# The Effect of the LEFT Smartwatch App as Sleep Positional Therapy for Nocturnal Gastroesophageal Reflux Symptoms.

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The main objectives of the study are to investigate if sleep positional therapy, using the LEFT smartwatch app, reduces nocturnal gastroesophageal reflux symptoms and can train patients to avoid sleeping in right side position.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal motility and defaecation conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53443

**Source**
ToetsingOnline

**Brief title**
LEFT-APP

### Condition

- Gastrointestinal motility and defaecation conditions

**Synonym**
Gastroesophageal reflux disease, heartburn

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** gastroesophageal, positional, reflux, therapy

## Outcome measures

### Primary outcome

Relative change in total nocturnal gastroesophageal reflux symptoms measured by N-GSSIQ.

### Secondary outcome

• % responders as treatment success, defined as subjects with a minimal 50% reduction in nocturnal gastroesophageal reflux symptoms measured by N-GSSIQ

• Change in total N-GSSIQ.

• Change in sleep position (supine, prone or left or right lateral decubitus).

• Change in nocturnal reflux free nights measured by daily symptom diary.

• Change in reflux symptoms measured by RDQ

• Change in sleep quality and effect on daily (working) life measured by PSQI and FOSQ-10.

# Study description

### Background summary

Gastroesophageal reflux disease (GERD) is one of the most common gastro-intestinal disorders and approximately 50-80% of the GERD patients experience nocturnal gastroesophageal reflux symptoms. Symptoms at night have a negative impact on sleep quality, daytime functioning and quality of life. When sleeping in left lateral decubitus position, the stomach is positioned below the esophagus, resulting in less reflux compared to sleeping in right lateral decubitus position. Sleep positional therapy, using an electronic wearable device (the LEFT, an adaptation of the SNOOOR device designed to stop snoring), which gently vibrates when sleeping in the right lateral decubitus position, promotes sleeping in the left lateral decubitus position and effectively

alleviates nocturnal gastroesophageal reflux symptoms. The aim of our study is to investigate if sleep positional therapy, using the LEFT smartwatch app, can reduce nocturnal gastroesophageal reflux symptoms and increase sleeping in the left lateral decubitus position.

## Study objective

The main objectives of the study are to investigate if sleep positional therapy, using the LEFT smartwatch app, reduces nocturnal gastroesophageal reflux symptoms and can train patients to avoid sleeping in right side position.

## Study design

Single center, prospective, single-arm, non-blinded, interventional pilot study

## Intervention

The SNOOOR device is worn on the upper chest and is designed to measure sleep position and stimulate to avoid the supine sleeping position in subjects with positional snoring. It is normally programmed to vibrate when it measures that the subject is sleeping on the back, so it stimulates the subject to turn to a lateral sleep position in order to stop positional snoring. The LEFT is a small wearable device is the adapted version of the SNOOOR and gently vibrates when the body is in the right lateral decubitus position. This will train subjects to sleep in left lateral decubitus position, the position where the stomach is placed below the esophagus. The LEFT wearable device has been proven to reduce nocturnal reflux symptoms.

The LEFT smartwatch app is an app on the Apple Watch that works in the same way as the LEFT wearable device. It will gently vibrates in an annoying way when the body is in the right lateral decubitus position. All subjects will receive treatment. In the current study, the SNOOOR wearable device will only be used as a tracker device. The vibration option will be inactive. In this way, the device can be used to accurately measure the sleeping body position and these results can be compared to the results of the LEFT smartwatch app.

## Study burden and risks

The Apple Watch is a clinically validated and CE marked and a medical certified device. The risks associated with the use of the Apple Watch, like local skin rash on the wrist, are the same as would be the case if the subject uses the device outside the study context. An additional risk related to the use of the LEFT smartwatch app, is the disturbed sleep due to vibrations of the Apple Watch that will trigger changing position. However, this will only be at the start of the treatment, because the subject will be trained to avoid sleeping

in the right lateral decubitus position. No irreversible injury or damage to health is possible related to the use of the LEFT smartwatch app or Apple Watch.

Our study team has previously shown that sleep positional therapy, using an electronic wearable device (the LEFT wearable device), was effective for nocturnal reflux complaints without any adverse events. Other studies with sleep positional therapy for the indication obstructive sleep apnea have reported that sleep can be disturbed because of the vibrations of the device and sometimes neck or shoulder pain is reported, but no more adverse events have occurred.

Subjects have to come to the (online) screening visit and have to fill in questionnaires. Data of the LEFT wearable device and the Apple Watch will be extracted from the device. No additional tests or treatments are required. All subjects receive the Apple Watch for sleep positional therapy and there will be no placebo group. So, the burden of participate is low compared to the possible benefits of the sleep positional therapy.

## 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

• Written informed consent.
• Both male and female patients will be included.
• Age 18 years or older
• Symptoms of heartburn and/or acid regurgitation during at least three nights a week.
• A total reflux symptom score >=8 (measured through the GERDQ questionnaire score).
• Able to wear the Apple Watch on the left wrist.

## Exclusion criteria

• PPIs non-responders.
• Nightshift workers
• Surgery of the esophagus or stomach.
• Regular use of sleep medication (benzodiazepines) or medication which affect gastrointestinal motility (e.g. prokinetics or opioids) that cannot be stopped during the duration of the trial.
• Severe and clinically unstable concomitant disease (e.g. liver, cardiovascular or lung disease, neurological or psychiatric disorders, cancer or AIDS and other endocrine disorders).
• Patients with obstructive sleep apnea or esophageal motility disorder.
• Pregnant or lactating women.

# Study design

## Design

| | |
|---|---|
| Study phase: | 2 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

| | |
|---|---|
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 03-10-2023 |
| Enrollment: | 18 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | LEFT smartwatch app |
| Registration: | No |

## Ethics review

Approved WMO

| | |
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| Date: | 20-07-2023 |
| 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 | NL83321.018.23 |