ISRCTN21998507 https://doi.org/10.1186/ISRCTN21998507

Optimizing delivery of health care interventions

Submission date
17/10/2012

Recruitment status
No longer recruiting

Registration date
17/10/2012

Overall study status
Completed

Last Edited
26/08/2016

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The European level of alcohol consumption, and the subsequent burden of disease, is high compared to the rest of the world. While screening and brief interventions in primary health care are cost-effective, in most countries they have been rarely used in routine primary health care. This study aims to examine the effectiveness and efficiency of three implementation strategies which target key barriers for improvement: training and support to address lack of knowledge and motivation in healthcare providers, financial reimbursement to compensate the time investment, and referral to an internet-based programme to reduce workload. This study will collect data from Catalan, English, Netherlands, Polish and Swedish primary health care units on screening and brief advice rates for hazardous and harmful alcohol consumption.

Who can participate?
A total of 120 primary health care units will be included, equally distributed over the five countries. In England 24 GP practices will be enrolled; 12 in northeast England and 12 in London. Eligible GP practices will have about 5,000-20,000 registered patients. Within each GP practice, eligible health care providers will include any fully trained medical practitioner, nurse or practice assistant with a non-temporary employment contract working in eligible GP practices, and involved in direct medical and/or preventive care. Each health care provider individually will decide whether to sign up for the study.

What does the study involve?
The three implementation strategies will be provided separately and in combination in a total of seven intervention groups and compared with a control group who will provide treatment as usual. Each GP practice will be randomly allocated to one of the eight groups by the European coordinating centre. The health care providers will record their screening and brief advice activities at baseline (4 weeks), throughout the implementation period (12 weeks), and throughout the follow-up period (4 weeks).

What are the possible benefits and risks of participating?
Direct benefits to some GP practices will be in the form of training, payments and/or an internet support package. Patients may indirectly benefit due to an increase in screening and brief advice and support. There are no risks highlighted in taking part in the study.

Where is the study run from?
Goeteborgs Universitet and Linkopings Universtet, Catalonia

When is study starting and how long is it expected to run for?
January 2013 to April 2014

Who is funding the study?
Seventh Framework Programme, European Commission

Who is the main contact?
Dr Kathryn Parkinson
Kathryn.Parkinson@ncl.ac.uk

Study website
http://odhinproject.eu/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12870

Study information

Scientific Title
Optimizing delivery of health care interventions (ODHIN)

Acronym
ODHIN

Study objectives
The optimizing delivery of health care interventions study (ODHIN) is a Europe-wide project that will help to optimize the delivery of health care interventions by understanding how better to translate the results of clinical research into every day practice. ODHIN will use hazardous and harmful alcohol consumption in primary health care as a case study investigating the implementation of identification and brief intervention programme. This is an ideal health issue to investigate implementation of interventions because there is strong evidence for the effectiveness and cost-effectiveness of brief interventions in reducing hazardous and harmful alcohol consumption, but they are not routinely delivered by primary health care providers.

The aim of work package 5 is to study the improvement rates of alcohol screening and brief intervention activities in a cluster randomised controlled factorial trial with five arms (Catalonia; England; the Netherlands; Poland; Sweden) and three time phases (baseline; 12 week implementation period; 4 week follow-up period after 6 months has elapsed from end of implementation period). It will test the impact in primary health care (training and support; financial reimbursement; referral to an internet-based brief intervention package [e-BI]; the former strategies singly or in combination) on screening and brief intervention rates for Hazardous and harmful alcohol consumption compared with practice receiving treatment as usual (i.e. control group).

The English arm of the study will be conducted by Newcastle University in northeast England, and by King's College London in London. The unit of randomisation will be GP practices, and the participants will be the health care providers working within the GP practices. The two primary outcome measures will be screening and brief advice rates for patients. The results will add to the knowledge of how best to integrate evidence-based health intervention into primary health settings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee: South West - Central Bristol, 13/09/2012 ref: 12/SC/0439

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format. The primary health care providers letter and information sheet can be requested from: Dr Kathryn Parkinson (Kathryn.Parkinson@ncl.ac.uk) or by telephone on +44 191 222 7400.

Health condition(s) or problem(s) studied
Primary Care Research Network for England: all Diseases

Interventions
GP practices will be randomised to one of 8 groups. All participating health professionals within each practice will be in the same group. Each will be given either training and support; financial reimbursement; referral to an internet-based brief intervention package [e-BI]; or a combination of the former strategies or none (i.e., control group).
Follow Up Length: 6 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Screening rates and brief advice rates mesaured at baseline and followed up after 4 weeks, 8 weeks, 12 weeks.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2012

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. GP practices will have an approximate size of 5,000-20,000 registered or listed patients. Eligible health care providers will include any fully trained medical practitioner, nurse or practice assistant with a non-temporary employment contract, working in the GP practice and involved in medical and/or preventive care.
2. Male and female participants
3. Aged 18 years and above

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 24

Key exclusion criteria
If practice is already participating in an alcohol-related research study

Date of first enrolment
01/11/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle University
Newcastle Upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle University (UK)

Sponsor details
Institute of Human Genetics
International Centre For Life
Central Parkway
Newcastle Upon Tyne
England
United Kingdom
NE1 3BZ

Sponsor type
University/education

Website
http://www.ncl.ac.uk/

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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?
Protocol article	protocol	24/01/2013		Yes	No

Results article	results	01/11/2016	Yes	No