

# The pre-post differences in nutritional intake, information needs, motivation, lifestyle, clinical outcomes and fatigue symptoms of MASLD patients, and their engagement and adherence to the serious game: a pilot study.

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To determine the effect size of the difference in nutritional intake (carbohydrates, calories, fiber) of MASLD patients before and after playing the serious game. In addition, information provision, information needs, physical activity, response...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Hepatic and hepatobiliary disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON57363

### Source

ToetsingOnline

### Brief title

Pilot study MASLD game

### Condition

- Hepatic and hepatobiliary disorders

### Synonym

MASLD - fatty liver disease

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente

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

## Intervention

**Keyword:** App, Information, Lifestyle, MASLD

## Outcome measures

### Primary outcome

Primary outcome measure is the effect size of the difference in calorie, carbohydrate and fiber intake before and after using the serious game.

### Secondary outcome

Secondary outcome measures include information provision, information needs, response efficacy, self-efficacy, motivation to change lifestyle, exercise according to exercise norm, clinical outcomes (such as BMI and liver enzymes) and fatigue. Users' experiences with the game, actual game use and study procedures will also be evaluated during the study.

## Study description

### Background summary

Although lifestyle modification is currently the only remedy for improving metabolic dysfunction-associated steatotic liver disease (MASLD), in practice patients find it difficult to change lifestyle and maintain the new behaviors. A lack of knowledge about MASLD among patients plays an important role in this. As does the lack of time among healthcare providers to invest sufficient time in knowledge transfer and patient empowerment. eHealth offers the opportunity to share reliable information with a large group of patients in the patient's own time and in their own home environment. A serious game is an example of this. Serious games have shown to be effective in supporting behavior change

and factors related to it, such as increasing awareness, knowledge and motivation. Therefore, a serious game has been developed for MASLD patients. The preparations for developing the serious game consisted of a nationwide survey of 450 MASLD patients. This revealed, among other things, that patients would like to receive broad information about MASLD. Regarding eHealth, patients again indicated a need for information on MASLD, practical examples and referral to relevant websites/apps. The input from this survey was included in the development of the serious game.

## **Study objective**

To determine the effect size of the difference in nutritional intake (carbohydrates, calories, fiber) of MASLD patients before and after playing the serious game. In addition, information provision, information needs, physical activity, response efficacy, self-efficacy, motivation, clinical outcomes (such as BMI and liver values) and fatigue before and after using the serious game will be examined. Users' experiences with the game, actual game use and study procedures will also be evaluated during the study.

## **Study design**

Pilot study consisting of three aspects: 1) pre-post test, 2) in-depth interviews and 3) analysis of log data.

## **Intervention**

Each participant uses the serious game for 6 weeks in addition to usual care. The serious game consists of 5 levels with quiz questions and a nutrition game.

## **Study burden and risks**

The study requires some effort from the participant in the form of using the app (i.e. playing the quizzes), three 24h recalls and completing three questionnaires and possibly an interview. No physical exercise is required and the questionnaires do not contain burdensome questions. Also, the participant does not need to visit the hospital more often and no additional blood tests are performed. Participation in the study can be beneficial as the serious game can give the participant insight into his/her condition and also explain what possibilities there are to improve the condition by adapting to a healthy lifestyle. There are no risks associated with the use of the serious game itself.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Dutch adults diagnosed with MASLD in accordance with the current guideline (FMS, 2024).
- Age 18-70 years
- Referred to the MDL outpatient clinic of MST Enschede due to MASLD.
- Patients with and without MASLD-related liver cirrhosis.
- Proficiency in Dutch

### Exclusion criteria

- Compensated liver cirrhosis
- Expected survival < 6 months

- Diabetes mellitus type I or II and medication use (except monotherapy with metformin).
- Cognitive impairment
- Severe visual impairment that makes reading text on a smartphone difficult.
- Not having access to a recently updated Android (version 13) or Apple (version 16) smartphone and mobile internet
- Having no or insufficient experience in using a smartphone.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-04-2025

Enrollment: 32

Type: Anticipated

### Medical products/devices used

Registration: No

## Ethics review

Approved WMO

Date: 10-03-2025

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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	NL87269.100.24