

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

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| <b>Submission date</b><br>01/06/2017   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>02/06/2017 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>03/08/2022       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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 patients 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](mailto:j.e.clarkson@dundee.ac.uk)

### **Study website**

<https://w3.abdn.ac.uk/hsru/REFLECT/Public/Public/index.cshtml>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Prof Janet Clarkson

### **ORCID ID**

<http://orcid.org/0000-0001-5940-2926>

### **Contact details**

School of Dentistry  
University of Dundee  
Park Place  
Dundee  
United Kingdom  
DD1 4HN  
+44 (0)1382 381707  
[j.e.clarkson@dundee.ac.uk](mailto:j.e.clarkson@dundee.ac.uk)

## **Additional identifiers**

### **EudraCT/CTIS number**

2017-002402-13

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## 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.

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## 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 measure**

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.

## **Secondary outcome measures**

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).
2. Early caries lesion progression data is measured using ICDAS (in Scottish practices only) at baseline and 3 year (+/- 3 months) follow-up
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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
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 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

**Overall study start date**

12/05/2017

**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

**Age group**

Senior

**Sex**

Both

**Target number of participants**

1174

**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**

England

Northern Ireland

Scotland

United Kingdom

**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  
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**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

**Sponsor details**

Research Office  
NOWGEN Building  
29 Grafton Street  
Manchester  
England  
United Kingdom  
M13 9WU  
+44 161 276 4125  
[research.sponsor@mft.nhs.uk](mailto:research.sponsor@mft.nhs.uk)

**Sponsor type**

Hospital/treatment centre

**Website**

<https://mft.nhs.uk/>

**ROR**

<https://ror.org/00he80998>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Dissemination of the study findings will be via academic publications in high impact, peer reviewed journals, through presentations at national and international conferences and through press releases to mass media organisations.

**Intention to publish date**

31/12/2024

**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? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>     | protocol | 24/05/2019   | 29/05/2019 | Yes            | No              |
| <a href="#">HRA research summary</a> |          |              | 28/06/2023 | No             | No              |