# Translation, cross-cultural adaptation and validation of questionnaires for Turkish and Moroccan Dutch patients with mood, anxiety and/or somatoform disorders and a comparison between native Dutch and Turkish and Moroccan immigrant patients

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON41543

**Source**
ToetsingOnline

**Brief title**
Leiden Routine Outcome Monitoring Study for Moroccan and Turkish immigrants

### Condition

- Other condition
- Mood disorders and disturbances NEC

**Synonym**

affective symptoms, anxiety symptoms, mood, somatic symptoms

**Health condition**

angst- en somatoforme stoornissen

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Het onderzoek wordt gefinancierd door Rivierduinen.

## Intervention

**Keyword:** cross cultural comparison, medically unexplained somatic symptoms, mental health, transcultural psychiatry

## Outcome measures

**Primary outcome**

not applicable

**Secondary outcome**

not applicable

# Study description

**Background summary**

Many Turkish and Moroccan immigrants moved to the Netherlands in the 1960s and 1970s. They are currently forming the two largest ethnic groups in the Netherlands. A growing number of Turkish and Moroccan immigrants find their way to the mental health institutions, including Rivierduinen. However, these mental health institutions cannot offer accurate mental health care for the majority of the first generation Turkish and Moroccan immigrants, because the first generation immigrants often do not master the Dutch language.
Even for Turkish and Moroccan immigrants who do speak Dutch sufficiently it is difficult to complete a questionnaire, because current questionnaires are designed to measure symptoms of patients of Dutch ethnicity. This is not only due to the language barrier, but also due to cultural barriers. **

Mental health care institutions have the obligation to ensure high quality care for all patients. It starts with identifying the exact nature and severity of the symptoms. To offer high quality care it is essential to both translate and culturally adapt questionnaires to the Moroccan Arabic, Tarifit and Turkish language. Furthermore, translated and cross cultural adapted questionnaires are essential to adequately compare immigrants with the native population.

## Study objective

Our aim is to make ROM suitable for patients of Moroccan or Turkish origin. In order to achieve this, necessary steps need to be taken: (1) translate and cross cultural adapt ROM questionnaires; (2) validate the translated questionnaires; and (3) compare the results of the questionnaires obtained from patients with different ethnic backgrounds (native Dutch, Moroccan, Turkish).

## Study design

The process of translation and cross-cultural adaptation will follow internationally accepted guidelines and consists of six steps: (1) translation; (2) synthesis of translations; (3) backwards translation; (4) Review Committee; (5) pilot study; and (6) evaluation of psychometric properties of the adapted questionnaire. **
A pilot study will ensure the questionnaires are properly translated and culturally adapted. Interviews with a small number of patients and focus groups with healthy patients will take place to evaluate the comprehension and cultural relevance of the translated versions of the questionnaires. After this evaluation the psychometric properties of the translated instruments will be tested by assessing the results of Moroccan and Turkish patients with MAS disorders and healthy Moroccan and Turkish participants. Internal consistency and several aspects of validity (concurrent, discriminant, cross-cultural) will be investigated. In addition, the cut-off scores of the translated instruments for both the Moroccan and Turkish patients will be established.
**As part of sub-projects II and III, the participants will complete the standard ROM procedure, supplemented by additional instruments. The ROM data of native Dutch patients will be compared with ROM data from patients of Moroccan or Turkish origin throughout sub-projects II and III.

## Study burden and risks

There are no burdens or risks for participants during this study. ROM measurements are part of the standard diagnosis and treatment procedure of participating institutions and therefore the burden for patients participating in this study is minimal. Obtained data will be encrypted to protect the privacy of participants.**
Patients will be informed about the study and asked to sign an informed consent before participating. They will be given one or two weeks to consider

participating in this study. Participants are also informed that they can withdraw from participation any time and for any reason during the study without affect on future treatment at Rivierduinen, RIAGG Rijnmond or i-psy Amsterdam.

# 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

For the pilot- and validation study:*
Patients and healthy participants eligible for this study are: (1) those who have moderate mood, anxiety and/or somatoform (MAS) symptoms (applies only to patients); (2) those who are born in Turkey or Morocco or have at least one parent or a grandparent born in Turkey or Morocco; (3) between 18 and 65 years old; and (4) proficient in the Moroccan Arabic, Tarifit or Turkish language.**

All Moroccan and Turkish patients who are referred for treatment of mood, anxiety and/or somatoform (MAS) symptoms to Rivierduinen, RIAGG Rijdmond or i-psy Amsterdam will be approached to participate in this research, whether or not they are diagnosed with a MAS disorder.** ;For focus groups:*
Healthy participants eligible for this study are: (1) those who are born in Turkey or Morocco or have at least one parent or a grandparent born in Turkey or Morocco; (2) between 18 and 65 years old; (3) proficient in the Moroccan Arabic, Tarifit or Turkish language; and (4) proficient in the Dutch language.;For comparative study:*
Patients eligible for this study are: (1) between 18 and 65 years old; (2) have a Dutch, Moroccan or Turkish ethnic background; (3) proficient in the Dutch, the Moroccan Arabic, Tarifit, or Turkish language; and (4) referred for MAS symptoms to Rivierduinen, RIAGG Rijnmond, or i-psy Amsterdam, whether or not they are diagnosed with a MAS disorder.

### Exclusion criteria

For the pilot- and validation study*:
The following patients are excluded: (1) patients who have insufficient proficiency in the Moroccan Arabic, Tarifit or Turkish language; (2) patients with a primary psychiatric disorder other than a mood, anxiety and/or somatoform disorder; (3) with severe psychiatric problems; (4) patients with suicidal ideations; or (5) patients who display major impairment in social functioning.;The following healthy participants are excluded: who have insufficient proficiency in the Moroccan Arabic, Tarifit or Turkish language.;For focus groups:
There are no exclusion criteria.**;For comparative research:*
The following patients are excluded: (1) Patients with a primary psychiatric disorder other than a mood, anxiety and/or somatoform disorder; (2) patients with severe psychiatric problems; (3) patients with suicidal ideations; or (4) patients who display major impairment in social functioning.

## Study design

### Design

**Study type:** Observational non invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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| Recruitment status: | Recruiting |

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| Start date (anticipated): | 15-08-2012 |
| Enrollment: | 570 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 23-04-2012 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

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| Approved WMO Date: | 07-05-2014 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

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| Approved WMO Date: | 01-07-2015 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

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| Approved WMO Date: | 20-07-2015 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

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| Approved WMO Date: | 09-12-2015 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

# 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 | NL39051.058.11 |