Transmural care for hand eczema. A randomized controlled trial with an economic evaluation alongside

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1) To develop and implement a protocol for transmural, multidiscplinary care for hand eczema, coordianted by a case-manager.2) To evaluate the (cost)effectiveness of the multidisciplinary protocol for transmural care in hand eczema

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON31825

Source
ToetsingOnline

Brief title
Transmural care for hand eczema

Condition

- Epidermal and dermal conditions

Synonym
hand eczema

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: economic evaluation, hand eczema, occupational health, transmural care

Outcome measures

Primary outcome

1) Cumulative difference in reduction of clinical scores of hand eczema

Measured using the Hand Eczema Severity Index (HECSI)

2) Direct and indirect costs

Measured using a questionnaire, filled out every three months

Secondary outcome

1) Specific quality of life

Measured using the Imapct of chronic Skin Disease on daily Life (ISDL) and the

Skindex

2) Clinical scores of hand eczema

Measured using the Hand Eczema Area and Severity score (HEAS) and the

Photographic Guide

3) Overaal quality of life

Measured using the EuroQol

4) Patient satisfactory

Measured using the Patient Satisfaction with Occupational Health Services

(PSOHQ)

Study description

Background summary

Hand eczema is defined as an inflammation of the skin that is confined to the hands. It is a common disease, accounting for 90% of all work-related skin diseases. It is in the top-three of work-related disorders. Prevalence ranges from 25 to 66 per 1000 patient years. Point prevalence varies from 5 to 10% and incidence rates from 4 to 7%. Hand eczema has an unfavourable prognosis; 5 years after diagnosis, 50% of all patients reports mild to moderate and 32% severe hand eczema. It is also associated with high medical consumption. 60% of all patients visit their general practitioner and 20% visits a medical specialist. High costs are also related to productivity loss and sick leave. Total costs of medical consumption, absenteeism and disability pensions due to occupational skin disease were estimated at ¤98,1 million in 2001.

Usual care of hand eczema by a dermatologist is lacking. In this randomized, controlled trial, usual care is compared to a transmural multidisciplinary treatment, coordinated by a case-manager. Cost-effectiveness of this new approach is also evaluated.

Study objective

1) To develop and implement a protocol for transmural, multidiscplinary care for hand eczema, coordianted by a case-manager.
2) To evaluate the (cost)effectiveness of the multidisciplinary protocol for transmural care in hand eczema

Study design

This study is designed as a randomized controlled trial. Patients are randomly assigned to the intervention group or the control group after baseline measurements. Groups will receive the following care:
- Intervention group: Patients will be diagnosed and will receive coordinated care from a multidisciplinary team, consisting of a case manager, a dermatologist, an occupational physician and a specialized nurse.
- Control group: Patients receive usual care, consisting of allergic-dermatological evaluation by their own dermatologist and usual medication, written information and advice.

The economic evaluation will be conducted from a societal perspective. Both medical costs (direct costs) and costs due to productivityloss (indirect costs) will be measured.

Het onderzoek is opgezet als een gerandomiseerde gecontroleerde trial. De patiënt wordt na de baseline meting willekeurig aan de interventie- of de controlegroep toegewezen. De groepen ontvangen de volgende zorg:
- Interventiegroep: De patiënt ontvangt gerichte diagnostiek en gecoördineerde zorg van een multidisciplinair team, bestaande uit een case manager, een (arbeids)dermatoloog, een klinisch arbeidsgeneeskundige en een gespecialiseerd

verpleegkundige.
- Controlegroep: De patiënt ontvangt *usual care*, bestaande uit allergo-dermatologische evaluatie door de eigen dermatoloog en gebruikelijke medicatie, schriftelijke informatie en adviezen.

Intervention

The intervention group will receive care of a multidisciplinary team, consisting of a dermatologist, a specialized nurse and an occupational physician.
The dermatologist does the allergic-dermatological test and the end-evaluation. The specialized nurse teaches the causes and mechanism that play a role in hand eczema. She discusses the therapy and patients consult her at set times. In emergency cases the specialized nurse could be consulted temporary.
The occupational physician is consulted if hand eczema is work-related. He lalso plays a role when patients need assistance considering social regulations. The occupational physician is the link between the hospital and the workplace of the patient. He gathers information about exposure to allergic substances and collects materials needed for the allergic-dermatological tests. The occupational pfysician visits the workplace if indicated.

The control group receives care by the dermatologist only. As in the intervention group, allergic-dermatological tests are performed. The dermatologist informs the patient about the results and provides the patient with information brochures.

Study burden and risks

Measurements will take place at baseline and after 4, 12, 26 and 52 weeks. Every measurement (existing of scoring clinical hand eczema and filling out a questionnaire) will take about 1 hour. Besides that, participants keep record of usage of care and absenteeism from work.
There will be no extra physical burden for patients in the intervention group. There is no higher risk in participating

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Moderate to severe chronic (>3 months) hand eczema
Participants are at least 16 years old
Participants are able to complete a Dutch questionnaire

Exclusion criteria

Systemic treatment of hand eczema
Generalized eczema, when hand eczema is not the main issue

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2008
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL21490.029.08