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Exploratory trial of brief alcohol advice in dental surgeries

Submission date
04/10/2013

Recruitment status
No longer recruiting

Registration date
04/10/2013

Overall study status
Completed

Last Edited
26/11/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Alcohol misuse is an important public health problem in the UK. There are evidences about the how well brief alcohol interventions given in GP surgeries. No studies have however been conducted to find out how well these work in general dental practice. Excessive alcohol consumption is a major risk factor for oral cancer, injury and dental erosion. The majority of the UK adult population visits a dentist within a two year period. This provides a unique opportunity to give preventive advice to dental patients to promote both their oral and general health. Increasingly general dental practitioners ask their patients about their tobacco and alcohol habits but few dentists offer brief alcohol advice to patients who are drinking excessively. The aim of the study is to find out the acceptability and feasibility of giving a brief alcohol intervention.

Who can participate?
Any adult patient with a positive alcohol screening result attending the participating dental practice can participate in the study.

What does the study involve?
Participating dental practices will be randomly allocated to one of two groups: control and intervention practices. In control practices participants will be given an oral cancer prevention leaflet about reducing alcohol intake and stopping smoking. Participants attending the intervention practices will be given up to five minutes of brief advice about alcohol consumption. All participants will be contacted through telephone after 6 months. At the end of the study all participants will be sent a summary of the study results and an information leaflet on responsible alcohol consumption.

What are the possible benefits and risks of participating?
Participants in the intervention group will potentially benefit through changing their alcohol consumption pattern. Those attending the other dental surgeries will still receive standard advice and support from dental teams and at the end of the study they will also receive the brief advice. No additional appointments will be required for the study. All participants will be sent by post a £10 gift token after they complete the 6 month follow up phone call. In this study the intervention is non-invasive in nature but alcohol is a sensitive issue. Carefully designed

procedures and policies will be developed to minimise participants' potential feelings of guilt or pressure and their time involvement.

Where is the study run from?
The study is being conducted in the general dental practices across North Central London, UK.

When is the study starting and how long is it expected to run for?
August 2013 to February 2016.

Who is funding the study?
National Institute for Health Research (NIHR), UK.

Who is the main contact?
Professor Richard Watt: r.watt@ucl.ac.uk
Ms Antiopi Ntouva: a.ntouva@ucla.c.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15167; PBPG021227029

Study information

Scientific Title
An exploratory cluster randomized controlled trial of brief alcohol advice delivered in general dental practice

Acronym
DART (Dental Alcohol Reduction Trial)

Study objectives
We are hypothesizing that the brief advice intervention will be more effective at reducing alcohol consumption than the standard advice currently given at dental surgeries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Camden and Islington REC, 22/04/2013, Ref: 13/LO/0292

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Prevention

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
Alcohol consumption

Interventions
In the control practices participants who have a positive screening result will be initially given an oral cancer prevention leaflet which includes brief guidance on reducing alcohol intake and stopping smoking.

Participants attending the intervention practices who have a positive screening result will be given up to five minutes of simple structured brief advice using the Screening and Intervention Programme for Sensible drinking (SIPS) brief advice tool 'Brief advice about alcohol risk' which was based on the Simple Structured Advice intervention tool as part of the UK version of the WHO collaborative Drink Less brief intervention programme. To support and reinforce the advice, the Department of Health leaflet 'How much is too much?' will also be given.

Any participants in either the control or intervention groups who are identified as being alcohol dependent will be referred to local services for help.

After all the follow-up data has been collected, those participants attending the control practices who had a positive screening result will then also be offered the 5 minute brief advice and given a copy of the Department of Health alcohol leaflet.

Secondary sponsor:
Professor Richard G Watt

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Score on Extended AUDIT questionnaire cut off 8 or more as used in SIPS programme measured at baseline and 6 months

Secondary outcome measures
1. Mean weekly units of alcohol consumed during the previous 90 days using the Form 90
2. Average drinks (8 mg of pure ethanol) per day
3. Percentage days abstinent from work due to alcohol
4. Readiness to change measured by modified readiness to change ruler
5. Health related quality of life measure using EQ5D
All outcomes measured at baseline and 6 months

Overall study start date
12/08/2013

Completion date
12/02/2016

Eligibility

Key inclusion criteria
Any patient with a positive screening result on Fast Alcohol Screening Test (FAST), aged 18 years or above, attending dental practice and able to speak, read and write English sufficiently well to complete study questionnaires/interviews.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
248 - 200 for main intervention and 48 for the exploratory and process evaluation focus groups.

Key exclusion criteria
Patients already involved in any research study conducted in dental practice and those seeking help for alcohol dependence will be excluded

Date of first enrolment
12/08/2013

Date of final enrolment
12/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCL Department of Epidemiology and Public Health
London
United Kingdom
WC1E 7HB

Sponsor information

Organisation
Central and North West London NHS Foundation Trust (UK)

Sponsor details
Greater London House
Hampstead Road
London
England
United Kingdom
NW1 7QY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05drfg619

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Patient Benefit Programme; Ref: PBPG021227029

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	06/10/2015		Yes	No
Results article	results	01/02/2018		Yes	No
HRA research summary			28/06/2023	No	No