

AI for Diabetes Prevention

NIH Clinical Trials Collaboratory, DCRI

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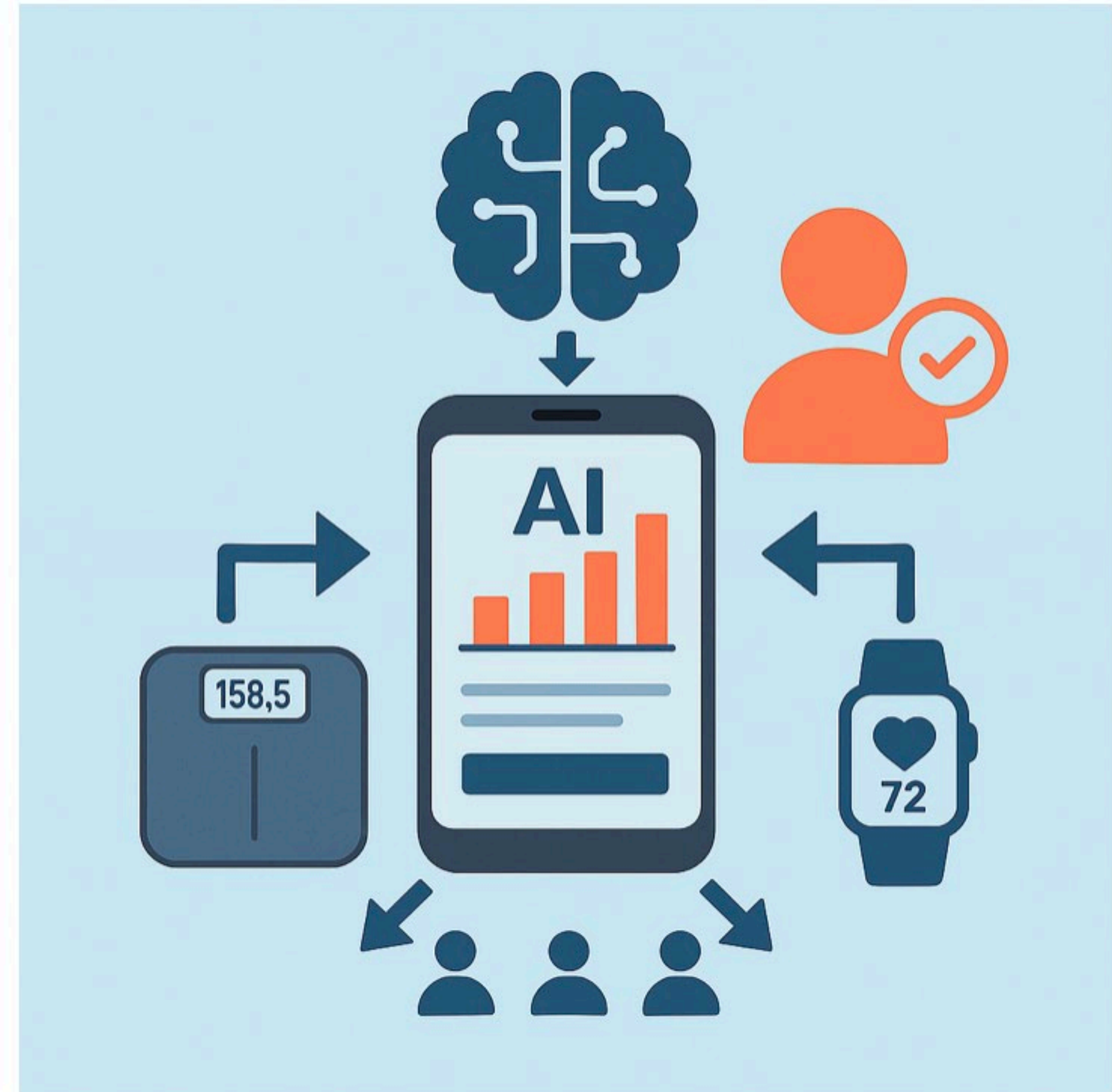
Objectives

- Identify key barriers to effective diabetes prevention in the United States.
- Assess the comparative effectiveness of a fully automated, AI-driven Diabetes Prevention Program (DPP) versus the standard-of-care, human coach-led DPP.
- Evaluate participant engagement, acceptability, and preferences for AI-driven versus human coach-led DPPs.

AI for Diabetes Prevention: Closing the Implementation Gap








Digital DPPs

- **Promising approach** to increase utilization
 - Asynchronous
 - App-based delivery
- **Role of AI**
 - Enhance scalability
 - Personalize behavior change support
 - Reduce need for human coaches

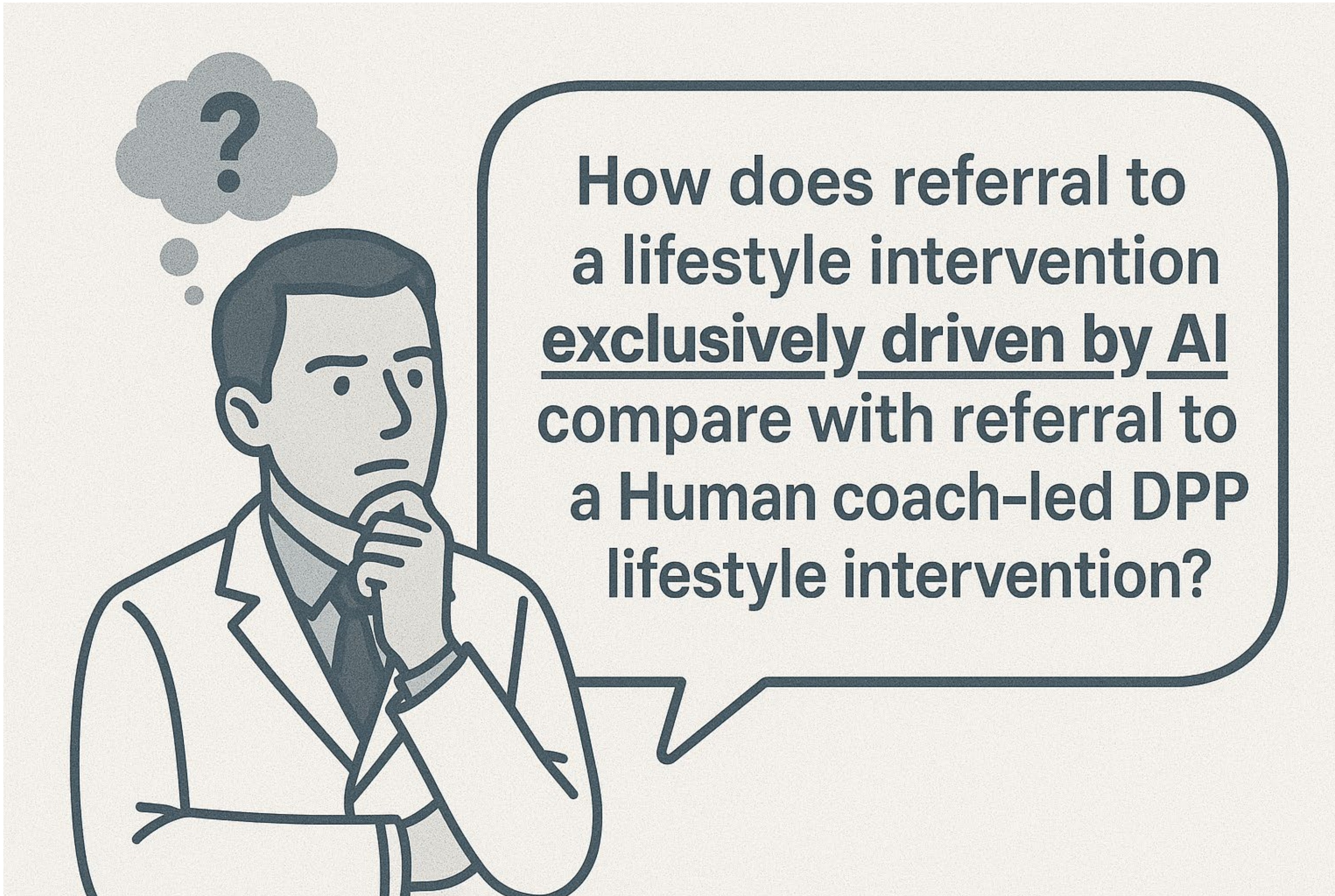


Everett E, J Med Internet Res, 2018;20(2):e72.
Lalani B, J Diabetes Sci Technology. 2025 Jul 8.

Evidence Gaps

Study Design	Study 1	Study 2	Study 3	Study ...	This Study
Fully Automated Experimental Group					
Comparison to Gold-Standard Human-led DPP					
Randomized Design					

Study Question



Mathioudakis N, Lalani B, Abusamaan MS, et al; for the AI-DPP Study Group.

An AI-Powered Lifestyle Intervention vs Human Coaching in the Diabetes Prevention Program

A Randomized Clinical Trial

Published online October 27, 2025

Diabetes Technology Meeting 2025

Available at jama.com



Scan to read the article

Trial Objective – pragmatic lens

Compare a fully automated AI-led DPP to standard of care human-led DPP in real-world settings to inform scale-up, not just efficacy



Assess engagement and acceptability

Hypothesis: Comparable outcomes with greater accessibility

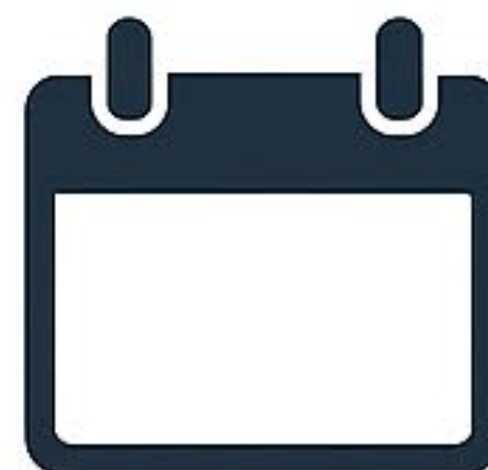
Study Design



Phase 3,
unmasked,
parallel-group,
non-inferiority
RCT



12 month
participant
duration



October 11, 2021
to December
16, 2024



Two U.S. sites:
Johns Hopkins
Hospital
(Baltimore, MD)
Reading Hospital
Tower Health
(Reading, PA)

Participants

- **Inclusion Criteria**

- Prediabetes diagnosed using standard laboratory criteria
- Overweight or obesity

- **Exclusion Criteria**

- Prior diabetes diagnosis
- Severe cardiovascular conditions
- Factors affecting HbA_{1c} accuracy
- Cognitive or psychiatric barriers
- Conditions/medications impacting body weight or blood glucose

Randomization

HbA1c	$\leq 6.0\%$ vs. 6.1 to 6.4%
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Recruitment Site	Baltimore, MD	Reading, PA
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1:1 Randomization



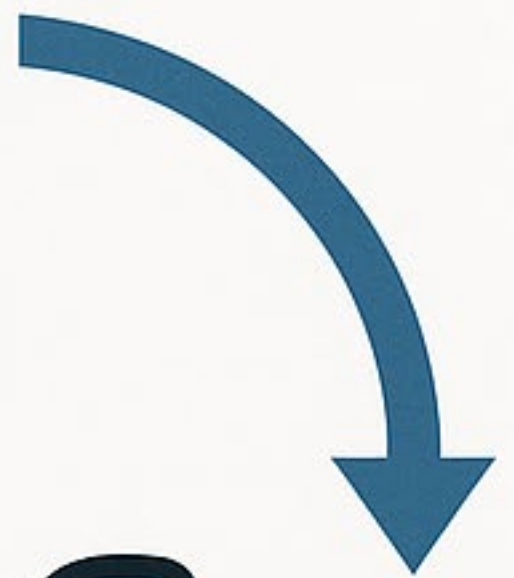
AI-led DPP



Human-led DPP



Research Team



**AI-Based
DPP**



**Human
Coach-Based
DPP**

Delivered independently of study team



**Permitted usual
medical care**



**Other trials/programs
related to nutrition,
weight, diabetes
excluded**

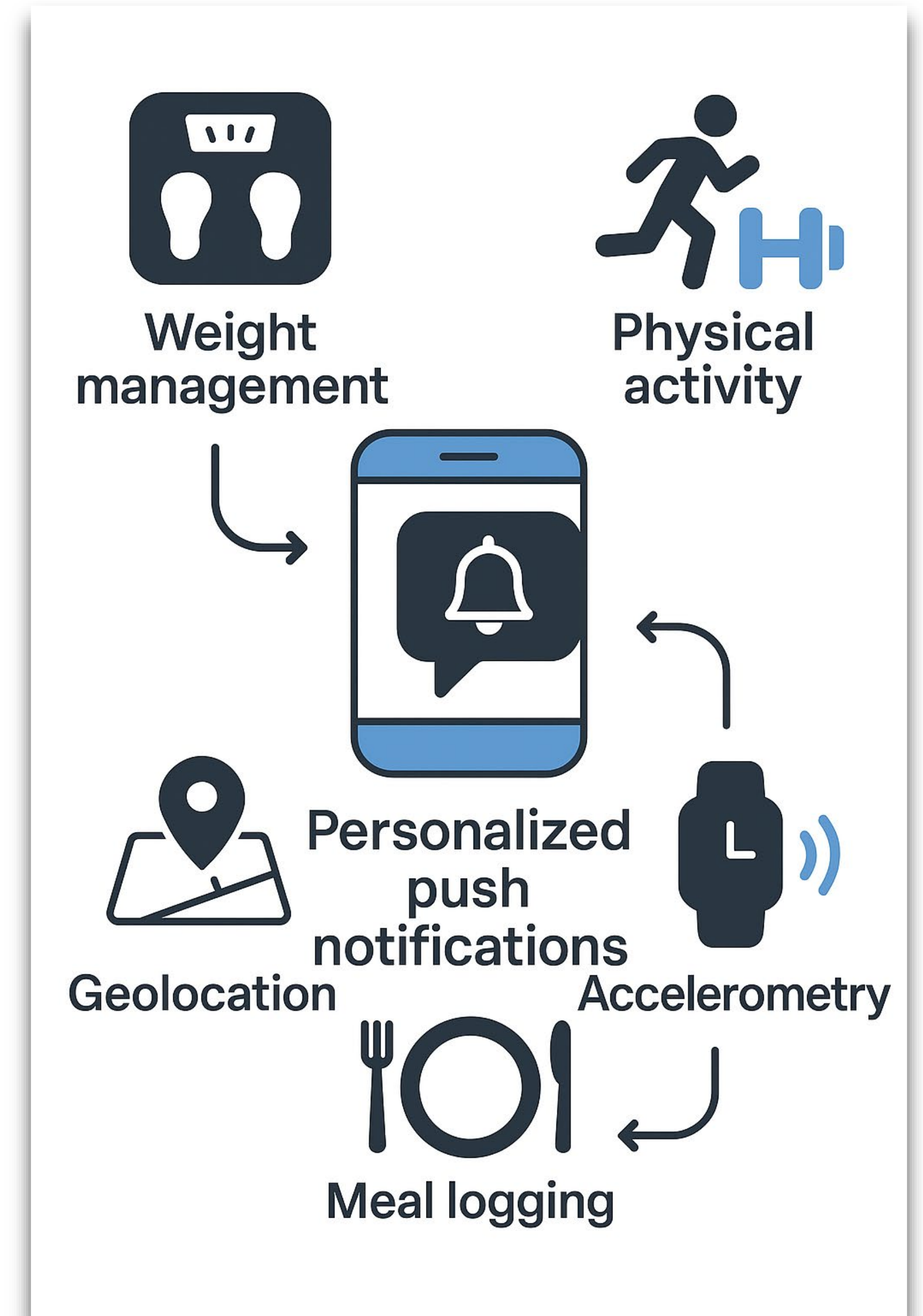


**Glucose/weight-
affecting medications
prohibited**

AI-led DPP

Referral to Sweetch Health, Ltd.

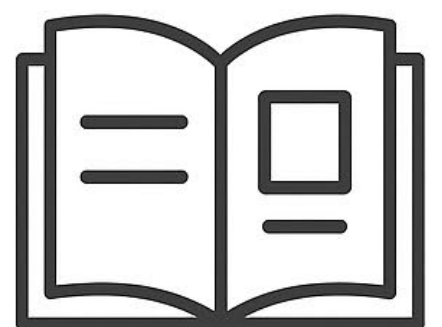
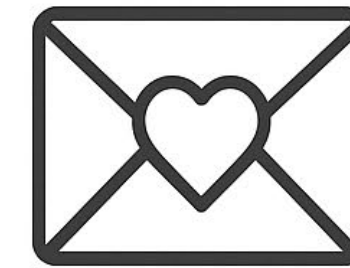
- Received digital health kit within 8-12 days after randomization
 - App registration instructions
 - Bluetooth enabled digital body weight scale



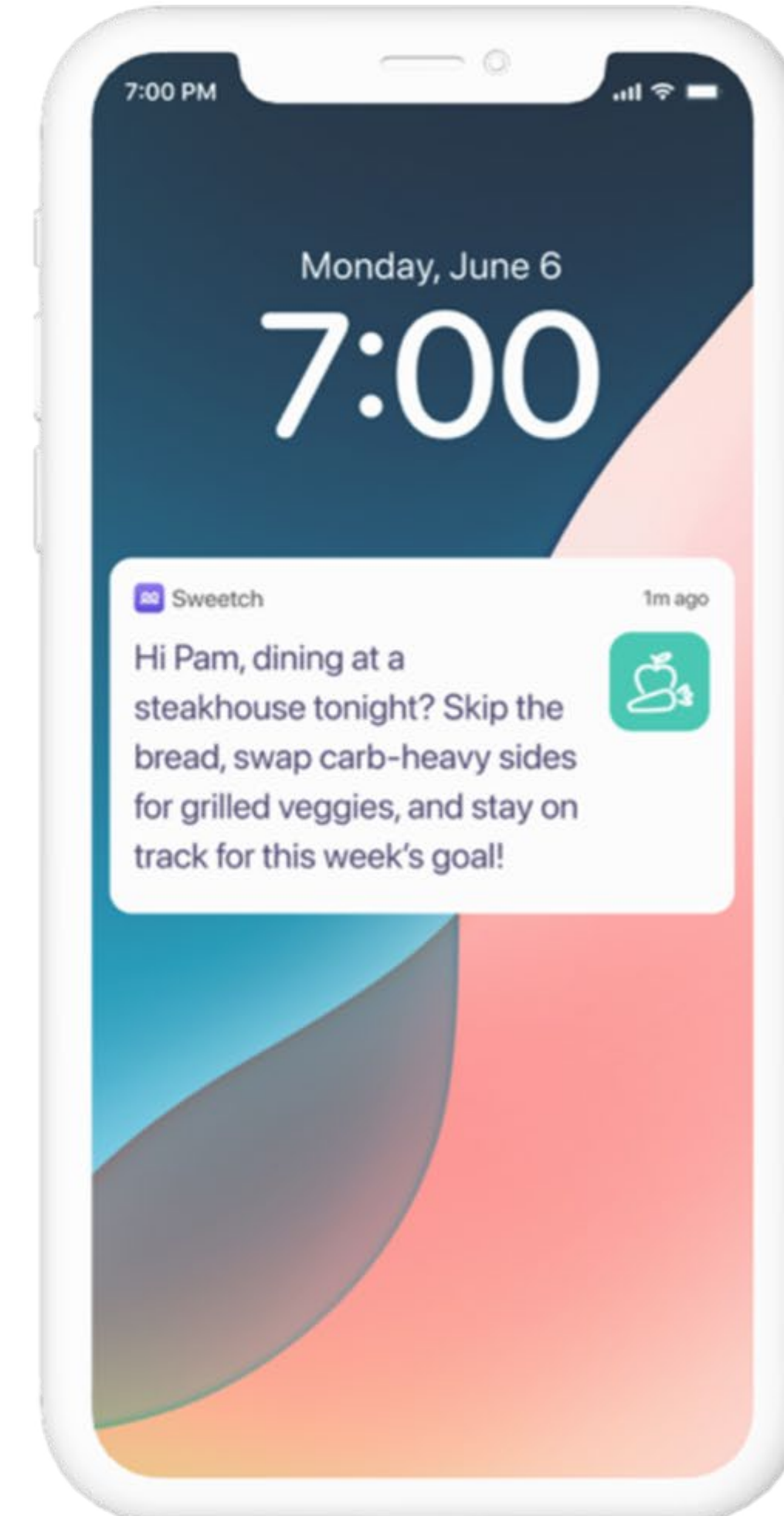
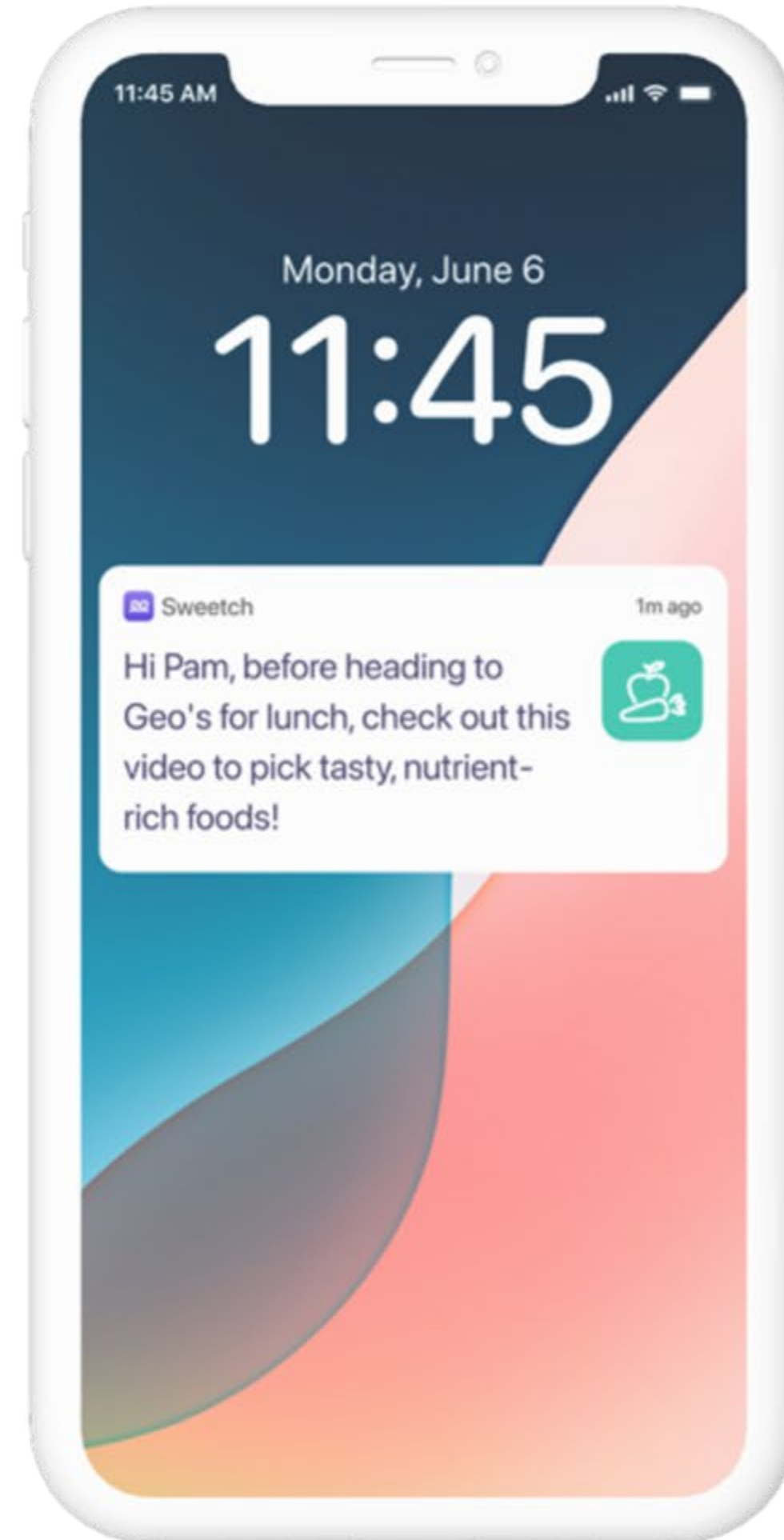
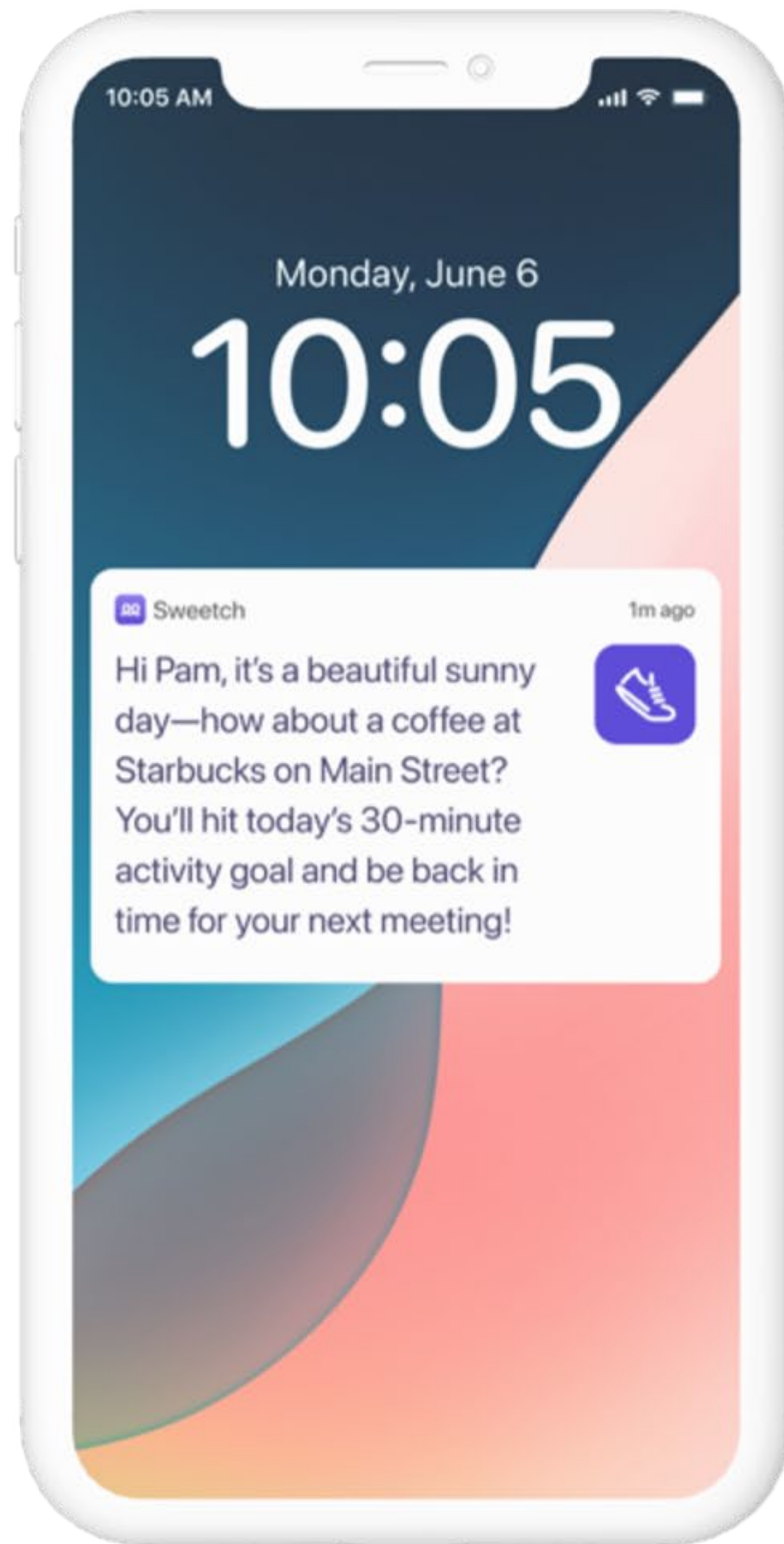
AI-led DPP

Reinforcement Learning Algorithm

- Did **not** use generative AI or large language model (LLM)
- Personalized messages by continuously learning how prompts, content, timing elicited engagement
- Location and goal-specific nutrition education
- Gamification elements
- Educational resources



AI-led DPP: Push Notifications



Push Notifications

AI-led DPP: Meal Analysis

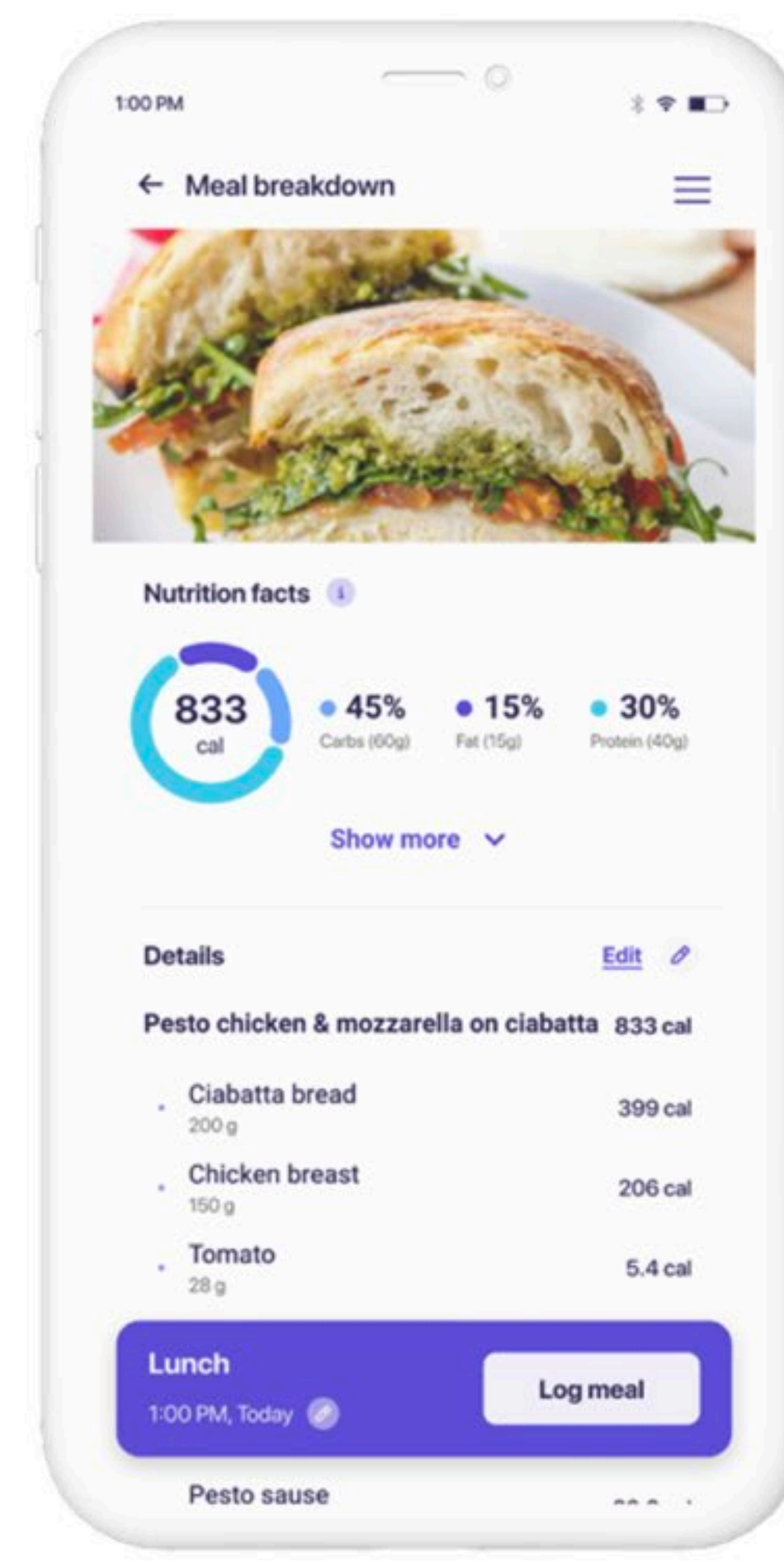
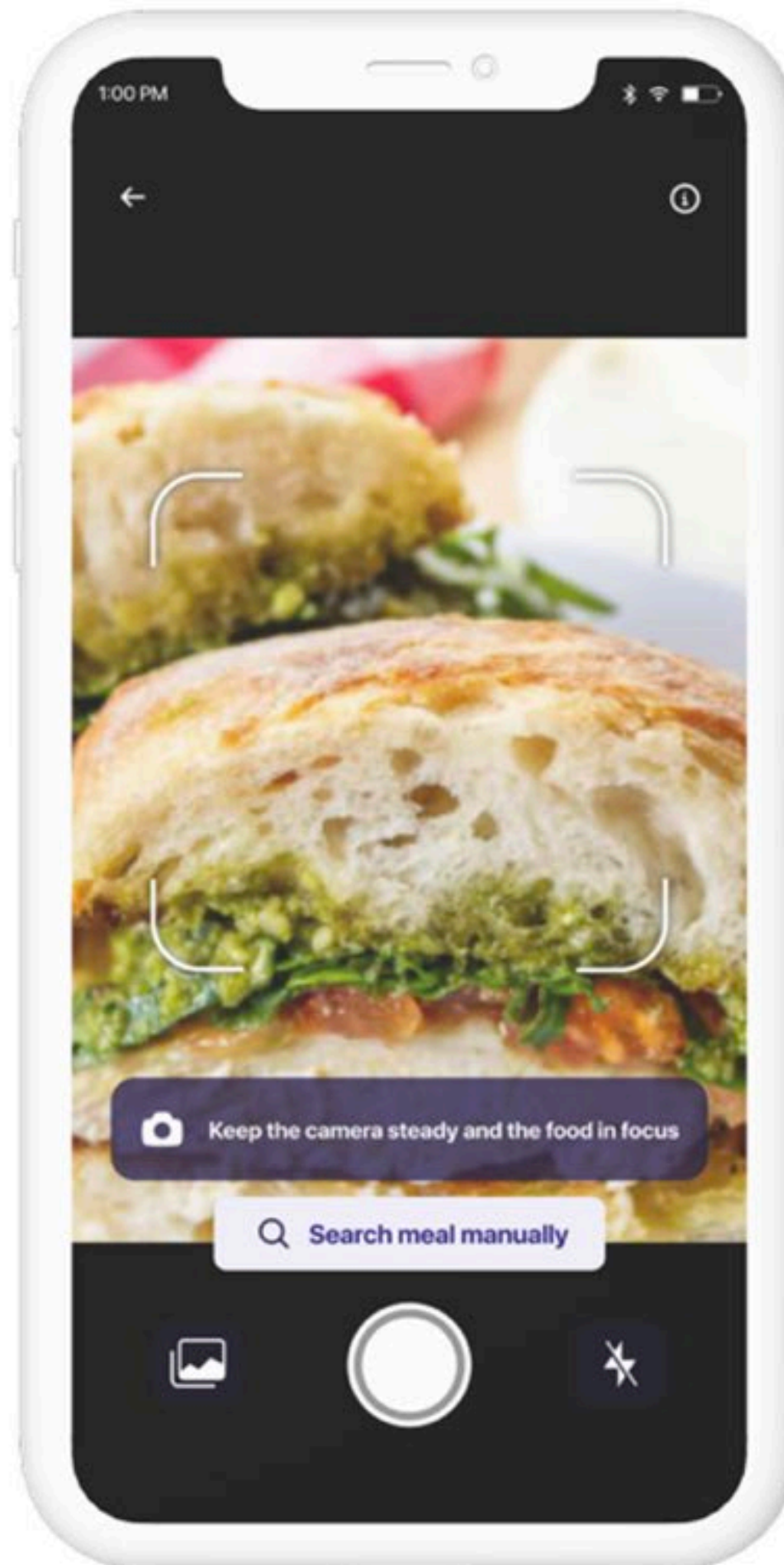
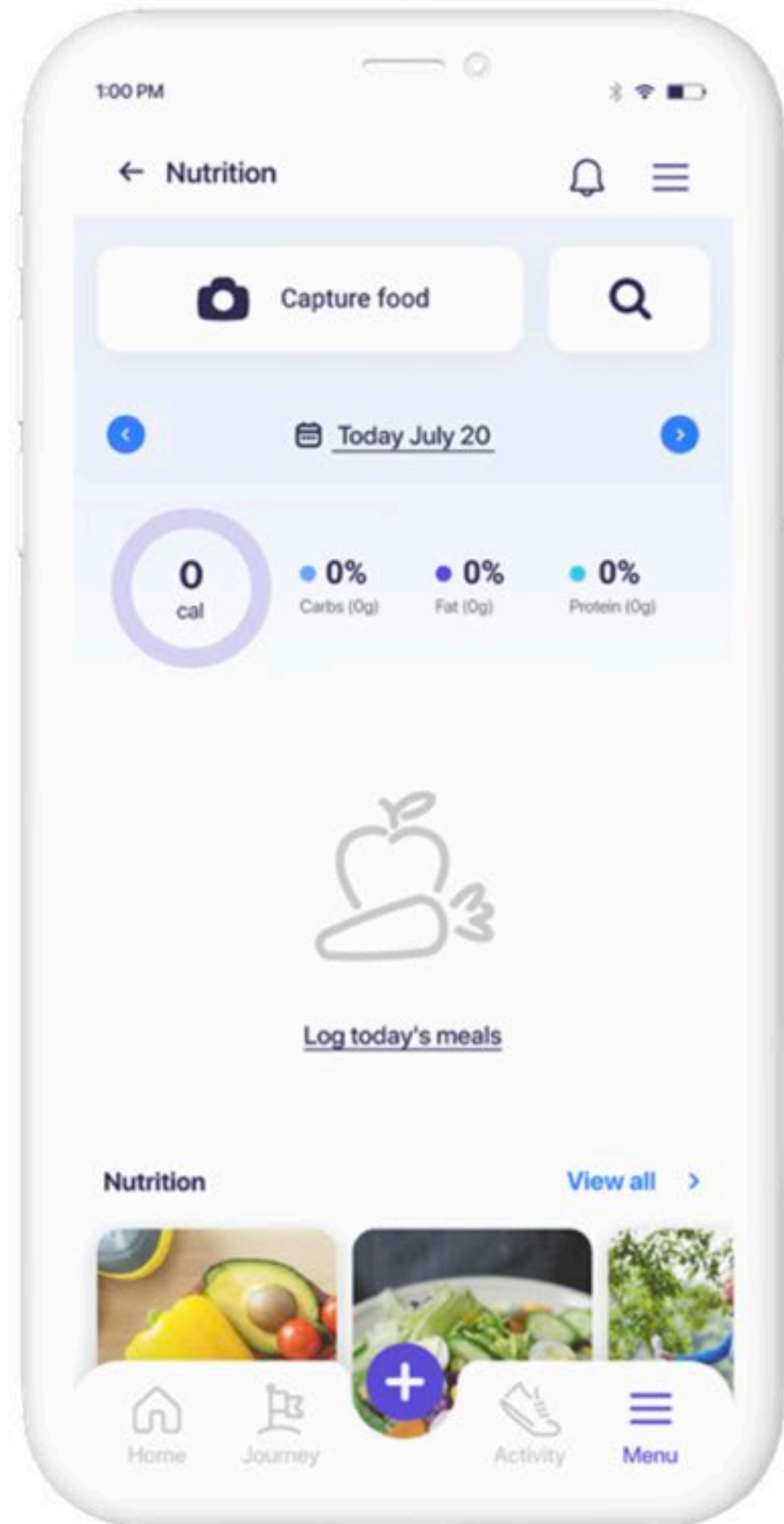
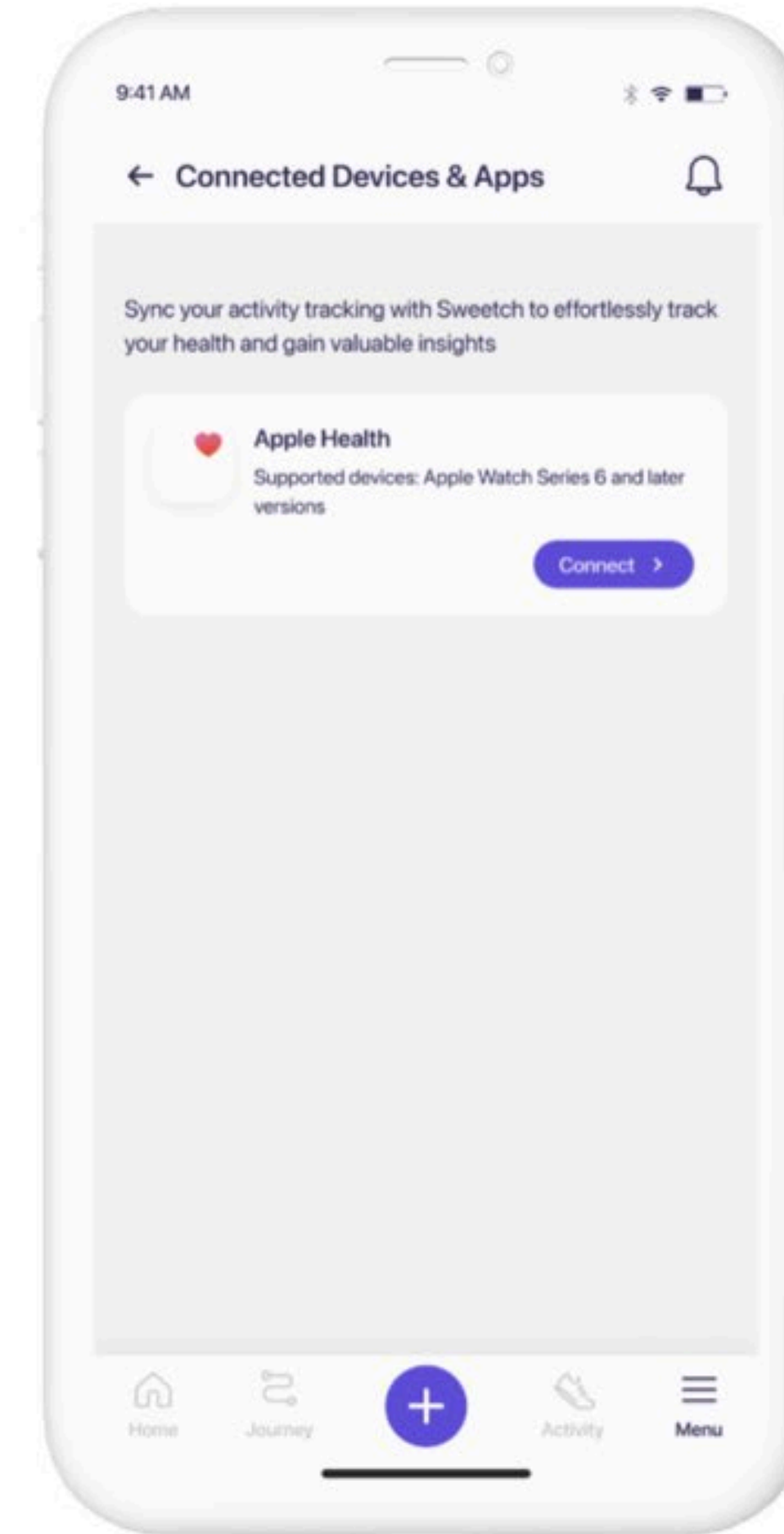
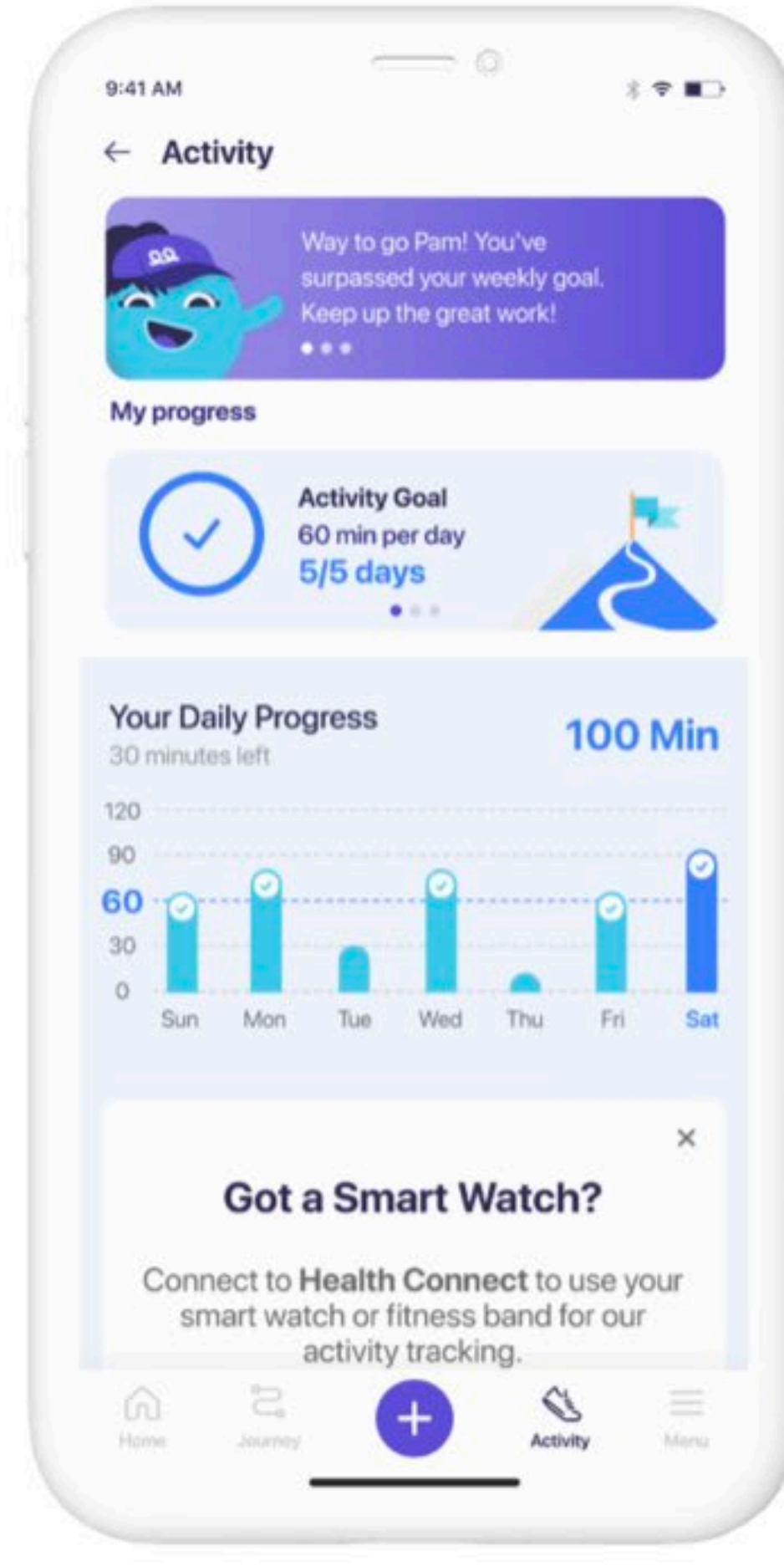
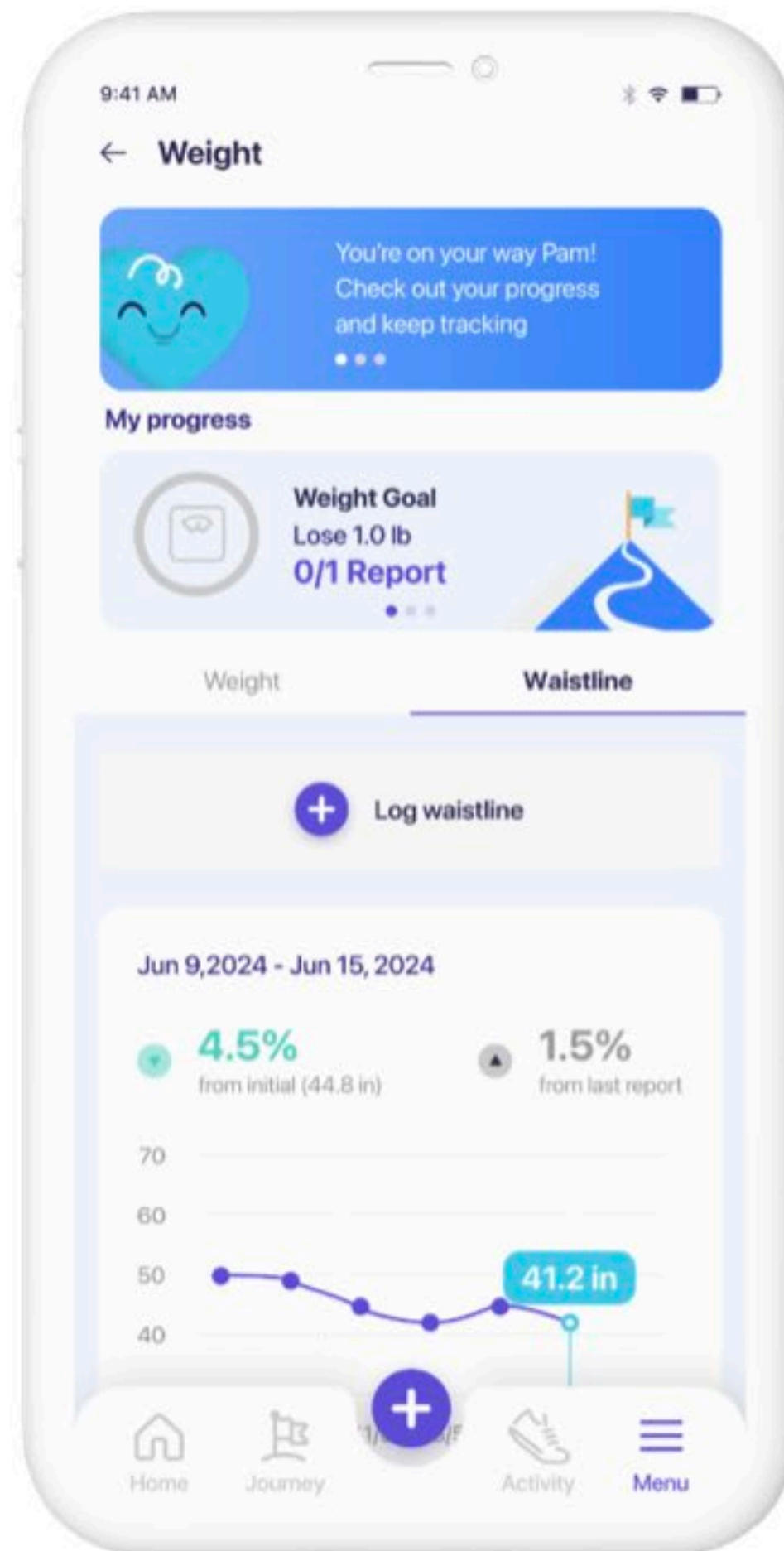


Photo-based Meal Analysis



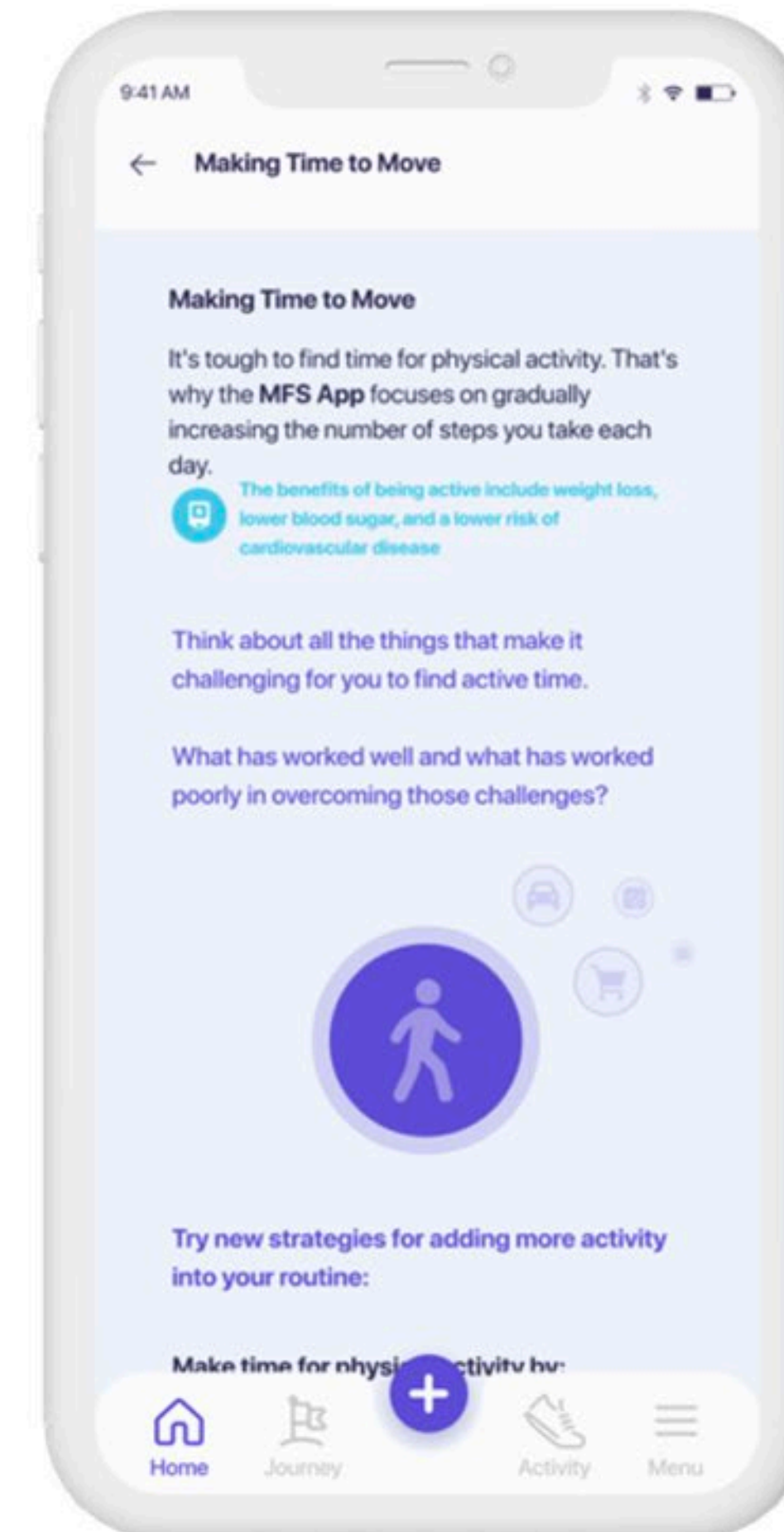
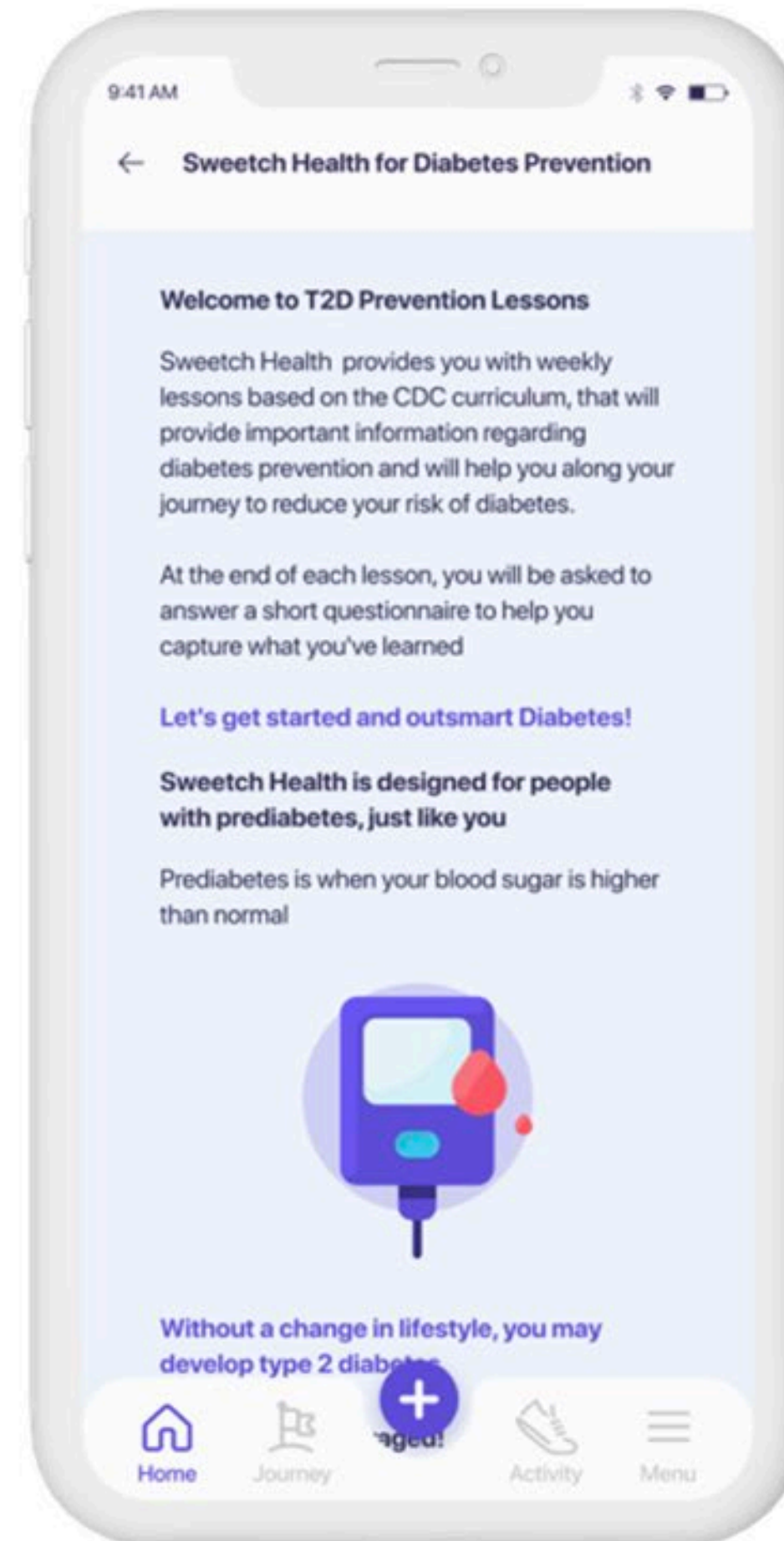
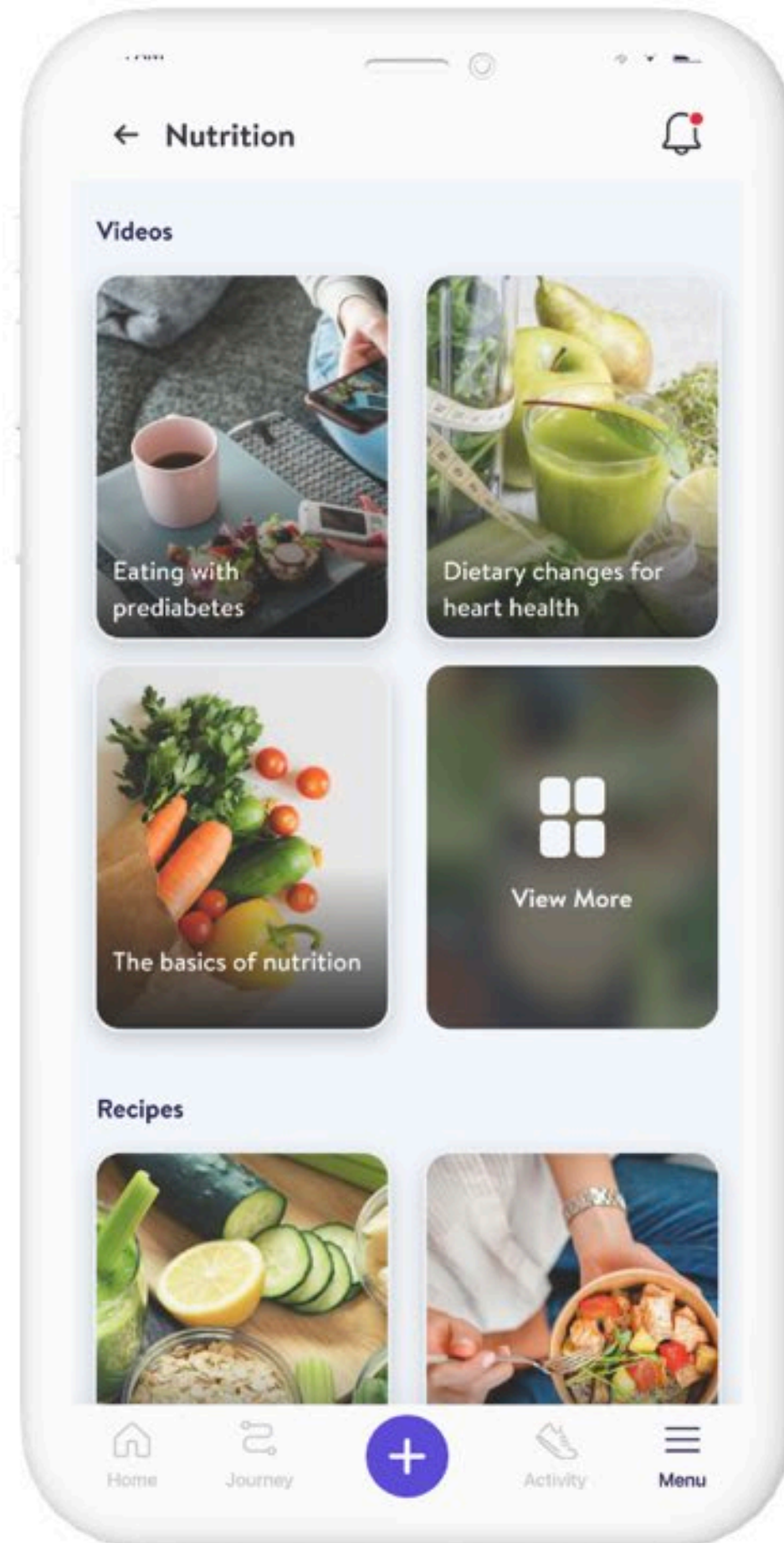
AI-led DPP: Weight & Physical Activity



Weight/Activity Tracking and Connected Devices



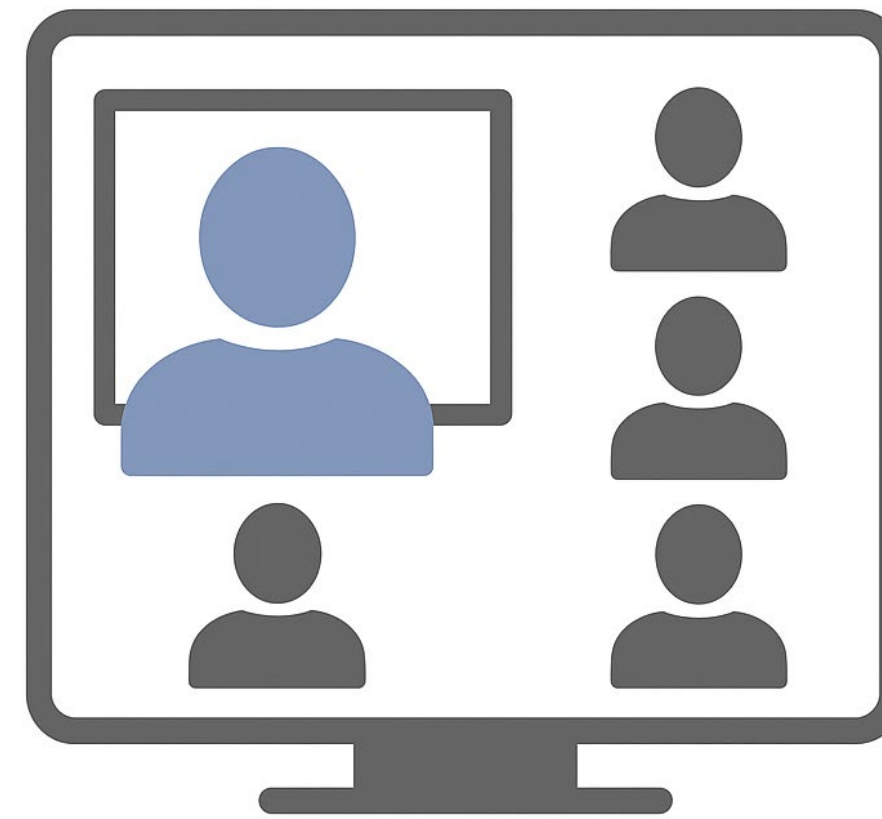
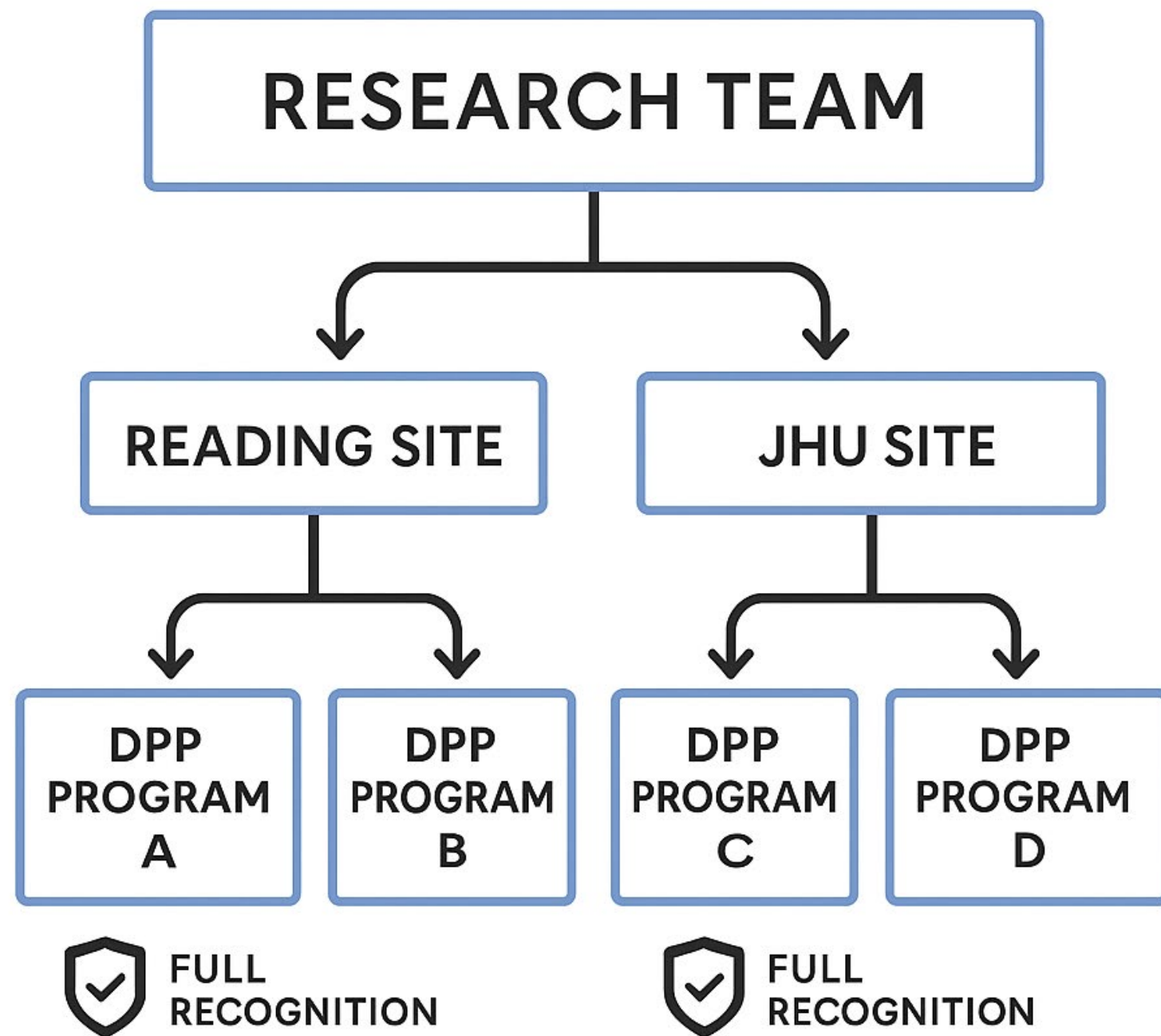
AI-led DPP: Educational Content



