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Long-term effects of time-restricted eating on liver health in people with metabolic fatty liver disease

Submission date
20/01/2026

Recruitment status
No longer recruiting

Registration date
26/01/2026

Overall study status
Completed

Last Edited
19/11/2026

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Fatty liver disease related to metabolic problems such as obesity and diabetes is common and can progress to liver damage and scarring. Lifestyle changes are recommended, but it is unclear which approaches lead to sustained long-term improvements in liver function. This study aims to determine whether time-restricted eating (limiting the daily eating window) leads to long-term improvements in liver fat, liver stiffness, and metabolic health compared with other commonly used lifestyle strategies.

Who can participate?
Adults aged 18–65 years diagnosed with metabolic dysfunction–associated steatotic liver disease or metabolic dysfunction–associated steatohepatitis, without other causes of chronic liver disease.

What does the study involve?
Participants receive standard lifestyle counselling and are followed over time as part of routine clinical care. Some participants choose to follow time-restricted eating, while others follow different dietary, pharmacologic, or exercise-based approaches. Liver health, blood tests, and body measurements are assessed at baseline and during follow-up using non-invasive methods.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in metabolic health and liver-related outcomes. Risks are minimal and include temporary hunger, fatigue, or digestive symptoms related to lifestyle changes, as well as minor discomfort from routine blood sampling and non-invasive liver assessments.

Where is the study run from?
Prince Sattam Bin Abdulaziz University Hospital (Saudi Arabia)

When is the study starting, and how long is it expected to run for?
October 2021 to March 2024

Who is funding the study?
Prince Sattam bin Abdulaziz University (Saudi Arabia)

Who is the main contact?
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Study information

Scientific Title
Durable improvement of hepatic steatosis and fibrosis with time-restricted eating in metabolic dysfunction–associated steatotic liver disease and metabolic dysfunction–associated steatohepatitis: a long-term comparative observational study

Study objectives
The primary objective of this study is to evaluate the long-term effects of time-restricted eating implemented as intermittent fasting on hepatic steatosis and fibrosis in adults with metabolic dysfunction–associated steatotic liver disease (MASLD) and metabolic dysfunction–associated steatohepatitis (MASH).

Secondary objectives are to compare the hepatic, metabolic, and anthropometric outcomes of intermittent fasting with other commonly used real-world lifestyle strategies, including calorie-restricted diets, pharmacologic therapy with Orlistat, and exercise without dietary restriction, and to assess the durability of these effects over extended follow-up using non-invasive imaging and serum-based fibrosis markers.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/03/2021, Prince Sattam Bin Abdulaziz University Review Board (Abdullah Bin Amer Street, Kharj, 16278, Saudi Arabia; +966 (0)538276418; a.m.asiri@psau.edu.sa), ref: IRB #PSAU-MED-2021/09

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Metabolic dysfunction–associated steatotic liver disease (MASLD) and metabolic dysfunction–associated steatohepatitis (MASH), hepatic steatosis, liver fibrosis, metabolic dysfunction

Interventions
This is a prospective observational cohort study. Adults with metabolic dysfunction–associated steatotic liver disease (MASLD) or metabolic dysfunction–associated steatohepatitis (MASH) were enrolled following eligibility screening and informed consent.

At enrolment, participants were allocated to different lifestyle or pharmacologic management strategies as part of routine clinical care, including time-restricted eating (intermittent fasting), calorie-restricted diets, pharmacologic therapy, or exercise counselling. The study protocol mandated no intervention, and adherence was voluntary.

Participants underwent baseline clinical, biochemical, and non-invasive hepatic assessments and were followed at regular intervals, with a total observation and follow-up duration of up to 48 months, after which participation ended.

Intervention Type
Mixed

Primary outcome(s)
1. Hepatic steatosis measured using controlled attenuation parameter (CAP) measured by transient elastography (FibroScan®) at baseline and longitudinal follow-up up to 48 months

2. Hepatic fibrosis measured using liver stiffness measurement (LSM) assessed by transient elastography (FibroScan®) at baseline and longitudinal follow-up up to 48 months

Key secondary outcome(s)
1. Body weight measured using standardized clinic scales at baseline and longitudinal follow-up up to 48 months

2. Insulin resistance measured using HOMA-IR calculated from fasting glucose and fasting insulin at baseline and longitudinal follow-up up to 48 months

3. Glycaemic control measured using fasting glucose (mg/dL) and HbA1c (%) at baseline and longitudinal follow-up up to 48 months

Completion date
10/03/2024

Eligibility

Key inclusion criteria
1. Adults aged 18–65 years
2. Diagnosis of metabolic dysfunction–associated steatotic liver disease (MASLD) or metabolic dysfunction–associated steatohepatitis (MASH)
3. Evidence of hepatic steatosis defined by:
4. Imaging (ultrasonography) and/or FibroScan® controlled attenuation parameter (CAP) ≥248 dB/m
5. Presence of at least one metabolic risk factor (e.g. overweight/obesity, type 2 diabetes, dyslipidaemia, hypertension)
6. For MASH: elevated aminotransferases with concordant FibroScan® liver stiffness measurement (LSM) ≥8 kPa
7. Ability and willingness to provide written informed consent
8. Willingness to participate in longitudinal follow-up

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
197

Key exclusion criteria
1. Chronic viral hepatitis (hepatitis B or C)
2. Autoimmune liver disease or cholestatic liver disease
3. Genetic or metabolic liver diseases (e.g. hemochromatosis, Wilson disease)
4. Drug-induced liver injury or use of known hepatotoxic medications
5. Decompensated cirrhosis or clinical evidence of portal hypertension
6. Active malignancy
7. Pregnancy or breastfeeding
8. Severe or unstable cardiovascular disease
9. Acute systemic illness at the time of enrollment
10. Significant alcohol intake
11. Inability to comply with follow-up or lifestyle intervention protocols
12. Prior bariatric surgery or planned bariatric surgery during the study period

Date of first enrolment
01/10/2021

Date of final enrolment
01/03/2022

Locations

Countries of recruitment
Egypt

India

Jordan

Philippines

Saudi Arabia

Tunisia

Sponsor information

Organisation
Prince Sattam Bin Abdulaziz University

ROR
https://ror.org/04jt46d36

Funder(s)

Funder type

Funder Name
Prince Sattam bin Abdulaziz University

Alternative Name(s)
, PSAU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/08/2026	19/11/2026	Yes	No