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StructUred eduCation programme
to improve Cardiovascular risk in
womEn with polycyStic ovary Syndrome;
SUCCESS study

PHASE 3
SUCCESS Study Randomised Controlled Trial:
PARTICIPANT INFORMATION SHEET

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Invitation to participate:

You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it involves. This information sheet is designed to help you decide whether you would like to participate in this study. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

As you may already know, PCOS is the most common hormonal disorder which affects up to 1 in 5 women in the population. Studies have shown that half of these women have some problems in controlling (metabolism) of their blood sugar and therefore are at increasing risk of developing Diabetes. This problem gets worse if the patient is overweight as well.
Studies have shown that if women with PCOS make change to their liftesyle (diet and activity), they may reduce their risk of getting diabetes and heart diesase in the future.
We have developed an educational programme that can be run in groups (Structured education) to support women with PCOS make the lifestyle changes needed to improve their PCOS and prevent health problems in future.

We are keen to find out whether this programme works and is it effective in improving the glucose metabolism in PCOS. This study is designed to test this programme and answer our question.

Why have I been chosen? Can anyone take part?

You have been invited to take part in the study because you have a diagnosis of Polycystic Ovary Syndrome (PCOS), you are aged between 18-50 years old and you have a recorded body mass index (BMI) of

Body Mass Index ≥ 23 kg/m^2 for Black and Minor Ethnicities

Body Mass Index ≥ 25 kg/m^2 for White Europeans

In order to take part we also need you to have a good grasp of spoken English because this study is designed around an educational programme which will be delivered in English. In addition, if you are taking steroid medication for any long-term medical condition you may not be eligible to take part.
It is also required that you have not been started on any new medication for treatment of your PCOS in the past 6 months.

Do I have to take part?

It is up to you to decide; participation is voluntary. We will describe the study and go through the information sheet. We will then ask you to sign a consent form to show that you have agreed to take part. You will be given a copy of the signed consent form. You are free to withdraw at any time without giving a reason. The treatment and standard of care you receive from the NHS will not be affected if you decide not to take part or to withdraw.

What will happen to me if I take part?

This study will last for 1 year and we will meet up with you at the start of the study, after 3 and 6 month and then at the end of the study at 12 months. At the first visit you will be invited to visit the diabetes research team at a convenient venue and this visit will take around 3 hours. You will have the chance to meet the friendly members of our team, and to ask any questions you might have before signing our consent form. You will be asked to fast for this visit (water only from midnight the night before). When we meet you, we will record information about your medical history, any tablets you take and any family history of any medical conditions. We will check your blood pressure, weight, height and waist measurement. Blood tests will be taken. You will then be given Lucozade to drink and your blood tests will be repeated after 2 hours. These blood tests help us assess your risk of diabetes.

During the 2 hour wait between blood tests, you will be asked to complete some questionnaires about your activity and diet, and also on your past medical history. We will also use this time to introduce the activity monitor, known as the 'Actigraph'. This small device is worn on your waist and records your movement during waking hours. We will demonstrate how to use the device and provide written instructions. After this study visit we would like you to wear the device for 10 days during waking hours. We do this to assess how active you are and how much time you spend

sitting. Once you have worn the device for 10 days, it is returned to us in the post (pre-paid envelop will be provided) so we can download information about how active you have been. Once your 2 hour blood test has been taken you are free to leave. We will give you tea and biscuit but we will not serve any food after the test, however you can bring your own light snack and food for after the test. We will send a copy of your blood results to your GP.

What happens next?

Taking part in the study involves being randomly entered into one of two study groups. The groups will be randomly selected by computer (a bit like tossing a coin), so you cannot choose which group you are in. You will *not* know which group you are in before consenting to take part in the study. Randomisation will happen after we have received the "Actigraph" monitor in the post but before we look at your data.

Group 1 is what we call the **'control' group**. If you are in this group, you will receive some useful leaflets informing you about PCOS and about how exercise can be used to help in treatment of this condition. At the end of the study period (one year) we will offer you the chance of attending the same educational programme that is being given to Group 2 (see below).

Group 2 is the education group. If you are randomly assigned to be in the education group, we will invite you to the SUCCESS education sessions. At SUCCESS education programme you, along with 4 to 7 other individuals like you, will be seen by two educators who will deliver an interactive seminar focusing on what it means to have PCOS, what are the effects of diet and exercise on it and how can we take control of our life with PCOS. During the visits we will discuss your blood results, blood pressure and weight with you and discuss ways of improving your results, one of which is increasing your physical activity. During the next year you will have the opportunity to be in regular contact with a healthcare professional with a wide range of resources to help you.
SUCCESS is offered in a format of a whole day programme or broken into 3 evening/weekend sessions of 2 and half hours.

Regardless of which group you are in at 3, 6 and 12 months, we will ask you to visit us for a further fasting and 2 hour glucose blood test. This will help us keep an eye on your diabetes risk and your general well-being. During these visits we will also take a blood sample to measure your cholesterol levels and some key hormones that we measured before. We will also measure your:

- Height
- Weight
- Hip and Waist Measurements
- Blood Pressure

We will ask you to complete a questionnaire at each visit, just as you did when you joined the study and we will ask you to wear the same small 'Actigraph' physical activity monitor for ten days after each visit.

Optional additional assessments

We would also like to collect some further important measurements from you. However these measurements are optional – it is for you to decide whether or not you would like to have them done.

We would like to give you the option of attending Glenfield Hospital (Leicester) to have the muscle and fat content of your body assessed by a dual energy X-ray absorptiometry (DEXA) scan and an abdominal magnetic resonance imaging (MRI) scan. These scans will give you and us a detailed picture of the amount of muscle and fat you have in your body. In particular these scans will be able to measure how much fat you have stored around your vital organs, such as your liver and kidneys. This type of fat is particularly harmful and is strongly linked to your future risk of both type 2 diabetes and heart problems. DEXA and MRI scans are routine clinical tests but carry a small risk. DEXA involves exposure to radiation. The level of radiation exposure is exceedingly small (20μSv per scan) in comparison to the natural background radiation we are all exposed to (approximately 3000 μSv per year). The same level of radiation exposure would be received during a 2 hour intercontinental flight from radiation arising in outer space. MRI scans can be of concern for individuals who are highly claustrophobic (uncomfortable in confined spaces) and may be unsuitable if you have certain medical conditions. Both scans require you to lie still for up to 30 minutes. It is important to stress that these scans are optional and will not affect your participation in the study. If you have these scans performed at the start of the study, we would like to invite you have them repeated at 12 months, the end of the study. This will help us to evaluate the effect of the study on body fat.

What do I have to do if I want to take part in this study?

If you decide to take part in the study you will be asked to sign a consent form when you come for your first visit. You will be given a copy of the patient information sheet and a copy of the signed consent form to keep for your own records.

What are the possible benefits of taking part?

By taking part in the study you and your GP will find out information about your diabetes risk, your cholesterol, your hormones, and your kidney and liver function from the blood tests. At the end of the study you will also be provided with information about how much activity was recorded at the four points over the year on the 'Actigraph' activity monitor. By attending the education programme either during the study (if you are in the "intervention arm") or after the study (if you are in the "control arm") you will have a better understanding of PCOS and the changes in the body and how you can manage the condition. The results of this study will be used to

improve future assessment and care for patients like you who have polycystic ovary syndrome. The results of this study will also help inform future guidance on the activity levels required for health.

What if I change my mind after taking part in the study and wish to withdraw my consent?

As explained before, your taking part in the study is your choice and you are free to withdraw from study without giving any explanation, and your care will not be affected in any way.
Your name will be removed from the study. Data collected from you in the study up to that point can also be removed on your request. You can also ask for you blood samples to be removed from storage and destroyed.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Data will be stored either in locked filing cabinets' or in password protected databases which are only accessible by members of the research team. Any information about you which is disseminated will have your name and address removed so that you cannot be recognised from it. Information collected will not be used for any other purpose than that explained here. Your GP will be informed that you are taking part in this study.

What are the side effects of any treatment received when taking part?

You will not be given any medication as part of this study. However you may suffer slight discomfort while the blood samples are being taken from your arm and some people do experience bruising after blood samples have been taken.

What are the risks of taking part?

Taking part involves minimal risk for you, just the inconvenience of taking the time to participate in the study. The aim of this study is to develop an understanding of the impact of an educational programme and increase in physical activity on PCOS. This will allow us to develop a fuller understanding of the role of lifestyle change in this condition.
This study itself may not be of direct benefit to you but it will contribute to the ongoing work aimed at the improvement in care for PCOS.
The tests in the study are not designed for clinical diagnosis, but in the unlikely event that we may find an abnormality (eg diabetes) this will be discussed directly with you. With your permission, we will pass this information to your GP and any relevant specialist(s) with the aim of organising prompt and appropriate investigation and treatment.

Will my taking part in this study be kept confidential?

Absolutely! All information that is collected about you during the course of the research will be kept strictly confidential in secure locations within Leicester Royal Infirmary.

Will my GP be informed of my results?

Yes, your family doctor will be informed of all the results of the tests taken as part of this study. When the study stops your GP will become the main point of contact for any ongoing concern. After the end of the study your care in regard to your diagnosis of PCOS will continue as it has always been. We will ask for your consent to contact your GP.

Will I get study and travelling expenses?

Parking charges and travelling expenses up to £25 per visit can be reimbursed on production or receipts.

What will happen to the results of the research study?

The results of the study may be published in a professional journal, but you will not be identified by name in any publications. You will be informed about the results of the study when it has finished.

Who is organising and funding the research?

This study is being organised and co-ordinated by the University Hospitals Leicester and Diabetes Research Group in University of Leicester. The funding is Diabetes Research Group and British Endocrine Society.

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What if something goes wrong?

It is very unlikely that you will come to any harm during this study. However, if you do come to harm through your direct participation this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the patient information and liaison service (PILS) are available to provide independent help, advice and support. They can be contacted at:

Patient Information and Liaison Service
Gwendolen House
Gwendolen Road
Leicester LE5 4QF

08081 788337 (free phone number)

Your legal rights to claim compensation for injury where you can prove negligence are not affected.

Who has reviewed the study?

This study was reviewed by the "Leicestershire, Northamptonshire & Rutland Research Ethics Committee".

Contact for Further Information

Thank you for taking the time to read this information sheet. The doctors involved in this study will be pleased to discuss any questions or concerns that you may have. If you have any further questions about this research please contact Dr Mani on 0116 2584084 or email him at Hamidreza.mani@uhl-tr.nhs.uk
Link for the website; http://www.leicestershirediabetes.org.uk/624.html