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Interventions to reduce inequalities in the uptake of routine dental care: the feasibility study

Submission date
07/10/2019

Recruitment status
No longer recruiting

Registration date
07/10/2019

Overall study status
Completed

Last Edited
07/02/2024

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
People living in deprived areas often put off visiting a dentist until they have a problem. But leaving it this late often means that decay is too far gone to save the tooth, meaning extraction is necessary. This affects peoples' dental health for the rest of their lives and can leave them embarrassed about their appearance (avoiding smiling etc). Since over half of people with urgent dental problems receive antibiotics for infection, leaving dental visits until there is pain and infection adds to the problem of antibiotics being less effective against bacteria because they are used so widely. By exploring barriers to dental visiting with both patients using urgent dental care services and local members of the community, the RETURN programme has developed the RETURN intervention to try and help patients to plan and keep appointments for dental check-ups. The RETURN intervention includes booklets about common barriers to visiting the dentist, providing information and persuasive messages designed to get patients back into planned care, video clips that can be viewed online showing patient stories, as well as a goal setting booklet enabling patients to set their own goals about future dental visiting, addressing their barriers. The intervention pack will also contain other resources such as a credit card sized card that can be given to the patient's employer, and relaxation exercises to use in the waiting room for anxious patients.

Who can participate?
Patients aged 18 or over who attend a recruiting site for urgent dental care and who have not routinely seen a dentist for at least 2 years

What does the study involve?
Participants are randomly allocated to receive either the RETURN intervention or standard of care during their urgent care treatment and are contacted 4 months afterwards for follow up.

What are the possible benefits and risks of participating?
The results from this study will be used to determine whether the RETURN intervention is practical and should be studied with a larger number of patients over a longer period. The results from the larger study may result in the RETURN intervention being made available UK

wide to increase the uptake in patients attending the dentist for regular visits. The researchers think that the RETURN intervention may help with the barriers that some people have with attending a dentist for regular check-ups and treatment and so help them to see the dentist more often. If patients receive standard of care then there will be no further risks than if a patient decided not to take part in the study.

Where is the study run from?
Recruitment is taking place in three sites in Merseyside and Cheshire; the Liverpool Dental Hospital, an in-hours urgent dental practise and an out of hours urgent dental practise.

When is the study starting and how long is it expected to run for?
August 2018 to October 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Amy Humphreys
returntr@liverpool.ac.uk

Study website
https://www.returnproject.co.uk

Contact information

Type(s)
Scientific

Contact name
Miss Amy Humphreys

Contact details
Liverpool Clinical Trials Centre (LCTC)
2nd Floor Institute in the Park
Alder Hey Children's NHS Foundation Trust
Liverpool
United Kingdom
L12 2AP
+44 (0)151 975 8766
returntr@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
265789

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS: 43352, IRAS 265789

Study information

Scientific Title
InteRventions to rEduce inequaliTies in the Uptake of Routine deNtal care: the feasibility study

Acronym
RETURN Feasibility

Study objectives
People living in deprived areas often put off visiting a dentist until they have a problem. But leaving it this late often means that decay is too far gone to save the tooth, meaning extraction is necessary. This affects peoples' dental health for the rest of their lives and can leave them embarrassed about their appearance (avoiding smiling etc). Since over half of people with urgent dental problems receive antibiotics for infection, leaving dental visits until there is pain and infection adds to the problem of antibiotics being less effective against bacteria because they are used so widely.

By exploring barriers to dental visiting with both patients using urgent dental care services, and local members of the community, the RETURN programme (WP1, REC ref: 18/NE/0061) has developed the RETURN intervention to try and help patients to plan and keep appointments for dental check-ups.

The RETURN intervention includes booklets about common barriers to visiting the dentist, providing information and persuasive messages designed to get patients back into planned care, video clips that can be viewed online showing patient stories, as well as a goal-setting booklet enabling patients to set their own goals about future dental visiting, addressing their barriers. The intervention pack will also contain other resources such as a credit card sized card that can be given to the patient's employer, and relaxation exercises to use in the waiting room for anxious patients.

The results from this study will be used to determine whether the RETURN intervention is practical and should be studied with a larger number of patients over a longer period. The results from the larger study may result in the RETURN intervention being made available UK wide to increase the uptake in patients attending the dentist for regular visits.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/11/2019, London - Bromley Research Ethics Committee (3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8063; Email: nrescommittee.london-bromley@nhs.net), REC ref: 19/LO/1510

Study design
Randomised; Both; Design type: Treatment, Psychological & Behavioural, 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Oral and dental public health

Interventions
Participants who do not have their own dentist and have not visited a dentist for a period of two years or more (unless they were in pain or symptomatic) will be identified on arrival at RETURN sites and entered onto the RETURN screening log by a trained RETURN researcher (either dental team member, or a member of the research team) and consent for the study will be sought.

If the participant agrees to take part in the study then a full check of the eligibility criteria will be completed. If eligible, the patient will be randomised to either the RETURN intervention or standard of care at their treating dental practice/hospital (randomisation is a ratio of 1:1).

The contact details of the participant will be collected on a tablet PC via a secure contact database held by the Liverpool Clinical Trials Collaborative (LCTC). Collection of this information is essential to allow for central follow up at 4 months and for Business Authority Services (BSA) data on dental visits to be obtained.

The participant will then complete some questionnaires on a tablet PC to capture: demographic information, details about previous receipt of antibiotics and painkillers due to dental problems, information about oral health, information about anxiety around dental visiting. Responses will allow us to measure indicators to behaviour change around regular dental care attendance and dental symptoms.

If participants are randomised to the RETURN intervention, then a RETURN researcher will run through the intervention with the participant (taking approximately 15 minutes). The intervention is comprised of a booklet, online videos, and asking participants to make a goal and action plan around attending for planned dental care. For those participants allocated to the intervention, they will be asked to repeat two of the questionnaires post-intervention receipt (questions about dental anxiety and indicators of behaviour change).

Recruitment, consent, data collection and intervention delivery will all be completed during their urgent dental appointment, either before, after or between seeing the dentist for their urgent care treatment.

Approximately 4 months after the participant is recruited into the study, a member of the central follow-up team based at the Department of Health Services Research (University of Liverpool) will contact the participant again by telephone, email or post to complete some questionnaires (many of the questionnaires completed at baseline, along with some health economics questionnaires). For those participants who are contacted by telephone, a short semi-structured
interview will be conducted (detailed below).

Data on dental care from the BSA will be collected to see if the information provided at sites and by the participants matches the information collected by the BSA.

To help determine the feasibility of the trial, fidelity of intervention delivery and to explore contamination and burden to patients, a three-component qualitative study will be embedded within the trial:

Component 1: Interviews, observations and audio-recordings of intervention delivery to assess the practicality of intervention delivery in the practice/hospital setting, the effectiveness of the training and the fidelity of the intervention delivery.
As many intervention deliveries and consenting procedures will be observed by the central researchers (at the Health Service Research Department, University of Liverpool) as possible, but where it is not possible for a central researcher to be present, the RETURN site researchers (dental teams) will audio-record. This will later be transcribed and analysed by the central follow-up team at the University of Liverpool.

Component 2: Semi-structured interviews with patients at the 4-month follow up. These will be conducted to explore: participant burden, the rate of intervention delivery, the potential for contagion, which (if any) patients took up planned care in student clinics at the dental hospital, whether receipt of the intervention before of after receipt of urgent care treatment made any difference. These interviews will take place over the phone and will be conducted by the central follow-up team at the University of Liverpool. The semi-structured interview will only be possible with those participants who we are able to contact via the method of telephone at follow up.

Component 3: Semi-structured interviews with dental teams members. These interviews will explore the practicality of intervention delivery. These will take place at the end of baseline recruitment in each site.

Intervention Type
Behavioural

Primary outcome measure
The following objectives and measures will be used as stop/go criteria for the main study. As this is a feasibility study, there is more than one primary outcome measure under study:
1. Rate of matching patient ID in BSA routine records and likely missing outcome data: matching patient name, date of birth, gender and contract number the service is delivered under against record of attending for NHS urgent dental practice care in Business Service Authority (BSA) database. The denominator is those recruited at baseline from NHS dental practice who would be expected to be in the BSA system. Measured at baseline and 4 months (where possible).
2. Rate of completeness of valid OHIP outcome data: proportion of participants with valid OHIP data at baseline and follow up (i.e. respond to 12 items or more). Measured at baseline and 4 months.
3. Recruitment rates: number of patients recruited across all types of sites with breakdown

description given by type of site. Measured at baseline.
4. Fidelity of intervention delivery: observations of participants to determine % allocated patients who are observed to receive at least some of the intervention (receive at least some of the intervention material). Measured at baseline.

Secondary outcome measures
1. Patient-reported visit information with BSA data and/or records completed by the dental practice and hospital at baseline about their dental visit and treatment received (CRF). For dental hospital this also includes records at 4 months where available (clinical records). BSA data available from 2 months post baseline visit) and /or CRF records completed by the dental practice at baseline and/or dental hospital at baseline and at 4 months follow up including:
1.1. Whether appointment is for urgent or planned dental care (baseline only for dental practices, for dental hospital this may be further appointments as well)
1.2. Start date and finish date of treatment plan (dental hospital only)
1.3. Treatment items provided (baseline for dental practices only. Baseline and further appointments for the dental hospital)
Dental hospital validation only where possible, and just for patients recruited at the dental hospital.
Measured at baseline for dental practice only, baseline and follow up at 4 months for the dental hospital where possible
2. Urgent dental attendance extracted from BSA database or dental hospital records and patient self-report:
2.1. In dental practice - BSA Band 1 (urgent) data
2.2. Dental hospital clinical records (if possible)
Measured at baseline
3. Antibiotic/analgesic prescribing from BSA prescribing data and CRF baseline report and patient self-report at baseline and follow up (self-report)
4. Practicality of intervention delivery in the dental hospital and dental practice setting assessed based on:
4.1. The required delivery time of the intervention
4.2. Observation of at least 4 intervention delivery in each site
4.3. Interviews with dental teams
Measured at baseline
5. Effectiveness of dental team and dental champion training based on:
5.1. Responses to questionnaires completed by dental teams and dental champions
5.2. Observation of intervention delivery
Measured at the end of training
6. Participant contamination assessed using interviews with patients in the intervention and control group at 4 months
7. Participant burden for the study and intervention assessed using participant interviews and completeness of data collection at baseline and 4 months follow up telephone call

Overall study start date
01/08/2018

Completion date
31/10/2020

Eligibility

Key inclusion criteria

1. Adults (aged 18 years or over) seeking urgent dental care
2. Has not visited an NHS or Private dentist for a non-emergency appointment i.e. when not in pain or symptomatic for 2 years or more
3. Willing to spend time completing assessments and receiving the intervention
4. Able to provide a telephone number and/or e-mail and/or postal address to allow follow up
5. Has provided written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 72; UK Sample Size: 72

Total final enrolment
28

Key exclusion criteria
1. Do not adequately understand spoken and written English
2. Not responsible for making own dental appointments i.e. made by a carer
3. Attends for planned dental care appointments i.e. confirms they have attended an appointment when not in pain or with symptoms within the past 2 years
4. Have previously been enrolled in the RETURN programme
5. Currently involved with another clinical dental trial
6. Lives with or is related to somebody participating in the RETURN feasibility study

Note: Patients who go on to have planned care with undergraduate students will not be excluded, although the route patients' take to planned care will be reported

Date of first enrolment
27/01/2020

Date of final enrolment
20/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool and Broadgreen University Hospitals NHS Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
NIHR CRN: North West Coast
-
United Kingdom
L7 8XP

Sponsor information

Organisation
University of Liverpool

Sponsor details
c/o Mr Alex Astor
2nd Floor Block D Waterhouse Building
3 Brownlow Street
Liverpool
England
United Kingdom
L69 3GL
+44 (0)1517948739
sponsor@liv.ac.uk

Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0616-20004

Results and Publications

Publication and dissemination plan
1. The protocol will be published
2. Peer reviewed scientific journals
3. Conference presentation
4. Publication on website

Intention to publish date
01/07/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Rebecca Harris (harrisrv@liverpool.ac.uk). The anonymised raw data will be available to be shared after publication for the participants who agreed to future use on their consent forms.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		18/11/2022	18/11/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		06/02/2024	07/02/2024	Yes	No