ISRCTN96479279 https://doi.org/10.1186/ISRCTN96479279

How effective and cost-effective is water fluoridation for adults?

Submission date
13/01/2020

Recruitment status
No longer recruiting

Registration date
25/03/2020

Overall study status
Completed

Last Edited
28/05/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Tooth decay is the most common disease affecting mankind. It causes pain, infection, sleepless nights and time off from work. Having dental treatment creates worry for many because of the discomfort involved, the inconvenience and the costs. Tooth decay is costly for the NHS and patients themselves unless they are exempt from NHS charges. The NHS currently spends £3.4 billion on NHS dental services, and patients pay another £653 million in patient charges. The majority of these costs are spent on the treatment of tooth decay and its consequences.
It has long been known that fluoride can prevent tooth decay. Since the 1940s, fluoride has been added to some public water supplies and it was first added to toothpastes in the 1970s. Since fluoride toothpastes became available, there has been dramatic improvement in dental health. People have fewer cavities and keep their teeth for longer, particularly in more affluent communities. In America and Australia, almost all public water supplies have fluoride added. In England, only 10% of our water supply contains fluoride. Local Councils decide if they want to add fluoride to the water to improve the dental health of local people.
The problem for Local Councils is there is very little modern research on water fluoridation to help them decide if this is a good idea. We don't know the present-day costs and benefits of water fluoridation, when almost everyone uses fluoride toothpastes. There is also very little research on adults, because it is difficult and very costly to enrol lots of adults into a long-term research study. For children, it is much easier and cheaper because they can be followed up in school. This study will provide added information to give a full picture of this issue.
The aim of the study is to find out how effective and cost-effective water fluoridation is in preventing dental treatment and improving oral health in modern adult populations who also have access to fluoride in toothpastes.

Who can participate?
The study will use anonymised NHS data that has already been collected from adolescents and adults attending NHS dental practices in England, therefore the researchers will not be seeking to recruit any participants

What does the study involve?
The researchers will use information that was submitted in payment claims by NHS dentists between 2010 and 2020. This information is held by the NHS Business Services Authority, who

are part of NHS Digital. The researchers will compare the number and type of NHS dental treatments that were provided to adults and adolescents who lived in fluoridated or non-fluoridated areas of England. All names, addresses and identifying information about both patients and dentists will be removed before the researchers access the payment records. Knowing the number and types of dental treatments received will show whether living in an area with water fluoridation reduces the costs of NHS dental care for both the NHS and for patients. Using the information recorded by NHS dental practices means that the researchers will be able to access information on very large numbers of people, over a period of ten years. This will keep the costs of the research low, and provide answers quickly.

What are the possible benefits and risks of participating?
The data has already been collected as part of routine NHS dental care in England, therefore there won't be any active 'participation' by individuals. Using this anonymised NHS data for research is in the public interest because it will provide information on how to improve oral health in adults, reduce the need for invasive dental treatments such as fillings and extractions, and how to save money for both the NHS and for dental patients themselves.
As this is a data-only study the only risks are related to data security. Despite the anonymity of the data the researchers take data security very seriously and will apply the same governance requirements as those we would use for identifiable data. Data access will be subject to appropriate ethical and legal approvals and will be carried out according to a formal data sharing agreement.

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

When is the study starting and how long is it expected to run for?
February 2020 to July 2022

Who is funding the study?
National Institute of Health Research (NIHR) Public Health Research programme (UK)

Who is the main contact?
Professor Tanya Walsh, tanya.walsh@manchester.ac.uk

Study website
https://sites.manchester.ac.uk/lotus/

Contact information

Type(s)
Scientific

Contact name
Prof Tanya Walsh

ORCID ID
http://orcid.org/0000-0001-7003-8854

Contact details
Division of Dentistry
Faculty of Biology, Medicine and Health

Coupland III Building
University of Manchester
Manchester
United Kingdom
M13 9PL
+44 (0)161 306 0236
tanya.walsh@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
274705

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44419, IRAS 274705

Study information

Scientific Title
How effective and cost-effective is water fluoridation for adults? A 10-year retrospective cohort study

Acronym
FLuOridaTion for AdUltS (LOTUS)

Study objectives
Research question: How effective and cost-effective is 10-year exposure to water fluoridation in preventing dental treatment and improving oral health in a contemporary adult population?

Background: Tooth decay can cause pain, sleepless nights, sepsis, overuse of antibiotics, embarrassment, and loss of productive workdays. It can also lead to complete tooth loss; one of the leading global causes of disability. Dental treatment can provoke severe anxiety, and is also very costly, both to the NHS and to patients. Health inequalities exist, with poor dental health strongly associated with deprivation. Artificial fluoridation of water was identified in the 1940s as a cost-effective method to prevent tooth decay. However, in the mid-1970s, toothpastes containing fluoride became widely available. It is now unclear how much added benefit fluoride in water provides for contemporary populations. Most water fluoridation research was carried out before the mid-1970s, and there is a paucity of evidence on the effects and costs of water fluoridation particularly in adults.

