ISRCTN15294714 https://doi.org/10.1186/ISRCTN15294714

A study to determine the effectiveness of a tailor-made prevention programme (as part of Minimally Invasive Dentistry approach) for individuals with dental phobia (high levels of dental anxiety) compared to usual care

Submission date
30/01/2018

Recruitment status
No longer recruiting

Registration date
02/05/2018

Overall study status
Completed

Last Edited
15/09/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims:
The number of people who report dental anxiety in the general population has been constant over the past decade. It varies from 5% to 22% of the population depending on how dental anxiety has been defined and measured. Dental anxiety has for the first time been measured / recorded in the latest Adult Dental Health Survey in the United Kingdom (ADHS, 2009). In ADHS (2009), 11.6% of the adult population in England, Wales and Northern Ireland had dental phobia (high dental anxiety that will have an impact on their quality of life) when it was measured using Modified Dental Anxiety Scale (MDAS).

Some people with high dental anxiety will have dental treatment with aid of pharmacological intervention (e.g. conscious sedation to make them relax) however in order to address their phobia non pharmacological intervention such as Cognitive Behavioural Therapy (CBT) is recommended. The department of Sedation & Special Care (SSCD) at Guy's & St Thomas NHS Trust is a major National provider of sedation services which also offers CBT services for people with dental phobia.
People with dental phobia suffer both short (pain) and long term problems (difficulty in eating) that arise from the common dental diseases (dental decay [caries] and gum disease) and treatment that is needed to improve their oral health. They present with active caries which indicates high risk of developing decay.
In advance stages of dental diseases, dental care (treatments such as extractions) are often needed. Tooth loss might have an effect on people's quality of life. Currently, there is not enough evidence to show how different types of dental treatments will affect patients' quality of life and wellbeing when they have dental phobia.

In order to address this group's high dental needs, a tailor-made prevention programme would be beneficial. Minimal Invasive Dentistry (MID) is where dentists try to preserve as much of

dental tissues as it is possible (less tooth loss) and to provide preventive interventions such as high fluoride varnish.

In this study, there will be two participants groups: the control arm (who will have the usual dental treatment [TAU]) and participants in the intervention arm (who will have prevention and treatment according to MID principles). The MID preventive intervention will comprise of provision of oral hygiene instruction, diet advice and fluoride varnish. A complete course of dental treatment according to MID principle will also be provided by the researcher. Participants in the control arm will be offered the TAU provided by SSCD dental staff. Upon completion of dental care, their oral health outcome will be measured by the department's staff.

The aim of this study is: A feasibility trial of the effect of providing Minimally Invasive Dentistry (MID) to patients with a dental phobia, compared to treatment as usual, on oral health outcomes. The purpose of this study is to determine:
• Recruitment rates into this study (how many will say yes to be part of this study)
• Adherence to the intervention (will stick to the proposed dental care)
• Follow up rates (coming back to see dentists in the department again) within the trial (study)

Who can participate?
Both female and male adults (18 and over) who may have been identified as having a dental phobia and are about to start dental treatment (care) in the Sedation & Special Care Dentistry department.

What does the study involve?
At the dental care (treatment) planning session, the participants will be invited to complete part A of a study questionnaire. The questionnaires are of a standard type commonly used and there are no right or wrong answers. The part A of the questionnaire is about participants' demographic (e.g. education, age, etc.) information, dental phobia, general anxiety and depression. Depending on their scores, they will be given part B of the study questionnaire. This part is about oral health related behaviours and quality of life.

When the participants are eligible, they will be allocated randomly to one of the above mentioned two groups on a simple randomisation procedure. After care planning visit, dental treatment will start as normal (TAU) for control arm and MID approach for intervention group.

6 months after the participants' dental care has been completed, the researcher will invite them for a follow up appointment visit when they complete all part of the study questionnaire (Parts A, B and C) as well as having an oral health assessment.

What are the possible benefits and risks of participating?
There are no advantages or disadvantages of taking part. However, this treatment approach might improve our patients' experience of treatment and their quality of life long term.
If this would be the case, the information from this study will be used to improve the services we offer to our patients for our future patients.

Where is the study run from?
King's College London Dental Institute: Department of Sedation and Special Care Dentistry, Department of Conservative & MI Dentistry

When is the study starting and how long is it expected to run for?
It started in July 2017 and complete in May 2020.

Who is funding the study?
King’s College London

Who is the main contact?
Dr Ellie Heidari
Email: ellie.heidari@kcl.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Ellie Heidari

Contact details
KCL DI
Fl 26 SSCD
Guys' campus
Great Maze
London
United Kingdom
SE1 9RT

Type(s)
Scientific

Contact name
Prof Jonathon Timothy Newton

Contact details
SSCD Floor 26 Tower Wing
Great Maze Pond, London Bridge,
London
United Kingdom
SE1 9RT

Type(s)
Scientific

Contact name
Prof Avijit Banerjee

Contact details
Floor 26 Tower Wing
Great Maze Pond, London Bridge,
London
United Kingdom
SE1 9RT

Additional identifiers

Integrated Research Application System (IRAS)
223614

Protocol serial number
IRAS number: 223614

Study information

Scientific Title
A feasibility trial to determine the effectiveness of Minimally Invasive Dentistry (MID) treatment intervention for individuals with dental phobia compared to usual care

Acronym
MID VS TAU

Study objectives
Providing Minimally Invasive Dentistry (MID) to patients with a dental phobia will have a positive impact on their oral health and oral health related quality of life in comparison to dental treatment provided as usual (TAU).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service, 14/06/2017, 17/ES/0067

Study design
Single-centre feasibility trial and pilot study/randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Treatment of dental caries and periodontal disease in patients with dental phobia

Interventions
Step 1: Recruitment and treatment provision for patients who have dental anxiety/phobia
The researcher (EH) will approach potential patients after they have been accepted for a dental treatment at SSCD to invite them to participate to the study. Then the participants will book an appointment which will be a care (treatment) planning appointment.
At that appointment and once consent has been obtained:
1. Participants will have a clinical examination (oral health measures) by EH or a staff member in SSCD.
2. Patients will be screened for suitability. The screening questionnaires are Modified Dental Anxiety Score (MDAS) and Hospital Anxiety and Depression Scale (HADS) which are in the part A

of the study questionnaire.
Participant will only be accepted for the study if they have MDAS score of >= 19, they have a specific phobia of dental injections / invasive dental treatment and a HADS score are: A<10; D<10).

When eligible participants also complete the 'Section B of the study Questionnaire'. This part of the questionnaire has measures of oral health related behaviour and oral health related quality of life (OHIP 14). Additionally, EH allocates participants to treatment as usual (TAU) or intervention groups on the basis of an allocation sequence set by the trial statistician (MA). Participants will draw a number from a concealed envelope.

Minimally Invasive Dentistry (MID) involves preservation of dental tissue and prevention from dental diseases (caries and gum disease) (Ericson, 2003). MID has been defined (Ericson, 2003) as 'a concept that can embrace all aspects of the profession. The common delineator is tissue preservation, preferably by preventing disease from occurring and intercepting its progress, but also removing and replacing with as little tissue loss as possible'.
In this study the MID intervention will comprise the provision of oral hygiene instruction, diet advice and fluoride varnish as their preventive intervention and a complete course of dental treatment according to Minimal Invasive Dentistry principle (MID) by the researcher (EH). The prevention regime will be based on individual basis depending on people with dental phobia's risk behaviours (e.g. sugar intake and oral hygiene regime).
Patients would attend 'preventive oral health related' sessions to discuss how to they can improve their individual oral health. Participants in the standard care arm will be offered the usual treatment (TAU) provided by SSCD dental staff.
Upon completion of dental care, study participants' oral health outcome will be measured by the department's staff.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility, based on the following:
1. Number of eligible patients attending screening appointment
2. Proportion of eligible patients recruited
3. Dentist adherence to intervention (assessed by independent review of case notes). This would be once the patient's dental treatment has been completed.
4. Patient adherence with behaviour required by intervention (assessed by self report data from questionnaire based on Adult Dental Health Survey [ADHS]) at the follow-up appointment
5. Compliance, assessed by the proportion of participants who attend the follow-up appointment

Key secondary outcome(s))
1. Recruitment rates into this study (how many will say yes to be part of this study)
2. Adherence to the intervention (how many will stick to the proposed dental care)
3. Follow-up rates (coming back to the department again 6 months after completion of their dental treatment) within the trial (study)
4. Completion rates of outcome measures such as:
4.1. Oral health data (number of tooth surfaces that are healthy/diseased) assessed using DMFS (Decayed, Missing, Filled Tooth Surfaces) score calculated according to Adult Dental Health Survey (ADHS, 2009) protocol.
4.2. Gum disease after oral health assessment measured by plaque score and Basic Periodontal (gum) Examination [BPE]) according to Adult Dental Health Survey (ADHS, 2009) protocol.

4.3. Oral health related quality of life (Oral Health Related Quality of life measure by Oral Health Impact Profile (OHIP 14) questionnaire at baseline and follow-up
4.4. Oral health related behaviours (Part B of the questionnaire) at baseline and follow-up
4.5. Research participants' views of the care provided (Part C of the questionnaire: Adapted version of Treatment Evaluation Inventory (Patient) (Newton& Sturmey, 2004).
Patients will complete the questionnaire (Parts A, B and C) upon return to the dental unit (SSCD). This visit will be after the patient has completed their dental treatment at least 6 months previously.

Completion date
28/05/2020

Eligibility

Key inclusion criteria
1. Potential patients after they have been accepted for a dental treatment in the department of Sedation and Special Care Dentistry (SSCD) at Guy's and St Thomas' hospital
2. Adult patients (age 18 and over)
3. Gender: both (Male and female)
4. Have been screened and are suitable if score:
4.1. Modified Dental Anxiety Score (MDAS score >= 19), or
4.2. Specific phobia of dental injections / invasive dental treatment
4.3. There are no comorbid psychiatric conditions noted by Hospital Anxiety and Depression Score (HADS) questionnaire (HADS Anxiety < 10; HADS Depression < 10)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
44

Key exclusion criteria
The following patient groups:
1. Those not meeting the inclusion criteria
2. Individuals with learning difficulty
3. Individuals with difficulty in communicating
4. Individuals who are unable to give informed consent
5. Potential participants who cannot understand spoken English (Not being able to speak English

is not an exclusion criterion as many patients with dental phobia are not able to speak English and always have translators).
6. Individuals who cannot read and write English
The above individuals will be excluded as ability to communicate clearly is essential for this study.

Date of first enrolment
03/07/2017

Date of final enrolment
26/02/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London Dental Institute (KCL DI)
Department of Sedation and Special Care Dentistry (SSCD) at GSTT
KCL DI, Fl 26 Department of Sedation and Special Care Dentistry
Guys' Campus, Guy's Tower
Great Maze
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
Guy's & St Thomas' Foundation NHS Trust

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Access to the data can be requested from:
Mr. Michael Ring (R&D Governance Facilitator, non-commercial team)
NIHR GSTFT/KCL Biomedical Research Centre
16th floor, Tower Wing, Guy's Hospital
Great Maze Pond,
London
SE1 9RT

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2020	14/06/2021	Yes	No
Results article		31/07/2023	15/09/2023	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 2	14/06/2017	22/08/2022	No	No