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Smoking, nicotine and pregnancy 2 trial

Submission date
15/03/2021

Recruitment status
No longer recruiting

Registration date
16/03/2021

Overall study status
Ongoing

Last Edited
01/07/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Nicotine replacement therapy (NRT) helps non pregnant smokers to stop smoking. However, during pregnancy adherence is often low, for example the duration women take it and/or the amount taken is often not enough. Poor adherence reduces pregnant women's chances of stopping smoking.
We have created an intervention called 'Baby, Me & NRT' (BMN) to help improve adherence to NRT during pregnancy which emphasises the use of NRT for longer and in more adequate doses. BMN will run alongside usual NHS smoking cessation care. The intervention includes reinforcement of key NRT adherence-enhancing messages via a leaflet and a website. It also includes personally tailored SMS text messages which support abstinence, encourage NRT use to control withdrawal symptoms and/or cravings, counters concern about nicotine and so intentional non-adherence and minimise forgetting NRT through prompts and reminders.
The aim of this study is to test whether the BMN intervention improves pregnant women's adherence to NRT and quit rates during pregnancy.

Who can participate?
We will recruit pregnant smokers aged 16 years or older, from antenatal care, smoking cessation clinics or online through various social media platforms such as Facebook/Google.

What does the study involve?
Participants will then be randomly divided into two groups. One group will receive usual NHS stop smoking support (NRT and behavioural support). The second group will receive the NAI, alongside usual NHS stop smoking support. We will compare the number of days NRT is used in the first 28 days following a quit date between the two groups. We will also compare the intensity of NRT use, days used NRT until the end of pregnancy, smoking status at the end of pregnancy and birth outcomes. Participants will provide saliva samples and possibly breath tests before and during the study to measure nicotine and carbon monoxide levels respectively. We will also ask about beliefs towards NRT before and during the study. We will follow women up at 36 weeks gestation and ask about their smoking and NRT use, a saliva sample and possibly a breath test will be requested from women who report not smoking. Birth outcomes will be collected from hospital records.

What are the possible benefits and risks of participating?
We cannot promise the study will help participants, but all participants will receive support to

stop smoking based on the best NHS standards of practice. The information they provide to us during the study will be invaluable in helping us devise ways of supporting women who want to stop smoking during their pregnancy. We do not foresee there being any risks from taking part in this study. However, we appreciate that taking part will take time and may therefore be inconvenient. Also, some participants may be upset about receiving some basic information about the risks of smoking in pregnancy.

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

When is the study starting and how long is it expected to run for?
November 2019 to April 2027

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

Who is the main contact?
Lucy Phillips, snap2@nottingham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Lucy Phillips

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Additional identifiers

Integrated Research Application System (IRAS)
287771

Central Portfolio Management System (CPMS)
48261

Study information

Scientific Title
Impact of the ‘Baby, Me & NRT’ intervention on pregnant women’s adherence to nicotine replacement therapy (NRT): a randomised controlled trial

Acronym
SNAP2

Study objectives
Current study hypothesis as of 25/01/2024:
To investigate whether the 'Baby, Me & NRT' (BMN) intervention increases pregnant women's rates of smoking cessation in late pregnancy.

Previous study hypothesis:
To determine whether the 'Baby, Me & NRT' intervention added to usual NHS cessation support increases pregnant women's number of days of NRT use in the first 28 days following a quit date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2021, London - Bloomsbury Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8196; bloomsbury.rec@hra.nhs.uk), ref: 21/LO/0123

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adherence to nicotine replacement therapy during pregnancy

Interventions
We will recruit 1320 pregnant smokers who want to use NRT and receive stop smoking support. We will then randomize participants into two groups. The control group will receive standard NHS stop smoking support (usual care) and the intervention group will receive the 'Baby, Me & NRT' intervention alongside standard NHS stop smoking support.

