# A Multicenter, Randomized, Crossover Clinical Trial Study of Digital Intelligence Software in Patients With MAFLD

NCT07233486

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| **Status** | RECRUITING |
| **Phase** | Not Applicable |
| **Sponsor** | The Affiliated Hospital of Hangzhou Normal University |
| **Enrollment** | 2,000 participants |

## Key Eligibility Criteria

### Inclusion (5)

- Adult patients aged 18-65 years with a BMI of 24-35 kg/m².
- Confirmed diagnosis of Metabolic-associated Fatty Liver Disease (MAFLD), defined by a FibroScan® result \> 248 dB/m or an MRI-PDFF \> 5%.
- Willing and able to provide written informed consent and comply with the study protocol, including the use of a compatible smartphone for digital health components.
- If treated for Type 2 Diabetes Mellitus (T2DM), must be on a stable medication regimen for at least 3 months prior to baseline (Day 0), with the expectation to maintain stability throughout the study barring medical necessity.
- If taking medications with potential NASH-remitting effects (e.g., vitamin E, thiazolidinediones), must be on a stable dose for at least 3 months prior to Day 0.

### Exclusion (34)

- Subjects were excluded from participation if they met any of the following criteria, based on the most recent pre-randomization assessments:
- Evidence of cirrhosis, defined as histological stage F4 or its clinical equivalent.
- History of heavy alcohol consumption (\>30 g/day for males, \>20 g/day for females) for more than 3 consecutive months within one year prior to screening.
- Prior or planned solid organ transplantation (excluding corneal transplants).
- Planned bariatric surgery. A history of bariatric surgery was permitted only if weight had been stable (variation \<10%) for at least 3 months prior to screening.

... and 29 more (see full listing online)

## Locations (1 total)

Hangzhou Normal University Hospital, Hangzhou, Zhejiang, China



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