

The impact of a positive psychology intervention on quality of life for women with polycystic ovary syndrome (PCOS)

Submission date 03/10/2013	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 06/12/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 17/06/2019	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Polycystic Ovary Syndrome (PCOS) is the most common endocrine disorder amongst women of reproductive age, affecting about 6.5% of women. PCOS is also the most prevalent cause of infertility. Women with PCOS are at an increased risk of miscarriage, cardiovascular disease, type 2 diabetes mellitus and cancer. Symptoms can include hirsutism (excessive hair growth), insulin resistance, infertility and obesity. Studies have shown that PCOS sufferers have higher levels of psychological distress than healthy individuals, including anxiety and depression. Studies show that PCOS can lead to lower quality of life and that women with PCOS are at an increased risk of suffering from a psychiatric disorder, including depression. Positive psychology interventions have been shown to help improve depressive symptoms in participants. Research has found that the positive psychology activity Three Good Things (whereby participants were asked to write down three things that went well each day and their causes) increased happiness and decreased depressive symptoms for six months. This study aims to assess the effectiveness of an online positive psychology intervention on improving the quality of life of women with PCOS.

Who can participate?

Patients aged 18 or over who have been diagnosed with PCOS by a clinician, live in the UK and have access to the internet.

What does the study involve?

Participants are randomly allocated to the intervention or the control group. The participants in the intervention group are invited to take part in a 4 week online positive psychology intervention. The positive psychology exercise is "Three Good Things". For this exercise participants are asked to write down three good things which have happened to them on each day of the intervention. They are directed to a website which enables them to fill in their three good things each day. Participants in the control group are asked to go about their usual routine and are offered the intervention after the follow-up period (6 weeks).

What are the possible benefits and risks of participating?

The positive psychology intervention, "Three Good Things", has been shown to increase

happiness and decrease depressive symptoms. There are no known risks to participating in this study.

Where is the study run from?

The lead study centre is the University of Derby. The trial is being run in association with a PCOS clinic at the Royal Derby Hospital (UK)

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

January 2014 to November 2015

Who is funding the study?

University of Derby (UK)

Who is the main contact?

Sophie Williams

s.williams3@derby.ac.uk

Contact information

Type(s)

Scientific

Contact name

Miss Sophie Williams

Contact details

University of Derby

Kedleston Road

Derby

United Kingdom

DE22 1GB

-

s.williams3@derby.ac.uk

Additional identifiers

Study information

Scientific Title

A randomised controlled trial to investigate whether an online psychology intervention can improve the quality of life of women with polycystic ovary syndrome (PCOS)

Study objectives

Women with Polycystic Ovary Syndrome (PCOS) can experience a low quality of life: a non-invasive clinical trial offering an online positive psychology intervention to women with PCOS may, therefore, be beneficial. We propose to carry out a fully randomised clinical trial into the benefits of an online positive psychology intervention for Derby-based women with PCOS over a four week period, using quality of life as an endpoint. This will be the first study to investigate whether an online intervention can improve the quality of life of women with PCOS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. University of Derby Psychology Research Ethics Committee (PREC), 21/08/2013, ref: 087-13-SW
2. NRES Committee East Midlands Nottingham 2, 14/11/2013, REC ref: 13/EM/0393

Primary study design

Interventional

Study design

Single-centre randomised controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Polycystic Ovary Syndrome (PCOS)

Interventions

Randomisation shall be stratified in order to ensure an equal distribution in length of diagnosis of PCOS. Pragmatic randomisation may be used if a participant has a strong preference to be in a particular group (either control or intervention).

All participants in the control group will be offered the intervention after the follow-up period. Intervention group: Four week online positive psychology intervention - "Three Good Things" activity.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Quality of life, measured using the PCOS QoL (in development) at baseline, 4 and 6 weeks

Key secondary outcome(s)

Anxiety and depression, measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 4 and 6 weeks

Completion date

01/11/2015

Eligibility

Key inclusion criteria

1. Aged 18 or over
2. Diagnosed with Polycystic Ovary Syndrome by a clinician

- 3. Lives in the UK
- 4. Has access to the internet

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

- 1. Participants with mental incapacity unable to give informed consent
- 2. Participants unable to understand verbal and written information in English (as the study is an online study and so translation for individuals not able to understand English is not possible)

Date of first enrolment

12/01/2015

Date of final enrolment

17/04/2015

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University of Derby

Derby

United Kingdom

DE22 1GB

Sponsor information

Organisation

University of Derby (UK)

ROR

<https://ror.org/02yhrrk59>

Funder(s)

Funder type

University/education

Funder Name

University of Derby

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

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?
HRA research summary			28/06/2023	No	No