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Feasibility of alcohol screening and treatment in dental settings

Submission date
02/05/2013

Recruitment status
No longer recruiting

Registration date
12/07/2013

Overall study status
Completed

Last Edited
17/01/2017

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
The majority of dental healthcare professionals (dentists, dental nurses and dental hygienists) do not routinely intervene to reduce the alcohol use of patients with hazardous and harmful drinking habits. The new dental contract being tested in practices across England aims to focus the attention of dental professionals on health promotion. Since harmful alcohol consumption can lead to the development of several mouth diseases such as mouth cancer and mouth and face injury, educating dental patients about safe drinking is therefore relevant to the governments health priorities, as well as world-wide initiatives to promote health. The objective of this study therefore is to determine whether it is possible to introduce alcohol misuse screening and treatment in a general dental practice setting.

Who can participate?
All new and routine patients, male and female, aged 18-65 will be eligible to be screened for alcohol misuse and receive a treatment.

What does the study involve?
Patients will be randomly allocated to one of two groups: the control group, who will be treated as usual, and the intervention group, who will be screened for alcohol misuse and will receive advice from a dental healthcare professional. All patients will be contacted after three months to analyse the results.

What are the possible benefits and risks of participating?
The study has the potential to improve dental service. It may also reduce the prevalence of alcohol-related harm and disease in the population. Furthermore, the study could help reduce the burden of alcohol-related illness on dental hospitals. There are no elements in the study that can cause physical or psychological distress to the patients.

Where is the study run from?
The study will take place in Glynneath Dental Centre, Wales, UK.

When is the study starting and how long will it run for?
The study will start in October 2013 and, allowing time to train the members of staff at Glynneath Dental Centre and for the two-month recruitment period, will run for 6 months.

Who is funding the study?
The Royal College of Surgeons of England, UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 8.0 (protocol approved by REC and R&D)

Study information

Scientific Title
A study to explore the feasibility of alcohol misuse screening and treatment interventions in a general dental practice

Study objectives
1. To conduct an exploratory Randomised Controlled Trial (RCT) with embedded process evaluation that determines the feasibility and barriers to brief alcohol interventions in primary dental care.
2. To assess the acceptability of brief alcohol interventions by patients in primary dental care

3. To determine opportunities to collect informed consent and screen patients in the reception area/waiting room environment
4. To determine appropriate sample size estimates for a larger, definitive implementation RCT
5. To assess time constraints on hygienists and dentists in delivering brief interventions
6. To determine intervention fidelity and selection biases
7. To inform the design of a larger trial

On 12/11/2013 the scientific title was changed from 'A study to explore the feasibility of alcohol screening and treatment in a primary care general dental practice setting' to 'A study to explore the feasibility of alcohol misuse screening and treatment interventions in a general dental practice'.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not available at the time of registration.

Study design
A randomised controlled trial with an embedded parallel process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Alcohol misuse prevention

Interventions
Current interventions as of 12/11/2013:
Patients will be sent an invite letter and an information sheet by staff at Glynneath Dental Centre one month before the start of the study and their attendance at the practice in order to give them enough time to decide whether they would like to take part. The study period will then take place within the practice during the following two months.

Patients who decide to take part in the study will be stratified according to their initial appointment (with the dentist or hygienist). Reception staff will administer packs to patients containing a consent form, screening materials (Modified-Single Answer Screening Question or M-SASQ) and a short survey collecting socio-economic information, reasons for attendance and contact details. Packs will be randomly pre-allocated into control and intervention groups by strata and will be administered in opaque, sealed envelopes to conceal allocation from

receptionists. Patients will be asked to read and fill out the packs while in the waiting area of the dental practice.

All staff in the practice will be trained on the scoring system of the screening instrument Modified Single Alcohol Screening Question (M-SASQ). Consenting patients identified as having risky alcohol use from the M-SASQ and allocated to the intervention group will then be eligible to receive the intervention from the hygienist or dentist. Staff will be trained in collaboration with Public Health Wales and the Knowledge Transfer Partnership that is currently implementing MIs in maxillofacial clinics across Wales. To ensure competency in delivering the intervention all staff will be audio taped and assessed prior to the start of the trial. A standard intervention (MI) incorporating the FRAMES approach will be used. Patients allocated to the control group will be treated as usual.

Replicating Screening and Intervention Programme for Sensible drinking (SIPS) trial methodology , patients in control and intervention groups will be followed-up at three months by their preferred means of contact.

Previous interventions:
Reception staff will administer packs to patients containing an invitation letter, screening materials (M-SASQ), study information sheets, a consent form and a short survey collecting socio-economic information, reasons for attendance and contact details. Patients will be asked to read and fill out the packs while in the waiting area.

The packs given to patients will be randomly pre-allocated into control and intervention groups by strata and will be administered in sealed envelopes to conceal allocation from receptionists. All staff in the practice will be trained on the scoring system of the screening instrument Modified Single Alcohol Screening Question (M-SASQ). Consenting patients identified as having risky alcohol use from the M-SASQ and allocated to the intervention group will then be eligible to receive the intervention from the hygienist or dentist. Staff will be trained in collaboration with Public Health Wales and the Knowledge Transfer Partnership that is currently implementing MIs in maxillofacial clinics across Wales. To ensure competency in delivering the intervention all staff will be audio taped and assessed prior to the start of the trial. A standard intervention (MI) incorporating the FRAMES approach will be used. Patients allocated to the control group will be treated as usual.

Replicating Screening and Intervention Programme for Sensible drinking (SIPS) trial methodology , patients in control and intervention groups will be followed-up at three months by their preferred means of contact and with standard safeguards to maximise compliance (details of a collateral individual will be noted).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
A short, valid screening tool, such as the Modified-Single Alcohol Screening Question (M-SASQ) used in identifying patients with risky alcohol consumption

Secondary outcome measures

Additional data will be collected to address secondary outcomes, including drinking and health status (EQ-5D). Patients will also be asked at three months whether they recall receiving a treatment intervention and what this comprised. A process evaluation will therefore be carried out to determine whether this framework of design is feasible to address the research studys objectives. It will also help identify recruitment biases by practitioner, whether interventions were delivered as instructed, whether there was enough time for patients to complete written material tasks, whether the process of randomisation and recruitment worked and whether trial attrition is related to alcohol use. Professionals will be asked to feed back at three months how they felt the screening and treatment intervention fitted into practice routine.

Overall study start date
01/10/2013

Completion date
01/04/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/11/2013:
All new and routine patients aged 18-65, male and female and able to read and understand English will be asked to take part in the sudy. Reception staff will identify those patients who fit within the inclusion criteria. Patients will also be identified and stratified according to their appointment with either a dentist or hygienist.

Previous inclusion criteria:
All new, routine and emergency patients, aged 18-65, male and female and able to read and understand English will be asked to take part in the study. Reception staff will identify those patients who fit within the inclusion criteria. Patients will also be identified and stratified according to their appointment with either a dentist or hygienist.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
800

Key exclusion criteria

Participants under the age of 18 years old will not be eligible to participate. Resources are not available for translators and interpreters and so participants who do not speak or cannot understand English and who have learning difficulties will not be invited to participate. There will also be no translators and interpreters for solely Welsh speakers. Participants who cannot provide written informed consent will also not be recruited.

Date of first enrolment
01/10/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff School of Dentistry
Cardiff
United Kingdom
CF14 4XY

Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Other

Funder Name
Faculty of Dental Surgery, Royal College of Surgeons (FDS Research fellowship) (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

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?
Results article	results	26/02/2015		Yes	No