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Dietary approaches to the management of polycystic ovary syndrome trial

Submission date
11/07/2025

Recruitment status
Enrolling by Invitation

Registration date
23/07/2025

Overall study status
Ongoing

Last Edited
01/09/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
This study aims to assess the feasibility of delivering an intervention (a low-energy, low-carbohydrate food-based diet and support from practice nurses) in primary care (primary outcome) and evaluate its impact on weight change alongside clinical and symptomatic markers of polycystic ovary syndrome (PCOS) (secondary outcome). Primary care records show that about 2% of women aged 15-45 years old have a coded diagnosis of PCOS, but it is likely underdiagnosed. People with PCOS commonly experience symptoms such as anovulation, menstrual cycle irregularity and hyperandrogenism. However, variability in presenting symptoms, provider confidence, and gaps in patient education contribute to delayed interventions, suboptimal patient care, and a diminished quality of life. This programme was developed using “real food”, supporting patient self-management to reduce the demand on practitioner time, so that it is realistic for the NHS. This was previously tested in a feasibility study for people with type 2 diabetes, which showed that people with T2D could be recruited who followed the programme with nurses delivering the programme as intended.

Who can participate?
Participation is by invitation only. This study will recruit GPs nationally, aiming to include 40 people from approximately 5-7 GPs who are socially representative of the UK population. GPs will be asked to invite people with PCOS who are overweight and meet the study criteria.

What does the study involve?
Interested persons will be able to contact the study team for more details. If the person appears eligible after a brief phone screening, s/he will see a nurse at their GP who will confirm eligibility and take informed consent and then measure height, weight, blood pressure, and take a blood test. They will be randomly allocated in a 1:1 ratio to intervention and control groups, stratifying by GP. Participants offered the programme will be invited to see the nurse for six extra appointments over 6 months. The baseline measures will be repeated for all participants at 3 and 6 months (post-baseline visit).

What are the possible benefits and risks of participating?
All participants will benefit from extra clinic appointments at their GP practice. This study will inform the feasibility of running studies in primary care for people with PCOS. People in the

study who are allocated to follow the intervention will benefit from support to achieve weight loss.

This study involves no identified significant risks to participants. Participants are primarily consenting to engaging with dietary and behavioural advice which is intended to support them to lose weight and improve their symptoms of PCOS and general health. There are no known significant risks of this advice. It is not thought that those in the intervention compared with usual care will be at a greater risk of serious adverse events (SAEs). In an earlier study that looked at a similar intervention for people with type 2 diabetes, there were no SAEs.

Venepuncture for blood samples may cause momentary discomfort. Standard NHS operating procedures as used in routine clinical care will be used for the collection and processing of samples, and all will be carried out by appropriately trained clinicians in the participants' usual GP practice. The main burdens are the short questionnaires and the additional visits to their GP practice. Participants will be compensated for the visits at 3 and 6 months to reflect the added burden.

Where is the study run from?
Nuffield Department of Primary Care Health Sciences, UK

When is the study starting and how long is it expected to run for?
October 2024 to October 2026

Who is funding the study?
The National Institute for Health and Care Research (NIHR), UK

Who is the main contact?
Jadine Scragg, jadine.scragg@phc.ox.ac.uk and post.study@phc.ox.ac.uk

Contact information

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Scientific, Principal investigator

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
331409

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 57348

Study information

Scientific Title
Polycystic ovary syndrome trial (POST): dietary approaches to the management of polycystic ovary syndrome

Acronym
POST

Study objectives
To test the feasibility of a behavioural and dietary intervention, delivered in primary care, aiming to promote weight loss and improved symptoms of PCOS, and determine whether to progress to a full scale RCT. The following progression criteria will determine whether to progress to a full trial:
1. That 60% of participants allocated to the intervention arm attempted the intervention after randomisation
2. Fidelity of intervention delivery: That healthcare professionals conduct the intervention delivery session with at least 60% of essential elements present.
3. Availability of data at final follow-up. That 60% of participants attend the final follow-up session or provide data
4. Ability to recruit primary care sites and patients within the recruitment period (6 months)

A mixture of quantitative and qualitative methods will be used to assess process measures and effectiveness measures. This feasibility study is not powered to detect statistical differences in efficacy outcomes but will examine the following parameters to test trial procedures, process, resources and management, to aid sample size estimates for a future trial, to determine the most appropriate primary outcome measures for a future trial, and to inform further development of the intervention strategy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/07/2025, South Central – Oxford B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048032; oxfordb.rec@hra.nhs.uk), ref: 25/SC/0210

Study design
Two-arm feasibility randomized controlled trial design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Polycystic ovary syndrome: disorders of other endocrine glands

Interventions
Following the principles of the Person-Based Approach, the research team has developed a behavioural and dietary intervention to support patients with PCOS to change their diet in primary care. This process involves examining the recent systematic review, reviewing qualitative studies and process assessments of these types of interventions, and developing the behavioural and dietary interventions with input from a dietitian, clinician and patients.

A full-scale RCT powered to detect significant clinical effect of this intervention would need to be large, and therefore expensive. Following the MRC framework for developing complex interventions, before this is justified, it is necessary to ensure that the intervention can be delivered as intended, that it works in the short term (6 months), and that recruitment and research methods run as planned, through conducting a feasibility study. Additionally, it is important to ascertain whether patients will accept the intervention to which they are randomised, and the degree of cross-contamination of study arms.

For this study, a two-arm feasibility randomised controlled study design will be employed, performed in adult participants with PCOS and BMI of ≥27kg/m² (non-white ethnicity) and ≥30kg /m² (white ethnicity), who would consider using dietary means rather than increasing medications to improve symptoms of PCOS and general health. Recruitment will take place from 5 to 7 GP practices. At least 2 of the GP practices will have a practice population from the IMD deciles 1–4. Potentially eligible participants will be identified by an electronic records search (with additional opportunistic recruitment possible during routine consultations), and will be invited to take part by letter or text message. Interested participants will be asked to contact

the research team (by email or telephone) and complete an over-the-phone eligibility assessment. A researcher will contact these patients once they have made contact, to discuss any further questions they may have about the study, and arrange a convenient time to book a baseline visit with the practice nurse during which any remaining eligibility questions will be re-assessed, informed consent will be sought, and baseline measurements and blood samples taken. Participating practices will submit data about the proportion of practice population with PCOS who are eligible to participate, and total number of invitations sent to patients, to inform process measure analysis.
Each participant will be enrolled for 6 months from baseline to final follow-up, and will attend a maximum of 9 appointments.
In determining thresholds for progression criteria, based on previous studies of a similar nature, at least 75% achievement is expected. If so, the 95% confidence interval will exclude 60% and therefore, this has been set as the progression criteria for each criterion, requiring a sample size of 40 participants allocated intervention: control in a 1:1 ratio to give this precision.

Allocation, randomisation and blinding:
Participants will be randomised to one of the two study arms (intervention or control), in a 1:1 ratio, using permuted block design randomisation. Allocation will be stratified by practice. Due to the nature of this study, it will not be possible to blind participants, clinicians or some of the study team to the treatment allocation once assigned. As it is not yet known whether this intervention will be more effective than "usual care" dietary advice from a practice nurse, it is important to include this control group in this feasibility study and any full-scale study. Process evaluation and qualitative analysis will also establish the acceptability to study participants of this control group, and any cross-contamination of dietary advice received, to inform future full-scale studies.

Intervention:
The intervention in this study draws upon the motivational importance of the relationship between the GP and the patient, but provides almost all technical knowledge through the use of structured materials such as meal plans, thus addressing the uncertainty that health professionals have about nutrition. Likewise, the aim is to improve patients' adherence to the programme by providing a structured, simple behavioural support programme to help in implementing this programme. The nurse will discuss the participant's goals for their PCOS and health and how remission may achieve these goals. They will see participants at 0, 2, 4, 8, 12, 16 and 26 weeks from the start of the programme, but respond flexibly to participants' needs, as would be the case in routine care. Appointments are up to 20 minutes long in up to week 12 and 10 minutes thereafter. These are expected to be face-to-face, but remote consultations will be offered and patients will be given the option to choose.

The dietary component of the programme is a low-energy low-carbohydrate diet (800–1000 kcal with a maximum of 50 g carbohydrate per day, or 20–25% total energy, compared to usual intake of 45%). The core principles include advice to exclude all sugary and starchy foods except very limited dairy and fruit, strict portion control and avoiding energy-dense foods. The maintenance programme supports a transition to a sustainable dietary regimen to control energy intake, provide about 125 g/day carbohydrate, less than half the average population intake (for example, 200 ml milk, 2 portions fruit and a modest portion of fibre-rich carbohydrate at each of three meals). It is based around the 3Rs: refrain (from high sugar foods, e.g. cakes and biscuits), restrict (frequency and portions of starchy carbohydrates), and replace (swap to high fibre varieties of carbohydrate).

Control Group:
Those randomised to the control group will receive "usual care" for PCOS management. All

patients will be invited for a 3- and 6-month study visit (with blood tests and questionnaires) to assess the feasibility, process and effectiveness outcomes described above. Participants allocated to the intervention group will be sent a questionnaire to collect data on how the programme was delivered. Patients who have consented to be contacted about this at the end of the intervention will be invited to qualitative interviews. Focus groups or 1:1 interviews will also be organised with health care professionals from the practices implementing the programme to understand their views on the benefits and any challenges of implementation. The data will be transcribed and analysed following a thematic approach.

Intervention Type
Behavioural

Primary outcome(s)
The following progression criteria will determine whether to progress to a full study; all will be measured at 6 months:
1. The proportion of patients who agree to start the dietary intervention, measured using data recording after intervention visit by the nurse delivering the intervention session
2. Fidelity of intervention delivery will be measured by assessing audio-recorded consultations against a checklist of essential elements
3. Availability of data at final follow-up will be measured from documentation of the final study visit and/or record of provision of relevant data
4. Ability to recruit primary care sites and patients within the recruitment period (6 months)

Key secondary outcome(s))
The following secondary outcome measures will be assessed at 6 months:
Process Measures:
1. Percentage of eligible patients as a proportion of total practice population
2. Percentage of people who fulfil the recruitment criteria who accept the invitation to participate
3. Participant adherence to the protocol: including, change in dietary composition (low-carbohydrate, energy restricted - assessed using dietary recall questionnaires); participants' self-reported concordance with the intervention; availability of data for outcome measures; attendance at follow up sessions; contamination of the control group (i.e., those who choose to follow the principles of the intervention (i.e. follow a low-carbohydrate diet), despite being allocated to the control group). This will be assessed using food frequency questionnaires to establish change in dietary composition (frequency of carbohydrate consumption, energy restriction) of control group participants.
4. Proportion of people diagnosed with type 2 diabetes at baseline and throughout the defined study period
5. Proportion of people who choose to receive the intervention face-to-face, remote (either video consultation or phone call) or a combination

Effectiveness Measures:
1. The change in weight
2. Mean change in systolic and diastolic blood pressure
3. Change in medication usage
4. Mean change in HbA1c concentration
5. Change in lipid profile – total cholesterol, HDL, triglycerides, calculated non-HDL cholesterol, and total cholesterol:HDL ratio
6. Change in QRISK3 score or SMART score
7. Change in the risk score for type 2 diabetes

8. Change in fasting glucose, fasting insulin and HOMA-IR score
9. Change in modified Ferriman-Gallwey score
10. Change in free androgen index
11. Change across total score of the EQ_5D_5L Qol questionnaire
12. Change across WHO-5 score
13. Self-assessment of the number of menstrual periods within the past 3 months, and the impact on menstrual bleeds

Qualitative Measures:
Experience of and insight into acceptability of the intervention, for patients and healthcare practitioners.

Completion date
31/10/2026

Eligibility

Key inclusion criteria
Patients:
1. Aged >= 18-45 years inclusive
2. BMI> = 27kg/m2 (> = 30kg/m2 if white ethnicity)
3. A coded diagnosis of PCOS
4. Able to attend the GP practice for appointments
5. Willingness and ability to provide informed consent

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Key exclusion criteria
Current key exclusion criteria as of 01/09/2025:
1. Current or recent (< 3 months) use of oral contraceptives or hormone replacement therapy
2. Current or recent (< 3 months) use of any hormonal contraception, including the contraceptive implant, contraceptive injection, contraceptive patch, vaginal ring or hormonal IUS systems (Mirena or JadeS)
3. Premature ovarian failure

4. Postmenopausal and/ or premature menopause
5. Pregnant, breastfeeding, currently undergoing fertility treatment
6. Type 1 diabetes
7. Active treatment for cancer (with the exception of non-melanoma skin cancer)
8. Following a structured weight-loss programme (including the use of GLP1 receptor agonists currently or in the 3 months prior to study enrolment)
9. SGLT2 inhibitors started in the 3 months prior to study enrolment
10. Unwilling to consider dietary changes
11. Clinician feels participation is inappropriate due to other reasons (such as, but not limited to mental health, awaiting surgery)
12. Diagnosed with a known eating disorder for whom the programme could be unsafe or require extensive monitoring to ensure safety
13. Diagnosed with a myocardial infarction or stroke in the past three months, uncontrolled cardiac conduction abnormalities, e.g. long QT syndrome, maculopathy or proliferative retinopathy
14. People with a diagnosis of type 2 diabetes
15. People taking part in other research that would compromise either their participation in POST or the other research study/ies that they are participating in

There will be no exceptions made to allow into the study people who do not fulfil all these criteria.

Previous key exclusion criteria:
1. Current or recent (< 3 months) use of oral contraceptives or hormone replacement therapy
2. Current or recent (< 3 months) use of any hormonal contraception, including the contraceptive implant, contraceptive injection, contraceptive patch, vaginal ring or hormonal IUS systems (Mirena or JadeS)
3. Premature ovarian failure
4. Postmenopausal and/ or premature menopause
5. Pregnant, breastfeeding, currently undergoing fertility treatment
6. Heart attack or stroke within the last 3 months
7. Type 1 diabetes
8. Active treatment for cancer (with the exception of non-melanoma skin cancer)
9. Following a structured weight-loss programme
10. GLP1-agonists or SGLT2 inhibitors started in the 3 months prior to study enrolment
11. Currently using insulin injections
12. Unwilling to consider dietary changes
13. Clinician feels participation is inappropriate due to other reasons (such as, but not limited to mental health, awaiting surgery)
14. Diagnosed with a known eating disorder for whom the programme could be unsafe or require extensive monitoring to ensure safety
15. Diagnosed with a recent myocardial infarction or stroke in the past three months, uncontrolled cardiac conduction abnormalities e.g. long QT syndrome, maculopathy or proliferative retinopathy
16. People with a current diagnosis of type 2 diabetes
17. People taking part in other research that would compromise either their participation in POST or the other research study/ies that they are participating in.

There will be no exceptions made to allow into the study people who do not fulfil all these criteria.

Date of first enrolment

01/08/2025

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Central RRDN
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
North East and North Cumbria RRDN
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Yorkshire and Humber RRDN
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
North West RRDN
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
East Midlands RRDN
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
West Midlands RRDN
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
East of England RRDN
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
North London RRDN
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
South London RRDN
St Thomas' Hospital
Westminster Bridge Road
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United Kingdom
SE1 7EH

Study participating centre
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Egerton Road
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United Kingdom
GU2 7XX

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South West Central RRDN
Trust Headquarters
Marlborough Street
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BS1 3NU

Study participating centre
South West Peninsula RRDN
Royal Devon University NHS FT
Barrack Road
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EX2 5DW

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name

NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes