Dietary approaches to the management of polycystic ovary syndrome (POST)

PARTICIPANT INFORMATION SHEET

- We'd like to invite you to take part in this research study.
- Before you decide, it is important that you understand why the research is being done and what it would involve for you.
- Please take time to read this information, and discuss it with others if you wish.
- If there is anything that is not clear, or if you would like more information, please ask us. Our contact details can be found at the end of this participant information sheet.

What is the purpose of the study?

Polycystic ovary syndrome (PCOS) is a common condition that affects approximately 1 in 10 women in the UK, and affects how a person's ovaries work and might cause their blood glucose levels (also known as 'blood sugar' levels) to be too high. It is also associated with excess weight. We know that what we eat affects our blood glucose levels and our hormones. People experience very individual symptoms with PCOS and not everybody will have the same symptoms. We want to study whether it is possible for GPs and practice nurses to support people with PCOS to change their diet to lose weight and see if some of their symptoms of PCOS improve. This is a feasibility study, which means we are testing whether it is possible to carry out a larger research study in the future. In this study, participants will be randomly assigned, like flipping a coin, to one of two groups. However, this is not a study designed to compare which group does better. Instead, we are focusing on whether the study processes, such as recruiting people, collecting information, and delivering the different parts of the study, can be done successfully. The results will help us decide if and how we should run a bigger study in the future.

The study will compare a new programme of support from a nurse and GP to help you change your diet and lose weight over 6 months with the current best dietary advice delivered at your GP practice. The new programme involves support from staff at your GP practice to make quite big changes to the amount of and type of food you are eating for 12 weeks, and the type of food you are eating thereafter. We will measure how well the advice is delivered, how successful people are in following different advice, and the changes people see in their weight, PCOS symptoms and hormones, over a 6 month period.

Why have I been invited?

We are looking for people with PCOS to take part in this study, who would like to use diet to improve their symptoms, lose weight, or improve their general health. Your GP has searched in their records to see who might be eligible to take part. Your medical records suggest that you may benefit from changing your diet in order to improve the symptoms of your PCOS and improve your general health.

The University of Oxford did not have access to any of your personal or medical information as part of the invitation process. The University of Oxford collaborates with GP practices

across the UK, of which your practice is one, who help to identify people who may be suitable and interested in taking part in research.

DO I HAVE TO TAKE PART?

No, it is up to you whether you take part or not. If you do decide to take part in the study you will be asked to sign a consent form at your first appointment. You are free to withdraw at any time without giving a reason. A decision to withdraw from the study will not affect the usual care you receive from your GP or practice nurse or other healthcare professional.

WHAT WILL HAPPEN IF I WANT TO TAKE PART?

If you are interested in taking part, please call or email the research team using the contact details at the end of this information sheet. A member of the research team will ask you questions to check if you may be suitable for the trial. If you are, then we will ask you to attend an appointment with one of the trial research nurses. The appointment will be at your GP practice and should not take longer than 30-45mins. We will ask you to sign a consent form agreeing to take part in the study, and the research nurse will complete questionnaires with you. The research nurse will also measure your blood pressure and take your blood to measure your hormone and blood glucose levels. You will also be asked to visit the GP practice after 3 months and 6 months to measure blood glucose and hormone levels. We will also ask you to fill in some questionnaires asking about your wellbeing and other PCOS symptoms.

Half the people who take part will be asked to continue with current best care for PCOS at the practice and half will be given this new programme. You will not be able to choose which group you are in as this is decided randomly, like tossing a coin. If you are asked to be a part of the new programme, in addition to your study visits at 3 months and 6 months, we will ask you to attend a structured programme six times over six months which will support you to change your diet and lose weight. If you take them, you will also be asked to stop, or reduce, your medicines for high blood pressure. Taking these medicines while being a part of this programme could cause some problems like feeling dizzy.

Interview

A few people who followed the new dietary programme (the 'intervention') will be asked to take part in a longer telephone conversation to understand how you felt about the dietary programme and how it helped you or did not help you. A researcher at the University of Oxford will contact you and arrange this at a convenient time. This part of the trial is optional. If you are invited and decide to take part in this conversation, we will audio-record and transcribe the conversation.

WHAT SHOULD I CONSIDER?

If you decide to take part, you should not be planning to get pregnant or breastfeed in the next 6 months, and should be willing to attend six support sessions over six months and change your diet to improve your PCOS symptoms and lose weight. To be able to take part

in the study, we need to confirm that you do not have any medical conditions that might make the dietary advice we are giving unsuitable for you. The programme is not suitable if you are taking certain medications, or having developed a serious medical condition within the last 3 months (like a heart attack, stroke, cancer, or heart failure). When you speak to our study team, we will go through a list of questions with you to check the programme is suitable for you, and our research team can check any answers that you are not sure about with your GP.

If you agree to take part in the study, you would need to:

- Follow your allocated treatment to the best of your ability
- Allow us to collect three blood samples from you (equivalent to 2 tablespoons at the first visit, and 3 and 6 month visit)
- Complete a questionnaire, which we will provide, after your first visit to your GP, and after the 3 and 6 month visits. If you are asked to follow the programme, we will also ask you to complete one extra questionnaire about your experience at the end of the 6 month study
- Attend appointments with your practice nurse, at your local practice. The maximum number of appointments you would be asked to attend would be 9 over a 6 month period.

When you have enrolled in the study, if you are due to book your next appointment but we haven't yet heard from you (or if you miss an appointment and don't manage to contact us beforehand to reschedule), we will attempt to contact you to remind you that you are due to book an appointment (by telephone, email or post, according to what contact information you have given us). We will aim to do this up to 3 times. If we haven't managed to contact you after this we will leave it to you to contact us if you still want to continue and book an appointment.

Are there any possible disadvantages or risks from taking part?

There are no known serious risks from the dietary advice that is being given in this study. However, sometimes when people change their diet they can become constipated –but this is easily prevented and treated, and if you take part in the study we will give you advice to help prevent this happening, or treat you if you do develop constipation.

If you are asked to follow the dietary programme and you agree to do so, we will stop or reduce your medicines for high blood pressure, if you take them. We will ask you to monitor your blood pressure to check that all is well and your GP may restart medications if not. Some changes to your diet can cause symptoms of constipation. In this instance, you can contact your GP to request laxatives, if required. If you take warfarin, changing your diet may change your INR level – so you should inform your local warfarin monitoring service, who may advise an additional blood test.

Most of the questionnaires we will use to ask about your feelings, symptoms and your diet have been previously used in many other studies and we do not expect these would cause

you any distress. If you were to experience any distress, the research team will be available to support you. If you do experience distress while answering questionnaires, you do not need to complete them. There are resources available to you in case you experience any problems, please see "What if there is a problem?"

Some blood tests for this study will require you to fast beforehand (this means nothing to eat, and nothing to drink except water, from midnight the night before your blood test) in order to get accurate results. As with any blood sample, there is possibility that you may develop some bruising around the area and some people occasionally faint while the sample is taken.

What are the possible benefits of taking part?

Everybody who takes part will receive at least three extra appointments with the practice nurse. The blood tests are also an additional health screening check. We will also share the results with you and your doctor who can arrange any further treatment you may need if a problem is detected. The knowledge gained in this study will help us know how best to help people with PCOS in the future and may mean people can experience improvements in their symptoms of PCOS.

Will I be reimbursed for taking part?

You will be offered a digital £25 Amazon gift card voucher after the 3-month appointment, and also after the 6-month appointment, as a way of reimbursing you for your time and any expenses in travelling to the appointment. If you prefer, we could send you a physical £25 Amazon gift card in the post after the 3-month and 6-month appointment.

Will my General Practitioner/family doctor (GP) be informed of my participation?

Your GP will be notified of your participation and will receive the results of your blood tests throughout the study. Taking part in the study will not affect care you receive from your GP for any other unrelated conditions. If you experience any side effects or have any health concerns throughout the study, your GP practice will be available to provide guidance and support.

Will my taking part in the study be kept confidential?

Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first. Any information that is collected about you during the course of the research will be kept strictly confidential. We will use codes to avoid identifying you with your name.

Responsible members of the University of Oxford, relevant NHS trusts and regulatory authorities may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with the appropriate regulations. Audio recordings will only be accessible by approved and relevant members of the research team, and will be deleted as soon as possible after they have been transcribed.

What will happen to the samples I give?

The blood samples that you provide will be sent from your GP practice to their local hospital laboratory, in accordance with standard NHS procedures, as they usually do for routine analysis of blood samples. The blood samples will be analysed in your local hospital to measure your blood glucose, hormone, liver function, and cholesterol levels. These results will come back to your GP and your GP could decide to take action as part of your usual care. The hospital destroys your samples after analysis. Therefore, it will not be possible for you to request that your blood sample is not analysed.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from your medical records and your GP for this research project. We will share your information related to this research project with the following types of organisations; relevant researchers at the University of Oxford, relevant NHS trusts and regulatory authorities.

This information will include your name, contact details and some health related information, like your weight, blood pressure and results of some blood tests. We will use the minimum personally-identifiable information possible. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure by storing data on secure University of Oxford servers. Where only approved and relevant people will have access. Access will be revoked to this data when it is no longer needed. If you take part in an interview, this will be audio-recorded, and then transcribed. The transcriptions will be anonymised as soon as possible, so that you are not identified in the transcript, and the original audio recording will then be deleted. The recordings will be transcribed by an approved external transcriber, with whom appropriate information security and confidentiality agreements are in place with the University. We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

Your personal data will not be shared outside the UK.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for the minimum period of time required by the University of Oxford Policy on Management of Data (http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/). Research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study. You will not have to do anything for us to collect this information. Personal contact information will be stored for one year after the end of the study, so we can share with you the results of the study. If, at the first appointment with your GP practice, you are not eligible to take part, no personal data will be stored about you.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your GP. If you do not want this to happen, tell us and we will stop.

You can find out more about how we use your information, by:

· asking one of the research team: post.study@phc.ox.ac.uk

· calling us on 01865 617131

· contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk · looking at the University's privacy notice available at: How we use your personal data for research purposes | Compliance.

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: Patient data and research leaflet - Health Research Authority.

What will happen if I don't want to carry on with the study?

Your participation is voluntary. If you decide you do not want to take part in the research at any point that is fine, and you can withdraw at any time without giving a reason. We will give you the opportunity to tell us the reason for withdrawing if you would like to. Your future medical care will not be affected.

We will use the data that has been collected up to the point at which you decide to withdraw from the study. This includes the data from the discussion if you have already taken part in this. We would continue to use this anonymised data after your withdrawal from the study.

What will happen to the results of this study?

The results of this study will help us to know how best to help people with PCOS improve their symptoms of POCS and improve their health. These studies may help to change guidelines for patients and their doctors, about the different ways to improve PCOS symptoms and general health if you have PCOS.

The study results will be presented at scientific meetings and published in a scientific journal. You will be not identified in the presentations and publications. We will send you a summary of the study results once the study has finished.

What if something unexpected is found?

Your blood tests will be sent to your GP for review, and he/she will be in touch if anything unexpected was found.

What if there is a problem?

If you have a concern about any aspect of this study, please speak with the research team. They will do their best to answer your questions. The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Dr Jadine Scragg (01865 6171960 & jadine.scragg@phc.ox.ac.uk) or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as

an NHS patient. PALS is unable to provide information about this research study. If you wish to get in touch with the PALS team please contact them at PALS@ouh.nhs.uk.

How have patients and the public been involved in this study?

Members of the public helped to shape the ideas for this research, and to decide the questions that we are trying to answer. In designing this study we have taken into account patient opinions on the schedule of appointments that you will be asked to attend, and what information people want to have available to help them change their diet. Two of our patient representatives have become a member of the study team and will continue to be involved throughout the study. They will oversee the progress of the study and will have a prime role in ensuring the public interest always comes first.

Who is organising and funding the study?

The present study is funded by the National Institute for Health Research (NIHR) Biomedical Research Centre. The University of Oxford is responsible for the design, conduct and publication of results from this study. No personal information about you will be shared with the funder or included in any future publication.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people called the Research Ethics Committee, who protect your rights, safety, wellbeing and dignity. This study has been reviewed and given favourable opinion by Oxford B Research Ethics Committee.

Further information and contact details:

If you want to discuss the study in more detail please contact us on:

Contact Name: Jadine Scragg
Tel: 01865 617131
Email: post.study@phc.ox.ac.uk

Thank you for taking the time to read this information sheet