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A behavioural intervention to reduce the inequalities in the uptake of routine dental care: main trial

Submission date 17/03/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/04/2021	**Overall study status** Completed	
Last Edited 09/06/2025	**Condition category** Oral Health	

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 about needing time off to visit the dentist, 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 at 6, 12, and 18 months for interview follow-up

What are the possible benefits and risks of participating?
The researchers think that the RETURN pack may help people use dental services more regularly. Visiting a dentist early means the dentist can pick up problems early and mend things e.g. with a

smaller filling rather than possibly losing the tooth. The researchers are not aware of any drawbacks of receiving the RETURN information pack. People who are in the group who do not receive the pack will just receive their dental care and information in the usual way. For people who didn't get the pack there are no more risks than not being in the study.

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
August 2018 to April 2024

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
288546

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 48068, IRAS 288546

Study information

Scientific Title
InteRvention to rEduce inequaliTies in the Uptake of Routine deNtal care - RETURN main trial

Acronym
RETURN Main Trial

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 also 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 and routine care.

The RETURN intervention includes booklets about common barriers to visiting the dentist, providing information and persuasive messages designed to help patients get back into planned care; video clips that can be viewed online showing patient stories, as well as a goal setting and action planning 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/03/2021, London – Camberwell St Giles Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8340; camberwellstgiles.rec@hra.nhs.uk), REC ref: 21/LO/0059

Study design
Randomized; Both; Design type: Prevention, Process of Care, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Study type(s)
Other

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

Interventions
The RETURN main trial is a randomised controlled open trial to develop and test a way to improve the routine use of dental services by deprived populations, by delivering a psychological intervention personalised to participants to address the significant barriers to attending regular dental appointments and to encourage behavioural changes. Participants who are over 18 and who speak English (as judged by the trained dental team member or researcher) will be given a flyer informing them that a research project is taking place in the dental practice. Posters /banners will also be in the waiting room. They will then be approached by a trained dental team member or researcher, and those 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) and do not have a dentist who they visit regularly for routine care will be 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 participation in the randomised controlled trial 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 (address, telephone number and email address) of the participant will be collected on a tablet PC via a secure contact database held by the Liverpool Clinical Trials Centre (LCTC). Collection of this information is essential to allow for central follow up at 6, 12 and 18 months and for Business Authority Services (BSA) data on dental visits to be obtained. Participants will be asked for all three contact details, but it is only a requirement to provide one.

The participant will then complete some questionnaires to capture: demographic information, details about previous receipt of antibiotics and painkillers due to dental problems, information about oral health, oral health symptoms and health more generally, information about anxiety around dental visiting and information detailing how the participants feel about visiting the dentist. 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, a RETURN trained dental team member or researcher will run through the intervention with the participant (taking approximately 15 minutes). The intervention is comprised of some booklets, online videos, and asking participants to make a goal around attending for planned dental care. All participants (control and intervention) will then be shown a brief video thanking them for their time, and providing information on what to expect for the follow-up. All participants will then be asked to repeat one of the questionnaires post-intervention receipt (psychological 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.

At three follow-up points 6, 12 and 18 months (+/- 4 weeks) after the participant is recruited into the study, a member of the central follow-up team based at the Department of Public Health, Policy and Systems (University of Liverpool) will contact the participant again by telephone, email or post to complete some questionnaires (most of the questionnaires completed at baseline, along with some health economics questionnaires). Participants will also be asked some questions about intervention fidelity and their experience of the trial and dental visiting more generally. The follow-ups will take around 20 minutes to complete.

Data on dental visiting and dental treatments provided to patients from the NHS Business Services Authority (NHSBSA) will be collected at 6, 12 and 18 months.

In addition, there is an embedded qualitative component to the trial, consisting of three components:

Component one comprises in-depth interviews with a small group of trial participants. These are planned with at least 50 recruited patients (35 in the intervention and 15 in the control arm), around the time of the three follow up points (6, 12, 18 months post-intervention). Patients will be given the information about a possibility of being invited to participate in the in-depth interviews at the time of enrolment, although patients will be given the option to opt out of this part of the study. These interviews will be conducted either face-to-face or by telephone, and will explore issues in-depth, gathering information on the impact and meaning of the

intervention in the wider context of people's lives, as well as an exploration of any differential effects of the intervention across the socio-economic gradient. This component of the programme will give us insight into changes in dental visiting patterns longitudinally, and factors in people's lives linked to these. This component will also give us insight into the service-related factors which contribute to inequalities in oral health.

Component two consists of in-depth interviews with dental staff involved in the trial. These will be either face-to-face or telephone semi-structured interviews with dental team members, taking place during or after the recruitment phase. The face to face or telephone interviews will take place in order to gather the insights from the dental team about the fidelity of intervention delivery, practical issues of delivering the intervention in this setting, and how they feel the intervention was both delivered and received. At least 15 dental team members will be interviewed in at least 5 different sites, covering all three site types.

The third component consists of observations during intervention delivery. A member of the central research team will observe the delivery of the intervention, in order to gather data on intervention fidelity. These observations will be recorded in fieldnotes. Where a researcher is not present, dental teams may audio-record intervention delivery sessions so that fidelity can be assessed. Patients and dental teams will consent to these observations or recordings in advance. The recordings will be captured by the dental teams themselves, and in the spirit of ongoing consent, patients will be asked to orally consent before the recorder is switched on.

Intervention Type
Behavioural

Primary outcome(s)
1. Attendance at a dental practice for a planned care appointment within 12 months, collected from NHS Business Services Authority (NHSBSA) data
2. Self-reported oral health quality of life, measured using Oral Health Impact Profile (OHIP)-14 at 12 months

Key secondary outcome(s))
1. Attendance at a dental practice for a planned care appointment, self-reported from phone calls at 6, 12 and 18 months
2. Attendance at a dental practice for a planned care appointment within 18 months, collected from BSA data
3. Self-reported oral health quality of life, measured using OHIP-14, at 6 and 18 months
4. Urgent attendance for dental care at dental practice, A&E, or dental hospital, within 12 months, self-reported from patient follow-up
5. Halitosis and bad taste measured by patient self-report measured at baseline (day 0), and at 6, 12 and 18 months
6. Treatment received, measured by BSA clinical dataset and patient self-report at baseline (day 0), and at 6, 12 and 18 months
7. Antibiotic prescription, measured by BSA data at baseline (day 0), and at 6, 12 and 18 months
8. Antibiotic prescription measured by patient self-report at baseline (day 0), and at 6, 12 and 18 months
9. Analgesic prescription measured by patient self-report at baseline (day 0), and at 6, 12 and 18 months
10. Dental anxiety measured by the Modified Dental Anxiety Scale at baseline (day 0), and at 6, 12 and 18 months

Completion date
30/04/2024

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, and do not have a dentist who they visit regularly for routine care
3. Able to provide either a telephone number, email or postal address to allow follow up
4. Has provided written consent
5. Adequate understanding of spoken and written English
6. Responsible for making their own dental appointments i.e. not done by a carer

Participant type(s)
Patient, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1180

Key exclusion criteria
1. Have previously been enrolled in the RETURN feasibility study or main trial
2. Lives with, or related to, a participant in the RETURN feasibility study or main trial

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
18/08/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool University Hospitals NHS Foundation 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

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

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

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?
Protocol article		07/06/2022	08/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Embedded fidelity assessment of the RETURN intervention focusing on the Behaviour Change Consortium (BCC) domains of training and delivery	13/05/2025	09/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes