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Supporting Parents and Carer's management of Childhood Eczema

Submission date
04/03/2011

Registration date
04/03/2011

Last Edited
29/01/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Skin and Connective Tissue Diseases

☐ Prospectively registered
☐ Protocol
☐ Statistical analysis plan
☒ Results
☐ Individual participant data

Plain English summary of protocol

Background and study aims
Childhood eczema is very common, affecting more than 20% of children aged 5 years or younger at some point. The symptoms can range from mild to severe but usually involves itchy, dry patches of skin. In some cases, the itchiness can be so severe that it interferes with daily life and causes sleep disturbances, which can be extremely distressing for both the child and their family. Healthy skin cells are plumped up with water, which is kept in by natural oils on the skin surface (barrier). If a person has eczema, then the skin often doesn’t produce these oils, leading to loss of moisture and dryness. The main treatments for eczema are emollient creams (moisturisers) and topical corticosteroids (creams or gels containing hormones that reduce inflammation (swelling) which are applied to the skin) in order to prevent flare ups of the condition. Many carers find it difficult to carry out these treatments, as they may not fully understand what the different creams are for and their children may refuse treatment. Carers also need lots of other information, for instance about avoiding things that make eczema worse (such as soap) and how to deal with scratching. The aim of this study is to test the effectiveness of a new internet-based program which offers help and advice to carers of young children with eczema.

Who can participate?
Carers of children under 5 years old who are suffering from eczema.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group continue to receive usual care and are also given access to the internet-based program for 12 weeks, which includes 14 modules aiming to provide advice and information about caring for children with eczema, such as diet and allergy information, medications, bath time, sleep problems and managing scratching. Those in the second group also receive usual care and access to the internet-based program, but are also given health care professional (HCP) support. This involves phone calls in which the HCP encouraging the participant to use the website. Participants in the third group received usual care only for the 6 months of the study. At the start of the study and again after 6 months, participants complete a number of questionnaires in order to assess whether the way they care for their child’s eczema has changed.

What are the possible benefits and risks of participating?
Participants who have access to the web-based program may find new ways of helping their children, and may be more confident in using different treatments. There are no risks of taking part in this study.

Where is the study run from?
Aldermoor Surgery, Southamptom (UK)

When is the study starting and how long is it expected to run for?
November 2010 to December 2012

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Miriam Santer
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8427

Study information

Scientific Title

Supporting Parents and Carer's management of Childhood Eczema: development of a web based intervention and pilot randomised controlled trial (RCT)

Acronym
SPaCE

Study objectives
Objectives
1. Explore the concerns of parents/carers of children with eczema through qualitative interviews.
2. Develop a website based intervention to support self-management amongst parents/carers of children with eczema.
3. Carry out pilot RCT of intervention, examining recruitment, randomisation procedures, response rate, outcome assessment and estimating effect size.
4. Randomise participants to normal care, intervention, intervention plus support from health professional to ascertain whether such support has an impact on intervention effectiveness.

Design
Development of intervention and pilot feasibility RCT

Outcomes
This research will allow optimal design of an intervention and provide the necessary information to design a phase 3 trial to test this intervention. If shown to be effective, the intervention would improve quality of life for children with eczema and their families and potentially reduce their risk of progression to other atopic disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Ethics Committee on 05/08/2010 (ref: 10/H0505/56)

Study design
Pilot randomised controlled trial

Primary study design
Observational

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Eczema

Interventions
LifeGuide, Internet based behavioural intervention under development; Follow Up Length: 6 month(s); Study Entry : Registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Dermatitis Family Impact questionnaire measured at baseline and 6 months

Secondary outcome measures
1. Infants Dermatology Quality of Life Index measured at baseline and 6 months
2. Patient Oriented Eczema Measure measured at baseline and 6 months

Overall study start date
15/11/2010

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Carers of children aged 5 years or less
2. Those whose children have a diagnosis of eczema on their GP record

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
Planned Sample Size: 180; UK Sample Size: 180

Key exclusion criteria
1. Child protection issues
2. Severe mental distress
3. Palliative care
4. Recent bereavement
5. Known opposition to involvement in research or inability to complete research measures, e.g. main carer has learning disability

Date of first enrolment
15/11/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Aldermoor Surgery
Primary Medical Care
Aldermoor Close
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Southampton Primary Care Academic Unit
School of Medicine, Aldermoor Close
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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/06/2014

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/03/2014		Yes	No