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A randomised controlled trial to evaluate the cost effectiveness of prescribing high concentration fluoride toothpaste to prevent tooth decay in older adults

Submission date
01/06/2017

Recruitment status
No longer recruiting

Registration date
02/06/2017

Overall study status
Completed

Last Edited
03/08/2022

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Since the 1970s fluoride toothpaste has been widely used to prevent tooth decay. People who grew up before the 1970s did not have the benefits of fluoride toothpaste and so have lots of fillings and an increased risk of further tooth decay. There has been a huge increase in the number of older people keeping their teeth. In England in 2009 only 6% of people aged over 65 years had no teeth, compared to 28% in 1978. There is a concern that unless there is effective prevention of decay in older people, many will require complex dental treatment which may not be affordable. Standard fluoride toothpaste, available to buy on the high street, tends to contain around 1400 parts per million (ppm) of fluoride. High dose fluoride toothpaste, containing 5000ppm fluoride, is available by prescription from doctors/dentists. It is thought to be better than standard fluoride toothpaste at preventing tooth decay in people at high risk. In England in 2014 prescriptions of high concentration fluoride toothpaste cost £17 million and these costs are increasing. There is a lack of evidence to demonstrate that this use of resources benefits patients and is cost-effective for the NHS. The aim of this study is to evaluate the costs and effectiveness of high dose fluoride toothpaste prescribed in general dental practice to older individuals who have a high-risk of tooth decay.

Who can participate?
People aged 50 and over who have a high-risk of developing decay, based on their recent dental history and the opinion of their dentist.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive prescriptions for 5000ppm fluoride toothpaste from their dentist. Those in the second group receive usual care (any advice will be to use 1350-1500ppm toothpaste, available from pharmacies and supermarkets). Information about whether or not participants get fillings or extractions due to tooth decay is collected from participants' dentists over a 3-year period. In addition, in a sub-group of patients in Scotland more precise measurements are undertaken to

understand how much tooth decay develops in the 5000 ppm and usual care groups over the 3-years.

What are the possible benefits and risks of participating?
There are no notable benefits involved with participating. Risks for patents participating are very low, in some rare cases (less than 1 in 1000 people treated) allergic (hypersensitivity) reactions can occur, causing rash, itching swelling and redness.

Where is the study run from?
The study is run from the Centre for Healthcare Randomised Trials in Aberdeen and takes place in at least 60 NHS dental practices in Northern Ireland, Scotland and Greater Manchester (UK)

When is study starting and how long is it expected to run for?
May 2017 to December 2023

Who is funding the study?
National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?
Professor Janet Clarkson, j.e.clarkson@dundee.ac.uk

Contact information

Type(s)
Public

Contact name
Prof Janet Clarkson

ORCID ID
https://orcid.org/0000-0001-5940-2926

Contact details
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University of Dundee
Park Place
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DD1 4HN
+44 (0)1382 381707
j.e.clarkson@dundee.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2017-002402-13

Protocol serial number
HTA 16/23/01

Study information

Scientific Title
A Randomised controlled trial to Evaluate the effectiveness and cost benefit of prescribing high dose FLuoride toothpaste in preventing and treating dEntal Caries in high-risk older adulTs

Acronym
REFleCt

Study objectives
5000 parts per million fluoride toothpaste prescribed by General Dental Practitioners is effective in reducing the need for dental treatment due to dental caries in patients aged 50 years and over attending dental practices who have a high-risk of developing caries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/11/2017, North East - Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048103; nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net), REC ref: 17/NE/0329

Study design
Pragmatic open label randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Dental Caries

Interventions
Current intervention as of 15/07/2022:
Eligible and consenting participants will be randomised to one of the two intervention groups using the web-based application, both hosted by the CTU. The randomisation algorithm will use recruitment site, residential setting (own home/care home), exemption from dental treatment charges (yes/no) and age (50-65 years/over 65 years) as minimisation covariates to allocate treatment to intervention and control groups in a 1:1 ratio. A random element will be incorporated into the randomisation algorithm. The PI at site, or individual with delegated authority, will access the telephone or web-based system. Patient screening identification, initials and recruiting site (the stratifying variable) will be entered into the web-based system, which will return the allocation status. Participants will be informed of their allocated treatment group following randomisation.

Intervention: Prescription of 5000 parts per million (ppm) fluoride toothpaste. The amount and frequency of the toothpaste will be prescribed by the participant’s dentist according to their

clinical judgement of their patient's needs. Participants will redeem prescriptions from community pharmacists.

Comparator: Usual care. Any advice given by the GDP will be to use standard, off-the-shelf, fluoride toothpaste (1350-1500 ppm). The content and frequency of advice will be provided by the participant's dentist according to their clinical judgement of their patient's needs.

The total duration of both treatment and follow-up study arms will be 3 years.

Previous intervention:
Eligible and consenting participants will be randomised to one of the two intervention groups using the proven 24-hour telephone Interactive Voice Response randomisation application or via the web-based application, both hosted by the CTU. The randomisation algorithm will use recruitment site, residential setting (own home/care home), exemption from dental treatment charges (yes/no) and age (50-65 years/over 65 years) as minimisation covariates to allocate treatment to intervention and control groups in a 1:1 ratio. A random element will be incorporated into the randomisation algorithm. The PI at site, or individual with delegated authority, will access the telephone or web-based system. Patient screening identification, initials and recruiting site (the stratifying variable) will be entered into the voice-activated or web-based system, which will return the allocation status. Participants will be informed of their allocated treatment group following randomisation.

Intervention: Prescription of 5000 parts per million (ppm) fluoride toothpaste. The amount and frequency of the toothpaste will be prescribed by the participant's dentist according to their clinical judgement of their patient's needs. Participants will redeem prescriptions from community pharmacists. Compliance will be assessed by self report questionnaires and by reference to national datasets

Comparator: Usual care. Any advice given by the GDP will be to use standard, off-the-shelf, fluoride toothpaste (1350-1500 ppm).The content and frequency of advice will be provided by the participant's dentist according to their clinical judgement of their patient's needs. Compliance will be assessed by self report questionnaires.

The total duration of both treatment and follow-up study arms will be 3 years.

Intervention Type
Drug

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
5000 ppm fluoride toothpaste

Primary outcome(s)
Current primary outcome measure as of 15/07/2022:
Restoration or extraction or endodontic treatment due to dental caries (dichotomous outcome yes/no) will be recorded at scheduled and unscheduled dental visits on the Case Report Form (CRF) completed by PIs at each site on a rolling basis during the 3-year follow-up period

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Previous primary outcome measure:
Restoration or extraction due to dental caries (dichotomous outcome yes/no) will be recorded at scheduled and unscheduled dental visits on the Case Report Form (CRF) completed by PIs at each site on a rolling basis during the 3 year follow up period.

Key secondary outcome(s)

Current secondary outcome measures as of 15/07/2022:
Clinical:
1. Coronal and root caries increment , including dentist replacement fillings for caries, at tooth surface (DMFS) level is assessed using the ICDAS method to assess caries as it provides flexibility to analyse and present caries data at different diagnostic thresholds at baseline and 3 year (+/- 3 months) follow-up. This will also be used for collecting early caries lesion progression data (DMFS measured in Scottish practices only).
2. Early caries lesion progression data is measured using ICDAS (in Scottish practices only) at baseline and 3 year (+/- 3 months) follow-up
3. Bleeding on probing (BoP) will be recorded by the independent clinical examiners (in Scottish practices only) at baseline and 3 year (+/- 3 months) follow-up

Patient:
1. Oral health status using OHIP14, a measure of oral health-related Quality of Life (QoL), collected at baseline and annual follow up over the 3 year follow up period through patient administered questionnaires
2. The EQ-5D-5L profile measure of generic health status will be collected at baseline and annual follow up through patient questionnaires over the 3 year follow up period
3. Episodes of dental pain (number and an assessment of severity using a visual analogue scale) will be recorded at scheduled and unscheduled dental visits on the CRF. In addition questions about dental pain experience will be included in annual questionnaires sent to participants.
4. Oral health behaviour, including self-reported brushing/other sources of fluoride. Evaluated at baseline and through annual questionnaires sent to participants over the 3-year follow-up period of the trial

Economic:
1. Provision of NHS dental treatments will be collected using the CRF completed at each visit and by routinely collected data held by the Information Services Division (ISD) of NHS National Services Scotland, Business Services Authority (BSA, England) and Business Services Organisation (BSO, Northern Ireland)
2. All remaining resource use data will be use data collected using the CRF and annual patient-reported questionnaires over the 3-year follow-up period
3. A discrete choice experiment (DCE) with an online representative sample of the UK general population (aged 50 and over) will be undertaken to elicit willingness to pay (WTP) for high fluoride toothpaste and associated patient-relevant outcomes.
4. The “within trial” economic analyses will assess and report on the costs and outcomes of high fluoride vs. standard treatment up to 3 years post-randomisation

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Previous secondary outcome measures:
Clinical:
1. Caries increment , including dentist replacement fillings for caries, at tooth surface (DMFS) level is assessed using the ICDAS method to assess caries as it provides flexibility to analyse and

present caries data at different diagnostic thresholds at baseline and 3 year (+/- 3 months) follow-up. This will also be used for collecting early caries lesion progression data (DMFS measured in Scottish practices only).
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Patient:
1. Oral health status using OHIP14, a measure of oral health-related Quality of Life (QoL), collected at baseline and annual follow up over the 3 year follow up period through patient administered questionnaires
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3. Episodes of dental pain (number and an assessment of severity using a visual analogue scale) will be recorded at scheduled and unscheduled dental visits on the CRF. In addition questions about dental pain experience will be included in annual questionnaires sent to participants.
4. Oral health behaviour, including self-reported brushing/other sources of fluoride. Evaluated at baseline and through annual questionnaires sent by mail to the home address of participants over the 3 year follow up period of the trial

Economic:
1. Provision of NHS dental treatments will be collected using the CRF completed at each visit and by routinely collected data held by the Information Services Division (ISD) of NHS National Services Scotland, Business Services Authority (BSA, England) and Business Services Organisation (BSO, Northern Ireland)
2. All remaining resource use data will be use data will be collected using the CRF and annual mailed questionnaires over the 3 year follow up period
3. A discrete choice experiment (DCE) with an online representative sample of the UK general population (aged 50 and over) will be undertaken to elicit willingness to pay (WTP) for high fluoride toothpaste and associated patient relevant outcomes.
4. The “within trial” economic analyses will assess and report on the costs and outcomes of high fluoride vs. standard treatment up to 3 years post-randomisation

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/07/2022:
1. Patients attending dental practices participating in the trial
2. Aged 50 years or older
3. Diagnosis of active coronal caries (into dentine) in the last 12 months which may/may not have been treated, or any root caries; and\or other risk factors as determined by their GDP
4. Living in any residential setting
5. Receive their dental care in part or fully as an NHS patient
6. Patients whose GDP decides prescription of high concentration fluoride toothpaste is appropriate

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Previous inclusion criteria:
1. Patients attending dental practices participating in the trial
2. Aged 50 years of age or older
3. Diagnosis of active coronal caries (into dentine) in the last 12 months which may/may not have been treated, or any root caries; and\or other risk factors as determined by their GDP
4. Living in any residential setting

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
1161

Key exclusion criteria
Current exclusion criteria as of 15/07/2022:
1. Currently prescribed (by GDP or GP) high concentration fluoride toothpaste (for GDPs, prescription must have been issued at last examination visit)
2. Unable to provide informed consent
3. Hypersensitivity for sodium fluoride and/or other ingredients used in 5000ppm toothpaste
4. Are living in the same household as someone already recruited to REFLECT, or someone who is routinely using a high concentration fluoride toothpaste

