ISRCTN78626638 https://doi.org/10.1186/ISRCTN78626638

Feasibility trial of intervention for acne

Submission date	Recruitment status	[X] Prospectively registered
06/08/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/08/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/11/2021	Skin and Connective Tissue Diseases	

Plain English summary of protocol

Background and study aims
Acne is a skin condition that is very common amongst young people aged between 14 and 19 years. It can cause low moods, anxiety and embarrassment if not managed appropriately. The main treatments for acne are topical medications. These are creams and gels that can be applied to the skin. Many people don't use these long enough to see any improvement, as they need to be used for up to 8 weeks before they start working. Side effects including skin irritation can also stop people from using topical treatments regularly, although most side effects can be avoided with the correct detailed advice. For these reasons, many people go on to use antibiotics. This is a concern because of the rising levels of antibiotic resistance. Acne is usually treated in primary care but as treatment needs to be used daily in order for it to work, and healthcare professionals only have 10-minute consultations, it is important to give people the tools to manage their skin condition themselves. There are currently no websites available which support people in managing their acne. A website called 'SPOTless' has been developed from interviews with people with acne and is designed to promote the appropriate use of topical treatments. The aim of this study is to see whether the SPOTless website can provide support for young people to help manage their acne alongside their usual care. This will help shape research to improve care and support for people with acne.

Who can participate?
Patients aged 14-25 who have current acne or have had prescriptions for acne in the last 6 months

What does the study involve?
Participants answer some questions about themselves at the beginning of the study, and again after 4 weeks, and after 6 weeks. After answering the questions at the beginning of the study, they are randomly allocated to one of two groups. Group 1 has access to the website in addition to usual care, and Group 2 receives usual care only. Participants are given the option of whether or not they would like to take part in an interview at the end of the study. If they select yes to being contacted, a member of the study team contacts them to arrange a time, date and place that is convenient for them. They can choose to have the interview either face to face (at home or at the University of Southampton), or if they prefer, a telephone interview. The interview is about 30-60 minutes long and explores their thoughts and experiences of taking part in the trial and using the website. People who take part in the interview are given a £10 gift voucher for their time.

What are the possible benefits and risks of participating?
There are no risks or benefits to taking part, however participants may find it interesting.

Where is the study run from?
University of Southampton (UK)

When is the study starting and how long is it expected to run for?
July 2018 to April 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Athena Ip

Contact information

Type(s)
Scientific

Contact name
Miss Athena Ip

Contact details
University of Southampton
Aldermoor Health Centre
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United Kingdom
SO16 5ST

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
37769

Study information

Scientific Title
An internet intervention to support self-management of acne vulgaris amongst young people: a feasibility randomised trial

Study objectives

This study will invite people aged 14 to 25 via general practices and community advertising to see how a website can provide support for young people to help manage their acne alongside their usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Essex Research Ethics Committee, 30/07/2018, ref: 18/EE/0105

Study design
Randomised; Both; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Acne

Interventions
Participants will be randomised using the LifeGuide software. The randomisation sequence is automatically generated, and a computer-generated algorithm block randomises patients to the trial groups.

Participants in the intervention group will receive treatment as usual in addition to access to the SPOTless website to help them self-manage their acne. SPOTless is a web-based behavioural intervention developed to support self-management of acne and involves a 4-week challenge to promote the appropriate use of topical preparations. The intervention provides accessible information, tools and support for participants and is designed to be accessed wherever and whenever it is convenient for the participant.

Participants in the control group will receive all treatment as usual including appointments as required with their GPs. If necessary GPs may refer participants to specialists (e.g. dermatologists).

Intervention Type

Behavioural

Primary outcome measure
The primary outcomes from this feasibility trial will be as follows:
1. Number of practices required to recruit the participant numbers and the rate of recruitment
2. Number of participants withdrawing from the intervention and the trial at 4 weeks and follow-up retention rates at 6 weeks
3. With regard to the behavioural intervention, the extent of participant's usage of the website will be measured
4. Participant adherence to the behavioural intervention will be explored by examining intervention usage data, which will provide detailed information on number of logins, module accessed as well as time spent on each webpage (automatically collected on LifeGuide software)
5. The acceptability of measuring skin specific quality of life using the Skindex-16 instrument at baseline, 4 and 6 weeks, as a potential primary outcome for the main trial

Secondary outcome measures
The feasibility of a range of quantitative measures:
1. Demographic questions including age and gender measured at baseline
2. Health state measured using the EQ-5D-5L at baseline, 4 and 6 weeks
3. Perceived reasons for non-adherence to treatment measured using the Problematic Experiences of Therapy Scale (PETS) at baseline, 4 and 6 weeks
4. Belief about treatment and its likely success measured using the credibility/expectancy questionnaire at baseline, 4 and 6 weeks
5. Anxiety and depression measured using the patient health questionnaire (PHQ-4) at baseline, 4 and 6 weeks
6. Topical use and other treatments used measured at baseline, 4 and 6 weeks

Overall study start date
30/07/2018

Completion date
01/03/2020

Eligibility

Key inclusion criteria
1. Current acne vulgaris
2. Aged 14 to 25
3. Have had prescriptions for the treatment of acne within the last 6 months
4. Have access to the internet and an active email address
5. Able to read/understand English without assistance
6. People who are invited into the study may be using other medications (including oral antibiotics that still require topicals as well as people on isotretinoin) but people who have cleared up their acne will not be eligible to take part which will rule out anyone who is on isotretinoin for severe acne

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 65; UK Sample Size: 65

Total final enrolment
53

Key exclusion criteria
1. Under 14 or over 25 years of age
2. Have taken part in the study to develop the internet intervention
3. Have severe mental health problems
4. Their acne has cleared up

Date of first enrolment
20/08/2018

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
CRN Wessex
Clinical Research Network Wessex
Unit 7, Berrywood Business Village
Tollbar Way
Hedge End
Southampton
United Kingdom
SO30 2UN

Sponsor information

Organisation
University of Southampton

Sponsor details

Research & Innovation Services, Building 37
Highfield Campus
Southampton
England
United Kingdom
SO17 1BJ

Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR School for Primary Care Research

Results and Publications

Publication and dissemination plan
Findings from this study will be sent as feedback to participants, disseminated through peer reviewed publication and will also be presented at conferences.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
Contact details will be stored in a secure file on the University computer or locked in a filing cabinet with authorised access only for the researchers working on the project - this data will be deleted after 3-6 months and at no point will identifiable information be removed from University premises. The faculty of Medicine research conduct guidelines require anonymised data to be stored for 10 years. Audio recordings will be deleted immediately after transcription. After the study has finished the research data will be moved to an offsite storage facility which will have agreed to the terms and conditions laid out by the sponsor following the Standard Operating Procedure for archiving. Intervention usage data and outcome measures will be collected and managed on LifeGuide, which is hosted on a secure server at the University of Southampton. The data generated from the study will be analysed quantitatively and qualitatively by the Chief Investigator who will have collected the data. Support will be provided by the supervisors. This will involve simple descriptive statistics and discussing emerging codes and analysis at every stage. Analysis will be carried out at the University of Southampton on the university laptops. There are no plans to export the data outside of the UK.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V1.3	02/07/2018	07/08/2018	No	No
Protocol file	version v1.5	07/01/2019		No	No
Results article		03/11/2021	16/11/2021	Yes	No
HRA research summary			28/06/2023	No	No