Aim: To pragmatically assess the clinical effectiveness and cost-effectiveness of water fluoridation in preventing the need for dental treatment and improving oral health and in a contemporary population of adults, using a natural experiment design.

Primary Objective: To compare the effect of 10-year exposure to fluoridated water with no exposure on the number of invasive dental treatments, including restorations, endodontics or extractions, received by adults attending NHS dental practices

Secondary Objectives: To evaluate the cost-effectiveness of water fluoridation. To evaluate the impact of fluoridated water on oral health (number of remaining natural teeth and decay experience). To measure the impact of water fluoridation on oral health inequalities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 21/01/2022:
1. Approved 02/12/2019, University of Manchester Research Ethics Committee (Mrs Genevieve Pridham, Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK; +44 (0)161 275 2206/2674; research.ethics@manchester.ac.uk), ref: 2019-8391-12289
2. Approved 27/05/2020, North East - Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0) 2071048306; tyneandwearsouth.rec@hra.nhs.uk), ref: 20/NE/0144
3. Approved 07/07/2020, Health Research Authority (Skipton House 80 London Road, London, SE1 6LH; +44 (0)20 797 22557; cag@hra.nhs.uk), ref: 20/CAG/0072

Previous ethics approval:
Approved 02/12/2019, University of Manchester Research Ethics Committee (Mrs Genevieve Pridham, Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK; Tel: +44 (0)161 275 2206/2674; Email: research.ethics@manchester.ac.uk), ref: 2019-8391-12289

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Prevention

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 health

Interventions
Retrospective cohort study using routinely collected NHS dental treatment data. Individuals exposed to water fluoridation will be identified by continuous residence in a fluoridated area during the follow-up period of 2010-2020. The outcomes will be based on the number of invasive dental treatments received per participant, over ten years of observation (fillings, extractions, root canal treatments). Exposed individuals will be matched to non-exposed individuals (controls) using propensity scoring. Participants will be matched on a range of individual-level, dental practice-level and location-level characteristics. Cost-effectiveness will be assessed using the incremental cost-effectiveness ratio with uncertainty summarised using the cost-effectiveness acceptability curve (CEAC).

Intervention Type
Other

Primary outcome measure
Mean number of invasive dental treatments (restorations, endodontics, extractions) received by adults attending NHS dental practices, measured using routinely collected NHS dental treatment data over ten years of observation (2010-2020)

Secondary outcome measures
Measured using routinely collected NHS dental treatment data over ten years of observation (2010-2020):
1. Mean cost (£) per episode of invasive dental treatment avoided over ten years (2010-2020)
2. Mean number of natural remaining teeth at the most recent dental visit
3. Mean number of teeth affected by decay at the most recent dental visit, measured using the Decayed, Missing, Filled Index (DMFT)

Overall study start date
01/02/2020

Completion date
31/07/2022

Eligibility

Key inclusion criteria
Adolescents and adults (>12 years) attending NHS dental practices in England

Participant type(s)
Patient

Age group
Mixed

Lower age limit
12 Years

Sex
Both

Target number of participants
Planned Sample Size: 8000000; UK Sample Size: 8000000

Total final enrolment
6370280

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/07/2020

Date of final enrolment
01/08/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Faculty of Biology, Medicine and Health
Division of Dentistry
Dental Health Unit
Lloyd Street North
Manchester Science Park
Manchester
United Kingdom
M15 6SE

Sponsor information

Organisation
University of Manchester

Sponsor details
c/o Ms Lynne Macrae
Faculty Research Practice Co-ordinator
FBMH Research Office, 3.53 Simon Building
University of Manchester
Manchester
England

United Kingdom
M13 9PL
+44 (0)1612755436
fbmhethics@manchester.ac.uk

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR128533

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Impact and dissemination: Prevention of tooth decay for populations has recently been identified as the top priority for dental research in a recent James Lind Alliance facilitated

priority setting partnership. The proposed study will supplement the outputs of the CATFISH study of the costs and effects of fluoridation on children to inform local authorities' decisions on the introduction or cessation of water fluoridation schemes. A comprehensive dissemination strategy will be developed with input from key stakeholders. This will include sharing the results in a range of formats, both traditional academic routes and more innovative channels, including press releases, policy briefings, blog posts, and an animated video and infographic which can be shared on social media.

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan
The patient-level datasets generated during and/or analysed during the current study are not expected to be made available due to the terms of the data-sharing agreement with the NHS Business Services Authority (data provider and joint data controller).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V3.0	02/12/2019	25/03/2020	No	No
HRA research summary			26/07/2023	No	No
Results article		01/05/2024	28/05/2024	Yes	No