

# A clinical trial looking at maintaining hydration at the end of life

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<b>Registration date</b> 14/09/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/10/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The use of clinically-assisted hydration (CAH) in the last days of life is very variable and controversial because there is no good quality research to show whether it improves (or worsens) end-of-life care. In some cases there is a clear indication to start/continue CAH, whilst in other cases there is a clear indication to not start/discontinue CAH. However, in most cases there is no indication one way or another.

The research team has just completed a feasibility (provisional) study, which included 200 cancer patients from hospices/hospitals in England and Wales. The results suggest that CAH may delay the onset of delirium, but that CAH can cause side effects in some patients (e.g. fluid retention). A larger study is needed to properly evaluate the role of CAH. Recently, the Palliative and end-of-life care Priority Setting Partnership (involving patients, carers, patient support groups, members of the general public, and healthcare professionals) concluded that CAH was an important area for research.

The aim is to assess whether giving cancer patients in the last days of life clinically-assisted hydration (or CAH) is effective at preventing them from experiencing "terminal agitation". This is a distressing form of delirium that often occurs at end-of-life causing restlessness, anxiety and confusion in the patient, and which is very upsetting for family members. We will also explore if CAH affects other end-of-life symptoms (e.g. shortness of breath), length of survival and costs.

### Who can participate?

Adults aged over 18 years with a life expectancy of less than 1 week

### What does the study involve?

The study will be a so-called cluster randomised trial, which means that hospices/hospitals ('clusters') will be randomly allocated to one of two standard (usual) interventions. Intervention A involves supporting the patient to drink, regular mouth care, and management of pain and other symptoms. Intervention B involves supporting the patient to drink, regular mouth care, management of pain and other symptoms, and CAH. All eligible patients within each hospice/hospital will receive the same intervention (if appropriate). 80 hospices/hospitals in the United Kingdom and 1,600 cancer patients in the last week of life will take part in the study. Patients will be given fluids either into a vein or into the tissues under the skin. The amount of fluid given will be based on the patient's weight, and the decision to continue/discontinue the fluids will be

made by doctors.

Patients will be assessed for end-of-life problems every 4 hours by nursing staff, and data will be collected on the presence of problems, use of medication (to treat problems), and side effects of CAH.

What are the possible benefits and risks of participating?

None

Where is the study run from?

University of Surrey (UK)

When is the study starting and how long is it expected to run for?

September 2021 to February 2025

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Prof. Andrew Davies

andavies@tcd.ie

## Contact information

### Type(s)

Scientific

### Contact name

Prof Andrew Davies

### ORCID ID

<https://orcid.org/0000-0003-4207-4799>

### Contact details

School of Medicine  
Trinity College Dublin  
152-160 Pearse Street  
Dublin  
Ireland  
D2  
+44 (0)7786260295  
andavies@tcd.ie

### Type(s)

Public

### Contact name

Dr Andrew McClave

### Contact details

University of Surrey  
Surrey Clinical Trials Unit

Egerton Road  
Guildford  
United Kingdom  
GU2 7XP

-  
a.mcclave@surrey.ac.uk

### **Type(s)**

Public

### **Contact name**

Dr Andrew McClave

### **Contact details**

University of Surrey  
Surrey Clinical Trials Unit  
Egerton Road  
Guildford  
United Kingdom  
GU2 7XP

-  
chelseaii@surrey.ac.uk

## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

313640

### **Protocol serial number**

HTA NIHR131687, IRAS 313640

## **Study information**

### **Scientific Title**

A cluster randomised trial of clinically-assisted hydration in patients in the last days of life - CHELsea II

### **Acronym**

CHELsea II

### **Study objectives**

Clinically-assisted hydration (CAH) in the last days of life reduces the frequency of delirium (and the requirement for sedative medication), as a result of preservation of renal function, and prevention of build-up of drugs and toxins. Furthermore, CAH will prevent death due to dehydration occurring before death due to the underlying disease (or its complications).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Main: Approved 09/08/2022, London - Brighton & Sussex Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8202, +44 (0)207 104 8241; brightonandsussex.rec@hra.nhs.uk), ref: 22/LO/0475
2. Scotland: Approved 09/09/2022, Scotland A Research Ethics Committee (South East Scotland Research Ethics, Service, 2nd Floor, Waverley Gate, 24 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131465 5680; sesres@nhslothian.scot.nhs.uk), ref: 22/SS/0053

### **Study design**

Multi-centre cluster randomized trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Patients in the last week of life (cancer, non-malignant disease)

### **Interventions**

Research sites will be randomised to either “standard intervention A” or “standard intervention B” (see below), and this will become the standard of care at the research site for the duration of this study. The interventions represent the current typical standards of care in the UK. Randomisation will be undertaken 1:1 by cluster, to ensure balance and equal numbers in each intervention group, stratifying by home country (i.e. England, Wales, Scotland or Northern Ireland), and by type of unit (i.e. hospital or hospice).

Standard intervention A involves:

- continuation of oral intake (if appropriate) - includes assistance with drinking as required.
- regular “mouth care” - mouth care should be performed at least every four hours, and should correspond to the research site’s usual procedures for oral care in the terminal phase. Mouth care should be undertaken by the clinical team (but can involve carers if deemed appropriate). Mouth care should be discontinued/withheld if it causes distress/discomfort to the patient, or is otherwise difficult to undertake.
- standard management of pain and other end-of-life symptoms/problems - should correspond to the research site’s usual procedures for managing relevant problems in the terminal phase.

Standard intervention B involves:

- continuation of oral intake (if appropriate) - see above.
- regular mouth care - see above.
- standard management of pain and other end-of-life symptoms/problems - see above.
- CAH - see below.

The parenteral fluids may be given either intravenously (if an intravenous cannula is present), or subcutaneously (if no intravenous cannula is present). Intravenous fluids must be administered using an infusion pump, and subcutaneous fluids must be administered using gravity (and not using an infusion pump). The type/volume of fluid administered is based upon relevant NICE guidance: the fluid to be given is dextrose saline (4% dextrose, 0.18% sodium chloride), and the

volume to be given is dependent on the patient's weight. It should be noted that the volume of fluid is based on a figure of 25 ml/kg/day, which is the lower limit for generic patients, and the upper limit (for consideration) in "old" or "frail" patients. Intravenous fluids should be administered according to the research site's usual procedures. Subcutaneous fluids should be administered according to the following guidelines:

Patient's weight Volume of fluid

≤ 40 kg 1 L

50 kg 1.25 L

60 kg 1.5 L

70 kg 1.75 L

≥ 80 kg 2 L

Site of cannula - the preferred cannula sites are the lower lateral abdomen, and the upper lateral chest (rather than the upper arm, or the upper leg). If the cannula needs to be changed, then an alternative site should be used.

Type of cannula - the preferred cannula is a 24 g BD Saf-T-Intima cannula.

Rationale for changing cannula - the decision to change/re-site a cannula is at the discretion of the clinical team. Minimal (asymptomatic) swelling is expected at the site of the cannula, and is not in itself a reason to discontinue the infusion and/or re-site the cannula.

Rate of infusion - the preferred method of infusion is continuous infusion with the drop rate calculated in the usual manner.

Rationale for discontinuing the infusion - the decision to discontinue the infusion is at the discretion of the clinical team. Minimal (asymptomatic) swelling is expected at the site of the cannula, and is not in itself a reason to discontinue the infusion. The development of audible upper airways secretions ("death rattle") is also not in itself an indication to discontinue the infusion, since the development of this problem seems independent of hydration status/use of CAH.

Participants will be reviewed at least every four hours by the clinical team, and an assessment made as to whether or not certain symptoms/problems are present, i.e. delirium, audible upper respiratory secretions ("death rattle"), pain, shortness of breath, and nausea and vomiting. The clinical team will also assess patient's level of sedation every four hours, and document the indication for dispensing all as required and regular medication. The clinical team will complete a study-specific clinical observation document, which will be transcribed by the research team into the study case report form.

The maximum duration of the study is 14 days: the end of the study occurs with the death of the patient, the withdrawal of the patient, or the completion of 14 days. The duration of the interventions is the same as the duration of the study, unless the clinical team deem that the relevant intervention should be modified/discontinued. For example, mouth care should be discontinued if it causes distress/discomfort to the patient. Patients that have their treatment modified/discontinued will remain in the study (and their data analysed on an intention to treat basis).

## **Intervention Type**

Other

## **Primary outcome(s)**

Number of patients that develop delirium during the study. The Nursing Delirium Screening Scale (Nu-DESC) will be used to diagnose patients with delirium.

## Key secondary outcome(s)

Measured throughout the study:

1. The proportion of patients that receive as-required and/or regular medication for delirium (data derived from drug chart).
2. Time to the first dose of medication for delirium (as-required or regular – data derived from drug chart).
3. Modified Richmond Agitation and Sedation Scale (m-RASS) scores during the study (mean score; proportion time with score 0; proportion time with score 0 to -2 – data derived from clinical observation document).
4. The proportion of patients with audible upper airway secretions (“death rattle” – data derived from clinical observation document).
5. The proportion of patients that receive as-required and/or regular medication for audible upper airway secretions (data derived from drug chart).
6. Time to the first dose of medication for audible upper airway secretions (as-required or regular – data derived from drug chart).
7. Proportion patients that experience pain, shortness of breath, and nausea and vomiting (and require medication for these symptoms – data derived from clinical observation document and drug chart).
8. Adverse effects of clinically-assisted hydration (data derived from clinical observation document).
9. Overall survival (data derived from clinical observation document).
10. Health economic analysis (data derived from clinical observation document and drug chart).
11. Carer feedback on end-of-life care and research participation.

## Completion date

28/02/2025

## Eligibility

### Key inclusion criteria

1. Aged  $\geq 18$  years
2. Estimated prognosis of  $\leq 1$  week
3. Patient unable to maintain sufficient oral fluid intake (i.e.  $< 1$ l/day).

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Total final enrolment

1563

### **Key exclusion criteria**

1. Patient is dehydrated (patient eligible for inclusion after correction of dehydration)
2. Patient has a relevant Advance Directive to Refuse Treatment (ADRT)
3. Clinical indication for CAH
4. Clinical contraindication to CAH
5. Contraindication to cannulation
6. Total parenteral nutrition/enteral feeding in situ
7. Patient has had delirium in last 24 h
8. Patient has had audible upper airway secretions in last 24 h
9. Patient likely to be transferred elsewhere for end-of-life care

### **Date of first enrolment**

01/10/2022

### **Date of final enrolment**

28/02/2025

## **Locations**

### **Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

### **Study participating centre**

**Royal Surrey County Hospital**

Egerton Road

Guildford

United Kingdom

GU2 7XX

### **Study participating centre**

**Phyllis Tuckwell**

Waverley Lane, Farnham, Surrey

United Kingdom

GU9 8BL

**Study participating centre**  
**Princess Alice Hospice**  
West End Lane  
Esher  
United Kingdom  
KT10 8NA

**Study participating centre**  
**St Peter & St James Hospice**  
North Common Road  
North Chailey  
Lewes  
United Kingdom  
BN8 4ED

**Study participating centre**  
**St Catherine's Hospice**  
Grace Holland Avenue  
Pease Pottage  
United Kingdom  
RH11 9SF

**Study participating centre**  
**St Barnabas Hospice**  
Titnore Lane  
Worthing  
United Kingdom  
BN12 6NZ

**Study participating centre**  
**St Wilfreds Hospice**  
Walton Lane  
Bosham  
Chichester  
United Kingdom  
PO18 8QB

**Study participating centre**  
**Pilgrims Hospice In Thanet**  
Ramsgate Road  
Margate

United Kingdom  
CT9 4AD

**Study participating centre**

**St Wilfred's Hospice**

Broadwater Way  
Eastbourne  
United Kingdom  
BN22 9PZ

**Study participating centre**

**Hospice In the Weald**

Maidstone Road  
Pembury  
Tunbridge Wells  
United Kingdom  
TN2 4TA

**Study participating centre**

**St Elizabeth's Hospice**

Beccles Hospital  
St. Marys Road  
Beccles  
United States Minor Outlying Islands  
NR34 9NQ

**Study participating centre**

**Pilgrims Hospice In East Kent**

56 London Road  
Canterbury  
United Kingdom  
CT2 8JA

**Study participating centre**

**Ty Olwen**

Heol Maes  
Eglwys  
Swansea  
United Kingdom  
SA6 6N

**Study participating centre**  
**The Heart of Kent Hospice**  
Preston Hall  
Aylesford  
Maidstone  
United Kingdom  
ME20 7PU

**Study participating centre**  
**Wisdom Hospice**  
High Bank  
St Williams Way  
Rochester  
United Kingdom  
ME1 2NU

**Study participating centre**  
**John Eastwood Hospice**  
Mansfield Road  
Sutton-in-ashfield  
United Kingdom  
NG17 4HJ

**Study participating centre**  
**Loros**  
Leics & Rutland Hospice  
Groby Road  
Leicester  
United Kingdom  
LE3 9QE

**Study participating centre**  
**Lindsey Lodge**  
Burringham Road  
Scunthorpe  
United Kingdom  
DN17 2AA

**Study participating centre**

**Royal Derby Hospital (nuh)**

Uttoxeter Road  
Derby  
United Kingdom  
DE22 3NE

**Study participating centre**

**Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus**

Nottingham University Hospital  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**

**St Nicholas Hospice**

Macmillan Way  
Hardwick Lane  
Bury St. Edmunds  
United Kingdom  
IP33 2QY

**Study participating centre**

**Arthur Rank Hospice Charity**

Cherry Hinton Road  
Shelford Bottom  
Cambridge  
United Kingdom  
CB22 3FB

**Study participating centre**

**Specialist Palliative Care Services**

Priscilla Bacon Centre  
Unthank Road  
Norwich  
United Kingdom  
NR2 2PJ

**Study participating centre**

**Pilgrims Hospice at Ashford**

Hythe Road

Willesborough  
Ashford  
United Kingdom  
TN24 0NE

**Study participating centre**

**Alice House Hospice**

Alice House  
Wells Avenue  
Hartlepool  
United Kingdom  
TS24 9DA

**Study participating centre**

**Teesside Hospice**

1 Northgate Road  
Middlesbrough  
United Kingdom  
TS5 5NW

**Study participating centre**

**North Tyneside Specialist Unit**

Rake Lane  
North Shields  
United Kingdom  
NE29 8NH

**Study participating centre**

**St Davids Hospice**

Abbey Road  
Llandudno  
United Kingdom  
LL30 2EN

**Study participating centre**

**Ysbyty Penrhos Stanley**

Penrhos Beach Road  
Holyhead  
United Kingdom  
LL65 2QA

**Study participating centre**  
**Marie Curie Cardiff and Vale Hospice**  
Bridgeman Road  
Penarth  
United Kingdom  
CF64 3YR

**Study participating centre**  
**Velindre Cancer Centre**  
Velindre Road  
Cardiff  
United Kingdom  
CF14 2TL

**Study participating centre**  
**Wansbeck Specialist Unit**  
Woodhorn Lane  
Ashington  
United Kingdom  
NE63 9JJ

**Study participating centre**  
**St Cuthberts Hospice**  
Park House Road  
Durham  
United Kingdom  
DH1 3QF

**Study participating centre**  
**St Oswalds Hospice**  
Regent Avenue  
Newcastle upon Tyne  
United Kingdom  
NE3 1EE

**Study participating centre**  
**St Clare's Hospice**  
Hastingwood Road  
Hastingwood

Harlow  
United Kingdom  
CM17 9JX

**Study participating centre**

**Peace Hospice**  
Peace Drive  
Watford  
United Kingdom  
WD17 3PH

**Study participating centre**

**Farleigh Hospice**  
North Court Road  
Broomfield  
Chelmsford  
United Kingdom  
CM1 7FH

**Study participating centre**

**Saint Francis Hospice ScCs**  
The Hall  
Broxhill Road  
Havering-atte-bower  
Romford  
United Kingdom  
RM4 1QH

**Study participating centre**

**St. Helena Hospice**  
Myland Hall  
Barncroft Close  
Highwoods  
Colchester  
United Kingdom  
CO4 9JU

**Study participating centre**

**North London Hospice**  
47 Woodside Avenue  
North Finchley

London  
United Kingdom  
N12 8TT

**Study participating centre**  
**St Johns Hospice (in Wirral)**  
Mount Road  
Higher Bebington  
Wirral  
United Kingdom  
CH63 6JE

**Study participating centre**  
**Willowbrook Hospice**  
Portico Lane  
Eccleston Park  
Prescot  
United Kingdom  
L34 2QT

**Study participating centre**  
**St Catherines Hospice**  
Lostock Lane  
Lostock Hall  
Preston  
United Kingdom  
PR5 5XU

**Study participating centre**  
**Trinity Hospice Community**  
Low Moor Road  
Bispham  
Blackpool  
United Kingdom  
FY2 0BG

**Study participating centre**  
**St Columbas Hospice**  
15 Boswall Road

Edinburgh  
United Kingdom  
EH5 3RW

**Study participating centre**  
**The Prince and Princess of Wales**  
20 Dumbreck Road  
Bellahouston Park  
Glasgow  
United Kingdom  
G41 5BW

**Study participating centre**  
**Royal Trinity Hospice**  
30 Clapham Common  
London  
United Kingdom  
SW4 0RN

**Study participating centre**  
**St Raphael's Hospice**  
London Road  
Cheam  
Sutton  
United Kingdom  
SM3 9DX

**Study participating centre**  
**Weston Hospicecare**  
Jackson Barstow House  
28 Thornbury Road  
Uphill  
Weston-super-mare  
United Kingdom  
BS23 4YQ

**Study participating centre**  
**Marie Curie Hospice Edinburgh**  
45 Frogston Rd

Edinburgh  
United Kingdom  
EH10 7DR

**Study participating centre**  
**Dorothy House Hospice**  
Dorothy House Hospice Care  
Winsley  
Bradford-on-avon  
United Kingdom  
BA15 2LE

**Study participating centre**  
**St Margarets Hospice**  
Heron Drive  
Bishops Hull  
Taunton  
United Kingdom  
TA1 5HA

**Study participating centre**  
**Weldmar Hospicecare Trust**  
Herringston Road  
Dorchester  
United Kingdom  
DT1 2SL

**Study participating centre**  
**Countess Mountbatten Hospice**  
Botley Road  
West End  
Southampton  
United Kingdom  
SO30 3JB

**Study participating centre**  
**Earl Mountbatten Hospice**  
Halberry Lane  
Newport  
United Kingdom  
PO30 2ER

**Study participating centre**

**Winchester Hospice**

Royal Hampshire County Hospital,  
Romsey Road  
Winchester  
United Kingdom  
SO22 5DG

**Study participating centre**

**Countess of Brecknock Hospice**

Charlton Road,  
War Memorial Community Hospital  
Andover  
United Kingdom  
SP10 3LB

**Study participating centre**

**St Michaels Hospice**

Aldermaston Road  
Basingstoke  
United Kingdom  
RG24 9NB

**Study participating centre**

**St Peters Hospice (brentry)**

Charlton Road  
Brentry  
Bristol  
United Kingdom  
BS10 6NL

**Study participating centre**

**Sue Ryder Care Home**

Leckhampton Court  
Church Road  
Leckhampton  
Cheltenham  
United Kingdom  
GL53 0QJ

**Study participating centre**

**Birmingham St Mary's Hospice**

Birmingham St. Marys Hospice  
176 Raddlebarn Road  
Birmingham  
United Kingdom  
B29 7DA

**Study participating centre**

**Compton Palliative Care Team**

Compton Hospice Ltd, Compton Hall  
4 Compton Road West  
Wolverhampton  
United Kingdom  
WV3 9DH

**Study participating centre**

**St Giles Hospice**

Fisherwick Road  
Whittington  
Lichfield  
United Kingdom  
WS14 9LH

**Study participating centre**

**Douglas Macmillan Hospice**

Barlaston Road  
Blurton  
Stoke-on-trent  
United Kingdom  
ST3 3NZ

**Study participating centre**

**The Mary Stevens Hospice**

221 Hagley Road  
Stourbridge  
United Kingdom  
DY8 2JR

**Study participating centre**

**Warwick Myton Hospice**

Myton Lane  
Warwick  
United Kingdom  
CV34 6PX

**Study participating centre**

**Saint Michael's Hospice - Harrogate**

Crimple House,  
Hornbeam Park Ave.  
Harrogate  
United Kingdom  
HG2 8NA

**Study participating centre**

**Dove House Hospice**

Chamberlain Road  
Hull  
United Kingdom  
HU8 8DH

**Study participating centre**

**The Prince of Wales Hospice**

Halfpenny Lane  
Pontefract  
United Kingdom  
WF8 4BG

**Study participating centre**

**Saint Catherine's Hospice - Scarborough**

Throxenby Lane  
Scarborough  
United Kingdom  
YO12 5RE

**Study participating centre**

**Bolton Hospice**

Queens Park Street  
Off Chorley New Road

Bolton  
United Kingdom  
BL1 4QT

**Study participating centre**

**Kccg-chc St Julias**  
St Julia's Hospice  
Foundry Hill  
Hayle  
United Kingdom  
TR27 4HW

**Study participating centre**

**St Kentigern Hospice**  
Upper Denbigh Road  
St Asaph  
United Kingdom  
LL17 0RS

**Study participating centre**

**Oxford University Hospitals**  
John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**

**University Hospital Southampton NHS Foundation Trust**  
Southampton General Hospital  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

**Study participating centre**

**Sue Ryder Manorlands Hospice**  
Manorlands  
Keighley Road  
Oxenhope

Keighley  
United Kingdom  
BD22 9HJ

**Study participating centre**  
**Salisbury NHS Foundation Trust**  
Salisbury District Hospital  
Odstock Road  
Salisbury  
United Kingdom  
SP2 8BJ

**Study participating centre**  
**Dr Kershaws Hospice**  
Turf Lane  
Royton  
Oldham  
United Kingdom  
OL2 6EU

**Study participating centre**  
**St Christophers Hospice**  
51-59 Lawrie Park Road  
London  
United Kingdom  
SE26 6DZ

**Study participating centre**  
**Ipswich Hospital**  
Heath Road  
Ipswich  
United Kingdom  
IP4 5PD

**Study participating centre**  
**Prospect Hospice**  
Moormead Road  
Wroughton  
Swindon  
United Kingdom  
SN4 9BY

**Study participating centre**  
**Royal Marsden Hospital**  
Royal Marsden Hospital  
Downs Road  
Sutton  
United Kingdom  
SM2 5PT

## Sponsor information

**Organisation**  
University of Surrey

**ROR**  
<https://ror.org/00ks66431>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
National Institute for Health Research

**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

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Anonymised raw data will be available to bone-fide academic researchers on request at the end of the study (and for 5 years afterwards) - requests need to be made to the study chief investigator (Prof Andrew Davies - andavies@tcd.ie), and a data sharing agreement will be produced between the study sponsor (University of Surrey) and the researchers' academic institution outlining the conditions of use of the data (including proposed analysis of the data). The participant information sheet will discuss the issue of data sharing.

## 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>		23/11/2022	24/11/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	Qualitative study	29/10/2025	30/10/2025	Yes	No
<a href="#">Participant information sheet</a>	version 1.0	27/07/2022	20/10/2022	No	Yes
<a href="#">Participant information sheet</a>	version 1.0	27/07/2022	20/10/2022	No	Yes
<a href="#">Protocol file</a>	version 1.0	27/07/2022	21/10/2022	No	No
<a href="#">Protocol file</a>	version 1.2	09/09/2022	28/10/2022	No	No
<a href="#">Protocol file</a>	version 1.5	19/02/2025	05/03/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes