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Acne care online

Submission date	Recruitment status	[X] Prospectively registered
13/02/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/10/2025	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Acne is very common, frequently causes distress or low self-confidence, and may lead to permanent scarring, long-lasting dark marks, or depression. Treatment of acne is a major cause of antibiotic use amongst young people, leading to antibiotic resistance. Evidence and guidelines suggest that topical treatments (creams or gels applied directly to the skin) should be the main treatments for acne. Effective topical treatments are available from pharmacies without a prescription, but many people are unaware of these and buy cosmetic products that don't help instead. People often give up on topical treatments because they are not given full advice on how to use them. For example, they don't know how to reduce the risk of stinging and redness or that it takes several weeks for treatments to start working.

We have developed a new website to help young people with acne to manage acne more effectively, including information on how to obtain effective treatments, promote regular treatment use and advice on how to avoid side effects.

We will test the new website in a randomised trial: first of all to check that the website and the study procedures work as expected and are acceptable and accessible for the people who take part; and after this to see whether it improves outcomes for people with acne and reduces the use of long-term oral antibiotics.

Who can participate?

People with acne (aged 13-25 years) will be invited to take part in the study through a variety of sources including from GP practices, pharmacies, community and social media advertising, and through schools and other partner organisations.

What does the study involve?

Participants will be asked to register online and complete an online consent form and questionnaire before being allocated by chance (randomly) to either the new study website, or to the control group. All participants will be able to access their usual health care or acne treatments during the study. Participants will be asked to complete questionnaires at 12, 24, 36 and 52 weeks (1 year) asking about their acne, quality of life and their use of acne treatments. Participants in the control group will be signposted to standard NHS advice about acne. They will also be offered access to the new website at the end of the study period. We will also explore how the new website works and what its like for people taking part in the study, by talking to those that have taken part and analysing how they used the website.

What are the possible benefits and risks or participating?
Participants will get access (either immediately or at the end of the study) to a brand new website with advice and support about managing acne. Once they complete the study, they will also be entered into a prize draw to win one of 4 x £50 vouchers.
Participation will take up a small amount of participants time in answering online questionnaires (about 10-15 mins each time they are completed)

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

When is the study starting and how long is it expected to run for?
April 2023 to November 2026

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

Who is the main contact?
Julie Hooper, Trial Manager, acnecare@soton.ac.uk

Contact information

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
330774

Central Portfolio Management System (CPMS)
57037

National Institute for Health and Care Research (NIHR)
202852

Study information

Scientific Title
Acne Care Online (ACO): feasibility and full scale randomised controlled trials of a digital behaviour change intervention to improve acne-related quality of life amongst 13-25 year olds

Acronym
ACO

Study objectives

Feasibility trial objectives:
1. To determine the feasibility of an online behavioural intervention aimed at supporting self-management, improving outcomes and reducing antibiotic use in acne. The study also aims to test the trial processes and procedures to determine whether any changes are needed prior to the subsequent full scale trial.
2. Should no changes be required, the feasibility trial will become an internal-pilot for the full scale trial

Full scale trial objectives:
1. To evaluate the clinical effectiveness of the Acne Care Online self-management intervention for acne in improving acne outcomes
2. To explore mechanisms underlying effectiveness of the intervention through process evaluation
3. To undertake an economic evaluation to estimate cost-effectiveness of the intervention compared with usual care from NHS and patient perspectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/11/2023, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 207 104 8290; gmeast.rec@hra.nhs.uk), ref: 23/NW/0323

Study design
Feasibility randomized controlled trial with nested mixed-methods process evaluation becoming full scale effectiveness and cost-effectiveness trial with nested mixed-methods process evaluation. Feasibility trial will become internal pilot to full scale trial if no substantial changes to the intervention or trial processes are required (as determined by analysis of the feasibility trial and process evaluation data)

Primary study design
Interventional

Study type(s)
Other, Quality of life, Efficacy

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

Interventions
In both the feasibility and full scale trials, recruited participants will be randomised using the LifeGuide software hosting the digital intervention into one of two groups:

Intervention arm (immediate access to Acne Care Online):
1. Sign-up, consent, screening, baseline measures and randomisation (all completed online) – approx. 15-20 mins
2. Use of Acne Care Online – duration completed self-determined by participant – participant is able to use as much or as little as preferred within the 12 month study period
3. Follow-up measures at 4 subsequent time points: 12 weeks, 24 weeks, 36 weeks and 52 weeks – approx. 10-15 mins each time

Usual care arm (Access to standard care, sign-posting to NHS Acne advice, access to Acne Care Online after 12 month study period):
1. Sign-up, consent, screening, baseline measures and randomisation (all completed online) – approx. 15-20 mins
2. Access NHS Acne advice (optional) – duration self-determined by participant
3. Follow-up measures at 4 subsequent time points: 12 weeks, 24 weeks, 36 weeks and 52 weeks – approx. 10-15 mins each time

Randomisation will be completed by the LifeGuide software that will be hosting Acne Care Online.

Acne Care Online is a digital behaviour change intervention including advice, support and interactive tools to support effective self-management of acne.

Intervention Type
Behavioural

Primary outcome(s)
Acne severity measured using the Acne-QoL symptoms subscale at 12 weeks, compared with baseline

Key secondary outcome(s))
1. Acne severity evaluated over 12 months using Acne-QoL symptom subscale, using repeated measures analysis over 12 weeks, 24 weeks, 36 weeks and 52 weeks, controlled for baseline
2. Acne-QoL other subscales (self-perception, role-emotional and role-social) and total score evaluated over 12 months using Acne-QoL symptom subscale using repeated measures analysis over 12 weeks, 24 weeks, 36 weeks and 52 weeks, controlled for baseline
3. Use of topical treatment for acne at baseline, 12 weeks, 24 weeks, 36 weeks and 52 weeks (self-report and treatment adherence)
4. Use of acne-related antibiotics and other oral acne treatment use at baseline, 12 weeks, 24 weeks, 36 weeks and 52 weeks, including frequency of use (self-report)
5. Past use of topical and oral treatments for acne
6. Problematic Experiences of Therapy Scale (PETS) will be asked prior to adherence questions at baseline,12 weeks and 52 weeks.
7. Patient Enablement Instrument (PEI) at baseline, 12 weeks and 52 weeks
8. Brief Illness Perceptions Questionnaire (BIPQ) at baseline, 12 weeks and 52 weeks
9. Patient Health Questionnaire (PHQ–4) for Anxiety and Depression at baseline, 12 weeks and 52 weeks
10. EQ-5D-5L at baseline, 12 weeks, 24 weeks, 36 weeks and 52 weeks
11. Short Warwick Edinburgh Mental Well-being Scale (SWEMWBS) at baseline, 12 weeks, 24 weeks, 36 weeks and 52 weeks
12. Resource use will be measured at baseline, 12 weeks, 24 weeks, 36 weeks and 52 weeks (self-report)
13. Prior belief in effectiveness of online interventions will be asked at baseline and use and type of online resources previously used for acne will be asked at baseline, 12 weeks and 52 weeks
14. Demographics
15. Age of onset and duration of acne

Part of the objective of the feasibility trial is to assess questionnaire burden and if this is not acceptable to participants we will consider not including the Brief IPQ and SWEMWBS in the full scale trial

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Aged 13-25 years with self-defined acne with current active lesions (i.e. mild or worse on self-assessment scale)
2. Have internet access

For primary care recruitment GPs will invite potential participants via database searches that will identify patients aged 13 to 25 years who either:
1. Have been prescribed a topical treatment for acne or co-cyprindiol in the previous 12 months or
2. Have a diagnostic code for acne on their electronic record over the previous 12 months either with or without having been prescribed an oral tetracycline or erythromycin in that period.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
13 years

Upper age limit
25 years

Sex
All

Total final enrolment
1006

Key exclusion criteria
1. Their acne is currently clear or almost clear, i.e. if they answer ‘no’ to the following question asked online at baseline screening: “Do you have spots or acne on your face at the moment? This could include whiteheads or more red spots or bumps.”
2. They are unable to give informed consent or their parent does not provide consent (for participants aged 13-15 recruited via community or social media advertising)
3. They are unable to read and write English as the intervention content and outcome measures

are in English
4. They are currently taking oral isotretinoin or have taken it within the previous 3 months, as advice about topical acne treatments may be inappropriate in this case
5. They took part in interviews as part of Acne Care Online intervention development. (Qualitative interviewees who did not view intervention materials will NOT be excluded)
6. Only one person per household will be able to take part in the study. If someone from that household has already joined the study then they will be excluded from the study
7. If the feasibility trial remains separate to the full scale trial, participants in the feasibility trial will be excluded from the full-scale trial

Date of first enrolment
15/07/2024

Date of final enrolment
08/10/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton
University Road
Southampton
United Kingdom
SO17 1BJ

Study participating centre
Participating primary care practices identified by Wessex Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by North East and North Cumbria Clinical Research Network
United Kingdom
-

Study participating centre

Participating primary care practices identified by North West Coast Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by Yorkshire and Humber Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by Greater Manchester Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by East Midlands Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by West Midlands Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by West of England Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by Thames Valley and South Midlands Clinical Research Network
United Kingdom
-

Study participating centre

Participating primary care practices identified by East of England Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by Kent Surrey and Sussex Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by South West Peninsula Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by North Thames Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by South London Clinical Research Network
United Kingdom
-

Study participating centre
Participating primary care practices identified by North West London Clinical Research Network
United Kingdom
-

Study participating centre
Southern Health NHS Foundation Trust
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Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Miriam Santer, Chief Investigator, (acnecare@soton.ac.uk).
The type of data that will be shared: 1) potentially any non-identifiable quantitative data dependent on reasonable request; 2) non-identifiable qualitative data dependent on reasonable request, only where participants have consented to this use of their interview data.
When the data will become available and for how long: after all publications of study findings is complete.
By what access criteria data will be shared including with whom: upon reasonable request to /discussion with the chief investigator
Consent item for participation in the trial (quantitative data): “anonymised data may be used for

future research, clinical purposes, study materials or for teaching. These organisations may be universities or NHS organisations in this country or abroad." For participation in qualitative process interviews (qualitative data), the equivalent consent item is optional so only qualitative data from participants who provided consent for this item would potentially be shared comments on data anonymisation, only anonymised data will be shared any ethical or legal restrictions, As above, the researchers will share anonymised data for further research if participants have consented to this, upon reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	04/02/2025	20/03/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes