

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/09/2023	Condition category Oral Health	<input type="checkbox"/> 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
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

223614

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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& Sturme, 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.

Overall study start date

10/01/2017

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40 people in total (20 in the control arm and 20 in the intention arm)

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**

England

United Kingdom

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

Sponsor details

Director of Research Management and Innovation, King's College London, Room 5.23, James Clerk Maxwell
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Sponsor type

University/education

Website

<http://www.kcl.ac.uk/index.aspx>

ROR

<https://ror.org/0220mzb33>

Organisation

Guy's & St Thomas' Foundation NHS Trust

Sponsor details

R&D Department 16th Floor, Tower Wing Great Maze pond
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United Kingdom
SE1 9RT

Sponsor type

Hospital/treatment centre

Funder(s)**Funder type**

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The trial results will possibly be presented in journals and as an internal report once we have completed the study and analysed the data.

1. Internal report: to improve the services for people with dental phobia within SSCD
2. Peer reviewed scientific journals and conference presentation: to inform peers about the study outcome
3. In the PhD thesis

Intention to publish date

05/05/2021

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

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IPD sharing plan summary

Available on request

Study outputs

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