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Previous exclusion criteria:
1. Currently prescribed high concentration fluoride toothpaste
2. Unable to provide informed consent

Date of first enrolment
10/02/2018

Date of final enrolment
13/03/2020

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Study participating centre
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD

Study participating centre
North Street Dental Care
42 North Street
Lurgan
Craigavon
United Kingdom
BT67 9AH

Study participating centre
Brownlow Family Dental Care
5 Legahory Centre
Craigavon
United Kingdom
BT65 5BE

Study participating centre
DJ Maguire & associates
83a Bridge Street
Portadown
United Kingdom
BT63 5AA

Study participating centre
Bell & Thom Dental Surgery
17/19 Main Street
Portglenone
Ballymena

United Kingdom
BT44 8AA

Study participating centre
Bishop Street Dentalcare
21 Bishop Street Within
Derry/Londonderry
United Kingdom
BT48 6PR

Study participating centre
The Grange Dental Care
2 Crevenagh Rd
Omagh
United Kingdom
BT79 0AL

Study participating centre
Newcastle family Dental Care
Iveagh Court
2 Railway Street
Newcastle
United Kingdom
BT33 0SP

Study participating centre
Main Street Dental Care
45A Main Street
Thornliebank
United Kingdom
G46 7SF

Study participating centre
Kelvingrove Dental Care Ltd
1180 Argyle Street
Glasgow
United Kingdom
G3 8TE

Study participating centre
Lossiemouth Dental Practice
2 Clifton Road
Lossiemouth
United Kingdom
IV31 6DJ

Study participating centre
Bute Dental Surgery
14-16 West Princes Street
Rothesay
United Kingdom
PA20 9AF

Study participating centre
Montrose Dental Practice
Montrose
United Kingdom
-

Study participating centre
Discovery Dental Care
1 West Bell Street
Dundee
United Kingdom
DD1 1EX

Study participating centre
One Dental
1 Queen St
Derry/Londonderry
United Kingdom
BT48 7EF

Study participating centre
Haugh Dental Care
Newcastle St. Kilkeel
Newry
United Kingdom
BT34 4AF

Study participating centre
L.C. Milton BDS
1356 Barrhead Road
Glasgow
United Kingdom
G53 7DE

Study participating centre
Quinndental
53 Main Street
Randalstown
Antrim
United Kingdom
BT41 3BB

Study participating centre
Salisbury Villa Dental Surgery
1 Salisbury Terrace
Teignmouth
United Kingdom
TQ14 8JG

Study participating centre
Chudleigh Dental Practice
21 Old Exeter Street
Chudleigh
Newton Abbot
United Kingdom
TQ13 0LD

Study participating centre
Nethergate Dental Practice
86 Nethergate
Dundee
United Kingdom
DD1 4EL

Study participating centre

Camlough Dental Practice
27 Main Street
Camlough
Newry
United Kingdom
BT35 7JG

Study participating centre
Blairgowrie Dental Care
64 High Street
Blairgowrie
United Kingdom
PH10 6DF

Study participating centre
Livingston Dental Healthcare
38 Hamilton Road
Bangor
United Kingdom
BT20 4LE

Study participating centre
Cardonald Dental Practice
5 Lamington Road
Cardonald
Glasgow
United Kingdom
G52 2SF

Study participating centre
The Glens Dental Practice
2 Gortaclee Rd
Cushendall
Ballymena
United Kingdom
BT44 0TE

Study participating centre
Dental bees
1 St Andrew Street
Castle Douglas

United Kingdom
DG7 1DE

Study participating centre
Tannochside Dental Centre
499 Old Edinburgh
Tannochside
Glasgow
United Kingdom
G71 6PL

Study participating centre
Harpers Dental Practice
32 Bradford St
Haulgh
Bolton
United Kingdom
BL2 1JJ

Study participating centre
Craigentinny Dental Care
57 Duddingston Crescent
Edinburgh
United Kingdom
EH15 3AY

Study participating centre
Stevenston Cross Dental
14 Fullarton Place
Stevenston
United Kingdom
KA20 3EH

Study participating centre
McNally Dental Care
248 Drumchapel Road
Glasgow
United Kingdom
G15 6EG

Study participating centre
Rankin Dental
30 Ellon Road
Aberdeen
United Kingdom
AB23 8BX

Study participating centre
Links Lodge Dental Practice
26 John Street
Montrose
United Kingdom
DD10 8LZ

Study participating centre
Castlebawn Dental Practice
32-34 Victoria Road
Bangor
United Kingdom
BT20 5EX

Study participating centre
The Dental House
6-12 Derby Ln
Old Swan
Liverpool
United Kingdom
L13 3DL

Study participating centre
Sheil Road Dental Practice
74 Sheil Road
Liverpool
United Kingdom
L6 3AF

Study participating centre
Canmore Dental Practice
8 Abbey Park Place
Dunfermline

United Kingdom
KY12 7PD

Study participating centre
Hyland Dental Care
6 Park Road
Hamilton
United Kingdom
ML3 6PD

Study participating centre
Canmore Dental Practice
126 Main Street
Lochgelly
United Kingdom
KY5 9AA

Study participating centre
The Collegiate Dental Practice
76 Brideoak St
Cheetham Hill
Manchester
United Kingdom
M8 0AB

Study participating centre
Clark & Watson Dental Practice
27 Newmarket Street
Falkirk
United Kingdom
FK1 1JJ

Study participating centre
Sankey St. Dental Practice
61a Sankey Street
Warrington
United Kingdom
WA1 1SL

Study participating centre
Delicate Dental
106 Main Street
Lisnaskea
United Kingdom
BT92 0JD

Study participating centre
Dr Philip Chai K Wee
102a Cricklewood Broadway
London
United Kingdom
NW2 3EJ

Study participating centre
Abbey Dental Care
47 Causeyside St
Paisley
United Kingdom
PA1 1YN

Study participating centre
Montgomery Street Dental Care
96 Montgomery St
Edinburgh
United Kingdom
EH7 5HE

Study participating centre
Abbey Dental Clinic
620-630 Shore Road
Newtownabbey
United Kingdom
BT37 0ST

Study participating centre
Tarbert Dental
Harbour Street
Tarbert
United Kingdom
PA29 6UB

Study participating centre
Maryhill Smile Care
283 Maryhill Rd
Glasgow
United Kingdom
G20 7YA

Study participating centre
Truss Dental
85 East Road
Irvine
United Kingdom
KA12 0AA

Study participating centre
Ethos Dental Surgery
126 Wellington Road North
Stockport
United Kingdom
SK4 2LL

Study participating centre
Kirkmuirhill Dental Practice
14a Thornton Road
Kirkmuirhill
Lanark
United Kingdom
ML11 9QE

Study participating centre
Simply Smiles Dental Surgery
35 Holden Rd
Salford
United Kingdom
M7 4LR

Study participating centre

Alyth Dental Care
20 Commercial Street
Alyth
Blairgowrie
United Kingdom
PH11 8AF

Study participating centre
Hafren House Dental Practice
1 Cressy Rd
Alfreton
United Kingdom
DE55 7BR

Study participating centre
Cottage Dental Practice
58 Moor Street
Ormskirk
United Kingdom
L39 2AW

Study participating centre
Glumangate Dental Practice
46 Glumangate
Chesterfield
United Kingdom
S40 1TX

Study participating centre
Pearl Dental
1242 London Road
Alvaston
Derby
United Kingdom
DE24 8QH

Study participating centre
Church Road Dental Practice
-
United Kingdom
-

Study participating centre
Woodlands Dental Practice
-
United Kingdom
-

Sponsor information

Organisation
Manchester University NHS Foundation Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the sponsor (research.sponsor@mft.nhs.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/05/2019	29/05/2019	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes