ISRCTN11636488 https://doi.org/10.1186/ISRCTN11636488

Dentistry Responding In Domestic Violence and Abuse (DRIDVA)

Submission date
17/09/2018

Recruitment status
No longer recruiting

Registration date
18/09/2018

Overall study status
Completed

Last Edited
06/11/2023

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Background and study aims
Domestic violence and abuse (DVA) is a global clinical and public health problem, and healthcare professionals are in a good position to help victims and survivors. However, available research shows that dentists and dental care professionals are not actively supporting their patients who present with injuries that might have resulted from DVA. This research will assess the feasibility of delivering an intervention (the Identification and Referral to Improve Support [IRIS]) to improve how dentists and dental care professionals respond to adult patients presenting with injuries that might have resulted from domestic violence and abuse.
The IRIS care pathway has been used extensively within general medical practices (GMPs) to identify and support female patients experiencing DVA, and has been shown to improve identification and referral of victims and survivors to appropriate specialist agencies. It has also been shown to be cost effective. However, this care pathway has never been used within dental practices (GDPs). IRIS cannot be translated for use within GDPs dues to significant differences between GDPs and GMPs. We therefore need to assess the feasibility of the IRIS care pathway in dentistry. This research has two main aims:
1. To assess the feasibility of using the IRIS intervention in general dental practices
2. To explore the feasibility of a trial design to evaluate IRIS in dental practices.
First we will ask dental teams, people who have experienced DVA and those working with them how we can adapt the IRIS pathway to dental practices. Next, we will train dental staff to use the adapted IRIS pathways and then ask all relevant stakeholders about its feasibility and the trial design in dental practice. These are necessary steps towards a definitive trial to determine whether the IRIS care pathway is effective in supporting adult victims of DVA using general dental practices.

Who can participate?
Dental team members from general dental practices within the Manchester region

What does the study involve?
Involvement in the DRiDVA feasibility study will involve either treatment as usual (control arm) or undertaking a training session (intervention arm) on DVA and how to support victims of DVA presenting at dental practices. The training will be led by a dentist working with the project and an advocate educator from Manchester Women's Aid.

We will also ask both control and intervention groups for feedback on your experience of DVA in dentistry and how to access support services. The DRiDVA training should take about three hours and will be conducted in a group session with your participating colleagues.
We will assess the number of patients who have been successfully identified and encouraged to seek DVA support. We will ask each practice to provide basic details on each referral so we can monitor the success of the intervention (or treatment as usual) over a period of about 9 months.
We will also ask you to participate in short qualitative study about the training in the months after the training sessions to assess whether it was useful and where it could be improved, or your understanding of DVA identification and referral if you have not received the training. These may be individual interviews or part of a small focus group. We would like to audio-record the interviews and focus group sessions to aid verbatim transcription.

What are the possible benefits and risks of participating?
There are service costs that will be given to participating dental practices attending the training and for extra time spent identifying and supporting victims of DVA. As an additional benefit, all participants will receive CPD credit for participation, which will count toward professional career development. However, there is a potential inconvenience to study participants as a result of discussing DVA with patients

Where is the study run from?
The University of Manchester and 6 general dental practices within the Manchester region (UK)

When is the study starting and how long is it expected to run for?
September 2017 to September 2019

Who is funding the study?
NIHR Central Commissioning Facility (CCF) (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38426

Study information

Scientific Title
Dentistry Responding In Domestic Violence and Abuse (DRIDVA): feasibility study for a cluster randomised trial of a practice-based Intervention

Study objectives
1. To assess the feasibility of using the IRIS intervention in general dental practices
2. To explore the feasibility of a trial design to evaluate IRIS in dental practices

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Manchester Research Ethics Committee 2, 01/06/2018, 2018-4254-6223

Study design
Randomised; Both; Design type: Screening, Prevention, Process of Care, Psychological & Behavioural, Complex Intervention, Management of Care, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Specialty: Oral and Dental Health, Primary sub-specialty: Oral and dental public health; Health Category: Injuries and accidents; Disease/Condition: Injuries to the head

Interventions
We will identify general dental practices through Greater Manchester Dental Professional Network. The study will randomly allocate dental practices to either the usual practice arm or the intervention arm. Stratification of general dental practices will be done by characteristics such as number of dental care professionals and support staff, and location of the dental practice to account for practice size and the socio-economic status of the patient base as the incidence of domestic violence is higher among low-income groups.
The intervention will involve implementing the different components of the IRIS care pathway by training staff in general dental practices, installing software in the electronic medical system of the dental practice, and a link to a designated advocate-educator from the collaborating agency (e.g. Manchester Women's Aid). The IRIS care pathway uses an adult learning model framework in facilitating appropriate support for victims and survivors of DVA and referral to specialist DV services. It has three main components:
1. Practice level training for clinicians and support staff
2. Installation of software in the practice database to prompt enquiring and recording of DVA information
3. Referral to an advocate-educator who will support victims to contact appropriate domestic violence and abuse services.
We will implement all three components: training general dental practices using the adapted IRIS intervention over 5-months, with follow up for a further 9-month period. The practice-level training will be delivered by members of the national IRIS implementation team, and will be conducted in the general dental practices.
We intend to carry out some development work over a 6 month period, to ensure we have stakeholder's involvement in the research. Through our extensive Public and Patient Involvement (PPI) work, we have established some links with staff from domestic violence agencies (Manchester Women's Aid, Saheli), Public Health England, staff from Manchester City Council, Safeguarding Team at Central Manchester Foundation Trust (CMFT), and survivors of

domestic violence and abuse. During the development phase of this proposed study, we would strengthen these links, and further develop collaborations that will enhance public, patients /service user, and practitioners' involvement in the research. We will use arts-in-health methodologies to creatively facilitate this development phase. These stakeholder consultations will not be carried out under ethics as they are designed to inform the training pack for the education of dental teams in DVA and referral.
We will recruit and train general dental practices over a 9-month period, and have follow up for a further 9-month period. The practice-level training will be delivered by members of the DRiDVA study and the Manchester IRIS teams, and will be conducted in the general dental practices. During the follow up period, researchers will collect data from the electronic medical records of general dental practices in the intervention arms at 3 months and 9 months after the training sessions on the identification, recording and referral of adult patients. Researchers will also collect data from the dental practices in the usual practice arm 12 month after recruitment to the trial.
Researchers will collect data on the usability of IRIS with respect to completeness of data in the general dental practice electronic records and referral to a named advocate-educator. Data will also be collected from the collaborating agency on referral and advocacy contact. This will help to estimate the sample size required to adequately power the definitive trial, and establish the suitability of the primary and secondary outcome measures for the definitive trial

Intervention Type
Other

Primary outcome measure
Number of referrals to the collaborating DVA agency (Manchester Women's Aid) for 9 months after training of intervention practices. An adult patient is counted as a referral if the GDP records referral information.

Secondary outcome measures
Disclosure rate for 9 months following the training sessions within practices in the intervention arm. Cumulative and monthly (to assess season variation) identification, referral and advocacy contact figures will be calculated, along with loss to follow up. Descriptive analyses will be undertaken to summarise the total number of adult patient presenting with injuries from DVA identified and referred to the collaborating agency. Simple descriptive statistics involving calculation of ranges, frequency distributions and measures of central tendency and dispersion will be used to assess the completeness and variability of outcome measures.

Overall study start date
04/09/2017

Completion date
03/09/2019

Eligibility

Key inclusion criteria
Dental practices are the unit of analysis for this study. Staff members must include dentists, dental nurses, hygienists and practice managers. Participants must be aged 18 years and older.

Participant type(s)
Other

Age group
Other

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Planned Sample Size: 6; UK Sample Size: 6

Key exclusion criteria
1. Dental surgeries that do not have suitable data handling practices (such as IT systems SoE or Kodak) to refer from and gather study data. Data can be gathered manually as date from referred patients is limited, but IT recording of the referral would be preferable. The study aims to explore whether IT integration is feasible as a future direction
2. Failure of staff and clinicians to participate in the DRiDVA training prior to study commencement

Date of first enrolment
01/06/2018

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Vallance Dental Centre
Brunswick Street
Manchester
United Kingdom
M13 9UJ

Study participating centre
SimplyOne Dental
The Precinct
36 Queens Walk

Droylsden
United Kingdom
M43 7AD

Study participating centre
Dentology
563 Barlow Moor Road
Chorlton
Manchester
United Kingdom
M21 8AE

Study participating centre
Allan Dental Practice
60 Stamford Street East
Ashton under Lyne
United Kingdom
OL6 6QH

Study participating centre
The Lodge
6 North Road
Clayton
Manchester
United Kingdom
M11 4WE

Study participating centre
Calm Dental Care
132C Flixton Road
Urmston
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United Kingdom
M41 5BG

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0416-20015

Results and Publications

Publication and dissemination plan
We anticipate that the outcomes of the study will be published in a peer-review journal.

Intention to publish date
05/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the principal investigator, Prof Paul Coulthard, subject all legal restrictions and ethical regulations as stipulated by the sponsor.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Qualitative evaluation	12/07/2023	06/11/2023	Yes	No
Results article		09/12/2022	06/11/2023	Yes	No