WHat is the impact of recurrent scabies on young people's daily lives?

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Primary objective 1:To understand how individuals with recurrent scabies symptoms experience the impact of scabies on their daily lives over time following a visit to the scabies clinic.Primary objective 2:To understand how individuals with...

Ethical review	Not available
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON57514

Source
Onderzoeksportaal

Brief title
Impact of recurrent scabies symptoms on daily lives of young adults

Synonym
scabies, mite, Sarcoptes scabiei, parasitic mite

Research involving
Human, Data

Sponsors and support

Primary sponsor: GGD Amsterdam
Source(s) of monetary or material Support: R&D geld van Streeklaboratorium Amsterdam

Intervention

- Other intervention

Explanation

N.a.

Outcome measures

Primary outcome

Change in PROMIS T-scores between week 12 and week 0 on different domains of Promis-29 V2.1

Secondary outcome

Patients' satisfaction score on 5-point Likert schale Patients' treatment adherence score on 5 point Likert schale Proportion of respondents indicating that received information was clear and actionable

Study description

Background summary

Scabies, resulting from an infestation of the skin by the Sarcoptes scabiei mite, attained recognition as a significant public health concern in 2017 when the World Health Organization classified it as a neglected tropical disease. This acknowledgement led to its inclusion in the list of diseases requiring heightened attention and was followed by multiple reports of an increased scabies incidence over the beginning of the 21st century.

The number of scabies diagnoses in the Netherlands also increased over the past decade, particularly in young adults. To improve care for this group with often difficult-to-treat scabies due to their social connectivity and shared housing, the Infectious Disease Control Department of the Amsterdam Municipal Health Service (GGD) in October 2022, established a scabies clinic for young adults aged between 18 and 30. This clinic is designed for patients who suffer from recurrent scabies symptoms where they are examined by a nurse using dermatoscopy, microscopy and/or PCR to diagnose scabies.

The advantages of this clinic over a general practitioner consultation lie in the emphasis on diagnostics (possibly in consultation with an affiliated dermatologist), comprehensive contact tracing for possible group treatment and assistance in developing a treatment plan together with identifying any potential inaccuracies in their prior treatments.

Furthermore, attention is paid to the impact on patients’ daily lives and possible psychological consequences of recurrent scabies symptoms when contacting the scabies clinic. Skin diseases such as scabies contribute to the burden of stigma and emotional distress and with that, have profound effects on the overall quality of life. Something which is recognized in patients by the nurses working at the scabies clinic. Young adults contacting the scabies clinic often describe an isolated lifestyle and feelings of hopelessness due to their condition, underscoring that scabies, beyond causing intense itching and other physical symptoms, also has serious effects on patients' daily lives and well-being.

These signs of considerable impact of recurrent scabies symptoms on young adults' daily lives along with a continuous influx of new patients to the scabies clinic, underline the importance to better understand this impact and describe the course of symptoms after treatment to improve scabies guidance and care in high-income and resource-rich countries.

Study objective

Primary objective 1:

- To understand how individuals with recurrent scabies symptoms experience the impact of scabies on their daily lives over time following a visit to the scabies clinic.

Primary objective 2:

- To understand how individuals with recurrent scabies symptoms experience their symptoms over time following a visit to the scabies clinic.

Secondary objectives:

1. To evaluate how individuals visiting the scabies clinic experience the care provided by the scabies clinic.
2. To evaluate how individuals visiting the scabies clinic adhere to the treatment advice provided by the nurses.
3. To evaluate how contacts experienced the care provided by the scabies clinic.
4. To evaluate how contacts of individuals who visited the scabies clinic adhered to the treatment advice provided by the nurses.

Study design

- Prospective study of individuals with recurrent scabies symptoms who visited the scabies clinic at the Public Health Service of Amsterdam for the first time between June 2024 and March 2025. Individuals received the PROMIS-29 Profile v2.1 and PROMIS Social Isolation 8a questionnaires, supplemented with questions on scabies symptoms, immediately after their visit (t0) and at four (t1), eight (t2), and twelve (t3) weeks post-visit. Demographic characteristics and evaluation of the care provided at the scabies clinic were asked immediately after the first visit (t0). Treatment adherence was assessed four weeks after (t1) the initial visit. Refer to the appendices (1-4) for the questionnaires.
- Contacts received questionnaires assessing scabies symptoms immediately after (t0) and six weeks after (t1) their initial contact with the scabies clinic. Demographic characteristics and evaluation of the care provided by the nurses from the scabies clinic were asked immediately after the first visit (t0). Treatment adherence was assessed six weeks after (t1) the initial contact with the clinic. Refer to the appendices (5-6) for the questionnaires.

Intervention

- Patients: 4 online questionnaires, which are sent at week 0, week 4, week 8 and week

12.
- Contacts: 2 online questionnaires, which are sent at week 0 and week 6. Questionnaires are validated PROMIS questionnaires supplemented with questions about the course of complaints and questions to evaluate the care provided by the GGD, which have been approved by the GGD research team.

Study burden and risks

The burden and risks of participation remain very limited for participants, while the potential for positive social impact is great. The study has been carefully designed to minimize the burden on participants as much as possible. There are four measurement moments for patients at which an online questionnaire can be easily completed via an invitation link. The questionnaires have been pre-tested on people who visited the consultation hour before the inclusion period and have been drawn up in consultation with senior researchers. In consultation with a privacy officer, a DPIA has been drawn up to limit the infringement of the privacy of participants to the minimum necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Dutch-speaking outpatients aged 18 up to and including 30 years old who were diagnosed with common scabies at the scabies clinic through clinical diagnosis and/or dermatoscopy, microscopy and/or PCR, starting a treatment with topical permethrin and/or oral ivermectin following their visit to the scabies clinic. To be eligible for an appointment at the scabies clinic patients need at least one previous consultation with a health professional for scabies and had undergone at least one (prescribed) treatment for scabies before.

Contacts who are eligible for preventive treatment as described in the scabies guidelines by the National Coordination of Infectious Disease Control (LCI), and start one following their contacts' diagnosis, were also included in the study, provided that they have been assessed and informed by the source- and contacttracing team of the GGD Amsterdam.

Exclusion criteria

Patients in whom no scabies was found during their consultation at the scabies clinic were excluded from participation in the study.

Patients found positive on scabies but visited the clinic already before inclusionperiod of the research were excluded from study.

Contacts that were eligible for preventive treatment but were not assessed by the GGD Amsterdam for various reasons, were excluded from participation in the study.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-06-2024
Enrollment:	60
Duration:	3 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Not available

Date:	25-04-2025
Application type:	First submission
Review commission:	Validatie nWMO registratie door CCMO

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
Research portal	NL-009933