Study Protocol: Patient and carer perspectives on defining and measuring long-term control of eczema

Draft 1.0 / Final Version 1.0
27th May 2016

Short title: Long-term control of eczema
Funding Source: British Skin Foundation

STUDY PERSONNEL AND CONTACT DETAILS

Chief investigator:

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

Co-investigators:

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

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

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

Study Coordinating Centre:

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

SYNOPSIS

Title	Patient and carers' perspectives on defining and measuring long-term control in eczema
Short Title	Long-term control of eczema
Chief Investigator	Prof. Kim Thomas
Objectives	1. To understand how eczema patients define long-term control. 2. To explore what aspects of long-term control are most important to patients. 3. To explore what methods of measuring long-term control patients would find useful/acceptable in clinical trials
Study Configuration	Semi-structured online discussion groups with eczema patients and carers of children with eczema
Setting	Community sample of eczema patients taken from an online population
Eligibility criteria	Carers of children with eczema OR Adults (18 years +) with eczema Eligibility criteria: • Ability to give informed consent • Parental or self-report of diagnosis of eczema by doctor • English speaking
Duration of study	July 2016 – August 2017. Each participant will take part in an online discussion group that will last approximately 60-90 minutes.
Methods of analysis	Thematic analysis

ABBREVIATIONS

CI	Chief Investigator overall
HOME	Harmonising Outcome Measures in Eczema initiative
NHS	National Health Service
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
REC	Research Ethics Committee
R&D	Research and Development department
UoN	University of Nottingham

TABLE OF CONTENTS

STUDY BACKGROUND INFORMATION AND RATIONALE

Eczema (for the purpose of this study this term will be viewed as synonymous with atopic eczema and atopic dermatitis) affects up to approximately 20% of children and recent studies suggest eczema symptoms will persist into adulthood for over 80% of children with eczema [1,2]. It is a common, chronic condition that is characterised by periods of remission and relapse [3]. Eczema is where the integrity of the skin barrier breaks down, which can cause itching and dry skin [3]. Living with eczema can have a significant physical and emotional effect on patients and caregivers [4]. Therefore, much research is focused on secondary prevention of exacerbation in eczema to try and reduce the burden of the disease for individuals [5].

There is widely accepted support for the development of core outcome sets (COS) to be used for research in specific health conditions to enable comparison between studies [6]. The Harmonising Outcome Measures in Eczema (HOME) initiative to develop a COS for eczema clinical trials has decided that signs, symptoms, quality of life and long-term control are to be the core outcome domains to be included in eczema trials [7]. The HOME membership have decided on core outcome measures for the domains of signs and symptoms to be included in the COS, however there is still development work that needs to be done before a core outcome measure for both the quality of life and long-term control domains can be recommended [8].

For an outcome measure of long-term control to be recommended, there needs to be consensus on the best way to capture long-term control [9]. Definitions used for long-term control are currently heterogeneous both in the literature and amongst HOME members [10, 8]. There is also currently heterogeneity in the way long-term control is measured in clinical trials [9]. A recent systematic review found 91% of trials used repeated measures of either clinical signs or patient reported symptoms [9]. Less frequently, 25.7% measured a flare (defined as a worsening of the condition) or 28.7% measured use of eczema medication (defined as any treatment other than the randomly allocated intervention) [9].

The HOME initiative initially included long-term control of flares as the domain to be considered [7]. A systematic review in 2006 proposed that flares should be defined as the need to escalate eczema treatment in response to worsening of disease [11]. A systematic review of the definitions of eczema flares highlights that there are a wide range of definitions used in the literature, but none contain both important characteristics of being feasible to collect and being recorded at the time flare symptoms are experienced [10].

Two studies used this definition to measure flares and escalation therapy was defined on entry into the study based on discussion with patients or their guardians, and patients daily rated yes or no for whether therapy was escalated [12, 13]. A validation study found this measure had good face validity and construct validity [14]. However, concerns around resource intensive data management and difficulties pooling data may mean this measure is not suitable for all trials [14]. Another concept of long-term control that has been applied in asthma research is a well-controlled week and a totally controlled week. A well-controlled week has been defined as treatment "escalated" for 2 or more days plus 2 or more days with a bother score less than 4. This requires daily completion of diaries, which is resource intensive and therefore may also not be suitable for use in all trials.

Furthermore, it has been acknowledged that it may not be necessary to measure flares for the long-term control domain, and changes in the other three domains (signs, symptoms and quality of life) over time may adequately capture changes in disease [9]. Since repeated measurement of validated outcomes is the most commonly used method of capturing long-term control to date, it would suggest that it is likely to be an acceptable and feasible method to use in clinical trials, although the frequency of repeated measurements is still to be established [9]. Furthermore, repeated measures of physician-assessed measures may not be feasible for all trials.

Long-term control is an important outcome for patients as 75% of patients in a survey sample stated that being able to effectively control their eczema would be the single most important improvement to their quality of life [4]. Patients are key stakeholders and their involvement in developing COS may lead to outcomes not previously identified by other stakeholders [15]. It is important that the standardised definition and core outcome measure of long-term control captures patient's views and has been driven by patients, as they are best placed to understand whether their disease is being controlled [10].

The findings of this study will be used to inform the HOME initiative (http://www.nottingham.ac.uk/homeforeczema/index.aspx) to develop a COS for clinical trials in eczema and will be presented at the HOME V meeting in 2017.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

This study will help us to understand eczema patients' and carers' perspectives of long-term control of eczema. This will inform HOME V consensus meeting to help define long-term control in eczema and to decide the best way of measuring long-term control in the COS.

OBJECTIVES

1. To understand how eczema patients define long-term control.
2. To explore what aspects of long-term control are most important to patients.
3. To explore what methods of measuring long-term control patients would find useful/acceptable.

STUDY DESIGN

STUDY CONFIGURATION

This is a qualitative study using data collection from online discussion groups held in a secure chat room. Online discussion groups will take place separately for carers of children with eczema and adult patients with eczema. All discussion groups will take place online.

These online discussion groups will be repeated using the same methodology in different countries by other HOME members collaborating with this research team.

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 2016 and is expected to be complete by August 2017.

Participant Duration: Each participant will take part in one online discussion group that is expected to last approximately 60-90 minutes. There will be no follow-up. Participants will receive summarised information about study findings if they wish. The end of the study will be the last online discussion group where it is felt by the investigators that data saturation has been reached. It is estimated that approximately four online discussion groups will be ran.

End of the Study

The end of the study will be the last online discussion group with the last participants.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Patient groups (e.g. Nottingham Support Group for Carers of Children with Eczema and National Eczema Society) will be contacted to recruit via website pages/newsletters and social media. We have long-standing relationships with many of these organisations and have used them to help in a similar way with previous research projects. We will obtain permission from all organisations before recruiting via them. We will also recruit from our department, the Centre of Evidence Based Dermatology (social media/newsletters/website: http://www.nottingham.ac.uk/research/groups/CentreofEvidenceBased Dermatology/index.aspx). We will also use existing databases of eczema patients and carers from previous research who have consented to being contacted about future studies.

Please see the flow chart of the study procedure in Figure 1 for more information about the process from recruitment to informed consent.

The list of questions we will ask them once they have registered their interest will be:

1. Age
2. Ethnicity
3. Sex
4. Duration of disease
5. Severity
6. Previous experience of healthcare services
7. Previous experience in trials

This preliminary screening information will be used to enable us to use purposeful sampling which will aim to include a wide variation in participants experience of eczema including: severity of the eczema, use of healthcare services, age, sex, ethnicity, disease duration and previous experience in trials. This is to ensure our research is able to capture the opinions that are as representative of the population of eczema patients and carers as possible.

Eligibility criteria

Inclusion criteria

- Ability to give informed consent
- Self-report of diagnosis of eczema by doctor.
- English speaking

Either:

- Carers of children with eczema
- Adults (18 years +) with eczema

Exclusion criteria

None.

Expected duration of participant participation

Study participants will be participating in the study for 60-90 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 care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

Once providing an email address and proposing their interest in the study, patients will be sent some preliminary questions that will enable us to purposefully sample. They will also be sent a detailed information sheet explaining the purpose of the study and what their role in the study will be (see the Participant Information Sheet). Those chosen to participate in online discussion groups will be contacted via email with the dates they can participate. Once a participant has registered for the online discussion group they will be asked to complete an online consent form (see Online Consent Form) to indicate they understand the conditions of their participation and confirm that they wish to take part before they are given the details to access the online chat room.

STUDY REGIMEN

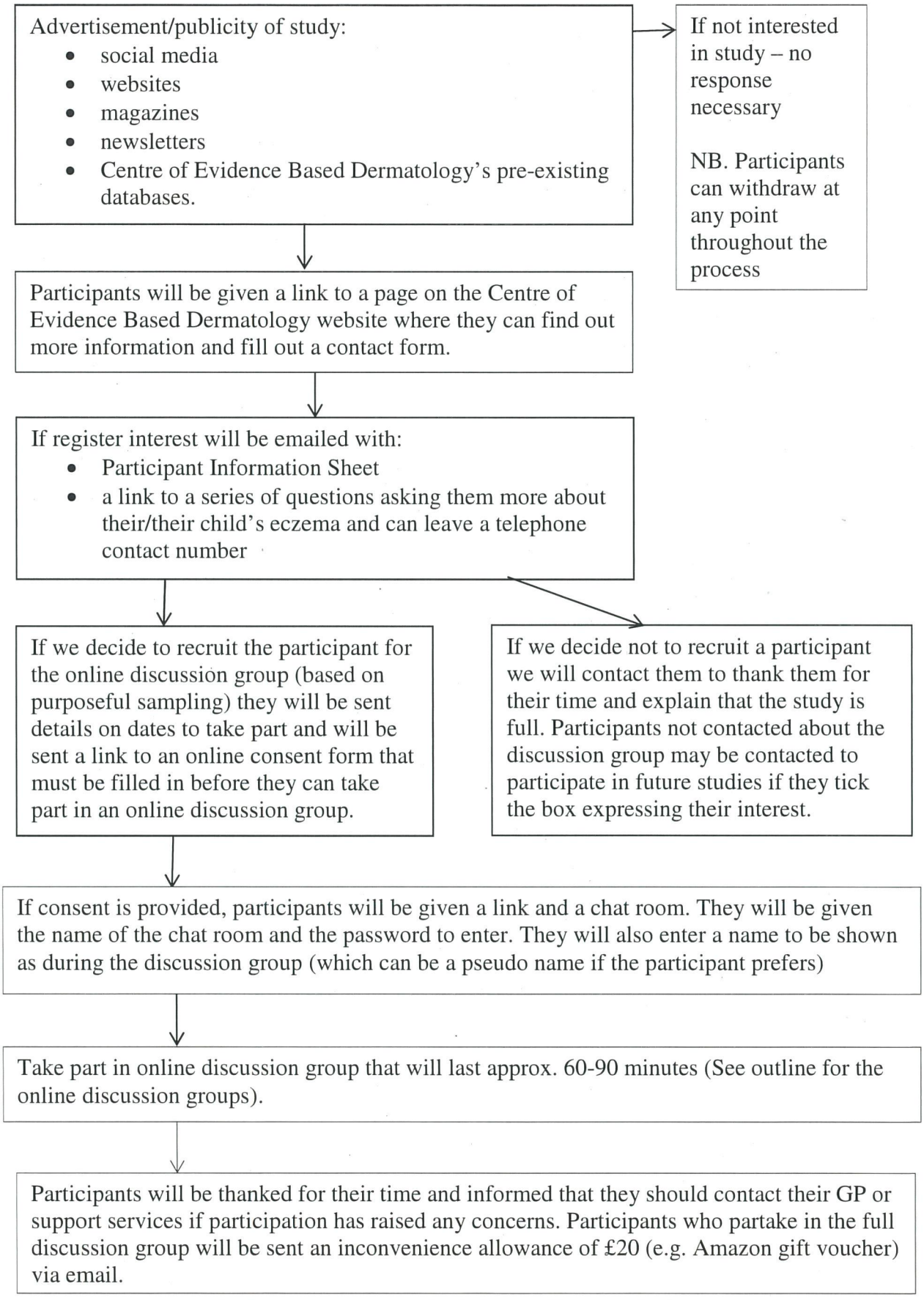
The process that each participant will undertake is illustrated in Figure 1. All online discussion groups will follow a common interview guide (see Outline of Online Discussion Groups). Moderators will ask participants a series of questions and will have pre-prepared prompts to help facilitate discussion. Each discussion group will be moderated by 2-3 researchers who will be assigned specific roles (e.g. one to introduce the interview questions, one to upload the questions and any additional information needed and one to problem solve access to the discussion group). Careful consideration will be given to the language used to ensure it is intuitively understandable for patients and limits suggesting favour to differing approaches to long-term control measurement. Language to be used will also be piloted using patient involvement with the Centre of Evidence Based Dermatology's patient panel and social media discussions with the public/patients/interested parties. The wording of online discussion groups will differ slightly for patients and carers. A guideline for the online discussion groups has been created, however the wording used here may alter depending on feedback from our patient involvement work and if initial discussion groups highlight to us that we may need to make alterations for subsequent discussion groups (See Outline for online discussion groups).

Participants will be allocated to different online discussion groups depending on their characteristics (if they are both they will be able to choose which they affiliate most with):

- Online discussion groups with patients (adults 18 years +) with eczema
- Online discussion groups with carers for children with eczema

We will aim to recruit approximately 6-8 people per online discussion group. However, due to the likelihood of various issues (e.g. participants forgetting, unable to connect etc.), researchers will over recruit to ensure adequate participation (e.g. 10-12 recruited per online discussion group).

Figure 1: Study Procedure



Compliance

From previous experience of using on-line discussion groups, we do not anticipate any compliance issues. However, compliance will be assessed by researchers moderating the online discussion group. If there is substantial deviance from the subject topic, inappropriate comments about other users, or clear evidence of participants pursuing their own agenda, a procedure for promoting compliance will be put in place

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, participants may be asked to leave the group or no longer contribute to enable the online discussion group to continue. This can be conducted as a private message to the individual so that the whole group cannot see.
3. If the non-compliance still persists and it is deemed disruptive for other participants, the online discussion group will be closed down after debriefing and explanation of why the online discussion group has been terminated early.

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

A copy of the discussion thread for each online discussion group will be saved (with personal identifiers omitted e.g. assigned "participant 1"). These will provide a transcript that will be analysed by at least two researchers. Thematic analysis will be used. All collaborating centres will follow the same methodological approach to analysis to ensure consistency across countries.

Sample size and justification

Participants will be chosen using purposeful sampling to ensure a range of disease severities, ethnicities, ages, sexes, previous experience in trials, disease duration and previous experience of healthcare services. When the researchers feel the objectives have been reached and data has been saturated, data collection will end. It is estimated that approximately 4 online discussion groups will be ran in the UK (two with adults with eczema and two with carers of children with eczema).

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

When entering the online discussion group, participants will be able to input an identifying name. It will be suggested to participants that if they wish to remain anonymous they should input a pseudo name. Furthermore, participants will be warned that if they provide any confidential information (e.g. address, name, email) in their responses then the researchers will not be able to prevent other participants from seeing this information. If patients do report any details in the text that is classified as confidential information this will be omitted from the saved copies of the transcripts.

The chatroom used to host the surveys is https://chatstep.com/ which has a valid HTTPS certificate to ensure that the connection to this site is using a valid, trusted server certificate.

2. Research raises concerns for patients

The researchers will not be able to provide medical information. Therefore, if any medical concerns arise the researchers will suggest patients visit their GP or healthcare professional to discuss their concerns. Similarly, if feelings of distress are detected during the online discussion group, the researchers will suggest patients contact relevant support services.

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 online 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 required 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. The software will use encryption of messages and will delete all information from the server once the chat room is closed down by all participants. No audio recordings will be required as the discussion will be entirely in written format. 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. We intend to present the results at the HOME V meeting in April/May 2017. The work is also intended to inform future work and decisions made by the HOME membership regarding COS for eczema clinical trials. Participants will not be identified in any publications.

USER AND PUBLIC INVOLVEMENT

We intent to use social media networks and patient panel members to help us decide on the appropriateness of language we will use within the online discussion group to discuss the

topic with participants. A very short survey with different wording options to find out what patients and other interested parties find out what terms patients think are the best way of describing "long-term control" will be circulated on social media networks such as twitter.

There has been patient involvement in HOME meetings to date that have agreed that long-term control of eczema is one of the four domains to be included in a COS for eczema clinical trials.

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. An inconvenience allowance of a £20 gift voucher (e.g. Amazon) will be given to thank participants for their time.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name) Kim Thomas

Signature: KS Thomas

Date: 7/6/16.

REFERENCES

1. H. Williams, et al. Worldwide variations in the prevalence of symptoms of atopic eczema in the International Study of Asthma and Allergies in Childhood. J Allergy Clin Immunol, 1999; 103:125-138
2. Margolis, J. S., Abuabara, K., Bilker, W., Hoffstad, O., & Margolis, D. J. (2014). Persistence of mild to moderate atopic dermatitis. *JAMA dermatology*, *150*(6), 593-600.
3. Schofield JK, Grindlay D, Williams HC. Specific skin disease areas. In: Skin Conditions in the UK: A Health Care Needs Assessment (Schfield JK, Grindlay D, Williams HC, eds). Nottingham: Centre of Evidence Based Dermatology, University of Nottingham, 2009; 85
4. Zuberbier T, Orlow SJ, Paller AS, Taïeb A, Allen R, Hernanz-Hermosa JM, Ocampo-Candiani J, Cox M, Langeraar J, Simon JC. Patient perspectives on the management of atopic dermatitis. Journal of Allergy and Clinical Immunology. 2006;118(1):226-32.
5. Thomas KS, Stuart B, O'Leary CJ, Schmitt J, Paul C, Williams HC, Langan S. Validation of treatment escalation as a definition of atopic eczema flares. PloS one. 2015 Apr 21;10(4):e0124770.
6. Gargon E, Gurung B, Medley N, Altman DG, Blazeby JM, Clarke M, Williamson PR. Choosing important health outcomes for comparative effectiveness research: a systematic review. PLoS One. 2014;9(6):e99111.
7. Schmitt J, Spuls P, Boers M, Thomas K, Chalmers J, Roekevisch E, Schram M, Allsopp R, Aoki V, Apfelbacher C, Bruijnzeel-Koomen C. Towards global consensus on outcome measures for atopic eczema research: results of the HOME II meeting. Allergy. 2012 Sep 1;67(9):1111-7.
8. HOME IV Meeting Minutes (Malmo, Sweden)
9. Barbarot S et al., Strategies for measuring long-term control in atopic eczema trials: a systematic review (in review)
10. Langan SM, Schmitt J, Williams HC, Smith S, Thomas KS. How are eczema 'flares' defined? A systematic review and recommendation for future studies. British Journal of Dermatology. 2014 Mar 1;170(3):548-56.
11. Langan SM, Thomas KS, Williams HC. What Is Meant by a "Flare" in Atopic Dermatitis?: A Systematic Review and Proposal. Archives of dermatology. 2006 Sep 1;142(9):1190-6.
12. Langan SM, Silcocks P, Williams HC. What causes flares of eczema in children?. British Journal of Dermatology. 2009 Sep 1;161(3):640-6.
13. Thomas KS, Dean T, O'Leary C, Sach TH, Koller K, Frost A, Williams HC, SWET Trial Team. A randomised controlled trial of ion-exchange water softeners for the treatment of eczema in children. PLoS Med. 2011 Feb 15;8(2):e1000395.
14. Thomas KS, Stuart B, O'Leary CJ, Schmitt J, Paul C, Williams HC, Langan S. Validation of treatment escalation as a definition of atopic eczema flares. PloS one. 2015 Apr 21;10(4):e0124770.
15. Williamson PR, Altman DG, Blazeby JM, Clarke M, Devane D, Gargon E, Tugwell P. Developing core outcome sets for clinical trials: issues to consider. Trials. 2012 Oct;13(1):132.

Faculty of Medicine and Health Sciences Research Ethics Committee

Notice of Amendment

Please complete this form electronically and submit by e-mail to the Ethics Committee administrator: louise.sabir@nottingham.ac.uk Please ensure that you complete this form in language comprehensible to a lay person.

1. Details of Principal Investigator / Supervisor

Name:	Prof. Kim Thomas
School and Department:	Centre of Evidence Based Dermatology, School of Medicine
Telephone:	0115 846 8632
Email:	kim.thomas@nottingham.ac.uk

2. Details of Student Investigator (if applicable)

Name:	Laura Howells
School and Department:	Centre of Evidence Based Dermatology, School of Medicine
Telephone:	0115 84 68634
Email:	mzxlmh@nottingham.ac.uk

3. Details of Research Project

Full Title *(short title in brackets)*:	Patient and carer perspectives on defining and measuring long-term control of eczema (Long-term control of eczema)
Research Ethics Reference Number *(as detailed on Approval letter/email)*:	F14062016
Date of Ethics Committee approval:	27th June 2016
Date Study Started:	1st July 2016
Date Study Ends:	31st August 2016
Amendment Number and Date:	Number:1 Date:28/07/16

4. Type of Amendment(s)

1) Amendment to information supplied in original Medical School Research Ethics Approval application form (i.e extension of end date of the study)

   YES ☐ NO ☐

- ***If yes, please clearly state which sections in the Summary box below.***

2) Amendment to information sheet / consent forms or other supporting documentation for the study

YES ☒ NO ☐

- ***If yes, please submit these documents with all changes highlighted to louise.sabir@nottingham.ac.uk***

5. Details of Amendment(s) – *Please summarise in language comprehensible to a lay person, including what measurements have been put in place for any additional ethical issues that may arise as a result of the amendment (s).*

Amendments to all terms that were originally in square brackets as they were informed by patient and public involvement (PPI) - mostly using "long-term management" to refer to the concept
Amendment to title for PIS and consent form - felt more appropriately conveys what we are doing

Preliminary Questions document:
- Addition of question “what country do you live in?” for the preliminary questions asked as we felt this would be useful information.
wording altered slightly for tick box to provide consent as feel it now is easier to understand and read
-asking carers age - to know if have informed consent
- asking carers sex - interesting to know if mothers or fathers respond
- asking do you have eczema yourself - may feed into their experiences

Topic guide documents:
– changes based on PPI work (and split into 3 documents: adult version, carer version, general comments to use)
Additional debrief email instead of all the information at the end of the discussion (as felt some information would be more useful this way when they have time to think and reflect e.g. where to contact if group as raised any concerns)

It is not anticipated that any ethical issues will arise as a result of the amendments to the documents.

6. List of Enclosures

Participant Information Sheet version 1.1
Consent Form version 1.1
Topic guide adults version 1.1
Topc guide carer version 1.1
Topic guide general comments version 1.1
Website information and contact form version 1.1
Preliminary questions version 1.2

7. Declaration (for signatures, please type names or use electronic signature)

• **The information I have provided in this form is accurate to the best of my knowledge.**

Signature of Principal Investigator / Supervisor: *(please delete as appropriate)*	**Prof. Kim Thomas**
Signature of Student Investigator: *(if applicable)*	**Laura Howells**
Date:	**28/07/2016**

Faculty of Medicine and Health Sciences Research Ethics Committee

Notice of Amendment

Please complete this form electronically and submit by e-mail to the Ethics Committee administrator: louise.sabir@nottingham.ac.uk Please ensure that you complete this form in language comprehensible to a lay person.

1. Details of Principal Investigator / Supervisor

Name:	Prof. Kim Thomas
School and Department:	Centre of Evidence Based Dermatology, School of Medicine
Telephone:	0115 846 8632
Email:	kim.thomas@nottingham.ac.uk

2. Details of Student Investigator (if applicable)

Name:	Laura Howells
School and Department:	Centre of Evidence Based Dermatology, School of Medicine
Telephone:	0115 84 68634
Email:	mzxlmh@nottingham.ac.uk

3. Details of Research Project

Full Title *(short title in brackets)*:	Patient and carer perspectives on defining and measuring long-term control of eczema (Long-term control of eczema)
Research Ethics Reference Number *(as detailed on Approval letter/email)*:	F14062016
Date of Ethics Committee approval:	27th June 2016
Date Study Started:	1st July 2016
Date Study Ends:	31st August 2016
Amendment Number and Date:	Number:2 Date:29/07/16

4. Type of Amendment(s)

1) Amendment to information supplied in original Medical School Research Ethics Approval application form (i.e extension of end date of the study)

   YES ☒ NO ☐

- ***If yes, please clearly state which sections in the Summary box below.***

2) Amendment to information sheet / consent forms or other supporting documentation for the study

YES ☒ NO ☐

- ***If yes, please submit these documents with all changes highlighted to louise.sabir@nottingham.ac.uk***

5. Details of Amendment(s) – *Please summarise in language comprehensible to a lay person, including what measurements have been put in place for any additional ethical issues that may arise as a result of the amendment (s).*

Change in consent age:

The Code of Research Conduct and Research Ethics for the University of Nottingham regards research involving children as those under 16 years old (http://www.nottingham.ac.uk/educationstudentintranet/resources/code-of-research-conduct-and-research-ethics-version-5-june-2015.pdf) The Good Clinical Practice guidance also refers to a minor requiring parental consent as being a child under 16 years (http://www.rcpch.ac.uk/sites/default/files/page/Guidance%20on%20clinical%20research%20involving%20infants,%20children%20and%20young%20people%20v4%20FINAL.pdf)

Therefore, after much consideration amongst the team, it is was felt that it would be ideal to include those 16-18 years old (which will be amended from originally 18 years or over). This would be beneficial to the research as the opinions of 16-18 year olds may be different to older participants and important to capture. Furthermore, we feel, based on the teams research experience, that they would be able to effectively and competently take part in this discussion.

Changes to forms:

The consent form and preliminary questions now both ask participants their name and email address. We will already have this information from their contact form/communciating with them via email, however it was noted that we would need this identifying information to be able to match the documents to each participant (e.g. so that we are confident that those participating have definitely provided informed consent).

6. List of Enclosures

Consent Form version 1.2
Preliminary questions version 1.3

7. Declaration (for signatures, please type names or use electronic signature)

• **The information I have provided in this form is accurate to the best of my knowledge.**

Signature of Principal Investigator / Supervisor: *(please delete as appropriate)*	**Prof. Kim Thomas**
Signature of Student Investigator: *(if applicable)*	**Laura Howells**
Date:	**28/07/2016**