Poster Category: NAFLD Therapy

A novel prescription digital therapeutic for the treatment of non-alcohol related fatty liver disease: feasibility study

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Introduction

- Nonalcoholic fatty liver disease (NAFLD) is a global public health crisis growing in parallel with the obesity and diabetes pandemics.
- Behavioral modification including weight loss, improving dietary quality, and increasing physical activity have been proven to have favorable effects on slowing or reversing the progression of liver steatosis and fibrosis.
- However, behavior change is difficult to facilitate in clinical practice and health systems are poorly equipped to scale behavioral interventions needed to address the enormous population with NAFLD.

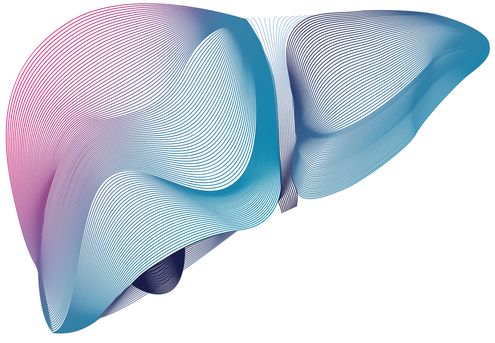
Aim

- The aim of this feasibility study was to explore the safety, efficacy, and usability of a novel prescription digital therapeutic (PDT) platform, in individuals with NAFLD or non-alcoholic steatohepatitis (NASH).

Method

This single arm study was conducted at two affiliated specialty hepatology clinics. The PDT was created by Better Therapeutics using a novel form of cognitive behavioral therapy (CBT) intended to treat cardiometabolic disease.

- Participants accessed the PDT on their smartphone for up to 90 days.
- The intervention was delivered without requiring additional participation from clinic providers.
- Laboratory assessments, FibroScan and magnetic resonance imaging proton density fat fraction (MRI-PDFF) imaging were conducted at baseline and post-intervention.
- Percent change in steatosis was measured by MRI-PDFF in participants with elevated baseline liver fat (PDF >= 10%).



Results

The study enrolled 22 participants. Baseline characteristics are described in Table 1.

- The mean baseline fat fraction on MRI-PDFF was 19%. After 90 days of exposure to the PDT, the mean relative reduction in MRI-PDFF was -16% (p = 0.011) in the primary ITT population (Fig. 1) .
- ALT was reduced by an average of -17 IL/U (p = 0.002) (Fig. 2).
- FibroScan Controlled Attenuation Parameter (CAP) Score was reduced (-19 dB/m, p = 0.021) and was accompanied by an average relative reduction of -20% in the Fast^{TM} Score (p = 0.011) (Fig, 3).
- Participants achieved an average weight loss of -3% (p = 0.008) of total body weight, following a pattern of gradual and consistent weight loss without any signs of a plateau or peak.
- No serious adverse events nor any device related adverse events were reported.
- Participants reported an improvement in their health-related quality of life (assessed via CDC HRQOL-4) with an average improvement of 2.2 Healthy Days per month added (p = 0.500) and a high degree of satisfaction with the treatment (mean Net Promoter Score of +75).

Baseline Demographics

Parameter / Category	Safety Population (n=22)
Age (mean)	48 yrs
% Female	0.77
% Non-white	0.47
% Hispanic/Latino	0.41
Body Mass Index (mean)	38 kg/m²
Liver Disease Diagnosis at Baseline	
NASH	0.77
NAFLD	0.23
Baseline Liver Fat (mean MRI-PDFF %)	0.19
Number of Comorbidities (mean)	6
Type 2 Diabetes	0.46
Hypertension	0.59
Hyperlipidemia	0.55

Table 1: Baseline characteristics of the study population.

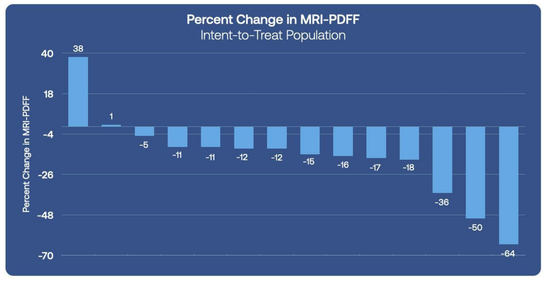


Fig. 1: Waterfall plot shows change from baseline in MRI-PDFF for participants with a baseline PDFF ≥ 10% (n=14). A mean change of -16% (p=0.011) was observed.

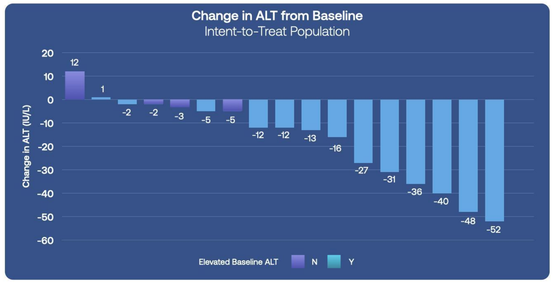


Fig. 2: Waterfall plot shows change from baseline in ALT for all participants in the ITT population (n=17). A mean change of -17.1 IU/L (p=0.002) was observed in the ITT population. In those with an elevated ATL at baseline (n=13), a mean change of -22.5 IU/L (p=0.001) was observed.

Fig. 3: 45 % of participants experienced an improvement in Fast^{TM} risk category, moving from the high or indeterminate to low-risk category after exposure to the PDT

Conclusions

- Clinically meaningful improvements in liver health were observed in multiple endpoints after 90 days of digitally-delivered CBT without any adverse device effects.
- Weight data suggests that further liver health improvements may be possible with further PDT use beyond 90 days.
- The totality of safety, efficacy and usability data collected strengthen the hypothesis that a PDT could be an important and scalable clinical tool for the treatment of NAFLD and NASH.

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References

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