Guy's and St Thomas' NHS
NHS Foundation Trust

PROTOCOL TITLE:

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

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11. Finance & Publication Policy

Study Synopsis

Title of clinical trial	**A feasibility trial to determine the effectiveness of Minimally Invasive Dentistry (MID) treatment intervention for individuals with dental phobia compared to usual care**
Protocol Short Title/Acronym	**Feasibility of MID in dental phobia**
Protocol version number: **Date:**	**V 2** **14 June 2017**
Study Phase if not mentioned in title	**III**
Is this study a pilot?	**No. This study is a feasibility trial.**
Study Duration:	**This will be from 27th May 2017 to 28th May 2020.** **The duration of the study remains for 3 years and 1 day.**
Methodology	**Type of study: a feasibility trial**
Sponsor name	**King's College London** **GSTT is a co-sponsor**
Chief Investigator	**Professor Tim Newton**
REC number	**17/ES/0067**
Medical condition or disease under investigation	**Dental phobia**
Purpose of clinical trial	**To determine:** **Recruitment rates into the trial** **Adherence to the intervention** **Follow up rates within the trial** **Completion rates of outcome measures**
Primary objective	**To determine:** **Proportion of patients eligible for recruitment** **Proportion of eligible patients actually recruited to trial** **Dentist adherence to intervention** **Patient adherence with behaviour required by intervention** **Proportion of participants captured at follow up** **Estimates of means and standard deviations for outcome measures**
Secondary objective (s)	**Views of participants of intervention**

Trial Design	**A feasibility trial / Randomised Control Trial (RCT)**
Endpoints	**Proportion of patients eligible for recruitment** **Proportion of eligible patients actually recruited to trial** **Dentist adherence to intervention** **Patient adherence with behaviour required by intervention** **Proportion of participants captured at follow up** **Estimates of means and standard deviations for outcome measures**
Sample Size	**40**
Main Inclusion Criteria	**Adult patients (≥18 years old) who have:** • **Dental Phobia (Modified Dental Anxiety Score: MDAS score >= 19) OR** • **Specific phobia of dental injections / invasive dental treatment** • **No comorbid psychiatric conditions (Hospital Anxiety & Depression Scale: HADS A < 10; HADS D < 10)**
Version and date of protocol amendments	**Version 2** **14 June 2017**
Statistical Methodology and Analysis:	**The following descriptive statistics will be calculated:** • No. of eligible patients attending • Proportion of eligible patients recruited • Dentist adherence to intervention (assessed by independent review of case notes) defined as proportion adhering to specific behaviours within the intervention • Patient adherence with behaviour required by intervention (assessed by self report data from questionnaire based on Adult Dental Health Survey [ADHS]) • Proportion of participants captured at follow up **Means and Standard deviations for the following variables will also be determined:** • DMFS (baseline and follow up) • Plaque score (baseline and follow up) • Basic Periodontal Examination Score (baseline and follow up) • OHIP-14 score (baseline and follow up) • Treatment Evaluation Inventory (follow up only, Secondary outcome)

This study does not involve testing a device.

1. Introduction:

1a. Brief description of the proposed study

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.
Null hypothesis: there are no differences in oral health outcomes between participants who are treated according to MID principles or patients who will receive treatment as usual.

Caries (dental decay) and periodontal disease (gum disease) are chronic conditions which are preventable. Our previous research has highlighted that people with dental phobia presented with more teeth with active disease (dental decay), less restored dentition (filled teeth), and increased periodontal (gum) bleeding and plaque levels (Heidari *et al*, 2015). 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, caries risk assessment, diet advice and Duraphat 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 individually tailored and will depend 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 (control) care arm will be offered the usual treatment (TAU) provided by the department of Sedation and Special Care Dentistry (SSCD) dental staff. Upon completion of dental care, their oral health outcome will be measured by the department's staff.

Potential participants will be drawn from patients that have been accepted by clinicians for dental care within SSCD. All participants will be required to have a dental phobia defined using the standardised cut-offs for the Modified Dental Anxiety Scale (MDAS), or having a specific phobia of certain aspects of dental treatment. Participants will have no co-morbid psychological conditions.

At 6 months' post treatment, participants will be contacted for follow up.

The following data will be collected:

Screening Data

Dental Anxiety assessed by the Modified Dental Anxiety Scale (MDAS)
Levels of General Anxiety and Depression assessed by the Hospital Anxiety & Depression Scale (HADS)

Oral Health data (Taken at base line and follow up appointment)

- DMFS (Decayed, Missing, Filled Tooth Surfaces) score calculated according to Adult Dental Health Survey (ADHS, 2009) and also based on x-rays data (see 4.5.: X-rays will be taken once patients have been accepted for care at SSCD. X rays will be taken regardless participation in this study and is part of a standard care)
- Periodontal status (Plaque score and Basic Periodontal (gum) Examination [BPE])

Oral Health Related Quality of Life Questionnaire

- Oral Health Impact Profile (OHIP14)

Oral health related behaviours

- Questionnaire covering oral health behaviours
  - Toothbrushing
  - Interdental cleaning
  - Fluoride supplementation
  - Sugar intake and frequency of intake

Feasibility Data

- No. of eligible patients attending
- Proportion of eligible patients recruited
- Dentist adherence to intervention (assessed by independent review of case notes)
- Patient adherence with behaviour required by intervention (assessed by self report data from questionnaire based on Adult Dental Health Survey [ADHS])
- Proportion of participants captured at follow up

Participant views

Views of patients participating in the trial will be collected using the adapted version of Treatment Evaluation Inventory (Newton & Sturmey, 2004)

1b. A description of the population

The incidence and prevalence of dental anxiety in the general population has been constant over the past decade. Its' prevalence 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). The 2009 ADHS is the fifth in a series of national dental surveys that has been carried out every ten years in the United Kingdom since 1968. According to the ADHS (2009), 11% of the adult population in England, Wales and Northern Ireland have severe dental anxiety, measured using the Modified Dental Anxiety (MDAS) with the cut off point, 19 and above.

Service:
The department of Sedation & Special Care at Guy's & St Thomas NHS Trust is a major National provider of sedation services and Cognitive Behavioural Therapy (CBT) services for people with dental phobia. It has been recognised as a centre of excellence by the Department of Health. Approximately 3,000 out-patient episodes of care take place for adults with dental phobia in the Trust each year.

Potential risk and benefit to patients/health:
There are no anticipated risk or direct benefits to the participants. However, the findings may inform future care of dentally phobic patients. If we find the treatment regime successful, the information from this study will be used to change the service we offer to our patients and to care (treatment) plan more appropriately for our future patients. This might improve our patients' experience of treatment and their quality of life long term.

The consent form and Patient Information Sheet (PIS) will clearly explain for the patients that they have the right to participate and withdraw at any time.

Study outcome:
There may be differences in oral health outcomes between the treatment as usual (TAU) and intervention (MID) groups, at the end of the trial. If outcomes are worse in the intervention group (MID) we will recall the patients to ensure their oral health is in an optimal state.

1C. Summary of findings from non-clinical studies

Previous research by the present group has established that individuals who have a dental phobia have different oral health when compared with the non-phobic population. Specifically, after correcting for age and gender, they are significantly more likely to have missing teeth and report poorer oral health related quality of life. The reason for this difference is unclear but may be the result of patient preference (Schuller *et al*., 2003; Wisloff *et al*., 1995) or the adoption of a more limited range of care options by dentists treating patient with dental phobia (Hill *et al*., 2013). The aim of the present study is to explore the influence of the latter factor, by systematically exploring the impact of the presence of a dental phobia on the different treatment provision by dental practitioners.

2 Trial Objectives, Design and Statistics

2.1. Trial Objectives

Aims:
To conduct a feasibility trial of the effect of providing Minimally Invasive Dentistry (MID) to patients with a dental phobia, compared to treatment as usual (TAU), on oral health outcomes.

Primary Objectives:

To determine:

- Proportion of patients eligible for recruitment
- Proportion of eligible patients actually recruited to trial
- Dentist adherence to intervention
- Patient adherence with behaviour required by intervention
- Proportion of participants captured at follow up
- Estimates of means and standard deviations for outcome measures

Secondary Objectives:

To determine participants' views of intervention

Primary and secondary end point:

Primary end points:

- Proportion of patients eligible for recruitment
- Proportion of eligible patients actually recruited to trial
- Dentist adherence to intervention
- Patient adherence with behaviour required by intervention
- Proportion of participants captured at follow up
- Estimates of means and standard deviations for outcome measures

Secondary end points:

- Treatment Evaluation Inventory scores for patients rating of the intervention

2.2 Trial Design & Flowchart

Study design: A feasibility trial (please see appendix 1 and 2) /RCT

Step 1: Recruitment and treatment provision for patients who have dental anxiety/phobia
The researcher (EH) is a member of staff and the direct care team in the department of Sedation and Special Care Dentistry (SSCD). SSCD is part of King's College Dental Institute based in the Guy's hospital and is part of Guy's and St Thomas' Foundation Trust.

