

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

Protocol

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Plain English Summary

Background

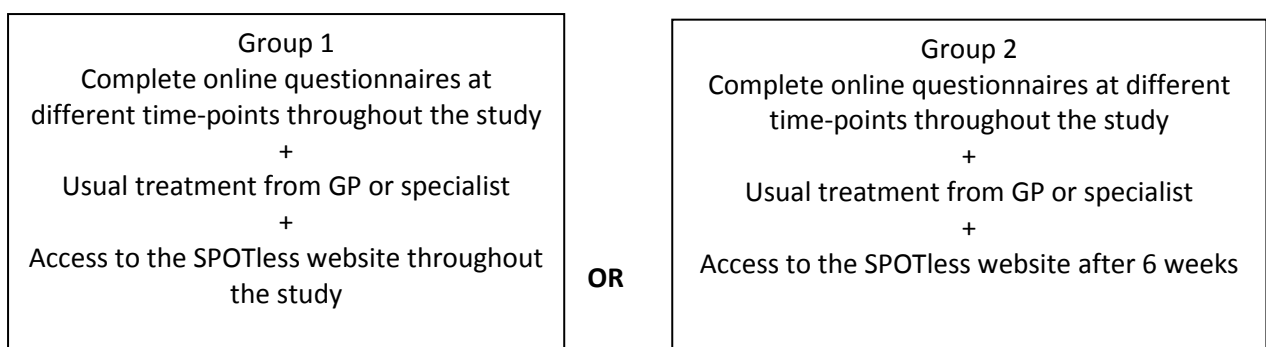
Acne is a skin condition that is very common amongst young people aged between 14 and 19 years. It can cause low moods, anxiety and embarrassment if not managed appropriately. The main treatments for acne are topical medications. These are creams and gels that can be applied to the skin. Many people 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 health care 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. This study is needed to explore whether this website is feasible in helping people manage their skin condition compared to usual care alone.

Aims

The aim of this study is to see how a website (SPOTless) 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.

Methods

A target of 65 people will be invited to take part in a trial through mail out or face to face by their GP, or through community advertising for instance using posters if necessary. Interested participants will follow the instructions on the included sign-up sheet which includes a direct link and participant ID. They will be asked to complete an online consent/assent form. After they have given consent they will be asked to 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 will be automatically allocated to one of two groups:



Additional interviews:

Participants will be given the option of whether or not they would like to take part in an interview at the end of the study. If they selected yes to being contacted, a member of the study team will contact 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, we could do a telephone interview. The interview will be approximately 30-60 minutes long and will explore their thoughts and experiences taking part in the trial and using the website. Whether or not they decide to take part in the interviews will not affect their participation in the trial. People who take part in the interview will be given a £10 gift voucher for their time. We will recruit approximately 20-30 participants depending on when data saturation is reached. i.e. no unexpected major comments about the trial.

Outputs

The trial will help us to improve the website and inform the design of a larger study, where we will test how well it compares to usual care. The website could help people feel more confident in caring for their own acne and gain control of their condition more quickly. It could also potentially reduce the use of antibiotics for acne by helping people to use other treatments.

Scientific background

Acne vulgaris is a common skin condition that is most prevalent amongst adolescents and young adults (Summaries CKS, 2014). It has been estimated that about 30% of teenagers have acne that ideally requires medical treatment and facial scarring occurs in approximately 20% of cases (Williams et al., 2012). The impact of acne on individuals can be substantial, resulting in both physical and psychological symptoms. Physical symptoms comprise of soreness, itching, and pain, but its main effects are on quality of life (Williams et al., 2012). A recent review found that a significant portion of children with atopic eczema, molluscum contagiosum and acne experienced a large effect on their quality of life (Olsen et al., 2016). Case-control and cross-sectional studies assessing the impact of acne on psychological health found higher prevalence of depression, anxiety, psychosomatic symptoms, shame, embarrassment, and social inhibition (Kubota et al., 2010), which have been shown to improve with effective treatment (Hahm et al., 2009). Acne severity and the degree of psychological impairment do not necessarily correspond—mild disease can cause significant distress whereas some with more severe disease can seem less bothered by their acne (Law et al., 2010). Furthermore, the impact on self-confidence is particularly great in acne vulgaris as the peak incidence is in the teenage years, a time crucial for building confidence and self-esteem.

Mild to moderate acne is typically treated in primary care (Purdy et al., 2003). First and second line treatments for mild and moderate acne are topical preparations, yet recent data suggest that GPs prescribe long courses of oral antibiotics at 31% of first consultations for acne (Francis et al 2016).

Furthermore, non-adherence to topical treatments are common. Possible reasons for non-adherence include the need for continuous treatment for up to 8 weeks before onset of action and prevalence of side effects such as skin irritation (Snyder et al., 2014). The irritation can be minimised by starting with lower strength preparations and gradually increasing frequency, dose or duration of application. For these reasons, experts suggest that clinicians should spend time explaining that most treatments will not cure immediately and discussing skin irritation may all improve adherence (Williams et al., 2012).

Promoting self-management amongst people with mild to moderate acne might be an effective way of improving adherence to topical preparations and reducing the burden on healthcare services. Self-management refers to a person's ability to manage different aspects of their condition including symptoms, treatment and impact (Barlow et al., 2002). Because adolescents use the internet regularly, internet interventions could be a cost-effective alternative to frequent follow-up visits and an effective way of promoting self-management (Tuchayi et al., 2016). A recent meta-ethnography review of 30 papers found that patients who self-monitored their health felt more reassured, and perceived that they had more meaningful consultations with their health care professional (Morton et al., 2017).

There have been very few internet interventions specifically developed for acne. Park et al (2014) conducted a systematic review to determine the effectiveness of mobile and electronic (ME)-health technology on adherence to acne treatment. They included four trials which met their inclusion criteria. The interventions included within the trials consisted of text message reminders (Boker et al., 2012), telephone call reminders (Yentzer et al., 2011), an internet-based education tool (Yentzer et al., 2011) and an internet-based survey assessing acne severity and treatment (Wang et al., 2011). The findings from the review showed that the web-based educational tool was more effective at improving adherence than telephone based reminders. Although promising, the findings from these studies should be drawn with caution as sample sizes are small and the control groups are majority no treatment conditions. A recent exploratory randomised trial (Myhill et al., 2017) looked at the effectiveness of supplementary patient educational materials (video, information card and information online) in terms of patient satisfaction and adherence when using a fixed dosed topical treatment (Epiduo®). Findings suggested that patients who used supplementary educational materials in addition to receiving standard of care patient education, had improved adherence compared to those who received standard patient education only or standard patient education with additional visits to their GP. Again, this study has limitations, there was no statistical testing and very little explanation in regards to how the 30 participants were recruited into each group.

As there are very few studies and many of these with limitations, there is a need for more research looking at the effectiveness of internet interventions for acne. More specifically, there are no behavioural interventions in the form of a website. Our website 'SPOTless' has been informed by previous qualitative research with people who have mild-moderate acne and is developed using the Extended Common Sense Model to promote appropriate use of topical treatments.

Aims

The aim of this trial is to explore the feasibility of delivering a web-based behavioural intervention (SPOTless) to young people with mild-moderate acne vulgaris in addition to usual care compared with usual care alone.

Feasibility Objectives

1. Test feasibility of recruitment of general practices and participants.
2. Assess questionnaire completion and retention of participants.
3. Examine usability and acceptability of the internet intervention in supporting participants' use of, and adherence to, the intervention.
4. Explore experiences of participants, which will be explored at the end of the trial by qualitative interviews.

These objectives will allow us to make effective decisions regarding the design of the full-scale trial after the PhD.

6. TRIAL DESIGN

A randomised controlled trial with two parallel arms to explore the feasibility of a trial of an internet intervention for people with acne vulgaris recruited in primary care and community advertising if necessary.

7. SITES

Participants will be recruited into this feasibility trial via 10-20 primary care sites in the South of England. Primary care sites will be recruited through the NIHR Clinical Research Network Wessex . If necessary, additional sites will be sought and permission will be gained in other areas.

8. TIME LINE

Participants will be in the study for 6 weeks. They will be asked to complete questionnaires at baseline, 4 weeks (end of intervention) and 6 weeks follow up.

9. INTERVENTION + COMPARATOR

Participants will be randomised to one of two trial arms: 1) usual care or 2) intervention plus usual care. Below are details of what will be involved for participants in usual care arm and those in the intervention plus usual care arm.

Usual care:

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

Usual care plus SPOTless intervention:

Participants in this arm will receive treatment as usual in addition to access to the SPOTless intervention 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. The intervention was developed using LifeGuide software. Based on findings from previous qualitative research, the Extended Common Sense Model was used to inform the intervention and specific Behaviour Change Techniques were used to promote the target behaviour (appropriate use of topical treatments). Behaviour change techniques included: providing simple instruction on how to apply topical treatments, reassuring patients about side effects of topicals and how to overcome these, modelling through people's success stories, educating people on the misconceptions of acne and the dangers of antibiotic resistance.

The Person-Based Approach was used in the development process of the intervention (Yardley et al., 2015). According to the Person-Based Approach, conducting a qualitative study prior to intervention development is essential for enhancing acceptability and feasibility (Yardley et al., 2015). Secondary analysis of qualitative data from the SKINS study on people's experiences of skin conditions was carried out and subsequently informed the development of the intervention. Think aloud interviews (ongoing) were also conducted as part of a systematic process for iteratively developing the intervention. This enabled us to modify it, making it more acceptable and engaging to the user.

The final intervention comprises of seven modules identified as key themes from the qualitative analysis (universal core treatments, what are spots or acne, myth-busting quiz, oral antibiotics, living with spots or acne, talking to your GP and other treatments). The module 'universal core treatments' is a core module in which participants will need to click through until they get to a main menu where they have the option to choose other modules they would like to visit. As part of the core module, participants will be asked whether they would like to take part in a 4 week challenge. This will involve picking a topical treatment and using this for 4 weeks as advised by the intervention. A detailed developmental paper will be published to explain the process in more detail.

10. STUDY METHODOLOGY

10.1. Sample size and recruitment

We aim to recruit 25 participants in the control group and 40 in the intervention group. This sample size, within a feasibility study, will be sufficient to determine:

- The feasibility, acceptability and engagement of SPOTless for young people with mild-moderate acne
- Retention rates at 4 week and at 6 weeks follow up
- Willingness to be randomised
- Enable further refinement of SPOTless (user qualitative feedback)
- Evaluate the appropriateness of the outcome measures

Additional interviews: We aim to recruit approximately 20-30 participants depending on when data saturation is reached.

Eligibility criteria

Inclusion: Participants will: have current acne vulgaris; be between the ages of 14 and 25; have had prescriptions for the treatment of acne within the last 6 months; have access to the internet and an active email address; be able to read/understand English without assistance. 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) however, we have put on the information sheet that people who have cleared up their acne or are currently on isotretinoin for their acne will not be eligible to take part..

Exclusion: Participants will be excluded if: they are under 14 or over 25 years of age; they have taken part in the study to develop the internet intervention; they have severe mental health problems; they have cleared their acne; they are on isotretinoin

Invitation to participate

1) Primary Care:

Invitation for the trial will be through mail-out and opportunistic recruitment in primary care. Invitations will be sent to people aged 14-25 years whose records show that they have acne, or have previously consulted or obtained a prescription for their acne in the last 6 months. GPs will screen lists to ensure that the study pack is not sent to patients where they feel this would be inappropriate, e.g. severe mental health problems. Eligible patients will be sent a study invitation pack from the GP surgery including a flyer, the information sheet about the study and a covering letter from the GP.

2) Advertising:

Our emphasis is primarily on recruiting through primary care, however, if necessary we will also recruit via community advertising. We will display posters in GP surgeries, community pharmacies and at the University of Southampton. The posters will include a link to the website and telephone number to the study team which participants can phone if they have further questions. Study advertising posters may also be posted on social media e.g. facebook or twitter.

Randomisation and consent

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. Randomised participants will be automatically informed which arm they are in. Informed consent will be sought online before baseline questionnaires are administered. We will seek informed consent / assent online. All trial procedures will be automated using LifeGuide software.

Follow-up

The intervention will last for 6 weeks with questionnaires completed at baseline, 4 and 6 weeks. Questionnaires will be completed electronically via the LifeGuide website; participants will be prompted to do so via email.

Outcomes and measures

Feasibility outcomes:

The primary outcomes from this feasibility trial will be as follows:

- Number of practices required to recruit the participant numbers and the rate of recruitment.
- Number of participants withdrawing from the intervention and the trial at 4 weeks and follow-up retention rates at 6 weeks.
- With regard to the behavioural intervention, the extent of participant’s usage of the website will be described.
- 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).
- The acceptability of measuring skin specific quality of life using the Skindex instrument, as a potential primary outcome for the main trial.

Secondary outcomes:

- We will also explore the feasibility of a range of quantitative measures, see Table 1.

Table 1. Outcome measures as a collective

Name of questionnaire	What it measures	Time points it will be collected
EQ-5D-5L (Herdman et al., 2011)	The EQ-5D-5L consists of five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each domain has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The participant is asked to tick a box that is most appropriate to their current condition. Each domain gives a single number and the number	Baseline, 4 weeks & 6 weeks

	from each domain in combined to reflect a person's health state.	
Skindex-16 (Chren, Lasek, Sahay & Sands, 2001)	Skindex-16 is a skin specific quality of life measure that assesses how bothered participants feel about their skin condition in the past week. It is a 16 item questionnaire with a 6 point Likert Scale ranging from 0 (Never bothered) to 6 (always bothered). This measure has been used to assess the quality of life for a number of skin conditions including psoriasis, eczema and acne vulgaris.	Baseline, 4 weeks & 6 weeks
Problematic Experiences of Therapy Scale (PETS) (Kirby, Donovan-Hall & Yardley, 2014)	The PETS assesses a person's perceived reasons for non-adherence to therapy. This measure is has been validated and is a reliable measure. It is a 12 item questionnaire which comprises of four subscales: "problems due to symptoms" (items 1–3), "problems due to uncertainty about therapy" (items 4–5), "problems due to doubts about treatment efficacy" (items 6–8), and "practical problems" (items 9–12). Participant's responses are scored on a scale ranging from 1 (disagree strongly) to 5 (agree strongly).	Baseline, 4 weeks & 6 weeks
Credibility/expectancy questionnaire (Deville & Borkovec, 2000)	The credibility/expectancy questionnaire assesses a person's belief about their therapy and its likely success. It is believed that belief has 2 aspects: what one feels will happen and what one thinks will happen. This is a 6 item questionnaire that is split into 2 sets: Set 1 consists of 4 questions that assess what a person thinks about their therapy and set 2 consists of 2 questions that assess what a person feels about their therapy and its likely success.	Baseline & 6 weeks
Patient Health Questionnaire (PHQ-4) (Kroenke et al., 2009)	The PHQ-4 measures anxiety and depression. The questionnaire consists of 4 items that measure how bothered one feels in the last 2 weeks. Participant's answers are rated on a 4 point Likert Scale ranging from 0 (Not at all) to 4 (Nearly every day). A score of 3 or more is positive.	Baseline, 4 weeks & 6 weeks
Questions on topical use & other treatments used	Other treatments used will be noted down as participants will be having usual care in the control group and therefore treatments may vary. Specific questions will be asked about topical treatments including which topical they are using, how often they are using, whether they	Baseline, 4 weeks & 6 weeks

	experienced any side effects and how they dealt with these.	
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Additional measures:

Demographic data including gender, age and education are collected at baseline only. The EQ-5D-5L, PHQ-4, PETS, credibility/expectancy questionnaire and questions on adherence and other treatments will be secondary outcome measures.

Qualitative component

The aim of the interviews will be to explore participants' experiences of taking part in the trial including difficulties, positive or negative experiences. Approximately 20-30 participants will be asked about their experience of the trial and using the website or usual care.

Participants will be asked if they agree to be contacted about a follow-up interview at the time of giving consent for the feasibility trial. We will carry out either face to face interviews or telephone interviews depending on the preference of the participant. These will be conducted at a mutually agreed time and location (participant's home, University premises or alternative if mutually agreed). Parents or carers of children under the age of 16 will be given the option of attending the interview. However, if there are conflicting views between parent and child regarding participation, the researcher will ensure that the child's perspective is heard (Madden et al., 2016). The researcher conducting the interviews will follow a semi-structured interview guide to ensure that all topics are covered while leaving room for the participants to discuss any other concerns they may have.

The interview guide will include open questions to allow the participant to speak more freely about their views and perspectives. Prompts will be included to ensure that all topics are explored in detail.

The interview guide has been developed from the study objectives and has been further modified with input from the research team.

The interview guide will include questions about:

- Taking part in the trial
- Views of study materials
- Willingness to be randomised
- Thoughts on the website
- Experience following the intervention advice and key messages
- Experience / views on the 4 week challenge

Data collection, storage and sharing

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. After the study is finished, all data

will be archived for 10 years in line with the University of Southampton archiving policy. At no point will identifiable information be removed from University premises. Anonymised data (names and contact details removed) may be shared with other researchers.

Qualitative data will be audio recorded and transcribed verbatim with all identifying information removed. Anonymised transcripts will be password protected and stored securely on a password protected University computer.

Analysis

Quantitative- In terms of the primary feasibility outcomes the number of practices recruited and the number of withdrawals will be presented in simple descriptive statistics. Data in regards to the internet intervention will be collected using automatic data generated from LifeGuide including Logins and time spent on intervention. All other measured will be analysed and compared at each interval and between both arms.

Qualitative- All transcripts will be analysed using an inductive thematic approach. A coding framework will be developed from repeatedly reading the transcripts to identify emerging themes (Braun & Clarke 2006). The chief investigator who will have carried out the interviews, supported by the supervisors, will conduct Coding and analyses. The analyses and emerging coding will be discussed with the research team at every stage. Digital recordings will be deleted after transcription and any names anonymised. Early transcripts will be second-coded to prevent premature theme formation and deviant case analysis. Analyses and data collection will work in parallel to determine when data saturation has been achieved. NVivo software will be used throughout to manage the data.

Withdrawal

Participants will be made aware of their right to withdraw at any time. If participants wish to withdraw they can notify the research team and be withdrawn immediately, including withdrawal of their data if they wish. Once data has been anonymously reported then it is more difficult to remove their data.

Ethics

Ethical approval will be obtained from the University of Southampton Ethics committee and NHS Research Ethics Committee. No participants will be invited into the study until Ethics approval is obtained.

Participant incentives

Participants in qualitative interviews will be given a £10 gift voucher in acknowledgement of their time.

Study management

The study is funded by the NIHR SPCR Funding Round 11. Sponsorship and indemnity will be sought from the University of Southampton. The Chief Investigator has overall responsibility for the study and shall oversee study management. The data custodian will be the Chief Investigator.

TIMETABLE

- 25th January 2018 submit ethics
- 1st April 2018-1st January 2019: recruit, baseline randomisation & questionnaires
- 1st January 2019-1st August 2019: conduct interviews, transcribe data, analyse data and write up report

EXPECTED OUTPUTS

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

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