

The digital Hope Programme for adults with polycystic ovary syndrome (Hope PCOS): a mixed methods feasibility randomised controlled trial

PARTICIPANT INFORMATION SHEET

We are inviting you to take part in a research study to test a 6-week online course for people living with polycystic ovary syndrome (PCOS). Before you decide to take part, it is important you understand why we are doing the research and what it will involve. Please read this information carefully and talk about it with family or friends if you want to.

It is important to note that taking part in this study is not a substitution or replacement for psychological therapy or medical treatment, it is designed to be used alongside existing treatment options. Please contact your GP or another healthcare professional if you feel you would benefit from psychological therapy.

Information about the project:

What is the purpose of the study?

We want to test whether a 6 week online self-management programme, called the Hope Programme, is acceptable to people living with PCOS. The Hope Programme is a 6 week digital self-management course which has been co created with people living with PCOS and researchers from Coventry University and Hope For the Community CIC (H4C). H4C's trained facilitators will run the Hope Programme. The Hope Programme aims to provide you with skills to build resilience and self-confidence to manage PCOS related health concerns.

Who is organising and funding the research?

The research is being organised by Coventry University and funded by a Child Development Fund Research Grant from the Waterloo Foundation (Ref no. 1423-5084). The project has been reviewed by Coventry University Ethics Committee P146766.

Why have I been chosen?

We have invited you because you are living with PCOS. We would like you to take part in the Hope Programme intervention and tell us how you got on afterwards.

Do I have to take part?

No. It is up to you. If you do decide to take part, please complete the Informed Consent Form to show that you understand your rights in relation to the research. You are free to withdraw from the study or any parts of it at any time.

Please note that your data may be used anonymously in research outputs (e.g. journal articles, conference papers, theses and reports) prior to this date and so you are advised to contact the university at the earliest opportunity should you wish to withdraw from the study.

You do not need to give a reason for withdrawing from the study and neither participation nor withdrawal will have any impact on the care you receive.

What do I have to do?

You will be asked a number of questions including your name, email address, gender, age, postcode, occupation, highest level of education and some details about your quality of life, emotional health and confidence to self-management. Your name and email address will not be stored alongside your responses. For more information please see the section on '**How would you process my data?**' below. Once you have consented you will be asked to complete a questionnaire. The questionnaires should take around 20 minutes to complete. The questionnaires will be completed three times; once before the Hope Programme begins; and again 6 weeks and 3 months later, so we can compare your answers before the course and after the course. If you complete **all** 3 questionnaires you will receive £50 incentive in the form of an eAmazon voucher. No incentive will be provided for taking part in the interviews."

After you have completed the first questionnaire the computer will assign you to either attend the Hope Programme straight away or in 3 months time. This is decided at random, like the flip of a coin. You have a 50/50 chance of being put in either group.

After you have completed the questionnaire you will be sent an activation link to the Hope Programme. When you join the Hope Programme you will log in over a period of 6 weeks, to access weekly course materials and interact with other users. You will need to have access to the internet and an internet-enabled device (e.g. phone, tablet, desktop computer or laptop) so you can access the course and complete the study surveys.

We will also invite up to 20 participants to take part in an online interview using Zoom or Teams at the end of the Hope Programme to talk about their experiences of what was useful and not so useful about the course. Interviews will last about 30 minutes.

With your permission we will record the interview and then destroy the recording once the interview has been typed up. Your opinions will help us to make improve the course for future participants. If you are randomly selected for an interview, we will send you an invitation after the course. You do not have to decide now, and you do not have to say yes. We will send you the relevant information to help you decide at the time.

What are the benefits of taking part?

The Hope Programme may help you to manage your own mental wellbeing and improve your quality of life. You may meet new friends, or learn new skills, or find out something new about yourself.

Are there any risks associated with taking part?

There are no direct risks from taking part in this study. Whilst we do not anticipate the questionnaires will cause you any distress, some of the questions will ask about their health, which may touch on topics that you may find sensitive. However, you do not have to answer any questions that you are uncomfortable with.

The study is online and there is little physical risk of taking part. However, mental wellbeing can be a sensitive issue. You can decide how much to participate in topics that you might find uncomfortable. If you feel emotional or psychological distress at any time, you are welcome to leave the activity, or withdraw from the research entirely. If you want to discuss your sexual or psychological wellbeing with a professional, please contact your GP or NHS 111.

If we suspect that you may be at risk of harm to yourself or others, we will advise you to contact your GP, NHS 111, or call 999 (in an emergency). We may contact emergency services on your behalf if we feel there is an immediate risk to life. If you tell us you have engaged in criminal activity, we will report this to Coventry University Ethics Committee. They will decide on further action and may refer the matter to the police.

Do I have to take part?

No – it is your choice. If you are unsure, please take time to discuss with your family or friends or ask the researchers if you have any questions.

How do I withdraw from the study?

You can withdraw your participation from the study at any time. You do not need to give a reason, and your rights will not be affected. Just let the research team know, using the contact details on the study website. You can request to withdraw your data from the study until 31/05/2024, by contacting the research team and quoting your participant ID number. After 31/05/2024, all data will be analysed as a group, and it will not be possible to withdraw your individual data.

What will happen if I decide to take part?

There is a digital consent form on the next page. If you decide to take part, you will need to confirm all the statements to show that you understand your rights and are happy to participate.

You will be asked to fill in baseline questionnaires to tell us all about you, including contact details, education, marital status, and some details about your PCOS. You will only need to complete this once. We will also ask you about your quality of life and mental wellbeing. This will take you around 20 minutes.

Next, the computer will assign you to either: a) attend the Hope Programme straight away or b) attend after waiting for a period of 3 months. This is decided at random, like the flip of a coin. You have a 50/50 chance of being put in either group.

The 6 week Hope Programme contains a range of self-management tools, tips, and activities. Different formats such as videos, podcasts, and quizzes will be used to cover topics relating to psychological and emotional wellbeing, intimacy, and personal and social relationships. A different topic will be covered each week, with the content being released at the same time every week, e.g. 11am on a Monday. Each week's content will last around 2 hours, but you can work through it at your own pace across the week. All aspects of the course are **optional**.

You will have the chance to interact with other participants (i.e., your peers) and will be guided by a peer 'facilitator' who will oversee your progress and be on hand to answer questions.

How would you process my data?

You are currently on the research website Qualtrics. Qualtrics is an application for creating and hosting online questionnaires. It has been assessed and approved by Coventry University's Information Protection Unit. Researchers from Coventry University and regulatory organisations may look at your research records to check the accuracy of the research study. The only people at Coventry University who will have access to information that identifies you will be researchers who will use this to contact you or to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

We will collect standard internet and website login information and details of patterns about how frequently and for how long you access the Hope Programme. This information will help us improve the course experience for other users.

We will collect data on how the group uses the Hope Programme. For example, how many times the group visits specific pages and the date and time of those visits. This will allow us to find out which parts of the Hope Programme are more popular and useful. This information will be collected via the H4C.

Data Protection and Confidentiality

We will process your data in accordance with the General Data Protection Regulation 2016 (GDPR) and the Data Protection Act 2018. We will not tell anyone that you have taken part in our research and ask everyone to respect the confidentiality of their fellow participants. All information collected about you will be kept strictly confidential. All electronic data will be stored on a password-protected computer file on Coventry University's SharePoint. Your name and contact details will be kept separately from your anonymised questionnaire and interview data, to minimise risk of identification in the event of a data breach. The consent form that you sign digitally will be saved on a password protected computer (separate to your questionnaire responses).

Interview data will be audio/video recorded (.mp4) and transcribed (.docx) automatically via Microsoft Teams/Zoom. All transcripts will be checked by a member of the research team and de-identified with pseudonyms used in place of names. Audio recordings will be destroyed once the transcription has been saved.

You have the right to withdraw from the study at any time without having to give a reason. However, your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. In accordance with the Coventry University data retention policy, we will destroy all identifiable study data at the end of the study period on the 31/05/2024. We will retain anonymised project data in long-term archive storage for at least 3 years.

Data Protection Rights

Coventry University is a Data Controller for the information you provide. You have the right to access information held about you, in accordance with the General Data Protection Regulation and the Data Protection Act 2018. For more details, including the right to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk. Questions, comments, and requests about your personal data can also be sent to the Coventry University Data Protection Officer at enquiry.igu@coventry.ac.uk

What will happen with the results of this study?

This study will help us to make sure the research process is suitable, accessible, and appropriate for people with PCOS. Next, we aim to run a large-scale randomised controlled trial (RCT) to evaluate the effect of the Hope Programme on mental wellbeing and quality of life in a larger group of people with PCOS.

We will report results of this study in journal articles, research reports, newsletters, blogs, and presentations. Quotes or key findings will always be made anonymous for reporting purposes.

Making a Complaint

If you are unhappy with any aspect of this research, please contact the lead researchers:

Dr Carol Percy – hsx481@coventry.ac.uk

Prof Andy Turner – hsx116@coventry.ac.uk

If you still have concerns or wish to make a formal complaint, please write to: Coventry University Ethics Committee, Coventry University, Coventry CV1 5FB; or email ethics.uni@coventry.ac.uk. In your letter please provide information about the research project, give the names of the researchers, and detail the nature of your complaint.

Who has reviewed this study?

Coventry University Ethics Committee has reviewed and approved this study.

Thank you for taking time to read this information sheet and for considering participating in this research

Other information

if you do experience any distress from taking part in the study please contact your

GP, or

the Samaritans on 116 123 (24 hour telephone helpline) or jo@samaritans.org (you will receive an email response within 24 hours), or

MIND, mental health charity, www.mind.org.uk: Infoline 0300 123 3393