ACNE CARE ONLINE

Supporting self-management for acne: developing online resources

PROTOCOL

Version 1.1

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STUDY SUMMARY

Study Title	Developing and testing an online intervention to support self-management, improve outcomes and reduce antibiotic use in acne
Short title	Acne Care Online
Study Design	*Phase 1* Qualitative interviews with people aged 13 to 25 with acne Qualitative interviews with parents of children aged 13 to 15 with acne Qualitative interviews with primary care prescribers and community pharmacists *Phase 2* Think aloud interviews using draft intervention materials with people aged 13 to 25 with acne
Study Participants	*Phase 1* 15-25 people aged 13 to 25 with acne 8-10 parents of child participants aged 13-15 years. 15-20 primary care prescribers and community pharmacists *Phase 2* 15-25 think aloud interviews with people aged 13 to 25 with acne
Planned Size of Sample (if applicable)	*Phase 1* – Maximum 55 *Phase 2* – Maximum 25
Planned Study Period	1 April 2022 to – 31 March 2024
Research Question/Aim(s)	To improve outcomes for acne by promoting the use of appropriate treatments and reducing overuse of long-term oral antibiotics through an online intervention to support acne self-management

FUNDING

FUNDER(S)	
NIHR PGfAR	£1,901,577 (for whole programme, of which this is part)

ROLE OF STUDY SPONSOR

The University of Southampton will act as the sponsor and sees its responsibilities as follows:

The UoS as Research Sponsor will:

1. Assess the adequateness of any independent expert review.
2. Ensure that the Chief Investigators have the necessary expertise, experience and qualifications to conduct the study.
3. Provide a formal written agreement of the sponsorship conditions and formal notification of sponsorship.
4. Provide the necessary insurance to cover the Chief Investigator and research team.
5. Determine the arrangements for monitoring research studies.
6. Provide advice and guidance on study management, conduct and applicable legislation, guidelines and policies.
7. Determine the acceptability of the archive arrangements proposed by the Chief Investigator.

ROLES AND RESPONSIBILITIES OF PROGRAMME STEERING COMMITTEE

The role of the Steering Committee is to provide oversight of the conduct of the programme. This includes oversight of the practical aspects of the study as well as ensuring that the study continues to be run in a way which is both safe for the patients and provides appropriate safety and efficacy data to the sponsor and investigators.

Specific responsibilities of the Steering Committee include, but are not limited to, the following:

- to provide overall supervision of the studies within the Programme Grant
- to take steps to reduce deviations from the protocol to a minimum
- periodic review of the progress of the study
- to review safety data; this review is typically done blinded to treatment allocation (in case of a major safety concern, the Steering Committee can request unblinding and the review then can be done in an unblinded manner)
- to resolve any differences within the research team or between research team and sponsor on the data management and monitoring procedures in the trials or any recommendations for modifications to the protocol.

The Steering Committee will have ultimate responsibility for the trials and will assume primacy over the Data Monitoring Committee or principal investigator. The Steering Committee can prematurely terminate the trials. The sponsor and chief investigators will agree, in writing prior to the start of the study, to the charter of the Steering Committee.

KEY WORDS: Acne, primary care, community care, pharmacy, digital intervention, adherence, self-care

GANTT CHART

Months	1-3	4-6	7-9	10-12	13-15	16-18
Qualitative interview study with people with acne and parents/carers						
Develop prototype intervention for user feedback						
Carry out 'think aloud' study of prototype intervention content with young people						
Modify intervention content and format based on feedback						
Finalise intervention for RCT and rigorous testing of final versions						
Qualitative interviews with primary care prescribers and pharmacists						

LAY SUMMARY

Aim

To improve the health of people with acne by increasing use of effective treatments and reducing overuse of long-term oral antibiotics.

Background

Acne is very common, frequently causes distress, low self-confidence, and may lead to permanent scarring, long-lasting dark marks, and depression. Treatment of acne is a major cause of antibiotic use amongst young people, driving antibiotic resistance. Evidence and guidelines suggest that topical treatments (treatments applied directly to the skin) should be the main treatments used for mild and moderate 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 and that it takes several weeks for treatments to start working.

The main barriers to effective acne treatment are: inaccurate patient beliefs about unproven treatments; low awareness of effective topical treatments resulting in underuse; inadequate support around correct use of topical treatments leading to early discontinuation; delaying contacting health professionals, with increasing the risk of severe acne and scarring.

Methods

1) Interview young people with acne and parents/carers to explore barriers and facilitators to treatment use and help-seeking
2) Develop an online toolkit to support people with acne to obtain and use effective acne treatments, particularly promoting regular use and avoiding side effects with topical treatments
3) Refine the toolkits through feedback by asking people to use them and to 'think aloud' while they are using them
4) Interview health professionals to find out more about how best to promote the toolkit to people with acne
5) In a subsequent study, we will test whether the toolkit improves acne-related quality of life and reduces the use of antibiotics in a randomised trial. This is not included in the current protocol or ethics application

Patient and public involvement

Two people with extensive experience of managing their own acne are co-applicants on this research and we have spoken to many other young people about their experiences of managing acne. We will continue to involve both the public contributor co-applicants and wider public involvement in shaping this research.

BACKGROUND

Acne vulgaris (hereon acne) is extremely common, affecting over 90% of teenagers.[1] It is primarily a condition affecting the pilosebaceous unit (hair follicles in the skin and associated oil glands), leading to inflammatory and non-inflammatory lesions and scarring,[2] most commonly affecting the face. The aetiology remains unclear but research into dietary, hygiene or other lifestyle causes have shown these to have little influence.[2]

Acne can cause significant distress, decreased self-confidence and increased rates of depression and suicidal ideation.[2] Distress about the appearance of acne appears to be particularly high amongst women and people identifying as non-white.[3] The majority of acne is classed as mild, with moderate or severe acne combined making up less than 15% of acne.[4 5] Acne persists into 40-60% of people in their twenties and is thought to lead to some degree of scarring in approximately 20% of the population.[2 4]

As well as limiting quality of life, acne makes a major contribution to antibiotic use amongst young people,[6] results in substantial health service use[7] as well as causing skin changes that can be permanent, such as skin pigment changes and scarring.[2] Skin conditions account for 18% of antibiotics prescribed outside hospitals[8] and, although data are scarce, antibiotic resistance arising from acne treatment is a major and increasing concern.[9] Health service use for acne is substantial with approximately 3% of people aged 13-25 visiting their GP for acne each year[7] (10k consultations per year in the UK), of whom 8% are referred to secondary care.[7] The majority of people attending secondary care are prescribed isotretinoin and require frequent review (monthly for women).[10]

There is high-quality evidence supporting use of topical treatments for acne, which are recommended as first line treatment for mild-to-moderate acne in UK guidelines.[11] However, treatment adherence is low, mainly due to limited understanding, with insufficient motivation and support necessary to engage effectively with treatments (regular use is needed over several weeks) and the barrier of skin irritation unless mitigating advice is emphasised.[12] These problems can be overcome with better support.[13]

Another major barrier to the use of effective treatment is a perception that acne is not a problem that warrants medical attention, even where the condition has considerable emotional and social impact.[14 15] People with acne often have little awareness of effective topical treatments available via pharmacy or on prescription and instead use ineffective cosmetic products.[16] They frequently consult late, and at a point when they are disillusioned with topical treatments and are keen for oral treatments, commonly antibiotics, which are incorrectly perceived as being more effective than topical treatments.[16] GPs prescribe oral antibiotics during 31% of first consultations for acne,[17] with median duration 4 months,[6] partly due to perception of high patient demand for antibiotics.[18]

NHS England describes acne as a condition appropriate for self-management with pharmacy advice and use of over-the-counter medicine.[19] Accessible support is needed for people with acne to gain **early** control of the condition through helping them obtain effective treatment, use this regularly and avoid side effects. Early treatment of acne is a priority in order to avoid oral antibiotic use, lessen psychosocial impact and reduce risk of severe acne or scarring that may lead to further treatment, referral and psychological consequences,[9] as early treatment can minimise subsequent scarring and associated referrals.[20]

Although there have been many calls for improved education and information for people with acne,[2 12 13] there is little research evaluating behavioural interventions to date, and education and information are insufficient to change behaviour effectively: the most recent review identified four RCTs of interventions; two used emails or text messaging (both small and inconclusive) and two used increased follow-up visits.[21]

A recent study of an instructional video on how to use topical treatments for acne, delivered via a pharmaceutical company app, found weak evidence of increased treatment adherence, but there were methodological limitations and the app is not widely used.[22] An industry-funded guideline has been developed for pharmacists but not widely used.[23]

Digital interventions change health-related behaviours when based on robust development supported by theory and multiple behaviour techniques.[24] A Cochrane review has shown that digital interventions improve outcomes in long-term conditions.[25] Given the evidence above for behavioural barriers to treatment (i.e. low awareness of effective topical treatments, low adherence and insufficient management of side effects), there is a good case for the development of a robust intervention to support effective self-management of acne. We focus on young people aged 13-25 years with mild and moderate acne, as this is the largest group, most likely to benefit and because acne in people over the age of 25 and severe acne can be more difficult to manage.

An intervention to improve self-management for acne is likely to have the following potential benefits:

- Effective early management of acne may reduce the emotional, psychological, and social burden of acne
- Effective early management of acne may reduce the risk of sequelae such as skin pigment changes or scarring, for which there is little effective treatment
- Improved use of topical treatments is likely to reduce antibiotic use, reducing the risks from antimicrobial resistance

AIM AND OBJECTIVES

Aim

To improve outcomes for acne by promoting appropriate treatment use and reducing overuse of long-term oral antibiotics through an online behavioural intervention to help people to self-manage acne effectively.

Objectives

- Develop an online behavioural intervention for people with acne to support effective acne treatment, particularly through the promotion of evidence-based treatments, adherence to topical treatments and mitigating side effects
- Explore routes to future widespread implementation by exploring and addressing catalysts to implementation with people with acne and healthcare professionals managing acne

This study is part of a programme of work which aims to subsequently test the online intervention in a feasibility and full-scale trial. This will be covered in a separate protocol and HRA submission at a later date.

STUDY DESIGN

Phase 1 - qualitative interview study

Qualitative interviews with young people with acne, parents/carers of young people with acne and health professionals managing acne will inform development of the intervention.

Interviews with young people with acne and parents/carers of children with acne will explore: barriers and facilitators to treatment use and help-seeking; recruitment strategy for full-scale trial; and data collection for economic evaluation in full-scale trial. In particular, semi-structured interviews will explore the following topics:

- Understandings about causes of acne
- Views and experiences of living with acne and managing acne
- Understandings or concerns about acne treatments and any barriers or facilitators to adherence
- Specific views and experiences of using acne treatments including oral and topical treatments
- Current sources of information/advice about acne treatments, how this is sought and found, preferences regarding sources of information/advice
- Socio-economic influences and costs relating to acne self-management

While existing qualitative research explores some of these topics (particularly views and experiences of living with acne), there are gaps in terms of younger teens and people from ethnic minorities.[26] We will ensure that our interview guide covers the key constructs of our theoretical models to ensure we elicit views relevant to these constructs. We will draw on the extended Common-Sense Model (CSM), which includes the Necessity-Concerns framework, in exploring how young people's beliefs about acne symptoms and treatment relate to self-management[27] and treatment adherence.[28] A different version of the interview guide will be developed for interviewing children aged 13-15.

Qualitative interviews with health professionals (primary care prescribers and community pharmacists) will explore topics including:

- how the intervention could be implemented
- what factors could facilitate health professionals promoting the intervention to people with acne
- how health professionals would envisage the intervention being embedded within digital care pathways
- key constructs of Normalization Process Theory,[29] to understand the dynamics of implementing, embedding and integrating the acne intervention into practice

The findings from these qualitative interviews will provide us with the information with which to design an online self-management support intervention (or tool) for young people with acne. Further details of likely intervention content are given on page 18. The intervention will include support for young people with help-seeking from healthcare professionals for acne treatments and advice. We aim to embed a simple form of patient-held 'decision tool' into the intervention that people with acne can take to primary care or community pharmacy. This tool will be developed to support young people's treatment decisions, empower them to consult and support communication within the consultation. Development work will explore perception and acceptability of the decision tool for both young people and health professionals.

Phase 2 – think aloud interviews to carry out intervention optimisation

The intervention will be optimised through 15-20 qualitative think aloud interviews[30] to elicit young people's views on the draft intervention materials. This interview technique is particularly suitable for intervention optimisation as it enables an in-depth understanding of people's experiences using the intervention and improve usability, accessibility and ensure it is meaningful to target users. The patient-held 'decision tool' will also be iteratively developed with input from young people.

DATA COLLECTION

Phase 1 and 2 - young people with acne and parents/carers of young people with acne

Young people with acne and parents/carers of young people with acne will be recruited through a variety of sources including mail-out from primary care, opportunistic recruitment in pharmacies, community and social media advertising, and through schools and other partner organisations. Participants will be sampled purposively to include a range of age, gender, ethnicity and relative deprivation. We will over-recruit young people from ethnic minority backgrounds and under-served communities, as well as people aged under 16 years as these groups have been underrepresented in previous qualitative research amongst people with acne. We will ensure this by carrying out mail-outs working with NIHR Clinical Research Networks in areas densely populated with ethnic minorities, and by working with organisations such as the Centre for BME Health and South Asian Health Foundation. In terms of recruiting participants aged under 16, we will focus primary care mail-outs on parents/carers in these groups and work with secondary schools to reach younger participants who may not have engaged with health services. We will develop age-appropriate recruitment materials to appeal to our target group.

Primary care

Invitations will be sent through SMS text, email, postal mail out, advertising and/or opportunistic recruitment by participating practices, offering participation in either the qualitative interview study or (at a later date) think aloud interview.

Database searches will identify patients aged 13 to 25 years with a recorded diagnosis of acne and who have obtained one or more prescriptions for drugs acting on the skin (BNF chapter 13) over the previous 12 months. GPs will be asked to screen the lists to check for exclusions such as known opposition to taking part in research, recent bereavement or severe current mental health problems. Patients aged 16 and over will be contacted directly whereas for those under the age of 16, initial contact will be made with their parent or carer.

Potential participants (or their parent/guardian where under 16) will either be sent: 1) a SMS text message to their registered mobile number with a link to the study website; 2) an email to their registered email address with a link to the study website; or 3) a postal mail out pack including an information sheet and details of how to access the study website. The study website will include full participant information and parental information, in both accessible and detailed formats, information on eligibility and information on how to express interest in taking part, or giving online written consent for their child to take part, in a qualitative interview or (at a later date) think aloud interview.

Participants may also be recruited opportunistically during consultations. In this case, the GP will provide the patient (or their parent/ carer if under 16) with link to the study website or a study pack containing the enclosures listed above.

Once they have visited the study website, patients aged 16 and over, as well as parents/carers of children under 16 who are interested in participating, will be asked to complete an online form leaving their contact details. They will be contacted by the research team to discuss the study further and to invite them to an interview at a time, mode (videoconferencing, telephone or face-to-face) and location convenient to them, if they are still keen to participate. Online written consent will be obtained before commencing the interview.

Where parents/carers are contacted initially for patients under 16, they will be provided with a parental information sheet which will advise them what the study would involve for their child and will provide the opportunity to contact the research team to ask any questions. This will include a link to the study website where they can review this information and where they will be asked to complete an online consent form to agree to their child being invited to participate in the study. They will also have the opportunity to indicate whether they may be willing to participate in an interview themselves. Once they have consented for their child to be invited, they will be asked to provide details about how they would prefer their child to be contacted to invite them to participate – either directly or via themselves – e.g. phone, email or postal invitation. The study team will make contact with the young person as directed to provide an age-appropriate information sheet, to answer any questions they may have, and to arrange a convenient time/mode for the interview. Children under 16 will complete an online written assent form prior to the interview commencing. If a parent/carer also indicate their own willingness to participate in an interview they will follow the same process as invited patients aged 16 and over (see above).

Opportunistic recruitment in pharmacies

Potential participants, or their parent/carer if under 16, will be given a link to the study website (via advertisement on screens or by flier or study card) or a study pack containing a participant information sheet, freepost envelope and a reply slip. As above, the study website will contain full participant information sheet and information on how to take part. As above, where potential participants express an interest in participating, they will be contacted by the research team to discuss the study further and to invite them to an interview at a convenient time, mode and location. As above, parents of children under 16 will first need to online consent to their child being invited before the child is invited directly.

Community or social media advertising

Posters will be displayed in locations such as GP surgeries, hospitals, community pharmacies, the University campuses, local newspapers or social media inviting potential participants, directing them towards the study website with full information on the study and how to participate, as above.

As above, where potential participants express an interest in the study, they will be contacted by the research team to discuss further and to invite them to an interview at a convenient time, mode and location. As above,

parents of children under 16 will first need to provide online consent to their child being invited before the child is invited directly.

Recruitment through schools and other partner organisations

Posters will be displayed in schools, colleges and University campuses, directing potential participants towards the study website with full information on the study and how to participate, as above. We will engage with teaching, pastoral or school nursing staff to plan further opportunities to raise awareness of the research, including the possibility of research participation and how to take part. This may include invitations to take part in the study via letter, SMS text or email from the school or college directing students and/or their parents to the study website.

As above, where potential participants express an interest in the study, they will be contacted by the research team to discuss further and to invite them to an interview. As above, parents of children under 16 will first need to provide online consent to their child being invited before the child is invited directly.

Inclusion criteria

- Age 13-25 years, or parents of children aged 13-15, or health professionals regularly managing acne
- Experience of acne or spots (self-diagnosis or health professional diagnosis)

Exclusion criteria

- Unable to understand and communicate in English
- Where participants or children of participants are outside the stated age range

Sample size

Sample sizes will depend on when data saturation is achieved for the main themes but we anticipate the following approximate numbers:

Phase 1 – qualitative interviews

- 15-25 young people with acne
- 8-10 parents of child participants aged 13-15 years
- 15-20 health professionals (primary care prescribers and community pharmacists)

Phase 2 – think aloud interviews

- 15-20 young people with acne

Consent

All potential participants, who are young people aged 13-25 or their parents/carers, will either receive a SMS text, email or letter from their GP, be told about the study by a health professional, see a poster in the community or social media or receive information via their school/college. They will therefore either have received a (parental) Participant Information Sheet, or will have read the (parental) Participant Information Sheet on the study website. If they are interested in taking part, or if they are happy for their child under 16 to be invited, then they will complete an online form leaving their contact details. The study team will talk to them over the phone or via email and answer any questions they may have and arrange an interview if appropriate. Parents of children under 16 will complete an online parental consent form for their child to be invited, and will provide details of how they would prefer this to happen.

Informed participant consent, or online assent for children aged 13-15 years,will be sought prior to the start of all interviews. If the interview is taking place by telephone or by videoconferencing then they will be asked to complete online consent process prior to the interview taking place, or provide verbal consent at the start of the interview. Specific consent for recording of the interview will also be sought, but if this is declined the interview will proceed and the researcher will take detailed notes.

The initial invitation for children aged 13-15 will be to their parent/carer, i.e. for recruitment through primary care, the text, email or letter will be sent to the parent/carer. For social media, community, school and pharmacy-based recruitment, study advertising materials (e.g. posters/flyers etc) will be targeted at young people, and/or the parents of young people aged 13-15. When people visit the website from these advertising materials, they will be asked to indicate if they are: 1) A young person aged 16 or over who wants to participate; or 2) A parent/carer of a child aged 13-15. They would then be directed to an appropriate page where they can review an appropriate version of the information sheet and then: 1) for over 16s – a contact form to leave their details for the study team to contact them; or 2) for parents/carers – an online parental consent form for their child to be invited.. We will explain to parents/carers that we are interested in their child's views and will seek to interview young people individually, unless parental presence is preferred.

Interview conduct

Interviews will be carried out by experienced qualitative interviewers, either face-to-face or remotely via videoconferencing or telephone. Face-to-face interviews will be held in participants' homes, but if they would prefer to meet elsewhere, alternative arrangements may be made for the meeting to be held on University Premises. Audio recordings will be professionally transcribed, anonymised and checked. Transcripts will be assigned anonymised identifiers and imported into NVivo for data handling.

All those participating in an interview will be offered a £15 voucher.

Interviews will be semi-structured following an interview topic guide. Interviews with young people with acne and parents/carers of children with acne will explore: barriers and facilitators to treatment use and help-seeking; recruitment strategy for full-scale trial; and data collection for economic evaluation in full-scale trial. In particular, semi-structured interviews will explore the following topics:

- Understandings about causes of acne
- Views and experiences of living with acne and managing acne

- Understandings or concerns about acne treatments and any barriers or facilitators to adherence
- Specific views and experiences of using acne treatments including oral and topical treatments
- Current sources of information/advice about acne treatments, how this is sought and found, preferences regarding sources of information/advice
- Socio-economic influences and costs relating to acne self-management

Phase 1 – health professionals

Health professionals will be invited to participate in qualitative interviews through NIHR Clinical Research Networks, relevant national groups, contacts and professional lists and social media advertising. We will seek to interview Community Pharmacists and Primary Care Prescribers (e.g. GPs, Advanced Nurse Practitioners, Clinical Pharmacists).

Invitations will include an online link to express interest in participating. The study team will then send participants an information sheet and phone or email to arrange an interview. Interviews will take place by telephone, videoconferencing (e.g. Teams) or face-to-face, according to participant preference, at a time, mode and location workplace premises) convenient to them.

Informed consent will be sought prior to the start of all interviews. If the interview is taking place by telephone or by videoconferencing, then participants will be asked to complete online consent process prior to the interview taking place. If this hasn't been done prior to the arranged interview, then consent will be sought verbally at the start of the interview and recorded. Specific consent for audio recording of the interview will also be sought. Health professionals will be offered a voucher of £40 for their participation.

Qualitative interviews with health professionals will explore topics including:

- how the intervention could be implemented
- what factors could facilitate health professionals promoting the intervention to people with acne
- how health professionals would envisage the intervention being embedded within digital care pathways
- key constructs of Normalization Process Theory to understand the dynamics of implementing, embedding and integrating the acne intervention into practice

DATA ANALYSIS

Phase 1 - Qualitative interviews

Transcripts will initially be analysed using an inductive thematic approach.[31] The findings will then be examined to see how they relate to the constructs of our theoretical models. Findings will then be used to inform intervention development.

Phase 2 - Think Aloud interviews

Transcripts will initially be analysed using an inductive thematic approach.[31] The study team will then use feedback and findings to refine and adapt the intervention.

DATA STORAGE

All electronic data will be stored securely on a secure server until the transcriptions for the Qualitative and Think Aloud interviews have been completed. Once these have been carried out and unique identifiers have been assigned then the digital audio recordings will be destroyed.

Personal data will be kept for 3-6 months then destroyed. The research data will be stored for 10 years in accordance with the procedures agreed by the sponsor. Once it is appropriate for it to be stored off site from the University of Southampton, it will go to an approved storage facility that has been agreed by the sponsor.

DIGITAL INTERVENTIONS

The intervention will be developed using adaptive technology to ensure it is accessible on any electronic device and screen size. We anticipate that a web app (i.e., website that is designed fluidly and responds to being viewed on a smartphone) is more accessible than a mobile app, as a web app works across a range of platforms and ages of device. Furthermore, a web app can generally be updated more readily than mobile apps.

We will work with Global Initiative (https://www.global-initiative.com/), a leading web developer with extensive experience in delivering digital health interventions and platforms for clinical research, to develop the behavioural intervention and bespoke trial management system. This will include a content management system which will allow the research team to rapidly add and modify content, enabling the intervention to be developed and optimised iteratively incorporating user feedback. Co-applicants Yardley and Little have experience of working with Global Initiative to develop and trial complex behavioural interventions.

Intervention content is likely to focus on acne treatments, treatment adherence and managing side effects, as these are the key behaviours we hope to influence. Support and advice around help seeking, emotional management and lifestyle topics are also likely to be incorporated. We are likely to tailor intervention content by age and possibly by gender and acne severity. We anticipate the inclusion of intervention features such as videos, 'before and after' photos, a '4-week challenge' where people can try using treatments for four weeks with reminders.

The intervention will support young people with help-seeking from healthcare professionals for acne treatments and advice. We aim to embed a simple form of patient-held 'decision tool' into the intervention that people with acne can take to primary care or community pharmacy. This tool will be developed to support young people's treatment decisions, empower them to consult and support communication within the consultation. The tool will be iteratively developed with input from young people and health professionals.

Based on our experience of developing successful digital behaviour change interventions, we anticipate that the intervention will include behaviour change tools such as support for choosing suitable treatment goals (e.g. online diaries and decision support aids) and support adherence (e.g. through supportive emails or texts). We will incorporate interactivity (e.g. quizzes) and audio-visual features (e.g. short videos) to encourage

engagement. We will also incorporate personal narratives from other young people (anonymised) as these have been a particularly popular feature in our previous research in young people with skin conditions.

THEORETICAL FRAMEWORK

We will draw on two theoretical models (the extended Common-Sense Model and Social Cognitive Theory model) to design interview guides and interpret findings in qualitative studies with young people and healthcare professionals; and to provide a framework for intervention planning and development (Phase 1).

The extended Common-Sense Model (CSM), which includes the Necessity-Concerns framework, is highly relevant to theorising how the beliefs of patients concerning symptoms and treatment may relate to self-management generally[27 32] and adherence to medication specifically.[28] We will supplement this with the self-efficacy construct from Social Cognitive Theory (SCT),[33] as this provides valuable suggestions for intervention elements likely to be effective (e.g. self-demonstrations, modelling) and has proven highly predictive of patient behaviour in our own and other interventions.[34-36] We believe that the extended Common-Sense Model will cover the Outcome Expectancies element of Social Cognitive Theory.

Intervention development will follow the Person-Based Approach[37] and we will use the Behaviour Change Wheel[38] and associated Theoretical Domains Framework to identify likely influences on behaviour not covered by core theoretical models and not identified through inductive qualitative work. A taxonomy of behaviour change techniques will be used to identify methods of addressing each of the identified influences on behaviour in the intervention.[39]

ETHICAL AND REGULATORY CONSIDERATIONS

Assessment and management of risk

There is no anticipated risk associated with this study. The interviewers will follow the University of Southampton and Primary Care Department. Lone working policy will be followed when visiting participants in their homes. All participants will be made aware that they can withdraw from the study at any time and it is not expected that the topic being discussed will cause them any undue stress.

A full risk assessment will be reviewed by the sponsor prior to commencement of the study.

Research Ethics Committee (REC) and other Regulatory review and reports

The research activities outlined within this protocol will be reviewed by the Health Research Authority (HRA) and the National Research Ethics Service (NRES) and no work will start until full approval is given by the HRA and a favourable opinion is gained from NRES. All relevant documents will be reviewed and agreed and any future amendments to any of the documents or the protocol will be submitted to these bodies prior to any implementation of those changes, if they are deemed to be substantial by the sponsor (University of Southampton).

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

- All correspondence with the Research Ethics Committee (REC) and Health Research Authority (HRA) will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

No sites will commence recruitment until full HRA approval has been received and each site has been assessed for capability and compliance.

Amendments

If the sponsor or sponsor's representative wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC and HRA for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Protocol compliance

- Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.
- Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

The means whereby personal information is collected, kept secure, and maintained. In general, this involves:

- The creation of coded, depersonalised data where the participant's identifying information is replaced by an unrelated sequence of characters.
- Secure maintenance of the data and the linking code in separate locations using encrypted digital files within password protected folders and storage media.
- Limiting access to the minimum number of individuals necessary for quality control, audit, and analysis.

- The confidentiality of data will be preserved when the data are transmitted to sponsors and co-investigators
- The custodian of the data is Professor Miriam Santer (Co-CI of the Programme Grant for Applied Research)

Indemnity

The protocol has been reviewed and approved by the Research Governance office and insurance office and the Chief Investigator is an employee of the University of Southampton.

1. The University of Southampton has arrangements that will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor for harm to participants arising from the management of the research.

2. The University of Southampton has arrangements that will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor or employer for harm to participants arising from the design of the research.

3. The GP surgeries will have arrangements in place for insurance and/or indemnity to meet the potential legal liability of investigators/collaborators as long as their activities are within their normal course of duties. Hospital sites will be covered by the NHS indemnity scheme.

NB Usually the responsibility for sections 1&2 lie with the sponsor, section 3 with the participating site and section 4 with the sponsor. Section 4 is not mandatory and should be assessed in relation to the inherent risks of the study; however, it may be a condition of REC favourable opinion to have these arrangements in place.

Access to the final study dataset

- The CI, Programme Manager and Research Fellows employed on the grant to collect data and build the intervention will have access to the final data.
- The qualitative work is aimed at developing an intervention therefore it is not intended that the dataset will be used for secondary analysis but the anonymised dataset will be made available upon reasonable request as required.

DISSEMINATION POLICY

On completion of the study, the data will be analysed and tabulated for publication and for a Final Study Report submitted to funder, which will be publicly available.

We do not foresee any commercially exploitable results from this study; rather the aim is to better inform NHS best practice and decision making.

Ownership of any Foreground IP generated through this grant will be vested in the University of Southampton, which will grant to all the other academic and NHS partners the right to use all foreground IP for patient benefit and academic purposes (research, teaching and training) by loyalty-free license in perpetuity.

The NIHR Programme Grants for Applied Research (PGfAR) will be acknowledged within the publications and will be informed in advance of any planned publications.

Participants will be notified of the outcome of the study and given the link to the website that will have been developed.

PATIENT AND PUBLIC INVOLVEMENT

PPI co-applicants and collaborators will be actively involved in all aspects of research design, delivery and dissemination.

The PPI coordinator will further facilitate working with young people in 'outreach' projects and will support the team in seeking representative public involvement and engagement more widely, including supporting recruitment to the stakeholder groups and running groups. We will also liaise with wider public engagement networks and groups, in order to seek diversity in public involvement and engagement in the programme.

We will include evaluating and reporting the impact of patient and public involvement activities in our reporting.

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