

# The Q in the QALY: exploring new methods

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The aim of this proposal is to investigate the potential use and value of experienced utility, as measured by the ESM and the DRM, in the economic evaluation of health care. Research question: 1. What are the differences between the utilities measured...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON38213

### Source

ToetsingOnline

### Brief title

MOMENTUM

### Condition

- Other condition
- Anxiety disorders and symptoms
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

### Synonym

Anxiety or depressive complaints, atherosclerose and venous insufficiency, tinnitus

### Health condition

Tinnitus

### Research involving

Human

## Sponsors and support

**Primary sponsor:** KEMTA

**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** decision utility, experienced utility, quality of life, well-being

## Outcome measures

### Primary outcome

1. Quality of Life (measured with a Visual Analogue Scale, EuroQol, Experience Sampling method, Day Reconstruction Method, en Time Trade-Off)

### Secondary outcome

2. Life satisfaction measured with the Satisfaction with Life Scale
3. Subject characteristics and demographics
4. Respondent burden for each method
5. Severity of anxiety and depression is measured with the Hospital Anxiety and Depression Rating Scale (HADS).
6. Optimism is measured with the Life Orientation Test (LOT-r).

## Study description

### Background summary

Over the last decades the use of utilities in economic evaluations of health care programmes has received some serious critique. Criticism was mainly aimed on the fact that utilities are based on preferences for hypothetical situations (decision utilities), and not on real experiences. It was suggested to use utilities based on experienced well-being (experienced utility) should be used in stead of utilities based on preferences in economic evaluation of health care programmes. New state-of-the-art methods to assess experienced utility are the Experience Sampling Method (ESM) and the Day Reconstruction Method (DRM). However, empirical evidence regarding the use of these methods to assess

experienced utility as outcome in the economic evaluation of health care is virtually lacking.

## **Study objective**

The aim of this proposal is to investigate the potential use and value of experienced utility, as measured by the ESM and the DRM, in the economic evaluation of health care.

Research question:

1. What are the differences between the utilities measured using traditional preference based measures (decision utility), and using the new state-of-art methods ESM and DRM (experienced utility) in a range of populations with differing conditions and severity of health state?

## **Study design**

Observational study

## **Study burden and risks**

Subjects are invited to the health care setting of their choice (MUMC+ or Adelante). The first visit will take half a day, the second visit will take two hours maximum. All subjects receive an electronic device that will signal them 10 times a day (random) for 6 days, to answer questions on their feelings, thoughts and activities at that moment. Subjects are able to turn of the sound of the device at moments this is desirable. A lot of studies using the ESM have been done at the Maastricht University. Drop-out rates are comparable to other studies. These findings indicate that subjects do not experience this as burdening.

There are no risks linked to this study.

## **Contacts**

### **Public**

Selecteer

Postbus 5800  
6202 AZ Maastricht  
NL

### **Scientific**

Selecteer

Postbus 5800  
6202 AZ Maastricht  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

With regard to patients with tinnitus:

- Referral to an audiological centre because of tinnitus complaints;
- 18 years or older;With regard to the patients with anxiety complaints
- Anxiety or depressive complaints,
- A score >8 points at the anxiety or depression scale on the HADS or a total score of >12
- 18 years or older;With regard to the patients with atherosclerosis or venous insufficiency:
- Diagnoses of venous insufficiency or atherosclerosis;
- In case of a leg amputation: finished clinical rehabilitation at Adelante, centre of expertise in rehabilitation and audiology
- 18 years or older.;Healthy population:
- 18 years or older.

### **Exclusion criteria**

With regard to patients with tinnitus:

- Organic cause of tinnitus
- Not able to read in Dutch;
- Not able to handle the ESM device because of impaired motor skills.;With regard to the patients with anxiety or depressive complaints:
- Not able to read in Dutch;
- Not able to handle the ESM device because of impaired motor skills.;With regard to the patients that underwent a leg amputation:
- Not able to read in Dutch;

- Not able to handle the ESM device because of impaired motor skills.;With regard to the healthy population :
- Not able to read in Dutch;
- Not able to handle the ESM device because of impaired motor skills.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 07-09-2010

Enrollment: 184

Type: Actual

## Ethics review

Approved WMO

Date: 05-05-2010

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 30-07-2010

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 24-10-2011

Application type: Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	24-02-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

## 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
ClinicalTrials.gov	NCT01085409
CCMO	NL31422.068.10