Usual Care and intervention description:
Description of Usual Care - Usual care consists of standard NHS smoking cessation care in pregnancy, which includes:
• Behavioural support to quit smoking
• Nicotine Replacement Therapy (NRT); using NRT is established clinical practice and is recommended by NICE for pregnant women who cannot stop by other means. A 2015 survey found that 87% of English SSSs recommend 'dual NRT' to pregnant women who smoke
• Setting a quit date within 14 days of a support session
• Follow up support and a determination of whether cessation is achieved (usually a measure of carbon monoxide)
• At the initial consultation women are given advice on how to use NRT to avoid withdrawal symptoms and cravings and are usually issued with up to 14 days' NRT for use on and after the

quit dates, further NRT will then be issued (if required) after the first 14 days.
Description of the 'Baby, Me & NRT' Intervention (to be delivered alongside standard NHS smoking cessation care):
i) At initial consultation
• Amended behavioural support on how to use NRT, including using NRT throughout the whole of pregnancy, if needed, and not stopping NRT during brief lapses to smoking.
• Counselling on using dual NRT during pregnancy that assesses and addresses women's specific concerns about the safety of nicotine as determined from preparatory research.
• Support on how to maintain adherence to NRT (e.g. use of problem-solving skills to overcome barriers to using NRT as advised or to manage a brief lapse to smoking).
ii) Via leaflet, website or other media:
• Reinforcement of key NRT adherence-enhancing messages potentially using mixed text and media
iii) Up to 30 days of personally-tailored, automated text messages to:
• Support participants to maintain abstinence
• Encourage sufficient use of NRT for control of withdrawal symptoms or cravings
• Counter deliberate non-adherence to NRT (e.g. due to concerns about nicotine)
• Provide prompts or reminders and promote techniques to minimise forgetting to use NRT
iv) Via video/telephone calls:
• Assess participants' experience of tobacco withdrawal symptoms and cravings and advise on amount of NRT used. Providing enhanced support on NRT use.

The intervention will add no more than 30 minutes than usual care for the initial consultation, and the subsequent sessions will take no longer than 15 minutes each.

Delivery regimen:
Initial stop smoking practitioner (SSP) consultation: The SSP consultation will be delivered by a member of the research team who is also a fully trained Stop Smoking Practitioner working under an honorary contract. This consultation may occur in a variety of locations; by telephone /video call, in a private location in hospital or a community stop smoking service (SSS). All women will receive usual support, including provision of NRT. Women allocated to the NAI group will receive the behavioural support component of the NAI (see above, Description of the Intervention)alongside the following NAI components; leaflet, access to the intervention website, possibly a chatroom, and information about the intervention text-message support system, including how to stop messages. At the end of
the consultation, using information provided by the participant about their previous use of NRT, views about NRT and date they plan to quit smoking (see 'data collection regimen' below), the personalised text-messaging system will be initiated by a researcher. NRT will be posted to women's home after this appointment in preparation for their quit date.

Women who are recruited face to face in a clinic may have their first saliva sample and possibly a CO reading taken after recruitment process while in clinic, whereas others, in particular those recruited online or those identified through PIC sites will be expected to complete the first sample (before quitting smoking) and possibly a CO reading themselves. A member of the research team will post women saliva sample kits and CO monitors (if required) for this, plus prepaid envelopes for postal return. Saliva samples are required at baseline and Day 7 from all women and a random sample of women will be expected to provide CO readings. A member of the research team will provide guidance on how to complete biological samples at baseline and Day 7, plus participants will also receive instruction
forms.

Day 2 prior to quit date to day 28 after quit date: Participants in the NAI group will receive daily text messages according to a predetermined schedule and also in response to interaction by the participant. Participants will be asked to respond by text message to occasional, pre-scheduled queries about smoking status and/or NRT use and these responses will be used for ongoing tailoring of their text messages. Participants can cancel the text message element of the support at any time by sending a 'STOP' text message.

