ISRCTN19434288 https://doi.org/10.1186/ISRCTN19434288

Optimisation of acne treatment via mobile phone app assisted management

Submission date
06/04/2020

Recruitment status
No longer recruiting

Registration date
17/06/2020

Overall study status
Completed

Last Edited
19/12/2022

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Most people develop acne to some degree during their teenage years. For some women, acne develops in their 20s or 30s. The current system for acne management includes three steps: self-management, GP-led treatment, and dermatology-supervised treatment at a hospital-run clinic. Due to the high volume of patients with acne and the long waits to see specialists, patients often do not see a dermatologist as quickly as they should. This study will investigate whether or not patients engage and are satisfied with advice on acne management via a mobile phone app. The study will also investigate whether acne management can be made more efficient through this teledermatology pathway.
Patients with acne are vulnerable to psychiatric problems. Many studies have shown an association between acne and mood disorder. For this reason, the study will monitor patients' mood during the study using a validated measure for assessing depression. There is no good evidence for a link between drug treatments for acne such as isotretinoin and depression.
Teledermatology has been practised for the last 40 years. The main method is store and forward, whereby a doctor will take an image of a patient and send it to a colleague along with some clinical information. The aim has always been to save patient visits to specialist clinics. Teledermatology has never really been adopted in a large scale way for a number of reasons. When the costs of teledermatology are being evaluated they are divided into sections; firstly patient or societal costs and secondly healthcare system costs. Nearly all economic evaluations have shown that teledermatology saves money for the patient and general society due to saved time, fuel, parking and travel costs but does not save any money for the healthcare system due to the doctor and administration time that is still needed to process a teledermatology consultation. This study aims to investigate how teledermatology can evolve to the next stage.
The MySkinSelfie app (http://www.myskinselfie.com) was developed to allow patients to self-monitor their skin and to keep a secure record of consistent skin images. The app automatically dates images and allows notes to be added to images. There is a feature to allow consistent photos to be taken. All images are encrypted and stored securely in the cloud (Newcastle University Microsoft azure cloud storage). The MySkinSelfie app has been in use for over one year and has been fully tested. It works well and is reliable and will be used to conduct the study.
This study aims to investigate the usability of a mobile phone app to optimise the management of acne in primary care. The study will also investigate current management of acne in primary care, improve acne management in participants, monitor use of MySkinSelfie app by participants

over 3 months, and collect data in order to plan a full trial comparing standard acne management with app-referral acne management.

Who can participate?
Patients aged 16-35 who are currently receiving treatment for acne in primary care

What does the study involve?
Participants download the application to a smartphone, take skin images and complete questionnaires. Doctors assess the questionnaire responses and images and create a report to send to the participant and their GP.

What are the possible benefits and risks of participating?
The potential benefits for patients who suffer from acne can be substantial. One of the most important factors may be saved time, by avoiding long waiting times for appointments and prevent attending unnecessary examinations in a clinic. Through the MySkinSelfie app, patients can share the development of their condition with a doctor on which the professional can base recommendations. Moreover, it can help patients to have ownership of their condition and supports self-monitoring. This gives the patients control and a better overview of their condition. It can also prevent patients from forgetting about using their medicine/medical remedy.

Where is the study run from?
1. The Royal Victoria Infirmary (UK)
2. Park Road Medical Practice (UK)
3. Newburn Surgery (UK)
4. The Village Surgery (UK)
5. Belford Medical Practice (UK)
6. Marine Medical Group (UK)

When is the study starting and how long is it expected to run for?
August 2017 to October 2020

Who is funding the study?
Engineering and Physical Sciences Research Council (EPSRC) (UK)

Who is the main contact?
Dr Philip Hampton
Philip.hampton@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Philip Hampton

ORCID ID
https://orcid.org/0000-0001-6797-2697

Contact details

Chief Investigator
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP
+44 (0)191 28 24349
Philip.hampton@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
238481

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 38345, IRAS 238481

Study information

Scientific Title
A pilot study investigating the usability of a mobile phone app to optimise the management of acne in primary care

Acronym
App-Referral

Study objectives
This study will explore whether or not the use of a mobile phone app is a useful and acceptable way for patients to receive advice about their acne treatment. This study will also allow us to investigate the current management of acne in primary care and whether remote acne assessment via smartphone app can improve acne treatment in the community and the quality of referrals to secondary care. In doing so, this system could reduce the workload for both GPs and dermatology services.

Patients will be invited to join the study which will involve completing online questionnaires and taking selfie images of their acne using a secure smartphone app called 'MySkinSelfie' which has already been developed by Newcastle University. The use of teledermatology systems bring both advantages with respect to referral times but also potential disadvantages due to less contact with specialists and the potential for details to be lost from the consultation.

Teledermatology will always need to balance these pros and cons. This pilot study will help to determine whether mobile phone-based acne advice is desired by patients and GPs and start to explore whether it is effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2018, London Dulwich & Surrey Borders Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8241; dulwich.rec@hra.nhs.uk), REC ref: 18/LO/0739

Study design
Observational; Design type: Validation of investigation /therapeutic procedures

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
10 GP practices will be recruited to the study as Participant Identification Centers (PIC sites). Practice databases will be searched to identify patients with acne as an active problem, age range 16-30. The age range has been selected to both allow consent and to optimise likely engagement with an app-based project.

An invitation flyer will be sent to eligible patients inviting them to join the study. They will be offered a consultant or study doctor review of their acne based on selfie photos sent via the app and a review of their acne management so far. If they are interested they will reply to the study email address and will then be posted a patient information leaflet, consent form with instructions on how to complete the form (appendix 7). A stamped, addressed envelope will be provided for participants to return their form after signing.

Any questions will be answered via telephone to the study research nurses. Once the researchers have their signed consent, they will ask the patient to download the app and email a link to complete Questionnaire 1.

The patient will download the app and open an account using their own email address and password. The patient will own the app account and the images until they choose to share them with the study.

Baseline information will include data provided by the patient and also assessments made by the study Doctor.

Data provided by patients
Baseline self-reported questionnaires will be completed online using a secure survey system called Bristol online surveys.

Questionnaire 1 will include three sections:
1. Acne treatment history questionnaire (ATHQ)
2. Dermatology Life Quality Index (DLQI)
3. Patient Health Questionnaire 9 (PHQ9)

Questionnaire 2 (appendix 4) will include two sections:
1. ATHQ
2. DLQI

Assessment by Doctor:
1. Patient questionnaire responses will be reviewed
2. MySkinSelfie images will be reviewed and one representative image will be stored by the study. These images will be used to grade the acne according to LRAGS.
3. A baseline report will be created by the study doctor and sent to the patient and the GP.

Report by Study Doctor will include:
1. Grade of acne according to The Leeds Revised Acne Grading System (LRAGS)
2. DLQI and PHQ9 scores
3. Current acne treatment
4. Recommendations will be either:
4.1. Continue current treatment
4.2. Suggest a change in treatment (patient will need to get a new prescription from their GP)
4.3. Hospital referral needed (patient will need to be referred by their GP)

Progression through the study:
1. Patients will record images on MySkinSelfie weeks 0, 4, 8 and 12
2. Questionnaires 1 and 2 will be completed on weeks 0 and 12 respectively
3. A doctor assessment will be performed on weeks 0 and 12. This will include evaluation of skin images on MySkinSelfie and also evaluation of the completed online questionnaire responses. A report will be written at weeks 0 and 12 and a copy will be sent to both the GP and patient. Assessment time will be allowed to vary within 2 weeks before and after the 12-week target interval
4. A final usability questionnaire will be sent to the patient at week 14

Intervention Type
Other

Primary outcome(s)
1. Usability of mobile phone app measured using usability questionnaire at week 12 and week 14
2. Number of patients coded for active acne, age and sex distribution of acne patients in participating GP practices, measured by performing GP practice database searches at baseline
3. Number of patients responding to study invitation and consenting to join the study, measured at baseline
4. Patient's photographs quality, by gathering qualitative data on the quality of images recorded with the app mainly to identify users who have produced poor quality photos that limit clinical evaluation, by reviewing the uploaded photographs at baseline, week 4, week 8 and week 12

Key secondary outcome(s))
1. Acne grading by the study doctor, according to the Leeds Revised Acne Grading System (LRAGS) at baseline and week 12
2. Impact of skin disease on the quality of life, measured using the Dermatology Life Quality

Index (DLQI) (score ranges: 0-30) at baseline and week 12
3. Impact of mental health disorders (depression, anxiety, alcohol, eating, and somatoform disorders), measured using the Patient Health Questionnaire 9 (PHQ9) (score ranges: 0-27) at baseline and week 12

Completion date
10/10/2020

Eligibility

Key inclusion criteria
1. Age 16-30 and able to give consent
2. Currently receiving treatment for acne in primary care
3. Ownership of a smartphone (Android or Apple) with a camera and enough memory to operate the app
4. Ability to operate the smartphone independently
5. Home wifi and/or adequate mobile data allowance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Patients who are currently receiving treatment for depression or other psychiatric diseases. Mobile phone consultations have not been fully researched in vulnerable groups of patients
2. Currently under management in secondary care Dermatology

Date of first enrolment
11/07/2018

Date of final enrolment
27/01/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Study participating centre
Park Road Medical Practice
93 Park Road
Wallsend
United Kingdom
NE28 7LP

Study participating centre
Newburn Surgery
4 Newburn Rd
Newburn
Newcastle upon Tyne
United Kingdom
NE15 8LX

Study participating centre
The Village Surgery
Dudley Lane
Cramlington
United Kingdom
NE23 6US

Study participating centre
Belford Medical Practice
Croft Field
Belford
United Kingdom
NE70 7ER

Study participating centre
Marine Medical Group
Thoroton St

Blyth
United Kingdom
NE24 1DX

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research council

Funder Name
Engineering and Physical Sciences Research Council; Grant Codes: EP/L016176/1

Alternative Name(s)
EPSRC Engineering & Physical Sciences Research Council, UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, The Engineering and Physical Sciences Research Council (EPSRC), EPSRC

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 and/or analysed during the current study will be included in the subsequent results publication. The elements to be public will be in the papers, e.g. as supplementary data.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		06/07/2021	19/12/2022	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	version v1.4	22/02/2019	17/06/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes