Study objectives

It is hypothesised that patients in the intervention group will present a lower rate of smoking than the control group at six months post-randomisation. It is also hypothesised that patients in the intervention group will have a more important progression in the stages of change regarding their intention to quit smoking than the control group at six months post-randomisation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institut de Cardiologie de Montréal Ethics Committee gave approval on the 7th September 2007 (ref: 08-1012)

Study design

Pilot randomised controlled trial, single centre

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

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

Interventions

Eligible patients will be met by the research nurse during the hospitalisation and the research will be presented to them. Usual care will be provided to all patients during the hospitalisation

based on stages of changes and the motivational interview. The two groups will answer a questionnaire about the secondary outcomes and the baseline characteristics will be recorded. After being discharged from the hospital, the participants will be randomly assigned to the intervention or control group.

Intervention group:

After randomisation, the nurse will contact the patient by phone six times: one call per week for the first month (T2a, T2b, T2c, T2d), one call at the end of the second month (T2e) and the third month (T2f). During each of these contacts, the nurse will evaluate the stage of readiness to stop smoking and the conviction and confidence to stop smoking. Following the assessment, the nurse will intervene following a list of interventions specific to the stage where the patient belongs and depending on his conviction and confidence levels. The patient will be able to contact the nurse by phone from the third month until the sixth month after randomisation. Finally, motivational letters will be sent to the patient until six months post-randomisation to encourage and support the efforts of the patient.

Control group:

Usual care following discharge involved referring the control group patients as usual to external smoking cessation services. These services include follow up phone calls and interventions of social support, advices and pharmacological support. Patients are contacted by phone at different times after their discharge if they did refuse that service or if they were not referred at the time of discharge.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Smoking status (yes/no) at six months post-randomisation. This information will be provided by the patient himself. To validate this information the patient will be invited to have a nicotine detection test (saliva or urine).

Secondary outcome measures

Measured at baseline and six months following randomisation by phone and are as follows:

1. Progression in the stages of change. The stage of readiness to change will be evaluated by the nurse during the six contacts and at six months post-randomisation by the research assistant.
2. Patient's perception of control over the disease and of its consequences using three subscales of the Illness Perception Questionnaire - Revised (IPQ-R):
 - 2.1. Consequences (6 items)
 - 2.2. Personal control (6 items)
 - 2.3. Treatment control (5 items)
3. Patient's perception regarding the support received by a relative to increase perception of control to stop smoking using the Family Care Climate Questionnaire - Patient Version (FCCQ-P)
4. Cardiovascular risks factors used as a secondary outcomes are diet and physical exercise. To measure these two dimensions we will use two scales:
 - 4.1. Do you have a healthy heart?
 - 4.2. Are you eating healthily?

Overall study start date

02/09/2008

Completion date

30/09/2009

Eligibility

Key inclusion criteria

1. Male and female, aged greater than 18 years old or more
2. Daily smokers
3. Having the physical and cognitive capacities to fill out questionnaires and to communicate by telephone
4. Being able to communicate in French or in English

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

Total final enrolment

40

Key exclusion criteria

Currently participating in another smoking cessation therapies program

Date of first enrolment

02/09/2008

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

Canada

Study participating centre

R -1520, Montreal Heart Institute Research Center
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Sponsor information

Organisation

Montreal Heart Institute (Institut de cardiologie de Montréal) (Canada)

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Sponsor type

Research organisation

Website

<http://www.umontreal.ca/>

ROR

<https://ror.org/03vs03g62>

Funder(s)

Funder type

Research organisation

Funder Name

Groupe de recherche interuniversitaire en interventions en sciences infirmières du Québec (GRIISIQ) (Canada)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	pilot study	01/06/2011		Yes	No