Days 3, 7, 14, 21, 28 after quit date: On or around days 3, 7, 14, 21 and 28 all participants will be contacted to receive further smoking cessation support. As necessary, arrangements will be made for participants to receive further NRT supplies. Telephone/video calls will be delivered by a member of the research team who is also a fully-trained stop smoking practitioner. If participants cannot be reached by telephone, we will send them a text message inviting a response and will try to telephone again after this. Participants in the NAI group will receive smoking cessation support with a greater focus on participants' experience of using NRT and on providing specific advice to encourage adherence with NRT

Data collection:
Baseline: After obtaining consent but before delivery of study interventions and randomisation (participants will be randomised by the central research team), researchers (i.e. CRN working in trial centres or research team staff) will ask participants about gestation, nicotine dependence, current and pre-pregnancy smoking behaviours, prior experience using NRT, urges to smoke (cravings) and tobacco withdrawal symptoms. Participants will then be sent a link to survey to complete online about their NRT concerns and necessity beliefs, they will need to complete this survey before their first consultation with an SSP. Some of these items will be used to tailor /personalise text message support for women in the intervention group. Participants recruited through CRN researchers in the hospital will also
asked to provide a saliva sample and may also be asked for an expired air CO reading after being consented into the study. CRN researchers will send the samples directly back to the laboratory. Saliva samples will measure cotinine and anabasine concentrations; these are both metabolites of nicotine and reflect nicotine exposure. However, anabasine is tobacco-specific and so differentiates nicotine exposure which is specifically due to smoking with that from other sources (e.g. NRT or e-cigarettes). Exhaled CO is an indicator of heaviness of smoking. For participants recruited via online or through PIC sites, the research team will send out saliva collection kits and CO monitors designed for individual use with instructions. All equipment used will be CE marked and used within its intended purpose. These women will be expected to return saliva samples by post directly to the laboratory before their quit date. Participants may be instructed to use a smartphone app in conjunction with the CO monitor, to send exhaled CO readings directly to the research team. Before quit date: a researcher will ensure all participants have provided a baseline sample and breath test (if required) and contact women with outstanding information. The researcher will also ensure women have received a saliva collection kit and CO monitor instructions so they can provide another sample/possible reading at Day 7. All participants will be asked to provide the contact details of their GP when joining the study. We will ask GP's to contact us if they see any reason the participant should not take part in the study.

Post randomisation, smoking cessation appointment- To inform a fidelity checklist for intervention delivery, We will audio record, with consent, all initial intervention group consultations and will then select a random sample of these for further scrutiny. Recording equipment will only be activated once consent has been given. Consent for this is optional.

Day 7 after quit date: Participants are expected to provide a further expired air carbon monoxide reading (through the app, if possible) and saliva sample (using the postal kit sent to

them). A member of the research team (most likely a SSP) will guide women to do this during their Day 7 SSP consultation. Also on Day 7 participants will be contacted by text message/email /telephone/post to complete survey questions about current smoking behaviours, use of NRT, urges to smoke (cravings) and tobacco withdrawal symptoms. If a postal saliva sample is not received and/or CO reading and/or survey questions are not completed, participants will receive a reminder text/emails and, if data is still not received, we will try to contact participants via telephone, and send the survey by post as a final method of
obtaining survey data. We will aim to collect all data as close as possible to day 7 after quit date.

Day 28 after quit date: participants will be contacted by text message/email/telephone/post to complete survey questions about current smoking behaviours, use of NRT, urges to smoke (cravings) and tobacco withdrawal symptoms. They will also be asked questions relating to their concerns and necessity beliefs about using NRT. Women in the intervention group will be asked about their engagement with the intervention components.

Days 1 to 28 after quit date - All participants will be prompted regularly (maximum once daily) via an app they will install on their phone (called NicUse) which has been specifically designed for this study, and asked throughout the 4 weeks following their quit date to provide information on their daily use of:
i) long-acting and short-acting NRT
ii) e-cigarettes
iii) smoking
Participants who fail to supply adherence data via the NicUse app for 2 consecutive days will be sent an automated text reminder prompting them to restart this, followed by a further text reminder the following day if still not completed.

