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Tobacco treatment training network in Crete, Greece: TiTAN-Crete

Submission date
06/05/2015

Recruitment status
No longer recruiting

Registration date
01/06/2015

Overall study status
Completed

Last Edited
01/06/2015

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Stopping smoking can be very difficult for some people, and many people wanting to quit smoking might need a lot of advice and encouragement. Primary health care (PHC) providers, such as GPs, are one of the main points of contact for people wanting to quit smoking. GPs can help by providing advice ranging from available nicotine replacement therapies (gum, patches, e-cigarettes) to putting people in touch with group support programmes. The TiTAN Project is a programme dedicated to developing a PHC tobacco dependence treatment (TDT) network in Crete, Greece. TiTAN aims to provide PHCs with additional tools and training that they can use to help their patients successfully quit smoking. The aim of this study is to see how successful GP practices participating in the TiTAN programme are in helping their patients quit smoking, compared to GP practices providing standard stop-smoking advice. This study will also see how successful participating GP practices are at promoting the programme's values and providing patients with the best stop-smoking tools.

Who can participate?
Adult smokers attached to participating GP practices.

What does the study involve?
Participating GP practices are allocated into one of two groups. Those in group 1 (intervention group) are GP practices attached to the University of Crete research network. Group 1 GP practices adopt the TiTAN-Crete Global Bridges programme, and use their training to encourage and inform smokers attached to their practice about stopping smoking. A cross-section of smokers attached to group 1 GP practices is surveyed before the programme starts; a different cross-section of smokers is surveyed 2-4 months after the start of the programme. Those in group 2 (control group) are GP practices from the city of Rethymno, Crete. Group 2 GP practices provide smokers attached to their practices with standard treatment for stopping smoking. A cross-section of smokers attached to group 2 GP practices is surveyed before the programme starts. Surveys are completed by all participating GP practices at the start of the study, then again 4 months later.

What are the possible benefits and risks of participating?
There are no direct risks or benefits to participants.

Where is the study run from?
University of Crete - Clinic of Social and Family Medicine (Greece)

When is the study starting and how long is it expected to run for?
May 2015 to August 2016

Who is funding the study?
Global Bridges (USA)

Who is the main contact?
Prof C Lionis

Contact information

Type(s)
Scientific

Contact name
Professor Christos Lionis

Contact details
Clinic of Social and Family Medicine, Faculty of Medicine
Heraklion
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Global Bridges ID: 1352258

Study information

Scientific Title
Primary care tobacco treatment training network in Crete: a before and after study

Acronym
TiTAN-Crete

Study objectives
The intervention program will increase primary care providers':
1. Attitudes, beliefs, perceived behavioural control and intentions towards the delivery of evidence-based smoking cessation treatments compared to control practices

2. Rates at which they deliver evidence-based smoking cessation treatments to smokers compared to control practices

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics Scientific Committee, University Hospital of Heraklion, Greece, 27/04/2015, ref: 18078.

Study design
Two-arm pre-/post-cluster control group design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
The intervention program involves key opinion leaders, training, office support tools and coaching. The program has a core session which is followed up by 4 shorter booster sessions. Booster sessions are given over a 2-4 month period following the initial core session:
1. Core session content is composed of 2/3 theory and 1/3 practical (on the job). Core content includes: the burden of tobacco control in Greece, evidence-based tobacco treatment practices in primary care, first-line pharmacotherapies, behavioural counselling techniques for use in busy clinical settings, strategies for intervening with patients ready and not ready to quit smoking, special populations, setting up your practice for success, your role as clinician-advocate in tobacco control. Special emphasis will be placed upon training the primary health care (PHC) providers in overall tobacco control so that they develop the knowledge to act as policy advocates at a regional and national level. The program will employ teaching techniques such as role-play and case study approaches known to enhance up-take into practice.
2. Booster sessions are designed to reinforce the adoption of new practice behaviours and offer skill-based training, including case-based training focused on patients within a provider's own practice. Local faculty (opinion leaders) as well as international Global Bridges faculty will deliver program training and tailor its content to meet local needs. Participating clinicians will be provided with the necessary tools (tobacco use screener, provider consult form, patient self-help materials) to support their engagement of the program.

Intervention Type
Behavioural

Primary outcome measure
1. Program adoption: participation in TiTAN-Crete Global Bridges training program components and use of the Global Bridges Project Toolkit
2. Provider knowledge: knowledge of evidence-based tobacco treatment guidelines will be assessed using a brief 5-10 item knowledge assessment developed by project team
3. Theory of planned behavior constructs: attitudes, beliefs, control beliefs, subjective norms, normative beliefs, perceived behavioral control, intentions in next 6-months related to tobacco treatment delivery will be assessed using a pre-/post-intervention provider survey
4. Provider performance in the delivery of cessation treatments: performance in the delivery of each of the 3As ('ask, advise, assess') will be assessed via exit interview with eligible patients. The survey will ask participants to respond yes/no/don't know regarding whether their PHC provider asked them about their smoking status (ask), advised them to quit smoking (advise), assessed their readiness to quit (assess), provided assistance with quitting (assist), prescribed pharmacotherapy, provided self-help materials and arranged follow-up support (arrange).

Secondary outcome measures
PHC provider satisfaction with the program and sustainability of the program will be assessed by survey at the end of trial. Providers will be asked to report on the quality of global bridges training program, quality of in-practice support, quality support materials, feasibility of maintaining tobacco treatment delivery in 80% of patients, barriers, suggestions for improvement and suggestions for continued engagement of primary care practitioner network.

Overall study start date
01/11/2014

Completion date
30/08/2016

Eligibility

Key inclusion criteria
Inclusion criteria for general practitioners (GPs):
1. GPs from the practice-based research network at the University of Crete, Heraklion (intervention group)
2. GPs from the region Rethymno (control group)
Inclusion criteria for patients:
1. Current smoker (>5 cigarette/day on most days of the week)
2. 18 years and older
3. Scheduled for an annual exam or non-urgent medical appointment
4. Able to read and/or understand Greek
5. Has the mental capacity to provide informed consent and complete study protocols

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The total sample at the pre-assessment will be 864 (24 clinics x 36 patients/clinic). The patient sample at the post-assessment will be 504 patients (14 clinic x 36 patients/ clinic).

Key exclusion criteria
1. Participant does not have the mental capacity to complete study questionnaires
2. Participant is under the age of 18

Date of first enrolment
13/05/2015

Date of final enrolment
04/05/2016

Locations

Countries of recruitment
Greece

Study participating centre
University of Crete - Clinic of Social and Family Medicine
Faculty of Medicine
PO Box 2208
Heraklion
Greece
71003

Sponsor information

Organisation
Global Bridges

Sponsor details
Mayo Clinic
200 First Street
Rochester
United States of America
MN55905

Sponsor type
Research organisation

Website
http://www.globalbridges.org

Funder(s)

Funder type
Research organisation

Funder Name
Global Bridges (USA)

Results and Publications

Publication and dissemination plan
We intend to publish a descriptive paper on the characteristics of smokers identified in GPs offices at baseline as well as a main results paper of the pre-post assessment results. Results will also be submitted to international primary care and tobacco control conferences.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration