Transmural occupational care for hand eczema - a randomized controlled trial and cost-effectiveness evaluation

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25978

Source
NTR

Brief title
Transmural care for hand eczema

Health condition

Hand eczema

Sponsors and support

Primary sponsor: VU Medical centre, UMC Radboud Nijmegen, UMC Groningen
Source(s) of monetary or material Support: Zon MW, The national organisation for health research and development

Intervention

Outcome measures

Primary outcome

Cumulative difference in reduction of clinical severity scores

Direct and indirect costs

Secondary outcome

Specific Quality of Life,

Clinical score of severity of hand eczema,

Overall Quality of Life

Patient satisfactory with the program

Study description

Background summary

Hand eczema is a common disease with an unfavourable prognosis. It accounts for 90% of all occupational skin diseases and is in the top three of work-related disorders.
Medical consumption, as well as costs related to productivity loss and sick leave, are high. Target of this study is to evaluate the (cost)effectiveness of a multidisciplinary approach coordinated by a care manager, compared to usual care. Patients will be randomly assigned to either the intervention group or the control group. Primary outcome measures are difference in reduction of clinical severity scores and direct and indirect costs. Measurements will take place at baseline and after 4, 12, 26 and 52 weeks. Main research question is: Is transmural care for hand eczema by a specialized multidisciplinary centre aiming at coordination, optimal instruction and treatment (cost)effective as compared to regular dermatologist-led care?

Study objective

Is transmural care for hand eczema by a specialized multidisciplinary centre (cost)effective as compared to usual care?

Study design

At baseline and after 4, 12, 26 and 52 weeks

Intervention

Multidisciplinary treatment coordinated by a care manager consists of consults with a dermatologist, a specialized nurse (after 1,2, 4 and 12 weeks) and an occupational physician (if there is a relation with work).
The intervention takes up till 12 weeks. The control group receives standard care provided by

a dermatologist. After testing, results will be evaluated and patients will be informed by the dermatologist.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis is mild to moderate chronic (>3 months) hand eczema

2. Participants are >16 years

3. Participants are able to complete a Dutch questionnaire

4. Never visited the centre before for hand eczema, or last visit was at least one year ago.

Exclusion criteria

1. Systemic treatment of eczema

2. Generalized eczema, whereas hand eczema is not the main problem

3. Use of medication or phototherapy or than used in this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-02-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1194
NTR-old	NTR1239
Other	MEC VUMC : 2008/012
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A