Visit 1 (appendix 2 & 3):
EH will approach potential patients after they have been accepted for a dental treatment at SSCD, by inviting them to participate to the study. EH will give patients a patient information leaflet (PIS) and a consent form.

Visit 2:
Once consent has been obtained, a signed copy will be given to the patient. The other copies of a signed consent form will be in the research portfolio and in patient's dental record.

A letter will also be sent to the General Medical Practitioner (GMP)/ General Dental Practitioner (GDP), informing them that the patient will participate in this study if he/she is eligible. The letter also mentions that once his/her dental care has been completed, we (staff at SSCD) would refer him/her back to his/her GDP for continuous care.

At this visit the participants will have a care plan by EH or the dental practitioners who are the staff within the department (SSCD). Oral health measures and caries risk assessment will be taken at this stage. The care plan is based on information from an oral health assessment after performing an oral examination and reporting on radiograph findings. The participants will also be given part A of the study questionnaire.

The 'study questionnaire' will have 3 parts.

> **Part A:** demographic information and MDAS and HADS (screening questionnaires) which be given at the beginning of the study. This enable the researcher (EH) to assess if the participants are eligible. This part of the questionnaire should not take more than 10 minutes to complete.
> **Part B:** It has questions about oral health related behaviour and oral health related quality of life (OHIP 14). This part of the questionnaire will not take more than 10 minutes to complete.
> **Part C:** this part of the 'study questionnaire will be distributed only at the follow up appointment.
> The entire questionnaire will take approximately 25 to 35 minutes to complete.

Analysis of Part A screening data (MDAS and HADS) of the study questionnaire, will enable the researcher (EH) to screen and assess participants for suitability and eligibility. If participants are suitable (see inclusion criteria), they will complete part B of the questionnaire which has questions about oral health related behaviour and oral health related quality of life (OHIP 14). Then, EH will allocate patients to either TAU or intervention groups on the basis of an allocation sequence set by the trial statistician (MA).

If patients are not eligible they will not take part in the study and will be informed about this decision. Appropriate actions, such as referral to the patient's general medical practitioner, will be introduced after analysing high HADS scores and after discussions with the patient.

Visit 3 onwards:
At their next routine appointment, participants will have caries risk assessment and dental treatment by EH (intervention arm) or by dental practitioners who are the staff within the department (SSCD) in charge of their dental care in the control arm. At all the following visits, the intervention group will continue to be treated by EH according to the MID principle and the patients in the control group will have their dental treatment provided by dental practitioners in SSCD.

The participants' dental treatment will vary between individuals and is based on their individual's needs. Some participants might need to attend several sessions to achieve a 'healthy' dental condition. Each dental treatment session can be approximately 1 hour.

Both groups will be discharged to the care of their referred clinician(s) once their dental treatment has been completed. Once dental treatment is completed, the participants will be placed on a recall appointment waiting list.

Step 2: 6 months' recall (Follow up appointment after 6 month)

At 6 months' post treatment, the patients (from standard [control] and intervention arm) will be contacted by the researcher (EH) for a recall appointment. Data collected at that point will include questionnaire data (Part A, B and C) that has questions related to participants' oral health behaviour and oral health related quality of life; Treatment Evaluation Inventory and also clinical oral health data (if patient attends).

2.3 Trial Flowchart

The details of the study are mentioned in Section 1 (research protocol attached in the appendix 1).

A table of time/event matrix of trial procedures and stages are in Section 2. Appendix 2 and 3.

2.4 Trial Statistics

Statistical analysis:

The following descriptive statistics will be calculated:

- No. of eligible patients attending
- Proportion of eligible patients recruited
- Dentist adherence to intervention (assessed by independent review of case notes) defined as proportion adhering to specific behaviours within the intervention
- Patient adherence with behaviour required by intervention (assessed by self report data from questionnaire based on Adult Dental Health Survey [ADHS])
- Proportion of participants captured at follow up

Means and Standard Deviations for the following variables will also be determined:

- Decayed Missed Filled Surfaces (DMFS) (baseline and follow up)
- Plaque score (baseline and follow up)
- Basic Periodontal Examination Score (BPE) (baseline and follow up)
- OHIP-14 score (baseline and follow up)
- Treatment Evaluation Inventory (follow up only, Secondary outcome)

3. Sample size:

The sample size is based on the recommendations of Lancaster *et al*. (2004) and NIHR for feasibility trials and is 20 in each arm (total N=40).

Timing of the interim analyse:

There is no necessity for interim analysis.

Selection and Withdrawal of Subjects

3.1 Inclusion Criteria

The researcher (EH) will treat all participants with tact and sensitivity. The nature of the study will be explained at some length. Patients will be given the Patient Information Sheet (that has details of the study) and a consent form. Patients will be advised that non participation will not affect their treatment in any adverse way. Also, they may withdraw from the study at any time without any disadvantage.

- Patients who have agreed to participate and signed the consent form
- Are 18 years old and above
- Have been accepted for dental care at the department of Sedation and Special Care Dentistry (SSCD)

Screening data:

- Dental Phobia measured by
    - Modified Dental Anxiety Score (MDAS score >= 19) OR
    - Specific phobia of dental injections / invasive dental treatment
- No comorbid psychiatric conditions (HADS A < 10; HADS D < 10)

3.2 Exclusion Criteria

The following patient groups:

Those not meeting the inclusion criteria, and individuals with learning difficulty, difficulty in communicating or who are unable to give informed consent. Potential participants who cannot understand spoken English and who cannot read and write English will be excluded as ability to communicate clearly is essential for this study.

3.3 Criteria for Premature Withdrawal

Participants will be able to withdraw at any point, up to publication of the study without jeopardising their care provision.

4 Study procedures

Informed Consent Procedures

The researcher (EH) is a member of staff in the department of Sedation and Special Care Dentistry (SSCD) and has been involved in several studies where she has been recruiting study participants. She has also completed her Good Clinical Practice Training (GCP).

SSCD is part of King's College London Institute based in the Guy's hospital and is part of Guy's and St Thomas' Foundation Trust. EH will approach potential patients after they have been accepted for a dental treatment at SSCD.

While no classically vulnerable groups (children, those unable to consent) will be recruited, all of the patients meeting entry criteria will be approached to participate to the study.

- The nature of the study will be explained at some length.
- Patients will be advised that non participation will not affect their treatment in any adverse way. Patients also will be advised that any participant may withdraw from the study at any time without any disadvantage. EH will also explain to the patients that any identifiable data that is already collected with consent would be retained and used in the study if patients decide to withdraw. No further data would be collected or any other research procedures carried out when patients decide to withdraw from the study.
- Patients will be given the Patient Information Sheet (that has details of the study) and a consent form. Patients can take these forms home and can return the consent form at their next appointment at SSCD. When the participants feel ready to consent, have no further questions and wish to participate, they will sign the consent form with the researcher (EH). EH will then document in the patient's notes when the consent form has been received.

4.1 Screening Procedures

The researcher (EH) will approach potential patients after they have been accepted for a dental treatment at SSCD. Once patients have consented to take part in the study, the study questionnaire (part A) with

demographic and screening data will be distributed to the participants. Patients who are not meeting the inclusion criteria (MDAS > =19, not having a specific phobia and HADS scores of A <10 and D <10) will be excluded from the study. The data collected from these screening procedures will be logged and when appropriate used.

4.2 Randomisation Procedures

Simple randomisation will be used to develop an allocation sequence which will be a list of numbers which are randomly ordered, and are used to assign sequentially enrolled participants to the intervention and control group. The list will be given to EH by the trial statistician. Allocation will be concealed using opaque envelopes.

4.3 Schedule of Treatment for each visit

Please see Section 2 Appendix 2.
The randomisation process will allow EH to allocate the participants into two groups: the intervention and the control group. Participants in the intervention group will have dental treatment by the researcher (EH) and the control group will be treated (TAU) by staff at SSCD. Caries risk assessment and dental treatment might take place over multiple sessions. Each dental treatment session might be approximately 1 hour. Upon completion of dental care, patient will be on a recall appointment system.

4.4. Follow up Procedures

Please see Section 2 Appendix 2.
The researcher (EH) to send an invite (a letter) for a follow up appointment 6 months after completion of care. A follow up appointment for a dental assessment will be made by the participants at their convenience time. The study questionnaire (part A, B and C) will be given to the participants. The participant will put the questionnaire in the provided Box which is safely kept in the designated area. The Box will be emptied by EH by the end of each clinical session.
The questionnaires and clinical data are anonymised with a unique identifying number. The paperwork will be kept securely locked in KCLDI premises according to the Data Protection Act. EH and the researchers will analyse the data.

4.5. Radiology Assessments

Patients who are accepted for provision of care in the department of Sedation and Special Care Dentistry will routinely have radiographs. The amount and type of radiographs will depend on patients' needs and clinical presentation (e.g. if patients has a tooth abscess, a periapical view rather than bitewings will be taken). Radiographs are important tools for clinicians to make a diagnosis. Taking radiograph are part of a standard care and the clinicians who prescribe or take radiographs will follow the Ionising Radiation (Medical Exposure) Regulations.

4.6. End of Study Definition

The end of the study will be when the participants have attended the follow up appointment. However, if the participants have not made an appointment or have failed to attend the follow up appointment that they have made, that session will mark the end of study for these participants.

5. Laboratories

Not applicable

6. Assessment of Safety

Any adverse events occurring as a result of participation in the trial will be logged with the Trust Research & Development team.
There is no anticipated risk to the participants. However, the findings may inform future care of dentally phobic patients.
If there will be an unexpected occurrence, although very unlikely, this will be reported immediately upon knowledge of the event to R&D and always within 24 hours by the Chief Investigator. The occurrence will also be copied into the Annual Progress Report.

6.1. Ethics Reporting

An unexpected occurrence will be submitted to the Main REC within 15 days of the Chief investigator becoming aware of the event, using the NRES template.

6.2. Trial Steering Committee (if applicable)

Not applicable

6.3. Ethics and Regulatory Approvals

This study will be conducted in compliance with the principles of the Declaration of Helsinki (seventh revision 2013), the principles of GCP and radiographs regulatory requirements. Approval will be sought through the HRA for the participation of patients.

9. Data handling

All data will be assigned a unique anonymised code by the researcher (EH) to ensure confidentiality and anonymity. Paper copies of all completed research materials (the study questionnaires and clinical data sheets) will be safe in a locked cabinet in Dr Heidari's office at DI KCL. Electronic data will be held on computers accessed by an individuals' unique user and password details, in compliance with Trust policy. The data will only be transferred using an encrypted USB. The patients will be anonymised with regards to any future publications relating to this study.

Case Report Form
In case of any adverse event, appropriate steps will be taken according to the trust procedures to ensure patient's safety**.**

Record Retention and Archiving:
Once the research is complete, the study records will be kept safely for a further 5 years.

Compliance
The trial is conducted in compliance with the principle of the Declaration of Helsinki (1996).

Quality Assurance:

Returned questionnaires (at the beginning of the study and at the follow up session) and information on the clinical data sheet will be logged and transferred to a Microsoft Excel file. Ten per cent of the data entries will be checked against the returned questionnaires for accuracy.

Dr Heidari will be responsible for the day-to-day conduct of the trial. Conduct of the trial will be reviewed regularly by the investigators' PhD supervisors.

Clinical Governance Issues

The investigators, and the institution(s) will permit trial-related monitoring, audits, REC review, and regulatory inspections (where appropriate) by providing direct access to source data and other documents (i.e. patients' clinical data and X-ray reports).

10. Finance and Publication Policy:

The investigators are planning to present the data and publish this in a peer review journal.

Costs for materials (such as printing of the questionnaires) will be covered by King's College London.

We are planning to register our feasibility trial on International Standard Randomised Controlled Trials (ISRCTN).

11. Signatures

To be signed by Chief Investigator minimum and statistician if applicable.

Professor Tim Newton **June 2017**

_____ _____

Chief Investigators Date

Print name

Ellie Heidari **June 2017**

_____ _____

Chief Investigators Date

Print name

Professor Avi Banerjee **June 2017**

_____ _____

Chief Investigators Date

Print name

Mr. A. Manoharan. **June 2017**

_____ _____

Statistician Date

Print name

Appendix 1. Section 1. Research Flow Diagram

Appendix 2. A simplified version of the events' matrix

	Visit 1	Visit 2 (care planning session)	Visit 3 onwards	Follow up appointment after 6 month
PIS	X			
All patients who will be accepted for dental care will have radiograph examination according to their needs. This is a standard process and will not depend on participation in this study.	X			
Consent		X		
Part A questionnaire: Screening data: HADS and MDAS		X		
If eligible: Letter to GMP/GDP		X		
If not eligible and high scores of HADS a letter to GMP		X		
Oral health needs and caries risk assessment: In this part, the radiographs findings (radiographs have been taken when patients attended the department at visit 1) will complement the oral finings when an oral health examination takes place.		X		
If eligible: Randomisation		X		
Treatment sessions: (EH will have the intervention group for 'preventive oral health related' and treatment sessions and staff at SSCD the control arm).			X	
All 3 parts of the questionnaire (A, B and C) and an oral health assessment				X