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The effectiveness of high-protein meal replacements and digital coaching in fatty liver disease

Submission date 18/07/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/07/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/07/2023	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Non-alcoholic fatty liver disease is a serious disease that can increase the risk of death due to heart disease and can progress to more severe liver conditions. The aim of this study is to evaluate the effects and safety of mobile apps using high-protein partial meal replacements with digital coaching to improve liver function.

Who can participate?
Patients aged between 19 and 65 with nonalcoholic fatty liver disease

What does the study involve?
Participants will be randomly assigned to one of two groups: the intervention group, which receives immediate intervention, or the control group, which receives delayed intervention after 1 month. For 1 month, the intervention group will receive partial meal replacements with commercially available high-protein dietary replacement regimen and digital online lifestyle consultation through an app. The control group will receive usual care for 1 month then will receive the intervention after 1 month.

What are the possible benefits and risks of participating?
The partial dietary replacement therapy aims to create a deficit of about 500 calories. This can be carried out without significant risks for most individuals, although mild side effects related to weight loss may occur. These can include constipation, dizziness, hair loss, and cold-like symptoms, which are typically transient and mild. Additionally, individual allergic reactions may occur following the consumption of the dietary replacement.

Where is the study run from?
Bumin Hospital (South Korea)

When is the study starting and how long is it expected to run for?
June 2023 to December 2023

Who is funding the study?
Korean National IT Industry Promotion Agency (South Korea)

Who is the main contact?
Ju Young Kim, ceo@bionutrion.kr

Contact information

Type(s)
Principal investigator

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Study information

Scientific Title
Efficacy of high-protein meal replacements and digital coaching on nonalcoholic steatohepatitis: a stepped wedge randomized controlled trial

Study objectives
Mobile lifestyle intervention combined with high protein meal replacements will improve nonalcoholic steatohepatitis among patients with obesity

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/07/2023, Institutional Review Board of Bumin Hospital (389, Gonghang-daero, Gangseo-gu, Seoul, 07590, Korea, South; +82 (0)2 2620 0242; ranalee@bumin.co.kr), ref: BMH2023-06-017

Primary study design
Interventional

Study design
Stepped wedge randomized controlled trial

Study type(s)

Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Nonalcoholic steatohepatitis

Interventions
1. High-protein meal replacements at dinner. The meal replacements are commercially available, consisting of 150 kcal, 21g of protein, 14g of carbohydrates, and 1g of fat. The researchers recommend meal replacements mixed with 200 ml of low-fat milk.
2. Dr Coach App. Self-monitoring of weight, meal recordings and exercise will be done through a mobile app and one-on-one behavioral coaching with specialized dietitians or nurses will be provided through a mobile app.

Randomization stratified by gender and BMI group (≥30 kg/m² vs <30 kg/m²) will be generated using a random number generator by the study coordinator. Participants will be randomly assigned to one of two groups: the intervention group, which receives immediate intervention, or the control group, which receives delayed intervention after 1 month. For 1 month, the intervention group will receive partial meal replacements with commercially available high-protein dietary replacement regimen and digital online lifestyle consultation through an app. The control group will receive usual care for 1 month then will receive the same intervention after 1 month.

Intervention Type
Behavioural

Primary outcome(s)
Liver function tests including alanine transferase (ALT) measured using the NADH-UV method at baseline and 4 weeks

Key secondary outcome(s)
1. Height is measured on an electronic scale at baseline
2. Weight and body composition assessment using bioelectrical impedance analysis at baseline and 4 weeks
3. Waist circumference is measured with a measuring tape at the midline between the lowest rib margin and the iliac crest by the same personnel at baseline and 4 weeks
4. Blood pressure is measured with an electronic blood pressure meter at baseline and 4 weeks
5. Fasting blood glucose level measured using the hexokinase method at baseline and 4 weeks
6. Total cholesterol, high-density lipoprotein cholesterol measured using homogeneous enzymatic assays and triglycerides using a glycerol-3-phosphate oxidase peroxide method at baseline and 4 weeks
7. Glycated hemoglobin measured using a Bio-Rad Variant ll Turbo high-performance liquid chromatography analyser at baseline
8. Blood urea nitrogen measured using urease/glutamate dehydrogenase methods at baseline
9. Creatinine measured using Jaffe's kinetic method at baseline

Completion date
31/12/2023

Eligibility

Key inclusion criteria

1. Adults aged 19 to 65 years
2. Obese with a body mass index of 25 kg/m² or higher
3. Ultrasonically observed fatty liver within 1 month of evaluation
4. Alanine transferase level between 40 and 200 IU/L
5. AST/ALT ratio <1

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Body mass index below 25 kg/m²
2. Hepatitis B/C is confirmed in the medical examination or has a history of viral hepatitis
3. Meaningful alcohol consumption (140 g per week for women and 210 g for men)
4. Drug-induced fatty liver and toxic hepatitis (statin, steroid, amiodarone, rheumatoid arthritis, tamoxifen, and those who take health supplements containing biopharmaceuticals/han drugs) (*However, it can be registered during stable doses within at least 12 weeks)
5. Those who are unable to control their diet or exercise due to severe heart, lung, and underlying diseases (heart failure, ischemic heart disease, third-degree atrioventricular block, chronic obstructive pulmonary disease)
6. A person who is unable to control his/her diet or exercise due to a serious mental illness
7. Oral hemolytic drugs or insulin treatments for diabetes (if diagnosed with diabetes but determined to be treatable through lifestyle modification without drug treatment, registration can be made at the researcher's decision)
8. Pregnancy

Date of first enrolment
24/07/2023

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
Korea, South

Study participating centre
Seoul Bumin Hospital
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07590

Sponsor information

Organisation
Bionutrion

Funder(s)

Funder type
Government

Funder Name
Korean National IT Industry Promotion Agency

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Ju Young Kim (ceo@bionutrion.kr)

IPD sharing plan summary
Stored in non-publicly available repository, Available on request