Study Protocol: Patient involvement in the HOME V meeting – understanding it from the patient perspective

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Short title: Patient involvement at HOME V
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STUDY PERSONNEL AND CONTACT DETAILS

Chief investigator:

Dr Joanne Chalmers
Senior Research Fellow
Centre of Evidence Based Dermatology
University of Nottingham
King's Meadow Campus
Lenton Lane
Nottingham
NG7 2NR

Co-investigators:

Miss Laura Howells
PhD student
Centre of Evidence Based Dermatology
University of Nottingham
King's Meadow Campus
Lenton Lane
Nottingham
NG7 2NR

Prof. Kim Thomas
Professor and Deputy Director
Centre of Evidence Based Dermatology
University of Nottingham
King's Meadow Campus
Lenton Lane
Nottingham
NG7 2NR
Phone: 0115 8468630
Email: kim.thomas@nottingham.ac.uk

Dr Sonia Ratib
Assistant Professor
Centre of Evidence Based Dermatology
University of Nottingham
King's Meadow Campus
Lenton Lane
Nottingham
NG7 2NR

Rosemary Humphreys
West Hedges
6 Sherbrook Hill
Budleigh Salterton
Devon
EX9 6DA

Study Coordinating Centre:

Centre of Evidence Based Dermatology
University of Nottingham
King's Meadow Campus
Lenton Lane
Nottingham
NG7 2NR

SYNOPSIS

Title	Patient involvement in the HOME V meeting – understanding it from the patient perspective
Short Title	Patient involvement at HOME V
Chief Investigator	Dr Joanne Chalmers
Objectives	1. To understand how patients who attended the HOME V meeting perceived their role at the meeting 2. To understand the barriers and facilitators to patients being able to be effectively involved in the HOME V consensus meeting
Study Configuration	Semi-structured interviews with patient partners at the HOME V meeting
Setting	An international selection of patient partners invited to the HOME V meeting. Telephone interviews, skype interviews and face-to-face interviews.
Eligibility criteria	Must have attended the HOME V meeting and be able to speak English.
Duration of study	July 2017 – July 2018
Methods of analysis	Thematic analysis

ABBREVIATIONS

CI	Chief Investigator overall
COMET	Core Outcome Measures in Effectiveness Trials
HOME	Harmonising Outcome Measures in Eczema initiative
NHS	National Health Service
OMERACT	Outcome Measures in Rheumatology
PoPPIE	People and Public Participation, Involvement and Engagement
REC	Research Ethics Committee
UoN	University of Nottingham

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STUDY BACKGROUND INFORMATION AND RATIONALE

A core outcome set is an agreed standardised set of outcomes that should be measured in all trials for a specific clinical area (1). The development involves identifying what should be measured followed by how the outcomes should be measured (1). It is acknowledged that inclusion of patients in the developed of core outcome sets can be hugely beneficial to ensure the relevance of the outcomes to patients (2). Thematic analysis of interviews with a variety of stakeholders and documents four that patient involvement in OMERACT, which is an initiative developing COS in rheumatology, has widened the research agenda, inclusion of patient relevant outcomes in cores sets, enhanced patient reporting instruments, changed the culture of OMERACT and had consequences for patient involvement outside OMERACT (3). However, the results presented are contextually embedded within OMERACT, which make it important that the patient role at consensus meetings in other disease areas is considered (3). The Core Outcome Measures in Effectiveness Trials (COMET) initiative has developed a People and Public Participation, Involvement and Engagement (PoPPIE) international membership which leads COMET's public participation, involvement and engagement activities and aims to facilitate the optimal involvement of patients, parents, carers and members of the public as key stakeholders in the development of core outcome sets (http://www.comet-initiative.org/ppi/poppie).

The Harmonising Outcome Measures in Eczema (HOME) initiative (www.homeforeczema.org) is an international group working together to agree core outcome sets for eczema clinical trials and eczema clinical recordkeeping (4). To date, there have been five international face-to-face consensus meetings that have involved multiple stakeholders including healthcare professionals, methodologists, pharmaceutical industry representatives and patients (4-7).
In comparison to OMERACT, an international group of patients have been involved as stakeholders from very early on in the development of HOME (7). Although it is often expressed that patient involvement at consensus meetings for core outcome sets is vital and has a number of benefits, there is little guidance on how best involve patient partners in the process (2, 8). However, the experience of patient partners at HOME consensus meetings has not to date been formally and systematically investigated. We are interested in how the patient partners who attended the latest HOME V meeting perceived their role, their expectations, if their expectations were met and their interaction with others at the meeting. This seems an appropriate time to undertake this study as there have now been five meetings and many of the patient partners have attended multiple meetings. This will allow us to build an understanding of how to best involve patient partners in HOME core outcome set development consensus meetings and what aspects enhance or diminish the experience for patient partners.

Note. Although we refer to "patients" throughout the study documents, these are a group of people who are members of HOME due to their personal experiences of eczema or their role in an eczema patient support group, rather than patients as service users. They have NOT been recruited via the NHS or any other healthcare service but as part of their continued membership of HOME and their attendance at the HOME V meeting as patient partners.

STUDY OBJECTIVES

OBJECTIVES

1. To understand how patients who attended the HOME V meeting perceived their role at the meeting
2. To understand the barriers and facilitators to patients being able to be effectively involved in the HOME V consensus meeting

STUDY DESIGN

STUDY CONFIGURATION

Semi-structured interviews will be conducted either face to face or via telephone. Each interview will last up to 60 minutes.

STUDY MANAGEMENT

The study will be managed from the central coordinating centre (Centre of Evidence Based Dermatology, University of Nottingham).

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: This study is expected to commence July 2017 and is expected to be complete by July 2018. However, the interviews will take place as soon as possible following the consensus meeting.

Participant Duration: Each participant will take part in a telephone, skype or face to face interview that will last up to 60 minutes. They will be offered the chance to review the transcript and to receive a copy of the study overall results via email.

End of the Study

The end of the study will be the end of the last participant reviewing their transcript.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

All participants will be contacted via email based on a database held by the HOME V organisers that indicates who attended HOME V as a patient partner. All patient partners who attended HOME V will be invited to take part in an interview.

Eligibility criteria

Inclusion criteria

Attended HOME V as a patient representative and can speak English.

Exclusion criteria

None.

Expected duration of participant participation

Study participants will be participating in the study for by to 60 minutes.

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future involvement in HOME. Participants will be made aware that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

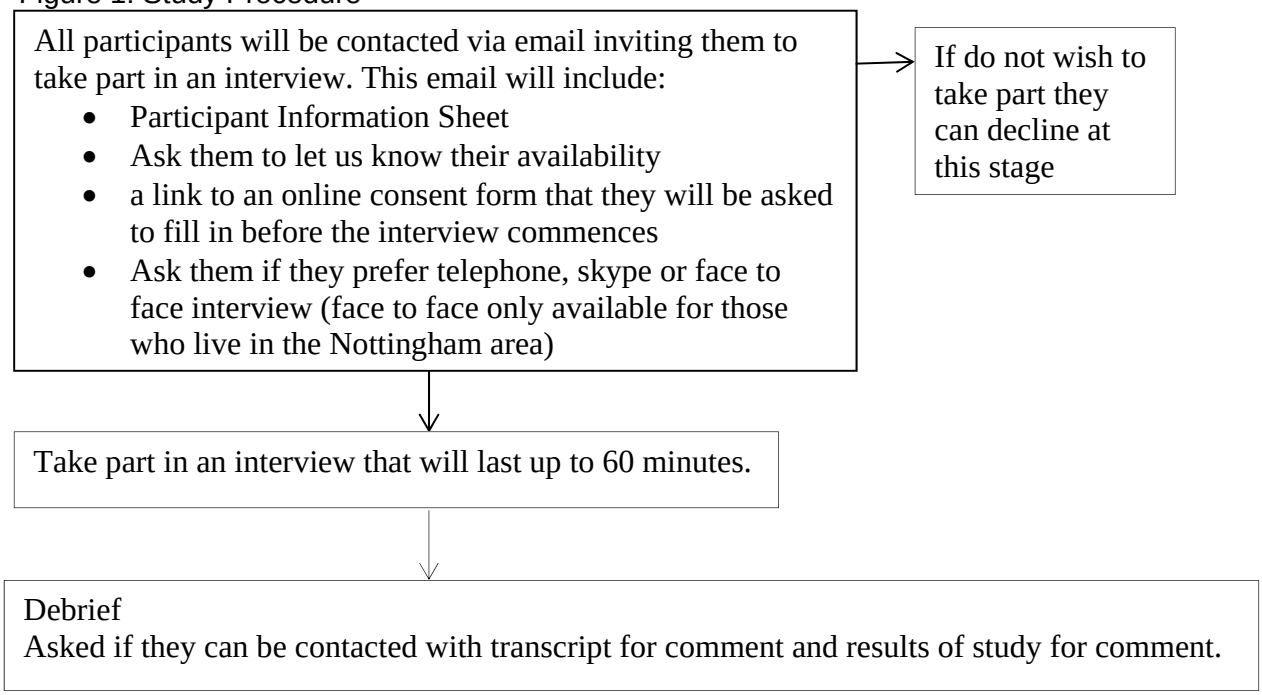
Informed consent

We will send participants an email with a link to give online informed consent (See Online consent form LauraHowells HOMEV v1.0). This procedure is necessarily online rather than paper format due to many participants taking part in the study from a different country. We will aim to ensure that participants fill out this online consent form prior to the interview. If for any reason they have not filled out this online form prior to the interview, we will gain verbal consent that will be recorded as at the start of the interview and ask them to fill out the online consent form retrospectively.

STUDY REGIMEN

The process that each participant will undertake is illustrated in Figure 1. The interview will take place at a time to suit the individual and will be in a mode that suits the individual. Given the participants will be international we will be aware of time zone differences when planning interviews. All interviews will follow a common interview guide (See Topic Guide LauraHowells HOMEV v1.0). The interviewer will ask participants a series of questions and will have pre-prepared prompts to help facilitate discussion.

Figure 1: Study Procedure



Compliance

Lack of compliance is not anticipated since these are patient representatives who have attended the HOME V meeting and are therefore engaged with the project. If there is substantial deviation from the subject topic or inappropriate comments to the interviewer the following steps will be taken:

Steps:

1. Initially participants will be asked to focus on the questions/task and asked not to make any other comments of that nature.
2. If non-compliance persists, the interviewer will terminate the interview early and inform the CI.

Criteria for terminating the study

If there are issues with study conduct (e.g. poor recruitment) the study may be stopped.

On event of study termination, in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study.

ANALYSES

Methods

All interviews will be recorded and transcribed by the interviewer. Thematic analysis will be used to analyse the transcripts (9).

Sample size and justification

The sample size will be n=13 if all patient partners who attended HOME V take part. This will ensure that we get the experiences from all patients who attended HOME V and understand the diversity of their experiences.

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

ETHICAL AND REGULATORY ASPECTS

1. Anonymity

Due to concerns that participants attending HOME V have an existing relationship with many other members of HOME and may be identifiable to individuals, we will take extra care to ensure anonymity and ensure participants are aware that we are mindful of this. The interviewer will remove all identifiable information (including name and country) before sharing the transcripts with the rest of the research team. They will also be given the opportunity for the participant to review their own transcript to ensure they feel all identifiable information has been removed. The participants will be made aware of this at the start of the interview.

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the University of Nottingham (UoN) Faculty of Medicine and Health Sciences Research Ethics Committee (REC). Should a protocol amendment be made that requires ethics approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

INFORMED CONSENT AND PARTICIPANT INFORMATION

Due to the wide geographical nature of this study, it will not be possible to obtain signatures from participants. However, they will be supplied with adequate information regarding the nature of the study and will be asked to fill in online informed consent where they will tick checkboxes confirming they understand the information given and what participation will entail and how to withdraw from the study. This is deemed adequate as participation will not be a risk to participants' health.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled.

RECORDS

Transcripts

Each participant will be assigned a study identity code number for all transcripts to be stored. The transcript of the online discussions will be downloaded and saved. They will be stored in a secure file that only the researchers can access. In line with UoN data storage procedures, data will be stored for at least 7 years.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The CRF will only collect the minimum required information for the purposes of the study. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. Access will be restricted by user identifiers and passwords.

Any medical information provided will be kept confidential.

QUALITY ASSURANCE & AUDIT

RECORD RETENTION AND ARCHIVING

In accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator shall be finally archived at secure archive facilities at the University of Nottingham. This will include anonymised transcripts and database of participant information.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the University of Nottingham.

PUBLICATION AND DISSEMINATION POLICY

We intend to submit the research as a journal paper for a relevant academic journal. The work is intended to inform future patient involvement at HOME meetings. Participants will not be identified in any publications.

USER AND PUBLIC INVOLVEMENT

Rosemary Humphreys has been involved as a co-designer of the study and has reviewed the participant information sheet, the online consent form and the topic guide for the interviews.

STUDY FINANCES

Funding source

This study is funded by the British Skin Foundation.

Participant stipends and payments

Participants will not be paid to participate in the study.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name) Dr Joanne Chalmers

Signature:_____

Date: _____

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