# *The Experience Sampling Method (ESM): Validation of a newly developed real-time Patient-Reported Outcome Measure (PROM) and its Evaluation of triggers for Functional Dyspepsia*

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON48356

**Source**
ToetsingOnline

**Brief title**
MEASuRE-D

### Condition

- Gastrointestinal disorders

**Synonym**
Functional dyspepsia, unexplainable stomach complaints

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Experience Sampling Method (ESM), Functional Dyspepsia, Patient Reported Outcome Measurement (PROM)

## Outcome measures

### Primary outcome

The main study outcome comprehends the psychometric properties of the PROM for

symptom assessment in functional dyspepsia.

### Secondary outcome

Secondary outcomes are associations between the presence of psychosocial and

environmental factors (e.g. as measured by the PROM) and an increase in ESM

score for gastrointestinal symptoms from one time point (t-1) to the next (t).

# Study description

### Background summary

Reliable patient reported outcome measures (PROM*s) for symptom assessment in functional dyspepsia (FD) are essential in order to evaluate dyspeptic symptoms, identify potential symptom triggers and optimize therapeutic strategies, since biological markers are unavailable. Currently used symptom assessment methods, i.e. end-of-day or end-of-week questionnaires, have considerable limitations. The Experience Sampling Method (ESM), an electronic questioning method characterized by random and repeated, momentary assessments in the subject*s current state and environment, might overcome these limitations. The aim of this study is to assess the validity and reliability of an FD-specific electronic patient-reported outcome measure (ePRO), based on the Experience Sampling Method-principle, for symptom assessment and identification of symptom triggers in patients with functional dyspepsia.

### Study objective

The aim of this study is to assess the validity and reliability of an FD-specific electronic patient-reported outcome measure (ePRO), based on the Experience Sampling Method-principle, for symptom assessment and identification of symptom triggers in patients with functional dyspepsia. In order to measur this, internal consistency, test-retest reliability, concurrent validity and the accuracy to differentiate between dyspeptic patients and healthy controls of the developed ePRO will be assessed. In addition, to objectify specific triggers for the onset of gastrointestinal symptoms in dyspepsia, using the FD-specific ESM tool.

**Study design**

This is a single center, prospective, cross-sectional study performed in the Maastricht University Medical Center (MUMC+).

**Study burden and risks**

The burden that is associated with participation in this study comprises completing the PROM questionnaire several times a day, which interrupts daily life due to its random character. Furthermore, the burden is limited to completing an end-of-day symptom diary and several end-of-week questionnaires. However, participating does not bring along important risks. No direct benefits are expected, since the study does not contain any interventions.

# 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

Inclusion criteria for patients with functional dyspepsia
* A diagnosis of functional dyspepsia according to Rome IV criteria (2):
- One or more of the following:
- Bothersome postprandial fullness
- Bothersome early satiation
- Bothersome epigastric pain
- Bothersome epigastric burning
AND
- No evidence of structural disease (including at upper endoscopy) that is likely to explain the symptoms.
- Criteria fulfilled for the last 3 months with symptom onset at least 6 months before diagnosis.
* Age between 18 and 75 years;
* Ability to understand and speak the Dutch language;
* Ability to understand how to utilize the ESM tool.

Inclusion criteria for healthy volunteers
* Age between 18 and 75 years
* Ability to understand and speak the Dutch language
* Ability to understand how to utilize the ESM tool.

## Exclusion criteria

Exclusion criteria for patients with functional dyspepsia
* Any organic explanation for the gastrointestinal complaints;
* Initiation of regularly used medication from one month before inclusion until the end of study participation;
* A history of upper digestive surgery influencing end points
* A history of radiation therapy of the abdomen
* Pregnancy
Exclusion criteria for healthy volunteers

* Current diagnosis of any gastrointestinal disorder
* Current gastrointestinal symptoms suiting the ROME IV criteria for FD
* Initiation of regularly used medication from one month before inclusion until the end of study participation
* Pregnancy

# 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: | Recruitment stopped |
| Start date (anticipated): | 29-05-2020 |
| Enrollment: | 72 |
| Type: | Actual |

## Medical products/devices used

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| Generic name: | Mobile application |
| Registration: | No |

# Ethics review

Approved WMO

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| Date: | 23-12-2019 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC 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 |
| --- | --- |
| CCMO | NL71810.068.19 |