Week 36 of pregnancy: on or around week 36 weeks of pregnancy (delivery if earlier) we will ask women (via text/email, telephone, postal) their smoking status, use of e-cigarette and NRT and whether they have delivered their baby. Women who report that they do not smoke will be sent a saliva sample to complete, and if they are using ECs or NRT they may also be asked to provide a CO reading. We will ask for a saliva sample to be returned by post to the laboratory and a CO reading to be obtained via participants own personal CO monitor, in some cases, for example when women are not contactable, the CO readings may obtained by hospital records (where possible). If a saliva sample and /or survey is not received, participants will receive a reminders by text/email/telephone to return outstanding survey/samples. The survey will then be sent by post if other methods fail. We will aim to collect all survey data/saliva samples/CO readings as close as possible to week 36 after quit date.

Post-delivery: members of the research team will liaise with CRN midwives/hospitals where women were booked to deliver their baby, in order to collect data on birth outcomes from hospital records. They will also collect smoking at delivery data from hospital records for women who do not respond to the 36 weeks follow up.

Fidelity of the intervention: This will involve audio recording, with consent, all initial intervention group consultations and we will then select a random sample of these for further scrutiny against a fidelity checklist which has been developed in a previous workstream. We will also conduct qualitative interviews with SSP who are members of the research team work under an NHS honorary contract. The aim of these interviews if to understand the barriers against and facilitators towards practitioners being able to deliver the intervention counselling combined with usual care support.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measure as of 25/01/2024:
Smoking cessation in late pregnancy or around childbirth by participant self-report, with appropriate biochemical validation in late pregnancy from either saliva cotinine concentration below ≤10 ng/mL or exhaled CO reading ≤9 ppm.

Previous primary outcome measure:
Reported number of days NRT is used in the first 28 days after the quit date (daily questions through a mobile phone app for 28 days, survey at Day 7 and Day 28)

Key secondary outcome(s)

Current secondary outcome measures as of 25/01/2024:
1. Smoking cessation at both 28 days and in late pregnancy or at childbirth by participant self-report, with and without appropriate biochemical validation in late pregnancy from either saliva cotinine concentration below ≤10 ng/mL or exhaled CO reading ≤9 ppm
2. Smoking cessation for 24 hours or 7 days by participant self-report at 28 days
3. Adherence to NRT use measured as the number of days NRT is used in the first 28 days following a quit date from participants' self-report
4. 'Intensity' of NRT use measured as mean daily nicotine dose in the first 7 days following quit date from participants' self-report
5. Engagement with BMN intervention measured in the first 28 days following a quit date by the participant reported engagement with components of the BMN intervention (daily tailored texts, leaflet and website)

Pilot phase outcomes:
6. Urges to smoke 'cravings' and tobacco withdrawal symptoms on Day 7 and Day 28 from participant self-report
7. NRT concerns & necessity beliefs using the 'NRT concerns & necessity beliefs' survey at baseline and Day 28 completed by participants
8. Fidelity of intervention delivery at the Initial Pre-Quit consultation as measured against the fidelity checklist by the researcher
9. Cessation practitioners' views on intervention delivery via semi-structured qualitative interviews at the end of delivery of the intervention

Other outcomes:
10. Nicotine exposure measured by mean saliva cotinine concentrations and exhaled CO concentrations measured at baseline and Day 7
11. Adherence to NRT use measured by the number of days NRT use reported by participants between a quit date and the end of pregnancy
12. Adverse pregnancy outcome rates at the end of pregnancy measured by birth weight
13. Adverse pregnancy outcome rates at the end of pregnancy measured by low birth weight (<2500 g)
14. Adverse pregnancy outcome rates at the end of pregnancy measured by gestational age at birth
15. Adverse pregnancy outcome rates at the end of pregnancy measured by maternal or fetal death (stillbirth or miscarriage)
16. Adverse pregnancy outcome rates at the end of pregnancy measured by caesarean section delivery
17. Adverse pregnancy outcome rates at the end of pregnancy measured by neonatal intensive

care admission
18. Adverse pregnancy outcome rates at the end of pregnancy measured by congenital anomaly
19. Cost-effectiveness of the BMN intervention measured by costs of usual care & intervention (e.g. cost of NRT, length and cost of consultations) at the end of pregnancy
20. Cost-effectiveness of the BMN intervention measured by costs of health care admissions for mother and infant at the end of pregnancy

Previous secondary outcome measures:
1. Reported mean daily nicotine dose in the first 7 days following quit date ('intensity' of NRT use) (daily questions through a mobile phone app for 28 days, survey at Day 7)
2. NRT concerns & necessity beliefs (survey at baseline and Day 28)
3. Mean saliva cotinine concentrations (baseline, Day 7 and possibly at Week 36 gestation in women who report they have quit smoking)

Other outcomes:
4. Number of days NRT use between a quit date and the end of pregnancy (Survey Day 7, Day 28 and Week 36 plus study app daily for first 28 days of intervention)
5. Self-reported smoking status in late pregnancy or at childbirth with (Week 36 survey)
6. Biochemical validation of reported cessation (Week 36 saliva sample)
7. Urges to smoke 'cravings' and tobacco withdrawal symptoms (survey at baseline, Day 7 and Day 28)
8. Exhaled carbon monoxide (CO) concentrations (Baseline breath test, Day 7 breath test and possible at Week 36 gestation in women who report they have quit smoking)
9. Birth weight (hospital records)
10. Low birth weight (<2500g) (hospital records)
11. Gestational age at birth (hospital records)
12. Maternal or fetal death (stillbirth or miscarriage). (hospital records)
13. Caesarean section delivery (hospital records)
14. Neonatal intensive care admission (hospital records)
15. Congenital anomaly (hospital records)
16. Fidelity of intervention delivery as measured against fidelity checklist (recordings of first consultation between Stop Smoking Practitioner (SSP) and participant)
17. Cessation practitioners' views on intervention delivery (qualitative interviews with SSP after delivering study intervention)
18. Engagement with intervention components (Survey at Week 36 gestation)
19. Costs of usual care & intervention (e.g. cost of NRT, length and cost of consultations) (economic evaluation by study economist at end of study)
20. Costs of health care admissions for mother and infant (economic evaluation by study economist at end of study)

Completion date
30/04/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/01/2022:

1. Pregnant (<25 weeks' gestation)
2. Aged 16 years or over
3. Having been referred for or having received any kind of appointment as part of standard

available antenatal care
4. Smoked 5 or more cigarettes per day pre-pregnancy and currently smoking at least 1 cigarette daily
5. Motivated to quit smoking, wants to try NRT and willing to set a quit date within 14 days
6. Agrees to accept the intervention or control, and to participate in study data collection
7. Owns a smartphone, uses it for sending and receiving SMS text messages, and agrees to install both the trial's 'NicUse' app (collects data on smoking and NRT use) and an app for transferring exhaled carbon monoxide (CO) readings to study team
8. Understands written and spoken English
9. Able to give informed consent

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Previous inclusion criteria:

1. Pregnant (<25 weeks' gestation)
2. Aged 16 years or over
3. Having had first antenatal contact with a health professional (e.g. 'booking' appointment at ~ 8 weeks)
4. Smoked 5 or more cigarettes per day pre-pregnancy and currently smoking at least 1 cigarette daily
5. Motivated to quit smoking, wants to try NRT and willing to set a quit date within 14 days
6. Agrees to accept the intervention or control, and to participate in study data collection
7. Owns a smartphone, uses it for sending and receiving SMS text messages, and agrees to install both the trial's 'NicUse' app (collects data on smoking and NRT use) and an app for transferring exhaled carbon monoxide (CO) readings to study team
8. Understands written and spoken English
9. Able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
100 Years

Sex
Female

Total final enrolment
938

Key exclusion criteria

1. Already enrolled in a smoking cessation study or NHS stop smoking support
2. Already enrolled in another text service to assist smoking cessation
3. Using an e-cigarette/vaping device and/or a heat not burn product, and not willing to stop using this to join the study
4. Already using NRT to quit or cut down smoking
5. Contraindications to NRT including: severe cardiovascular disease, unstable angina, cardiac arrhythmias, recent cerebrovascular accident or TIA, chronic, generalized skin disorders or sensitivity to nicotine patches, chemical dependence / alcohol addiction; major fetal anomalies

Date of first enrolment
21/06/2021

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Southport and Formby District General Hospital
Southport and Ormskirk Hospital NHS Trust
Town Lane
Southport
England
PR8 6PN

Study participating centre
Kings Mill Hospital
Sherwood Forest Hospitals NHS Foundation Trust
Mansfield Road
Sutton-in-Ashfield
England
NG17 4JL

Study participating centre
Queen's Medical Centre
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham

England
NG7 2UH

Study participating centre
Royal Derby & Burton Hospital
University Hospitals of Derby and Burton NHS Foundation Trust
Uttoxeter Road
Derby
England
DE22 3NE

Study participating centre
Birmingham Women's Hospital
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
England
B4 6NH

Study participating centre
Royal Preston Hospital
Lancashire Teaching Hospitals NHS Foundation Trust
Sharoe Green Lane North
Fulwood
Preston
England
PR2 9HT

Study participating centre
Sunderland Royal Hospital
South Tyneside and Sunderland NHS Foundation Trust
Kayll Road
Sunderland
England
SR4 7TP

Study participating centre
Leighton Hospital
Mid Cheshire Hospitals NHS Foundation Trust
Leighton
Crewe

England
CW1 4QJ

Study participating centre
Nottingham City Hospital
Nottingham University Hospitals NHS Trust
Nottingham
England
NG5 1PB

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Study participating centre
Northern Lincolnshire and Goole NHS Foundation Trust
Diana Princess of Wales Hospital
Scartho Road
Grimsby
England
DN33 2BA

Study participating centre
Surrey and Sussex Healthcare NHS Trust
Trust Headquarters
East Surrey Hospital
Canada Avenue
Redhill
England
RH1 5RH

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing

England
BN11 2DH

Study participating centre
West Suffolk NHS Foundation Trust
West Suffolk Hospital
Hardwick Lane
Bury St. Edmunds
England
IP33 2QZ

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
England
NR4 7UY

Study participating centre
Bedfordshire Hospitals NHS Foundation Trust
Lewsey Road
Luton
England
LU4 0DZ

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
England
DN2 5LT

Study participating centre
Royal Free Hospital
Pond Street
London
England
NW3 2QG

Study participating centre
The Hillingdon Hospitals NHS Foundation Trust
Pield Heath Road
Uxbridge
England
UB8 3NN

Study participating centre
University Hospital of Hartlepool
Holdforth Road
Hartlepool
England
TS24 9AH

Study participating centre
Wasall Manor Hospital
Moat Road
Walsall
England
WS2 9PS

Study participating centre
Dewi Sant Hospital
Albert Road
Pontypridd
Wales
CF37 1LB

Study participating centre
St Helier Hospital
Wrythe Lane
Carshalton
England
SM5 1AA

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0615-20003

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

Individual participant data (IPD) sharing plan
The SNAP 2 dataset will be available upon request but set processes will need to be completed prior to data being shared via a secure drop off service, for example a possible data sharing agreement and CI sign off.
snap2@nottingham.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/05/2024	29/05/2024	Yes	No
HRA research summary			28/06/2023	No	No

Participant information sheet	version v1.1	22/02/2021	16/03/2021	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes