The effect of the Happi Liver mobile health application on the reduction of non-alcoholic fatty liver disease

Published: 17-02-2022
Last updated: 05-04-2024

The purpose of this study is to determine the effect of using the Happi Liver application on the course of the liver disease non-alcoholic fatty liver disease (NAFLD).

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON52163

Source
ToetsingOnline

Brief title
THETA

Condition

- Hepatic and hepatobiliary disorders
- Appetite and general nutritional disorders

Synonym
fatty liver, non-alcoholic fatty liver disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Maag-Lever-Darm stichting Nederland

Intervention

Keyword: lifestyle, mobile application, Non-alcoholic fatty liver disease

Outcome measures

Primary outcome

Main study parameter/endpoint: a *5% reduction in weight measured in kg.

Secondary outcome

Secondary study parameters/endpoints:

1) Reduction of NAFLD (as measured by the FibroScan®).

2) Acceptability and satisfaction of the Happi liver mobile application.

3) An increase in knowledge concerning NAFLD.

4) Quality of life improvement.

Study description

Background summary

Non-alcoholic fatty liver disease (NAFLD) is the most important liver disease in Western society. The disease is mainly caused by Western lifestyles leading to overweight and obesity (50% of the Dutch adult population is overweight and 15% of these are obese). Fatty liver disease is an accumulation of fat in the liver cells. Excess fat prevents the liver from functioning properly and disturbs the metabolism, among other things. The cell packed with fat cannot process the substances absorbed from the intestine as well as it should. This leads to inflammation in the liver but also in the entire body. Fats can no longer be packed and processed properly, which plays a role in arteriosclerosis. If fatty liver disease exists for a long time, even without complaints, a chronic inflammation of the liver can develop. This can lead to scar tissue, which is an increased risk of developing cirrhosis. In addition, the inflammation of the liver can also lead to the development or worsening of diabetes, cardiovascular disease and cancer.
To date, no drugs have been registered for the treatment of fatty liver. Therefore, treatment focuses mainly on lifestyle changes, as this is the basis from which fatty liver develops. Previous research has shown that a reduction in weight is effective: 3 to 5% reduces fatty liver, 7% reduces inflammation,

and 10% reduces scar tissue. Lifestyle modification is thus the first and most important step in stopping the development of liver cirrhosis and other complications. However, lifestyle changes are difficult and often people fall back into their old, unhealthy habits. Support is therefore essential and the use of a smartphone application (app) could be a solution.

Study objective

The purpose of this study is to determine the effect of using the Happi Liver application on the course of the liver disease non-alcoholic fatty liver disease (NAFLD).

Study design

Eligible subjects already screened for NAFLD in previous studies will be asked to participate in the study. After signing of the IFC they will be randomized in either the control group that will receive standard of care or the intervention group that will use the Happi liver mobile application. The Castor EDC program will perform the randomization. Castor uses a validated variable block randomization model that ensures true randomness during allocation. The follow-up time for both control and app-group is one year and both groups are monitored parallel.

Intervention

The intervention in the app group consists of asking people to use this application during their follow-up time.

Study burden and risks

Participants are required to come to MUMC+ once at inclusion, 6 and 12 months and at 3 and 9 month a teleconsultation to monitor weight loss progression (0, 3, 6, 9 and 12m). For the first visit, anthropometric data collection, hand grip strength, blood collection, and FibroScan® with CAPTM will be performed during the study visit after signing the informed consent. In contrast to the study visits at inclusion and 12 months, the study visit in month 6 will not include a blood collection. The other visits will be planned with the participant. Participants are also asked to fill out different questionnaires.
If the participant is included in the app group than the questionnaires can be filled out in the app. The participants of the control group can fill out the questionnaires together with the researcher at the appointments or during the teleconsultation, or fill out the questionnaires via an online survey.
No side effects of the investigations are expected, apart from a small bruise of taking the blood samples. Four tubes (15 ml) will be collected for research purposes.
The time burden associated with participating in the research is: 90 minutes

per study visit. The questionnaires will take around 45 minutes to fill out. Leading to a total time burden over one year of 5,5 hours.
The participant will benefit through this study on receiving information on how to lose weight and in the intervention group more intensive monitoring and help with losing weight. When this weight loss of *5% is achieved, liver steatosis is expected to be reduced. However not only the risk of NAFLD progression diminishes, also the risk of developing extra-hepatic complications like cardiovascular diseases, type 2 diabetes mellitus and extra-hepatic malignancies.

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

• Aged 18 years or older

• Diagnosed with NAFLD by CAPTM (>215 dB/m) as measured by the FibroScan® device and VCTE <=7.2 kPa for the XL probe or <=7.9 kPa for the M-probe
• Able to give informed consent in Dutch
• Able to understand the information sheet and willing to comply with the study protocol
• For the mobile app: a smartphone with a software version of at least iOS 13 or Android 7.0 Nougat

Exclusion criteria

• Not proficient in the Dutch language
• Already in a weight-loss/management project included (e.g., weight watchers, dietitian guidance).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2022
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-02-2022
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	NL78245.068.22