

Harmonising Outcome Measures for
Eczema (HOME)

3rd HOME Meeting (HOME III)

*6th and 7th April 2013, San Diego,
USA*



HOME Symptom Group

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San Diego 07 april 2013



The goal of the HOME Symptom group

- Select core symptom outcome measure(s)
- Long-term goal is to standardize and better-validate the symptom measures for future studies

- Which symptoms outcome scales are available
- What is the quality of these scales validation studies
- Detect implications for research in this field



Atopic dermatitis



Definition

- A symptom (from Greek *σύμπτωμα*, "accident, misfortune, that which befalls", from *συμπίπτω*, "I befall", from *συν-* "together, with" + *πίπτω*, "I fall")
- is a departure from normal function or feeling which is noticed by a patient, indicating the presence of disease or abnormality
- a symptom is subjective and cannot be measured directly

Introduction

- A **symptom** can more simply be defined as any feature which is noticed by the patient
- A **sign** is noticed by other people
- It is not necessarily the nature of the sign or symptom which defines it, but who observes it



Signs and symptoms

- A feature might be sign and symptom depending on the observer(s).
 - such as skin [rash](#) may be noticed by either a healthcare professional as a [sign](#), or by the patient as a [symptom](#)
- Some features, can only be symptoms, because they cannot be directly observed by other people
 - such as [pain](#) and [itch](#)
- Other features can only be signs
 - such as a [blood cell count](#) measured in a [medical laboratory](#)

HOME Symptom Group Members

Amsterdam 2011

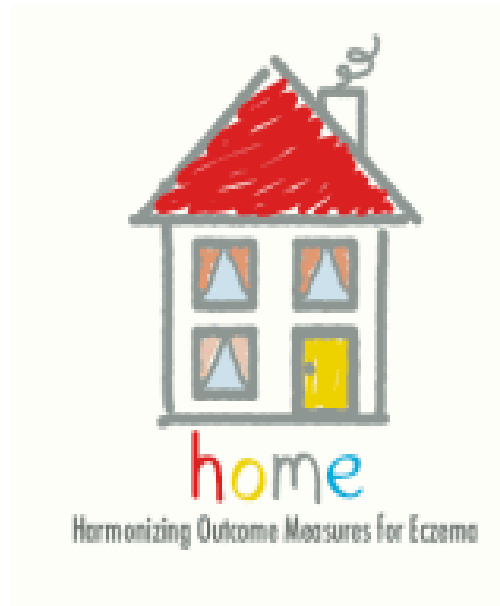
- Masutaka Furue
- Joanne Chalmers
- Carolyn Charman
- Baraka Chaula
- Ulf Darsow
- Regina Foelster Holst
- Jon Hanifin
- Ellis Hon
- Helen Nankervis
- Kim Thomas
- Elke Weisshaar
- Stephan Weidinger
- Matt Ridd
- Kyu-Han Kim
- Zhang Jian-Zhong
- Hitoshi Mizutani
- Hidehisa Saeki
- Satoshi Takeuchi
- Norito Katoh
- Phyllis Spuls (LEAD)



Project and Programme

- Phyllis Spuls, Joanne Chalmers
 - Systematic review of outcome parameters in the symptom domain - data from the GREAT database
- Laura von Kobyletski
 - Signs and Symptoms - content validity from the patient's perspective: call for contribution and first results
- Norito Katoh
 - Comparison of VAS and verbal rating scale in Japanese patients using VAS with 10 point end of "worst imaginable itch"





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The Use of Symptom Outcome Measures in Atopic Dermatitis Research - A Systematic Review of Randomized Controlled Trials

Chalmers J, Nankervis H,
Thomas K, Spuls Ph



Disclaimer

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The Global Resource of Eczema Trials (GREAT)

<http://www.greatdatabase.org.uk>

Although great care has been taken to ensure the accuracy of the information provided on the GREAT database, the authors are not responsible, or in any way liable, for any errors, omissions or inaccuracies in the information. The authors are not responsible for any of the information contained in any linked external sites.



Introduction

- 4 core outcome domains are identified for HOME
- Symptoms is one of these core domains
- Many symptom outcome measures are used in dermatology research
- The type of scales used and implementation methods vary between studies however



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Objective

- To review in randomized trials in AD
 - if symptoms were reported
 - which symptom outcome measures were used
 - if it was used as primary outcome



Search Methods

- We searched all RCTs published since 2000 – May 2012 using the GREAT database
- Database includes all published RCTs on atopic eczema



www.greatdatabase.org.uk

Campus maps Contact us Jobs Help A-Z index **UK Campus** China Campus Malaysia Campus

Global Resource for Eczema Trials

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

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Click to Browse the GREAT database.

Browse the GREAT database

Search the GREAT database

A comprehensive collection of detailed information on systematic reviews and randomised controlled trials of eczema treatments
GREAT database last updated: Tuesday 8th of May 2012

Background


Aims


Collaboration


Latest news
23/08/2012
Re-launch of the GREAT website – the new website is now live.

Data-extraction

- Year of publication
- Were any symptoms reported? Y/N
- How were they measured:
 - Any composite scales that include subjective symptoms e.g. SCORAD but not those that only look at objective signs (e.g. objective SCORAD, SASSAD)
 - Individual symptoms such as pruritus plus details of scale, markers and anchors used were reported
- Whether each symptom measure was the primary outcome
- Country / continent
- Sponsor / funder: industry or academic/governmental



Results

- Per outcome measure:
 - reported as total score/separate or both
 - as primary outcome
 - how was it measured/what scaling was used/what anchors were used



How many RCTs reported symptoms?

319 RCTs on atopic eczema treatments
In GREAT database 2000 – May 2012

243 RCTs
reported
symptoms
(76%)

65 RCTs
Did NOT report
symptoms
(21%)

11 RCTs
Unclear
(3%)

Were symptoms primary or secondary outcomes?

243/319 RCTs reported symptoms

In 141 RCTs (58%) symptoms were primary outcome

•SCORAD	96
•Pruritus	23
•Un-named composite	10
•mEASI	5
•ADASI	2
•ADSI	1
•PAIS	1
•POEM	1
•Dryness	1
•Unclear	1

In 102 RCTs (42%)
Symptoms reported only as a secondary outcome

What symptoms were reported?

- Pruritus
- Sleep loss
- Stinging
- Burning
- Smarting
- Pain
- Rash
- Dryness
- Irritation
- “Skin symptoms / overall symptoms”
- “Skin condition /appearance”

Often reported as part of a composite scale



What symptoms are included in the named composite scales?

	Signs	Pruritis	Sleep loss	Other
SCORAD Severity Scoring of Atopic Dermatitis	Yes Physician	Yes VAS	Yes VAS	No
POEM Patient Oriented Eczema Measure	Yes Patient	Yes Weekly question "Over the last week..."	Yes Weekly question "Over the last week..."	Yes (several) Weekly question "Over the last week..."
ADSI Atopic Dermatitis severity Index	Yes Physician	Yes Score 0-3	No	No
PAIS Physician Assessment of Individual signs	Yes Physician	Yes VAS	No	No
Modified EASI Eczema Area and Severity Index	Yes Physician	Yes VAS / score	No	No
ADASI Atopic Dermatitis and severity index	Yes Physician	Yes Intensity of itch	No	No

How many trials reported SCORAD?

	n(%)
How many RCTs that reported symptoms used SCORAD?	109 (45%)
As primary outcome	96
As secondary outcome (some also used as primary)	13

How was SCORAD reported?	n
Total score only	100
Separate scores only	1
Both	5
Unclear	3

Funding / sponsorship	n
Academic / government	31
Industry	28
Not known	50

Other named composite scales

Scale	Number of RCTs	As primary outcome?	Funding / sponsorship
POEM	3	1	2 academic, 1 unknown
ADSI	2	1	1 industry, 1 unknown
PAIS	1	1	1 unknown
Modified EASI	8	5	6 industry, 2 unknown
ADASI	3	2	1 academic, 2 unknown

How many trials reported pruritus?

Did the trial report pruritus?	Number of RCTs (%)
Yes (in named or un-named composite scale, single measure or both)	238 (98%)
Reported symptoms but NOT pruritus	2
Not clear	14
No symptoms reported	65

- 14 trials reported pruritus in an un-named composite measure

How was pruritus measured (when a stand alone measure)?

How was itch measured?	Number of RCTs
VAS	60
Scale / score	36
Other	9
Unclear	19

Other

- Pruritus intensity
- Participant assessed total pruritus over previous 24 hours
- Time to resolution of pruritus
- Location of pruritus attacks, itch sensation during attacks, diff in itching between baseline and last measurement
- JUCKKI / JUCKJU Itching behaviour measure
- Degree of pruritus
- Patient assessed daytime itch
- Number of scratch free days
- Investigator Pruritus Severity Assessment (IPSA)

How many trials reported sleep loss?

Did the trial report sleep loss?	Number of RCTs
Yes (as composite scale, single measure or both)	139
Reported symptoms but NOT sleep loss	102
No symptoms reported	67
Not clear	11

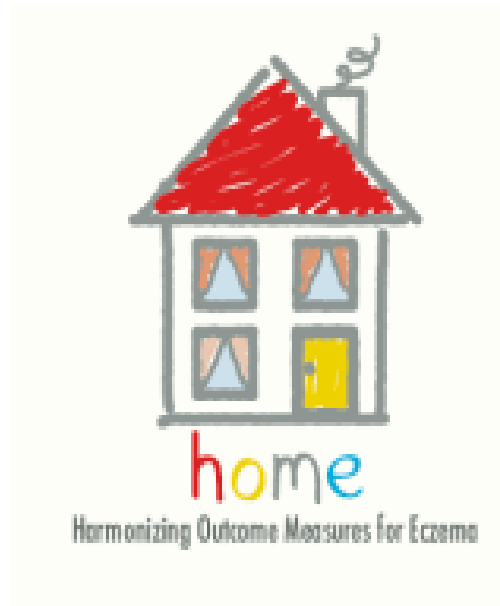
- 2 trials reported sleep loss in an un-named composite measure

What other symptoms were reported?

Symptom	Number of times reported alone
Stinging	2
Burning	4
Smarting	1
Pain	3
Rash	1
Dryness	5
Irritation	5
"Skin symptoms / overall symptoms"	2
"Skin condition /appearance"	3

Summary & Conclusions

- $\frac{3}{4}$ of RCTs published between 2000 and 2012 reported symptoms
- Virtually all of these RCTs reported itch
 - Most commonly measured by VAS
- Approx. half of these RCTs used SCORAD
 - Usually only total score reported so not possible to get historical data on symptoms from papers
- Sleep loss usually reported as part of SCORAD
- POEM unique – simple questions reflect the many symptoms experienced by patients and it is completed weekly by patients



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Thank you



Year of publication

- 2012 11 only up to May
 - 2011 38
 - 2010 35
 - 2009 23
 - 2008 26
 - 2007 27
 - 2006 40
 - 2005 29
 - 2004 16
 - 2003 17
 - 2002 23
 - 2001 21
 - 2000 13
-
- Graph?
 - Or percentage of all trials published that year?

Country/continent **need to tie this in with which scales were used if it is to be useful**

- Many trials multinational/continental
- 1 country: 129 trials
- Countries with > 10 trials
 - Germany 24 trials
 - USA 22 trials
 - Japan 13 trials
 - UK 10 trials
 - Netherlands 10 trials