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A feasibility trial of the digital Hope Programme for adults with polycystic ovary syndrome (Hope PCOS)

Submission date
11/07/2023

Recruitment status
No longer recruiting

Registration date
31/07/2023

Overall study status
Completed

Last Edited
11/12/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Polycystic ovary syndrome (PCOS) is a common hormone disorder affecting around 1 in 10 women and adults assigned female at birth. Those with PCOS can have issues including:
• Acne
• Alopecia – hair loss
• Hirsutism – unusual hair growth
• Weight gain
• Irregular or absent periods
• Problems with fertility

PCOS affects mental health, wellbeing and overall quality of life. For example, people with PCOS report more anxiety, depression, body image worries and issues around eating than those without.

The difficulties experienced by people with PCOS seem to be caused by:
• Body hormones affecting appetite, mood, sleep and how a person responds to stress.
• PCOS symptoms and visible body changes affecting a person's sense of identity.
• Self-criticism and/or stigma about being in a bigger body or looking different.
• Difficulty getting diagnosed, getting accurate information and treatments.
• Worries about long term health risks.

We have worked together with PCOS patients, a PCOS support charity and healthcare professionals to create an online group course to help people with PCOS.

The course is designed to educate, empower and support those with PCOS:
• To make changes.
• To live well.
• To reduce anxiety and depression.
• To improve quality of life and overall mental wellbeing.

People joining the Hope PCOS course are invited into an online group run by peers who have PCOS themselves and are trained to support and coach others.

We would like to find out whether we can test the Hope PCOS course in a trial to see if it improves anxiety, depression, quality of life and mental wellbeing. The fairest test is a randomised controlled trial. Before that, we need to do this feasibility study to test whether that kind of trial would be feasible (possible) to run.

Our main questions are whether adults with PCOS are willing:
• To take part in a study like this.
• To join and stay in the study.
• To use the Hope PCOS course.
• To complete the questionnaires.

Who can participate?
You can take part if you are an adult over the age of 18 years and been given a diagnosis of PCOS by your GP and/or by a hospital specialist.

What does the study involve?
• Half of the people who join the study will join the online Hope PCOS course, with opportunities to interact with the others on the course and with the peer facilitator/coach.
• The course lasts six weeks and takes about 2.5 hours to complete each week.
• The 2.5 hours can be done in smaller chunks at any time, day or night to suit you.
• You will need a device e.g. a phone, PC or tablet that gives you access to the internet.
• Half of the people who join the study will go on a waiting list and do the Hope PCOS course after waiting for 3 months.
• Everyone joining the study will be asked to fill in questionnaires at the beginning of the study, at the end of their Hope PCOS course and 3 months after their course ends.

What are the possible benefits and risks of participating?
• The Hope PCOS course may help you to manage your own mental wellbeing.
• You may meet new friends, learn new skills, or find out something new about yourself.
• The study is online and there is a little physical risk of taking part.
• PCOS and mental wellbeing can be sensitive issues.
• You can decide how much to participate in topics that you might find uncomfortable.
• If you feel distress at any time, you are welcome to leave the activity or withdraw from the research entirely.

Where is the study run from?
Coventry University (UK)

When is the study starting and how long is it expected to run for?
March 2023 to November 2023

Who is funding the study?
This work is supported by a Child Development Fund Research Grant from the Waterloo Foundation (UK)

Who is the main contact?
Dr Carol Percy, c.percy@coventry.ac.uk

Study website

https://www.h4c.org.uk/projects/hope-pcos

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
P17953

Study information

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

Acronym
Hope PCOS

Study objectives
PCOS is a common endocrine condition affecting around 1 in 10 women and adults assigned female at birth. People with PCOS can have a range of issues including insulin resistance and androgen excess. Symptoms may include acne, alopecia, hirsutism, weight gain, irregular or absent ovulation and subfertility. PCOS may increase the risk of sleep disorders, e.g. sleep apnoea, and risk of post-natal depression, type 2 diabetes, coronary heart disease or stroke. PCOS has an adverse impact on mental wellbeing due to a range of factors, including:
• Symptoms of PCOS and visible body changes affecting the person's sense of self and identity.
• Self-criticism and/or stigma about body size and appearance.
• Difficulty obtaining accurate information, diagnosis and appropriate treatment to meet individual needs.
• Worries about long term health risks.
Healthcare professionals can help manage the condition, but people with PCOS also need to undertake self-management. The digital Hope PCOS programme is a novel six week online course where adults with PCOS learn with and are supported by peers with the same condition. Hope PCOS aims to improve mental wellbeing and support self-management. In this project we will run a feasibility test of a randomised controlled trial of the Hope PCOS programme. The main research question is: Is it feasible to run a fully powered randomised controlled trial, to test whether the intervention has any measurable effects on self-management and mental wellbeing for adults with PCOS in the short, medium and longer term?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/04/2023, Coventry University Research Ethics Committee (Priory Street, Coventry, CV1 5FB, United Kingdom; +44 (0)24 7765 7688; ethics.uni@coventry.ac.uk), ref: P149968

Study design
Mixed methods feasibility randomized controlled trial with waitlist control

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
See study outputs

Health condition(s) or problem(s) studied
Self management and psychosocial wellbeing in adults with polycystic ovary syndrome (PCOS)

Interventions
The Hope PCOS intervention will be hosted on a digital platform owned by Hope for The Community (H4C) Community Interest Company, a research social enterprise spinout company from Coventry University (https://www.h4c.org.uk). The Hope PCOS course is a structured programme of 2.5 hours a week across 6 weeks, consisting of videos, educational content, activities with homework suggestions and suggested additional resources. These are released at set times over the 6 weeks and can be studied asynchronously in smaller chunks at participants' own pace. The intervention has been co-created using the Antecedent-Target-Measure approach, combining input from adults living with PCOS, PCOS charity representatives and healthcare professionals supporting patients with PCOS. The intervention is based on self-management theory and evidence from clinical and health psychology, including cognitive behavioural theory, hope, gratitude and self-compassion. The content is structured into six sessions, including positive self-management for PCOS, managing the stress of PCOS, feeding mind and body well, body image, intimacy and close relationships, staying healthy with PCOS and keeping PCOS in its place.

The content comprises text, images, downloadable documents, and links to external websites, and is configured into interactive activities (e.g., quizzes, self-monitoring tools, journals), supporting participants to learn and consolidate the content. The Hope PCOS programme also includes forums and messaging facilities that act as a conduit for communication between participants, peers and facilitators. Trained peer facilitators with lived experience with PCOS moderate the course and are trained to assist participants with goal-setting and solution-focused goal feedback.

The participants will be randomly assigned to the intervention group (IG) or waitlist control group (CG) using a 1:1 allocation ratio. Randomisation is initiated automatically on completion of the baseline questionnaires, through the bespoke algorithm embedded within the eNgage research management platform. The research team will be unable to influence any aspect of the randomisation procedure. The waitlist control group will be offered enrolment on the intervention (Hope PCOS course) three months after the intervention group course begins.

Upon completion of baseline questionnaires, participants will be notified of their allocated group (IG or CG), via an email generated by eNgage. Within the email, participants will also receive a link to join the Hope PCOS course they have been randomly assigned to. The research team will be blind carbon-copied into this email confirmation, thus making them aware of participant allocation at this point.

Participants will complete study questionnaires digitally (via the bespoke research management platform 'eNgage'), at baseline, 6 weeks, and 3 months. A sample of completers and non-completers will be randomly selected after the intervention has finished (i.e., 6 weeks) and invited to complete an online interview with a researcher to discuss their experiences of the study.

Intervention Type
Behavioural

Primary outcome measure
Recruitment; Retention; Follow-up; and Completion Rates, and adverse and serious adverse events
1. Recruitment rates will be calculated from the following: (1) providing consent and (2) completing baseline questionnaires. Direct email from participants indicating refusal or declining to participate in the study indicating a refusal. These participants will still be offered access to the Hope PCOS intervention but will not be contacted further.
2. Retention rates will be calculated as the percentage of participants attending all 6 programme sessions.
3. Follow-up rates will be calculated as the percentage of participants who complete all web-based study questionnaires. Participants lost to follow-up will be identified as those who do not complete the T1 or T2 questionnaires.
4. Completion rates will be calculated as the percentage of participants who attended at least half of the intervention (3 sessions) and completed the study questionnaires.
5. Participants will be requested to report any adverse events such as psychological distress to the study researchers.

Adherence and Engagement Measures
The intervention platform collects user engagement data, such as the number of pages viewed in each session and the number of goals set that assists the moderators with participant engagement and experience. We measure the mean percentage of pages viewed per session, and the number of posts or comments a participant made for key activities (e.g. setting goals, comments posted).

Secondary outcome measures
The following outcomes will be measured at baseline, after the intervention (6 weeks after baseline), and at follow up (3 months after baseline):
1. Health-related quality of life questionnaire for polycystic ovary syndrome (PCOSQ-50) assesses of quality of life of 50 items in six domains; psychosocial and emotional; fertility; sexual

function; obesity and menstrual disorders; hirsutism, and coping.
2. The Warwick Edinburgh Mental Well-being Scale (WEMWBS) assesses mental well-being. The scale includes measures of positive affect, satisfying interpersonal relationships and positive functioning.
3. The 9-item Patient Health Questionnaire (PHQ-9) assesses the frequency of experience of the symptoms of depression.
4. The 7-item Generalized Anxiety Disorder scale (GAD-7) measures symptoms of generalized anxiety disorder.
5. The 6-item Self-Efficacy for Managing Chronic Disease scale (SEMCD6) provides a robust measure of participants' confidence to self-manage their symptoms of LC. The questions relate to participants' confidence that they can keep issues relating to their condition from interfering with daily life.
6. System Usability Scale (SUS). The System Usability Scale (SUS) is reliable tool for measuring website an app usability.

Qualitative outcomes
A subset of participants will be randomly selected from the Intervention Group and Control Group to take part in post-course interviews with the research team to explore issues relating to acceptability of the Hope PCOS course. We will aim to interview participants who completed all or most of the intervention (N=10), as well as those who completed fewer than half of the sessions (N=10), to gain a balanced evaluation to inform future co-design of the intervention.

Overall study start date
06/03/2023

Completion date
16/11/2023

Eligibility

Key inclusion criteria
1. Age 18+ years
2. UK based
3. Self report that diagnosis of PCOS has been confirmed by participant's general practitioner and/or a hospital specialist.
4. Capacity to give informed consent
5. Ability to communicate in English, to participate in the intervention and complete outcome measures
6. Internet connection and internet-enabled device.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
109

Key exclusion criteria
1. Age less than 18 years
2. Non-UK based
3. No diagnosis of PCOS, or diagnosis has not been confirmed by participant's general practitioner and/or a hospital specialist.

Date of first enrolment
31/07/2023

Date of final enrolment
24/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hope For The Community - Community Interest Company - Coventry University
The Enterprise Hub, 5 Whitefriars Street
Coventry
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Sponsor information

Organisation
Coventry University

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Sponsor type
University/education

Website
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ROR
https://ror.org/01tgmhj36

Funder(s)

Funder type
Charity

Funder Name
Waterloo Foundation

Alternative Name(s)
The Waterloo Foundation, TWF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
An open access publication documenting the feasibility RCT results, outcomes and recommendations
Plain English Summary(ies) of project findings for public dissemination, via CU, partner organisations, newsletters, social media, blogs, etc.
A summary of research trial and findings will be emailed to all participants enrolled in the RCT

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitive nature of the data. Anonymised data that underpin outputs that result from the research will be deposited in the institutional repository, PURE. Readme files will accompany dataset records, to aid the understanding of the openly shared data and the processes and methodologies that were used during the project. Raw data will not be published openly but will be made available for audit purposes as required.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			18/07/2023	No	No
Participant information sheet	version 4	03/08/2023	03/08/2023	No	Yes
Poster results	ENDO24	20/05/2024	11/12/2024	No	No