DECEMBER 8, 2022

# LivVita Liver Health Feasibility Study Topline Data

Better THERAPEUTICS

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# Pioneering Prescription Digital Therapeutics for Cardiometabolic Diseases

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# Non-alcoholic Fatty Liver Disease (NAFLD) includes a spectrum of conditions rooted in unhealthy lifestyle behaviors

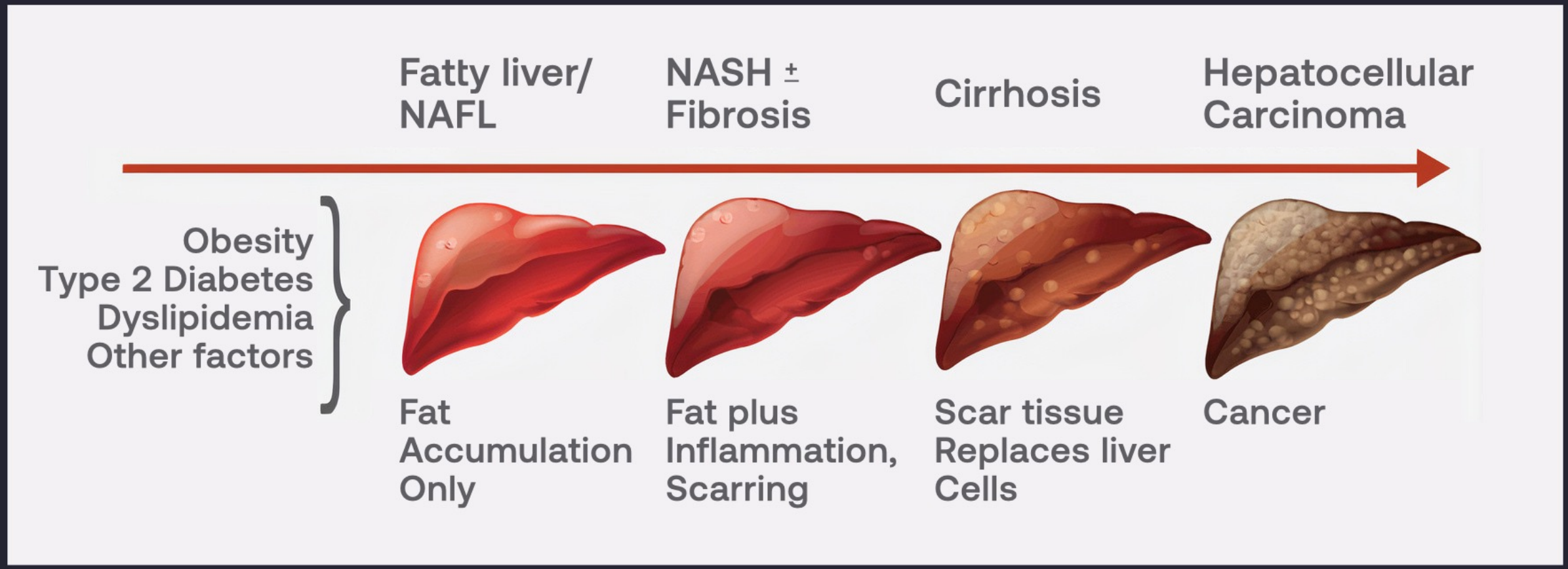
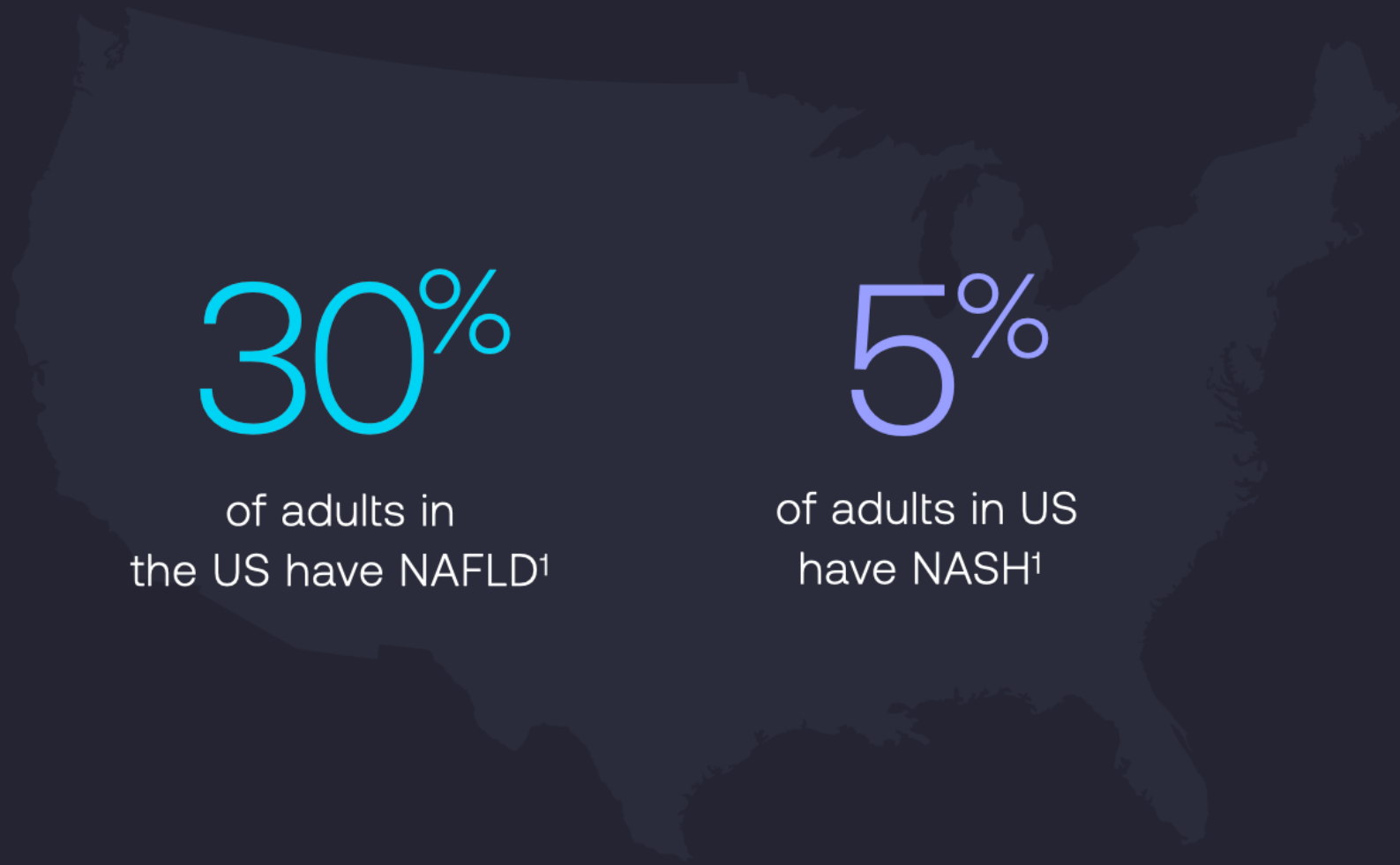



Image source: https://pharmaintelligence.informa.com/resources/product-content/nash-flying-the-plane-while-building-it

# NAFLD is at epidemic levels in the United States and is a leading cause of liver transplantation[1]



**30%**

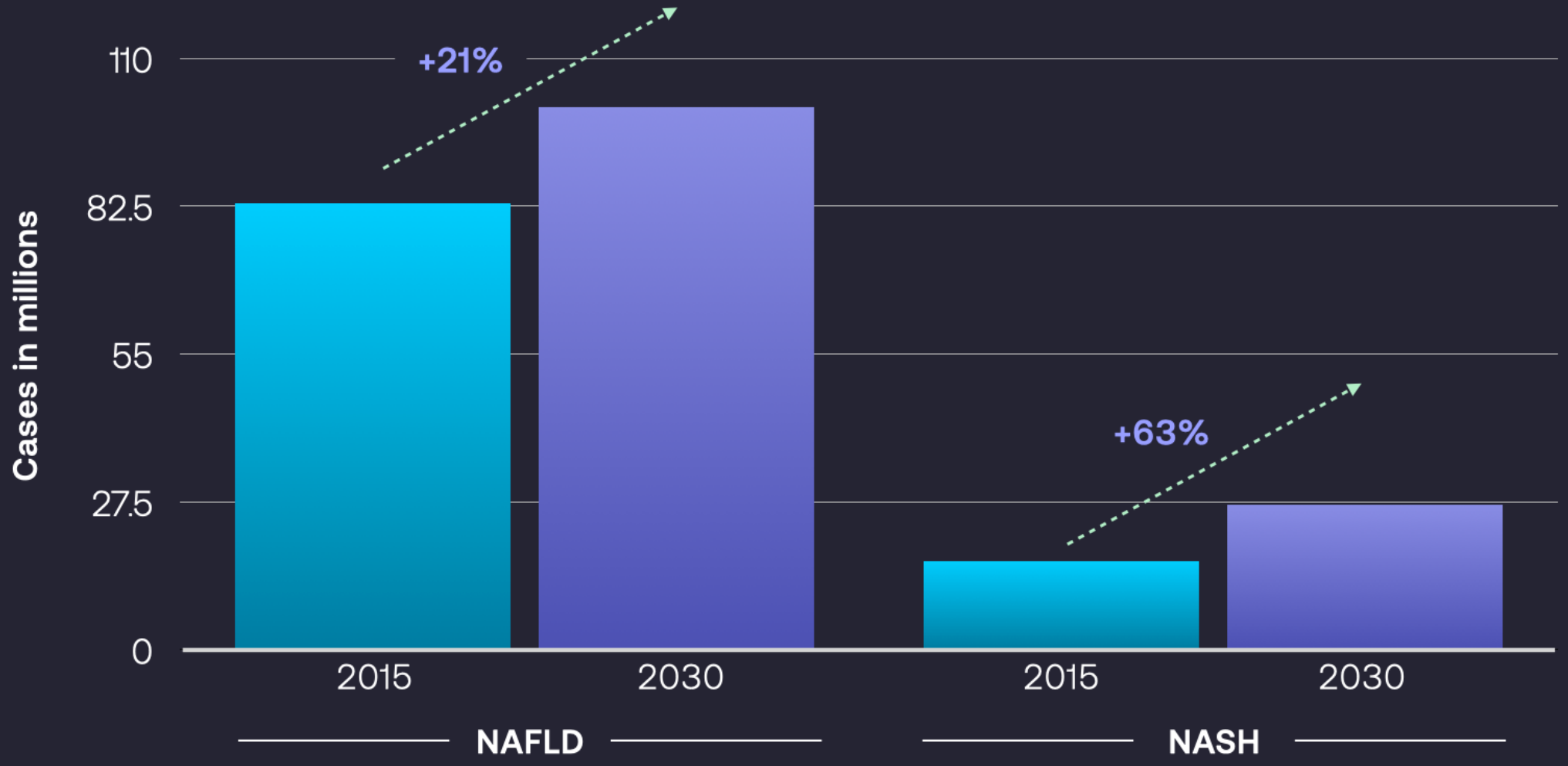
of adults in the US have NAFLD[1]

**5%**

of adults in US have NASH[1]

# NAFLD and NASH prevalence projected to increase significantly[2]

With a growing proportion of NAFLD patients progressing to NASH



# At present, despite billions invested, there are no FDA approved pharmacological agents for the treatment of NAFLD or NASH

## And leading candidates have frequent side effects

| | Diarrhea | Nausea | Vomitting | Itching |
|---|---|---|---|---|
| **Pemvidutide**[3]<br>*GLP1/glucagon dual receptor agonist*<br>Phase 1b | 22% | 52% | 9% | - |
| **Efruxifermin**[4]<br>*Fibroblast growth factor 21 (FGF21) analog*<br>Phase 2b | 33% | 33% | - | - |
| **Semaglutide**[5]<br>*GLP1 analog*<br>Phase 2b | 28% | 37% | 22% | - |
| **Resmetirom**[6]<br>*THR β-selective agonist*<br>Phase 2b | 31% | 18% | - | - |
| **Obeticolic acid**[7]<br>*FXR-agonist*<br>Phase 3 | 7% | 13% | 7% | 51%<br>*(28% characterized as intense or widespread)* |

We believe that addressing the unmet needs in NAFLD/NASH requires non-pharmacological therapies

## Qualities of an ideal new therapy in NAFLD

1. Addresses full breadth of modifiable behavioral root causes
2. Safe and well-tolerated
3. Readily accessible, convenient and desired by patients
4. Improves liver fat, glucose & lipid metabolism and inflammation
5. Reduce cardiovascular risk associated with common comorbidities
6. Sustained effect
7. Reduces burden on providers

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# LivVita Study was designed to assess potential for both efficacy and safety in NAFLD and/or NASH

**Partnered with leading specialty liver health clinic - Arizona Liver Heath - to design study and recruit diverse set of participants in 2 sites**

**BT's cardiometabolic Cognitive Behavioral Therapy (CBT) research platform was evaluated over a 3-month treatment period**

Basic liver health education provided in 1 phone session prior to treatment

**MRI-PDFF and robust set of biomarkers evaluated, to potentially enable planning of pivotal study**

**App-engagement and qualitative data collected, to inform customizations needed for liver-specific product**

# LivVita Study

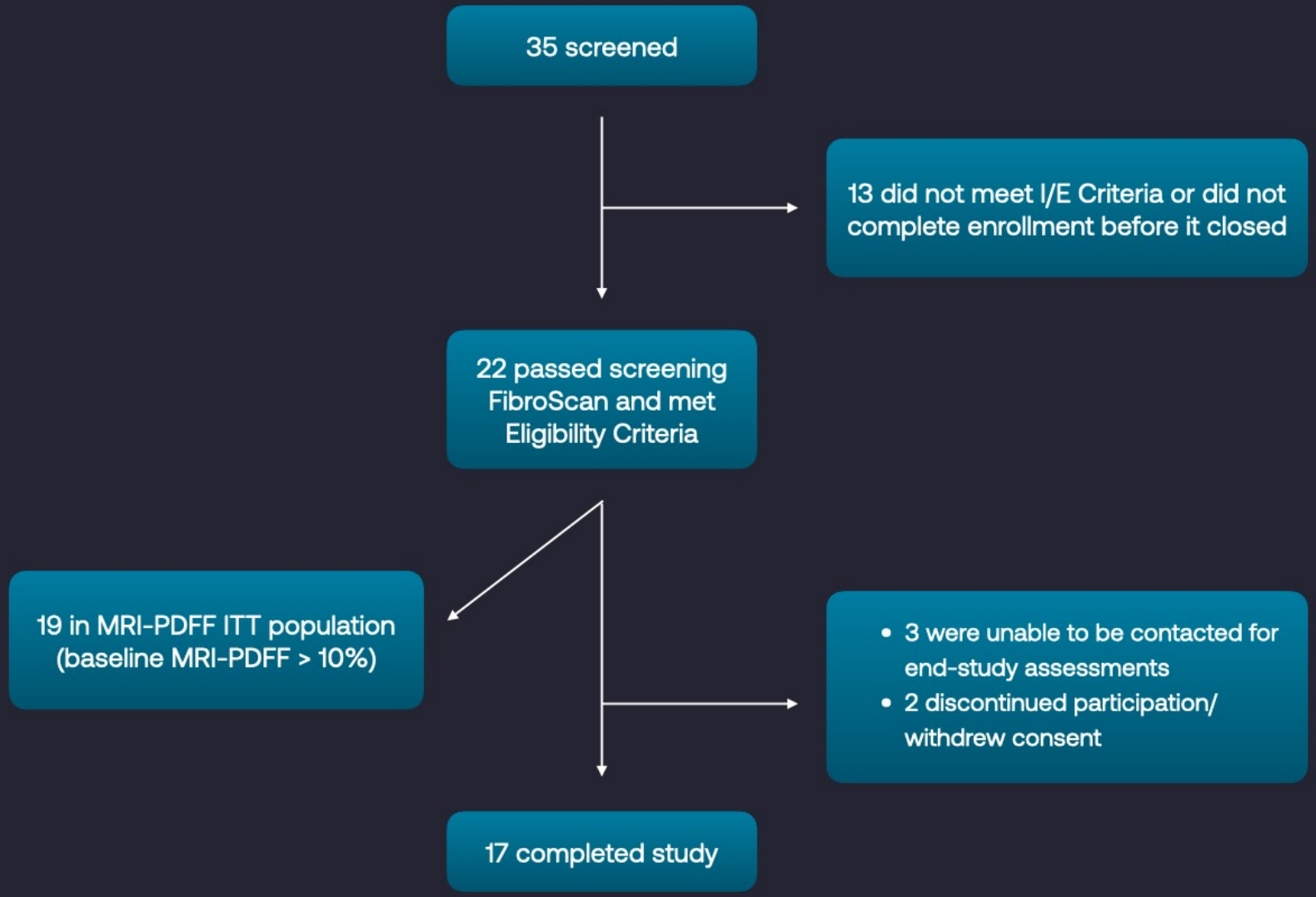
## Study Design and Participant Flow

### Key Inclusion Criteria

- Confirmed diagnosis of NAFLD or NASH
- Ages 18-75 years
- Possession of a smartphone capable of running BT app
- BMI ≥ 30kg/m2
- FibroScan CAP ≥ 300dB/m

### Key Exclusion Criteria

- History of a life-threatening medical illness, other liver disease, or alcohol abuse
- Weight loss >10 lbs in last 90 days
- Screening ALT/AST > 5x upper limit
- Concurrent enrollment in another interventional clinical trial



# LivVita Study

## Topline Key Endpoints

**Magnetic Resonance Imaging-Proton Density Fat Fraction (MRI-PDFF):** A specialized type of MRI that provides the most validated and reproducible non-invasive quantitative measure of liver fat

**Alanine Transaminase (ALT):** An enzyme produced by liver cells. ALT blood levels rise when the liver is damaged or injured

**FAST Score:** A composite score the uses FibroScan's measures of liver stiffness and fat combined with the Aspartate Transaminase (AST) blood test to predict degree of NASH risk

**FibroScan CAP Score:** A quantitative measure of liver fat using a specialized type of ultrasound that provides point of care screening and assessment of liver fat and stiffness

**Net Promoter Score (NPS):** A survey that measures user satisfaction and likelihood that the individual would recommend a product to a friend or family member. Scores range from -100 to +100

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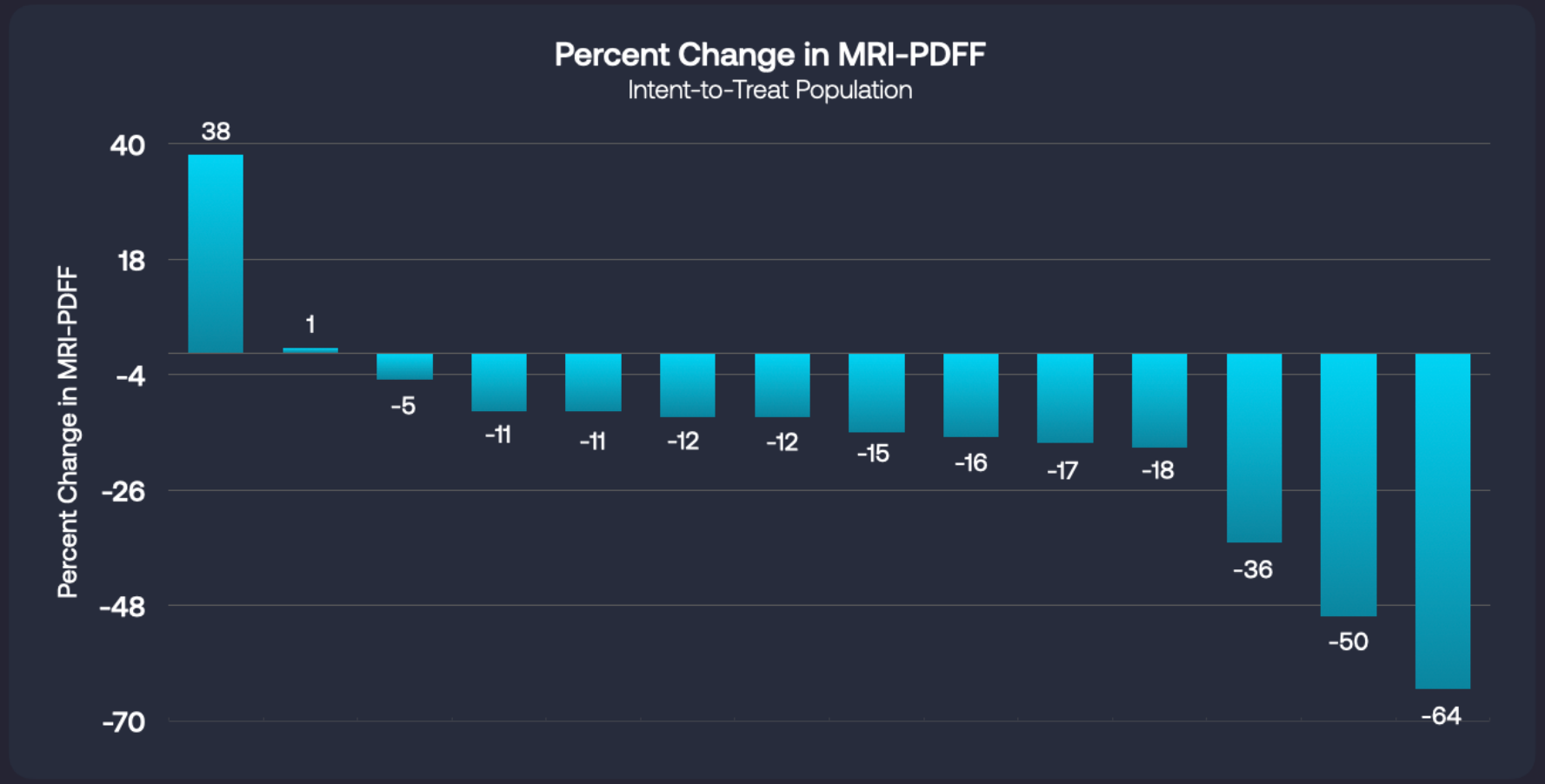
# Diverse set of patients recruited from 2 specialty liver clinics in Arizona

Baseline characteristics represent commonly occurring cardiometabolic conditions in patients with NAFLD and NASH

| Parameter / Category | Safety Population (n=22) |
|---|---|
| Age (mean) | 48 yrs |
| % Female | 77% |
| % Non-white | 47% |
| % Hispanic/Latino | 41% |
| Body Mass Index (mean) | 38 kg/m$^2$ |
| Liver Disease Diagnosis at Baseline | |
| NASH | 77% |
| NAFLD | 23% |
| Baseline Liver Fat (mean MRI-PDFF %) | 19% |
| Number of Comorbidities (mean) | 6 |
| Type 2 Diabetes | 46% |
| Hypertension | 59% |
| Hyperlipidemia | 41% |

# The primary endpoint, MRI-PDFF, showed positive signal with statistically significant reductions in liver fat (p = 0.01)




**Mean Change in MRI-PDFF**

**-16%**

**Relative Reduction**

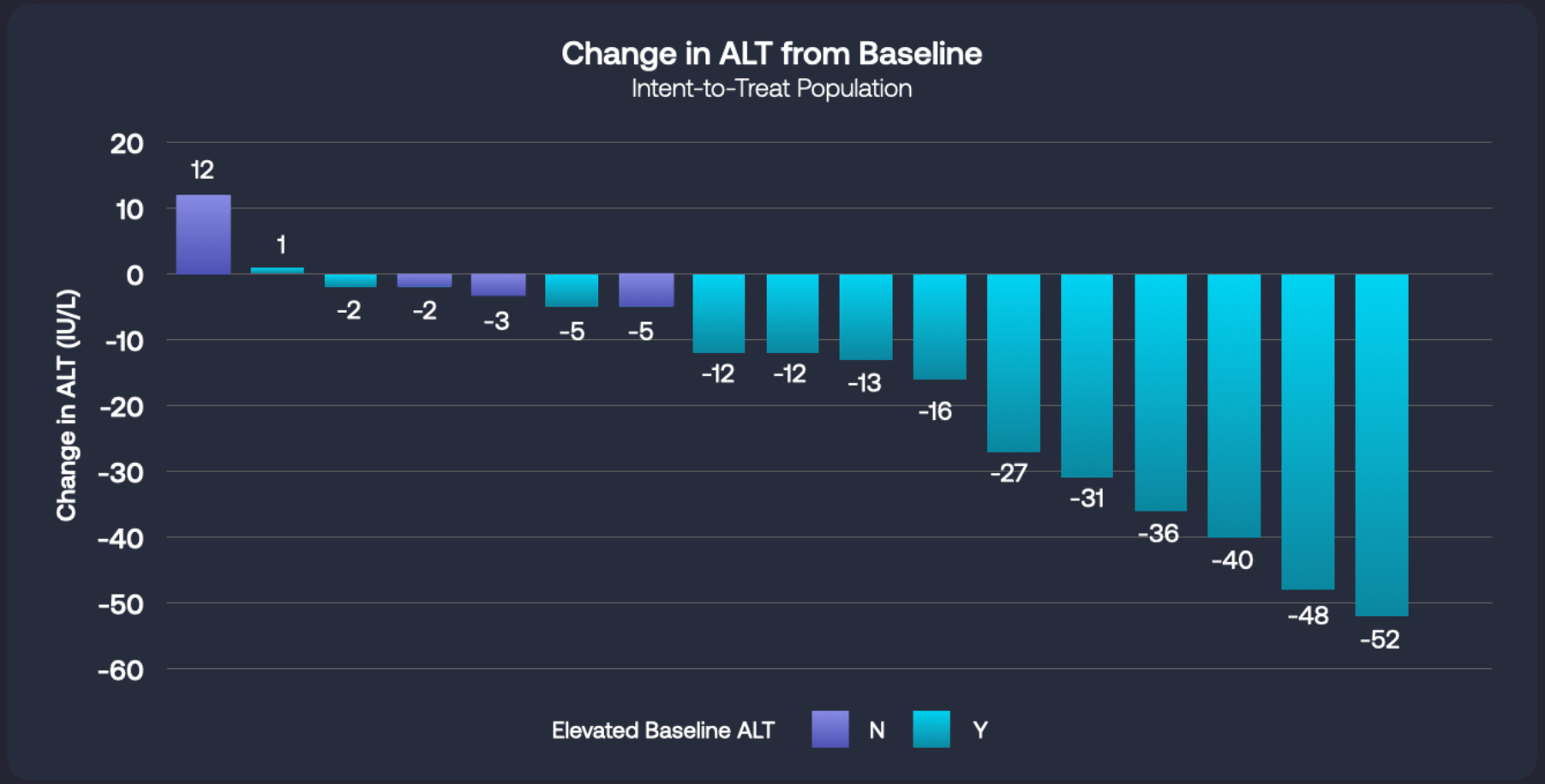
n=14 p = 0.01

**Max Change in MRI-PDFF**

**-64%**

**Relative Reduction**

# ALT results showed statistically significant reductions in marker of liver damage (p = 0.002)




**Mean Change in ALT**

**-17 IU/L**

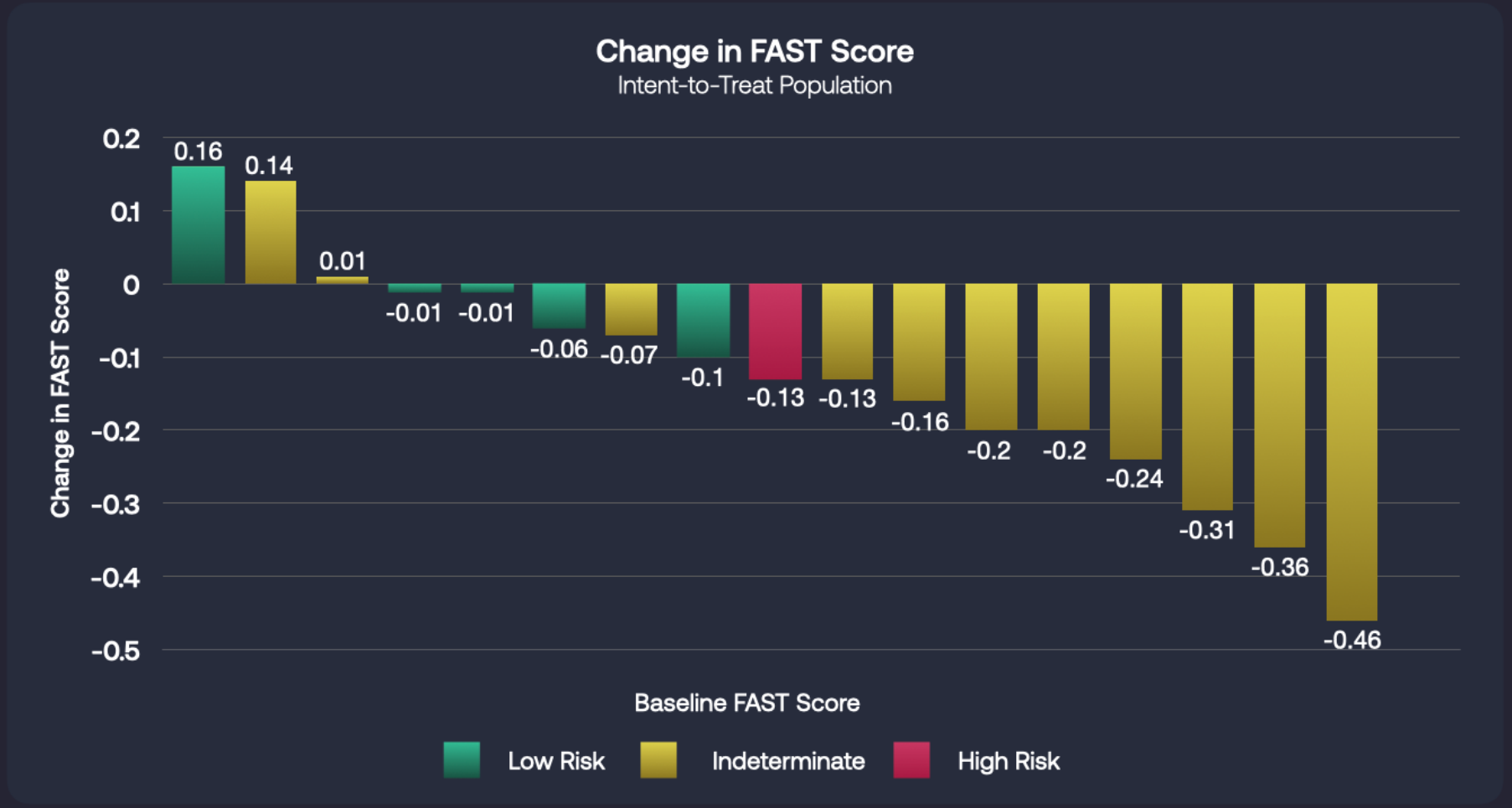
n=17 p = 0.002

**Mean Change in those with Elevated Baseline ALT**

**-23 IU/L**

n=13 p = 0.001

# FAST Score results showed statistically significant reductions in NASH Risk (p = 0.006)




**Mean Change in FAST Score**

**-0.13**

**Absolute Reduction**

n=17 p= 0.006

**Mean Change in FAST Score**

**-20%**

**Relative Reduction**

n=17 p = 0.01

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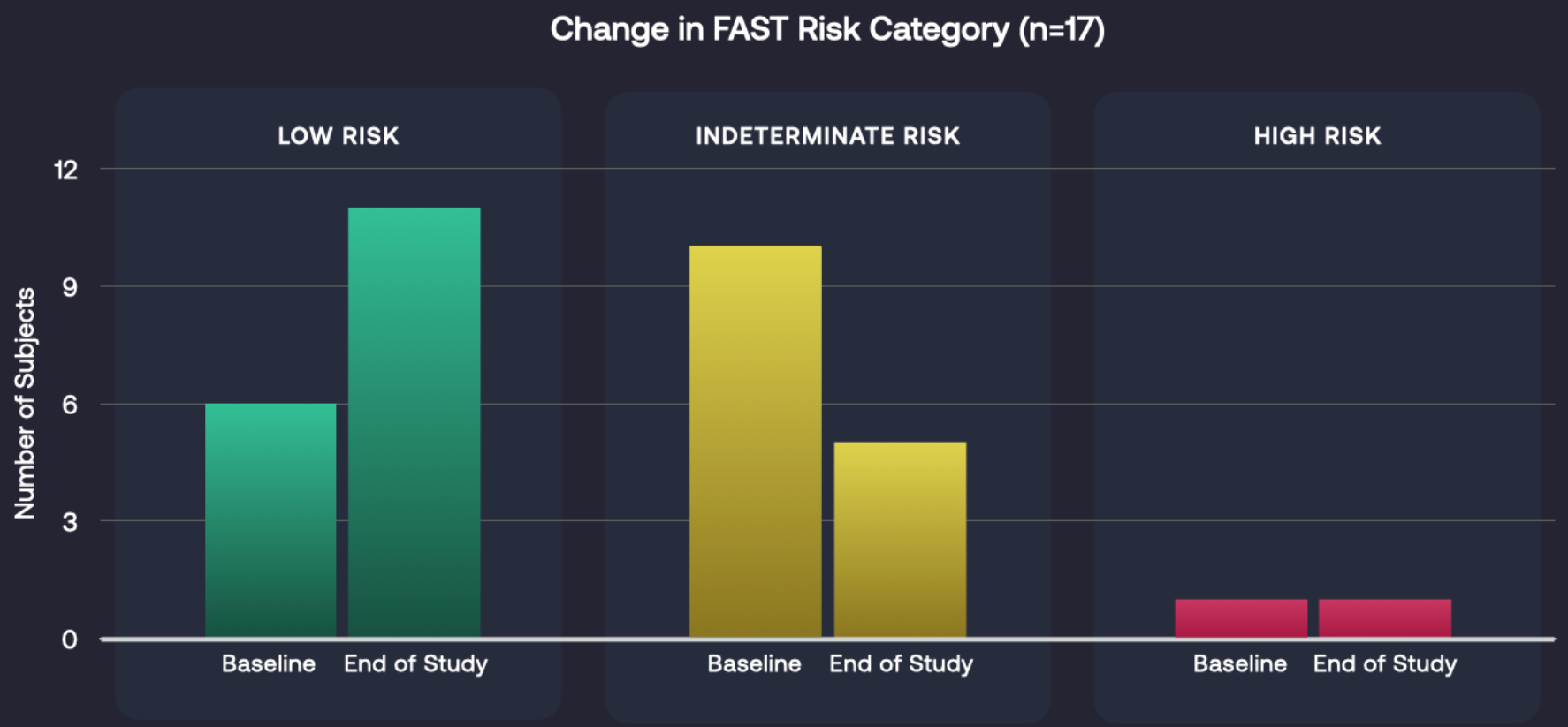
# FAST Score results showed statistically significant reductions in NASH Risk




**Reduction in FAST Score Category**

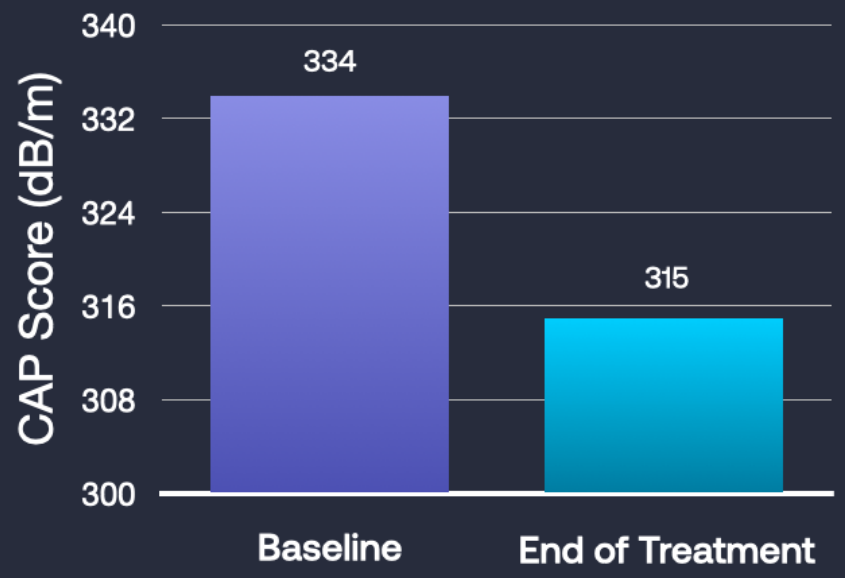
**50%**

**of Indeterminate Risk Patients Move to Low Risk**

# CAP and Weight Change showed statistically significant reductions in markers of liver damage

## Change in CAP Score

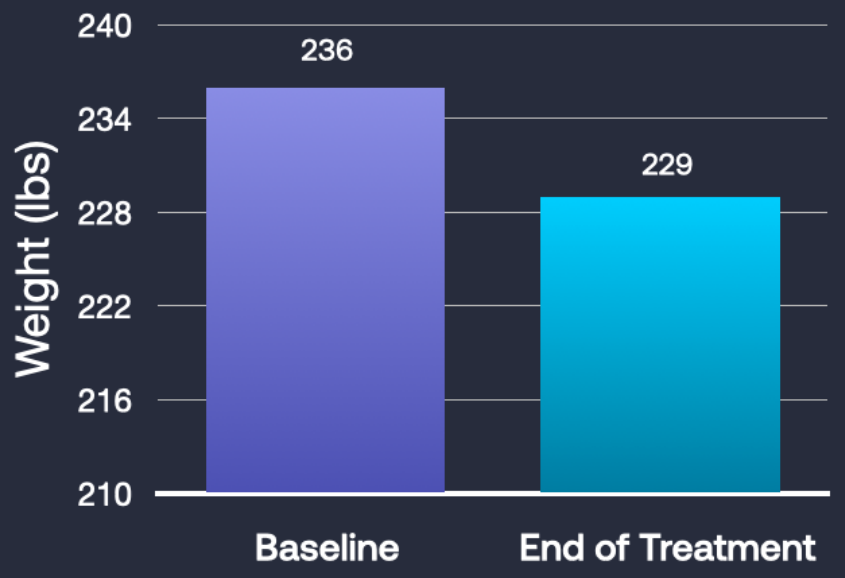
Δ = -19 dB/m (-6%)  p= 0.021




n=17

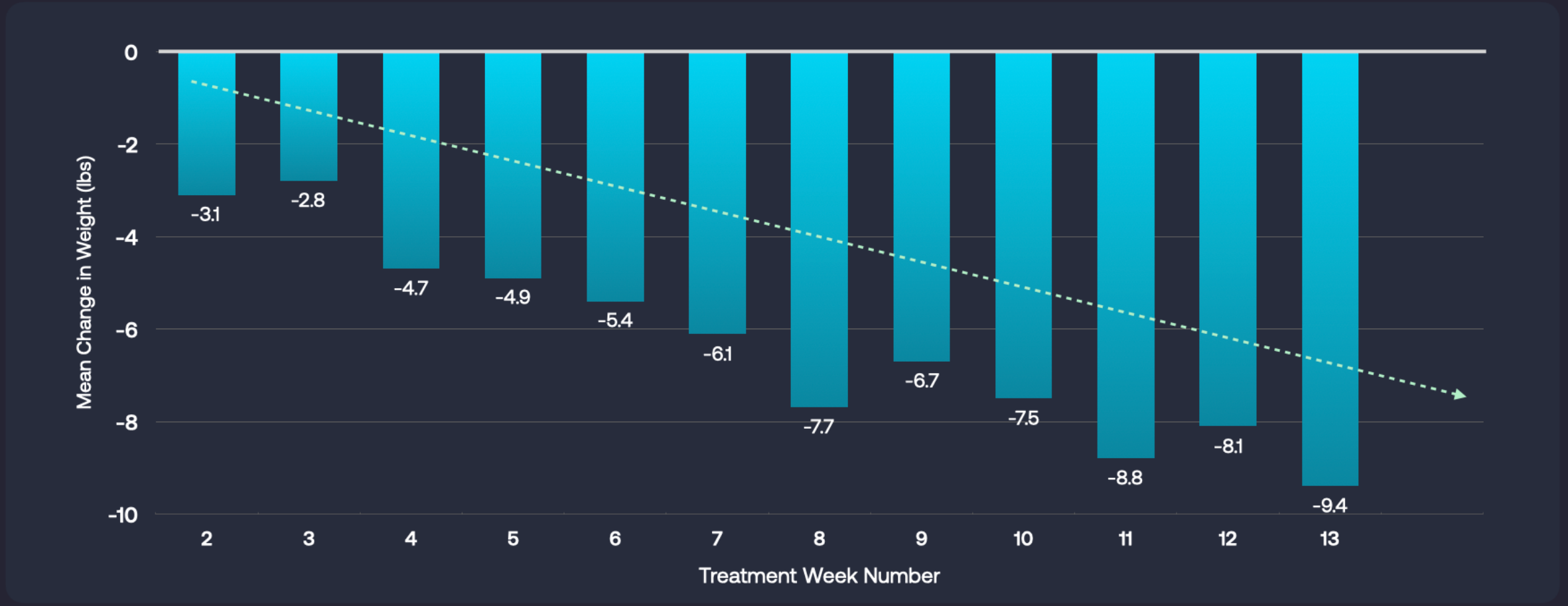
## Change in Weight

Δ = -7 lbs (-3% TBW)  p = 0.008

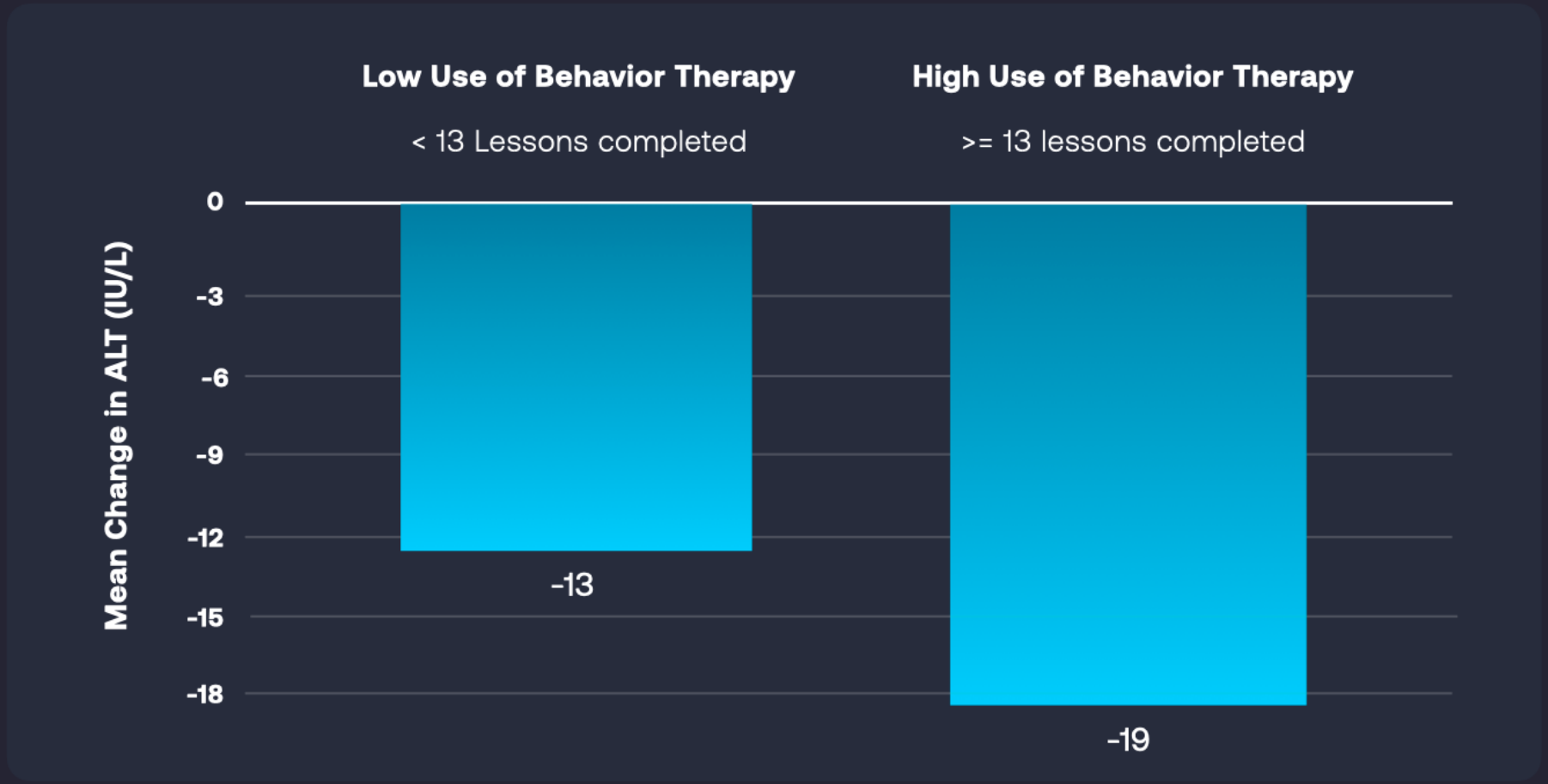



n=17

# Trending average change in patient-reported weight showed gradual and steady improvements, with no clear peak



# Dose response demonstrated positive relationship between CBT engagement and improvements in liver health biomarkers



# Safety data revealed no device related adverse events (AEs) were experienced

BT's CBT was generally well-tolerated with few overall AEs reported over 3-month period

| | Safety Population (n=22) | | | | |
|---|---|---|---|---|---|
| **Number of subjects who experienced:** | Subjects n (%) | Events n | Mild | Moderate | Severe |
| An Adverse Event (AE) | 6 (27%) | 10 | 5 | 5 | 0 |
| An AE Possibly/Probably Related to Study Intervention | 0 (0%) | 0 | - | - | - |
| An AE that is Related to Medical Device | 0 (0%) | 0 | - | - | - |
| Serious Adverse Event (SAE) | 0 (0%) | 0 | | | |

# During 90 days of use, patient engagement and satisfaction significantly exceeded benchmarks for consumer health & wellness apps[8,9]. Notable Quality of Life improvements also reported[10]

## 94%

**Percentage of subjects using the app in Week 12**


## 2.2

**Average added Healthy Days/month reported**

42% reported an improvement in 1 or more Quality of Life Category

## +75

**NPS Score after 90 days**

Scored on a scale from -100 to +100

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# LivVita Study demonstrated clear potential for response, with no safety related concerns observed, supporting our hypothesis and research platform

- Consistent improvements in MRI-PDFF and broad range of liver biomarkers found, with notable changes in ALT and FAST scores; improvements are consistent with our CBT's broad mechanism of action
- Generally well-tolerated profile and excellent patient-satisfaction scores suggests great potential for patient-centric NAFLD/NASH treatment
- Potential exists to establish NAFLD/NASH PDT as part of standard of care treatment either alone or alongside future pharmacotherapy treatments
- Study also serves as proof-of-concept of BT's indication discovery platform - which could afford for rapid ability to expand indication pipeline

## Naim Alkhouri, MD

Director of the Fatty Liver Program
Arizona Liver Health

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# Next Steps

- Submit manuscript for peer-reviewed publication
- Submit application to FDA for Breakthrough Device Designation and commence discussions on pivotal study design
- Consider partnership opportunities to accelerate development of BT's NAFLD/ NASH specific PDT

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