# Effectiveness of a web-based educational, quality of life intervention in non-segmental vitiligo patients: a randomized controlled trial.

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In this study, we will conduct a randomized controlled pilot study to assess the effectiveness of the EQoL-intervention combined with standard of care versus standard of care alone.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Pigmentation disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON42778

**Source**
ToetsingOnline

**Brief title**
EQoL intervention in non-segmental vitiligo patients

### Condition

- Pigmentation disorders

**Synonym**
Non-segmental vitiligo

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** E-learning, Intervention, Quality of life, Vitiligo

## Outcome measures

### Primary outcome

Mean differences in emotion and functioning scores of the Skindex-29 between

baseline and 3 or 6 months in both study groups.

### Secondary outcome

Secondary outcome measures are improvement on self-efficacy, coping strategies,

feelings of stigmatisation and symptoms of depression and anxiety.

# Study description

### Background summary

Vitiligo is an acquired cutaneous condition associated with depigmented macules caused by destruction of melanocytes. Until this day there is no cure for vitiligo and most therapies show rather disappointing results. Furthermore, the quality of life is significantly impaired in vitiligo patients. Recent guidelines recommend psychological interventions in vitiligo patients, however no specific psychological therapeutic intervention could be recommended based on current evidence. The psychosocial difficulties should be addressed and psychological interventions can be beneficial in vitiligo patients.

### Study objective

In this study, we will conduct a randomized controlled pilot study to assess the effectiveness of the EQoL-intervention combined with standard of care versus standard of care alone.

### Study design

Prospective mono-centre observer-blinded randomized controlled trial.

### Intervention

E-learning Quality of Life (EQoL); a Dutch web-based, educational, HRQoL intervention for patients with a chronic skin disease. The EQoL will be combined with standard of care in the intervention group and will be compared to standard of care alone.

**Study burden and risks**

Subjects participating in the study will not experience any delay or disadvantage in the medical care of vitiligo as the standard of care is continued in both study groups. The treatment with the E-learning quality of life has a hypothetically very low chance on adverse events and other risks. However, patients need to invest a considerable amount of time in the E-learning and this could be a burden for some patients. However, the E-learning could substantially improve the quality of life. We consider the burden due to participation in this study is in proportion with the expected effect of the treatment.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

• Diagnosis of non-segmental vitiligo
• Patient visiting the NIPD during regular outpatient clinic visit and receives standard of care
• Skindex-29 emotions subscore of >= 35 and/or functioning subscores of >= 32 (moderate and severe impairment)
• Age of 18 years or older
• Patient is willing and able to give written consent

### Exclusion criteria

• No access to a computer with internet connection
• Mental and/or physical impairment that could obstruct participation in the study
• Psychiatric comorbidity (e.g. depression, anxiety disorders)
• Insufficient mastery of Dutch
• Participation in another study with HRQoL as primary outcome.
• Currently receiving psychological and/or psychiatric treatment.

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 29-02-2016 |

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|---|---|
| Enrollment: | 100 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 29-01-2016 |
| 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 | NL55633.018.15 |