Educational Content



Human-led DPP



SYNCHRONOUS DISTANCE LEARNING
through video group conferences



Initial Core Phase

Core Maintenance Phase



Months 1-6

Months 7-12

16 weekly sessions

Biweekly / monthly sessions

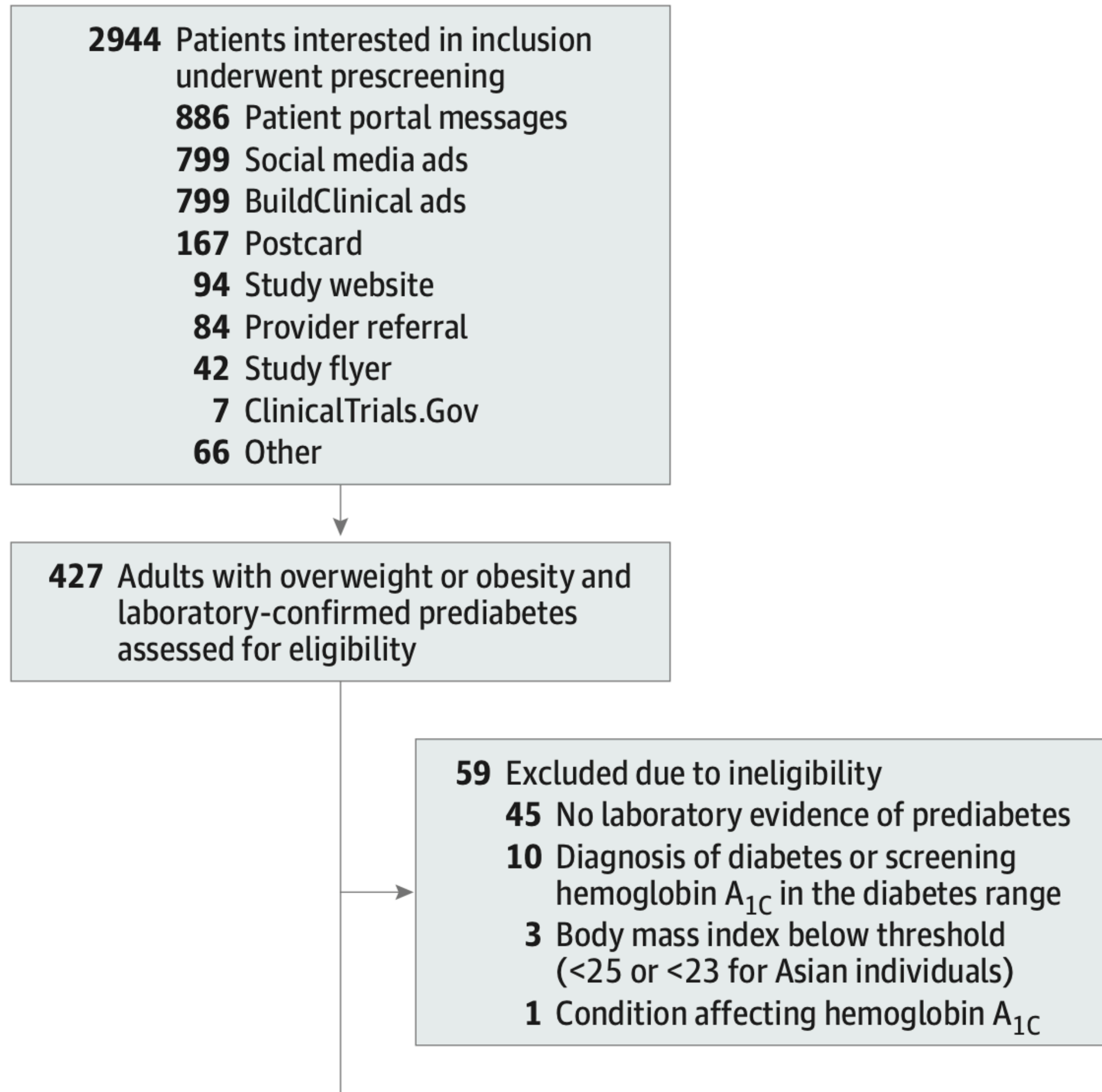
Primary Outcome

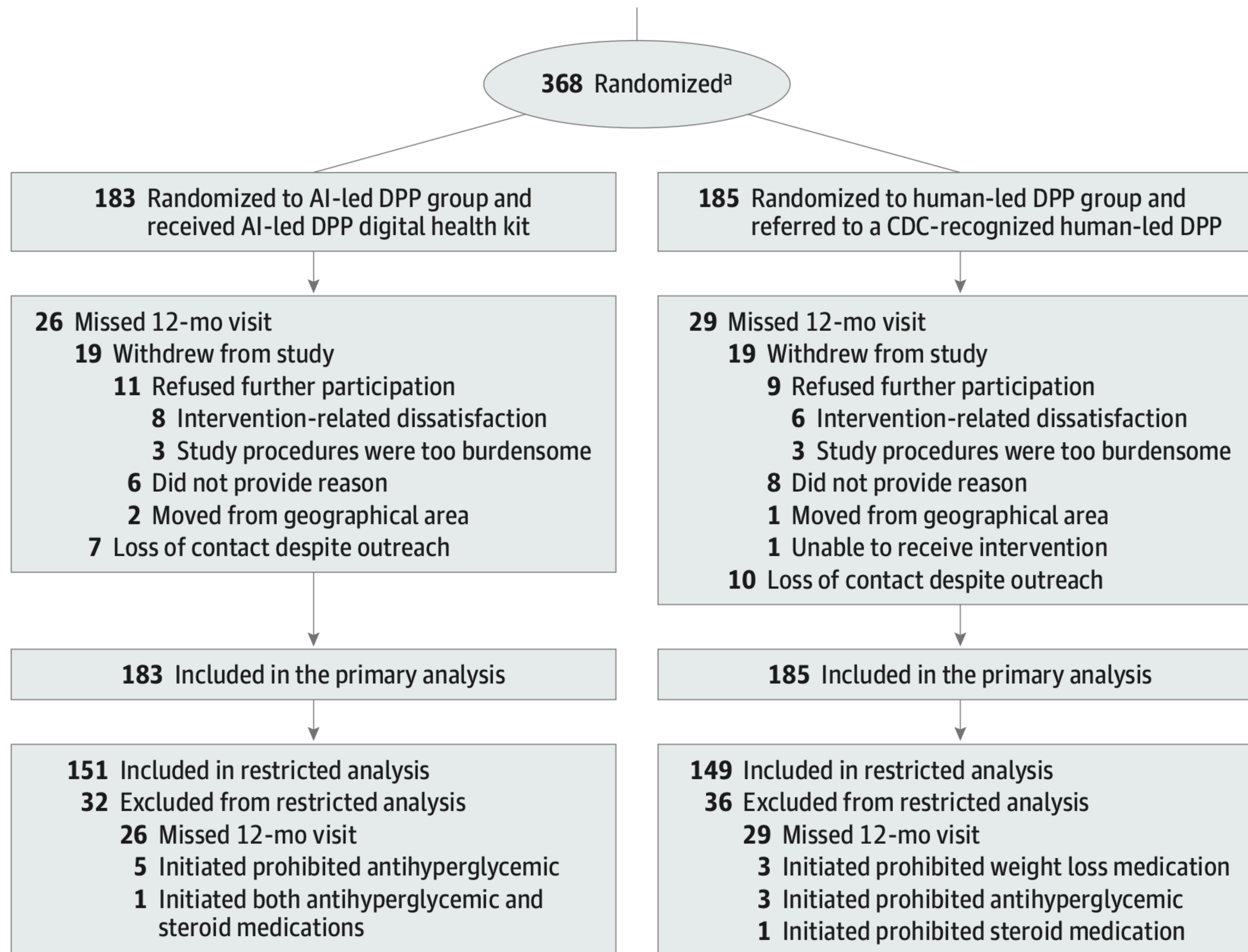
- Attainment of any of the following at **12 months***:
 - At least **5% weight loss**
 - At least **4% weight loss** combined with at least **150 minutes/week of moderate to vigorous physical activity (actigraphy)**
 - Absolute **decrease in HbA_{1c} of at least 0.2 percentage points****
- Composite endpoint defined by **2021 CDC Standards**

* Maintaining A1C <6.5% required; **applicable only to participants with baseline HbA1C of 5.7% to 6.4%

Recruitment

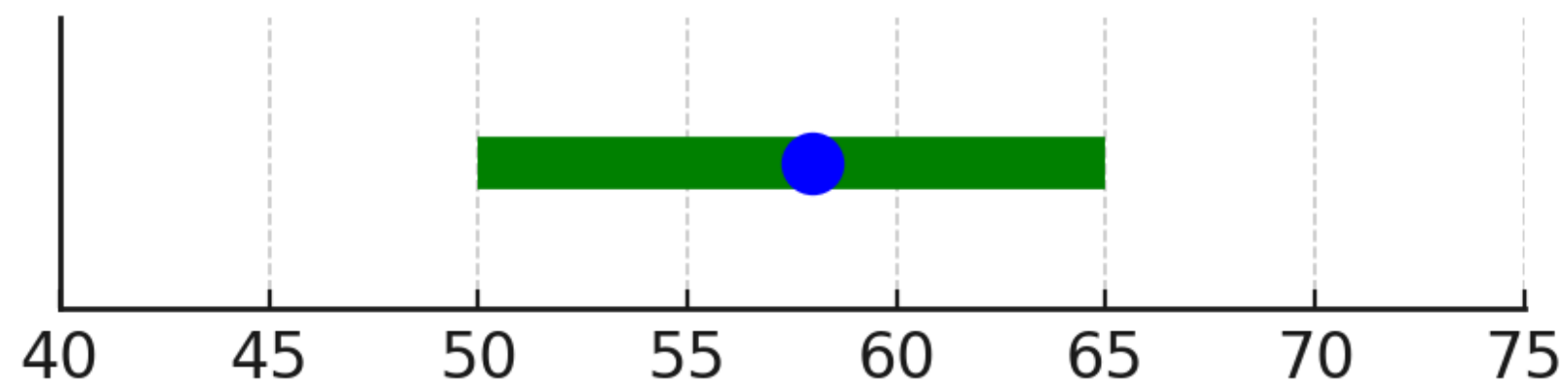
Patient portal messages were most effective recruitment strategy





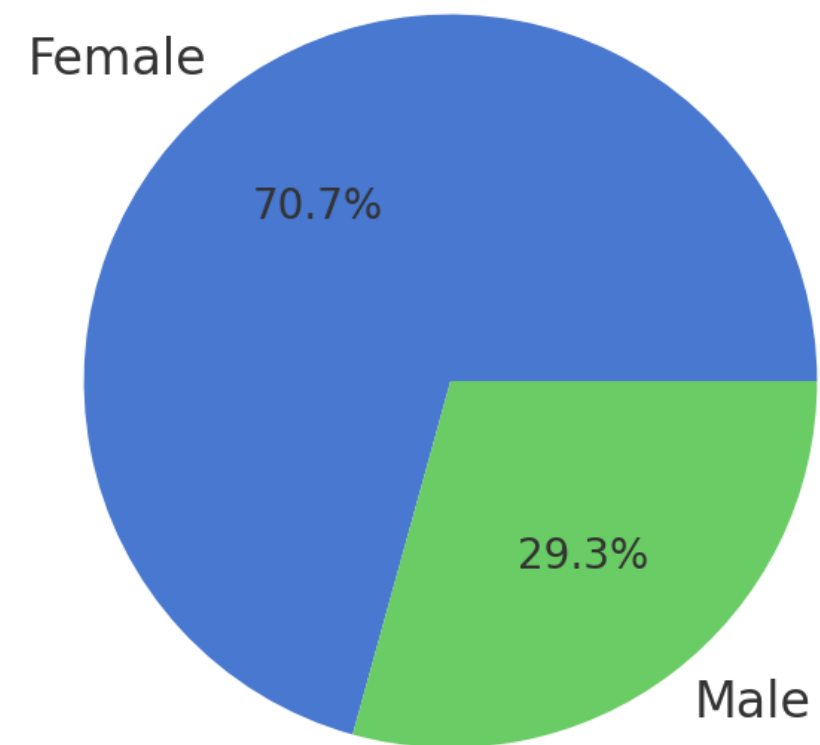
Study Participants

Median Age and Interquartile Range

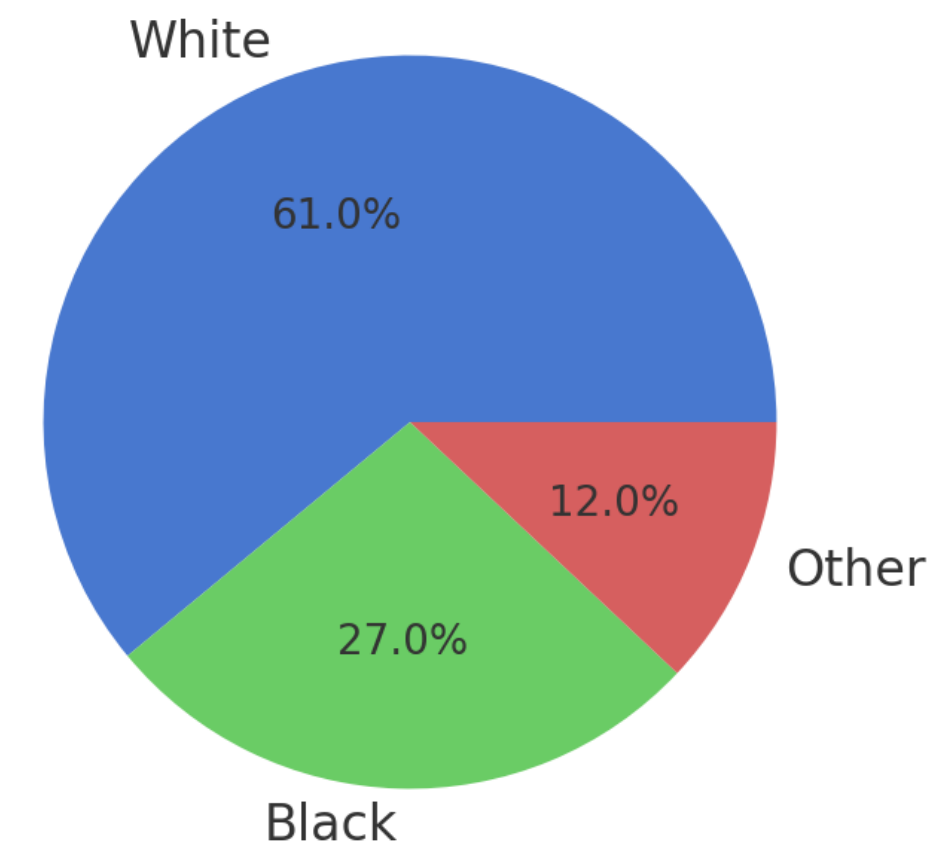


■ Interquartile Range (50-65 yrs) ● Median Age (58 yrs)

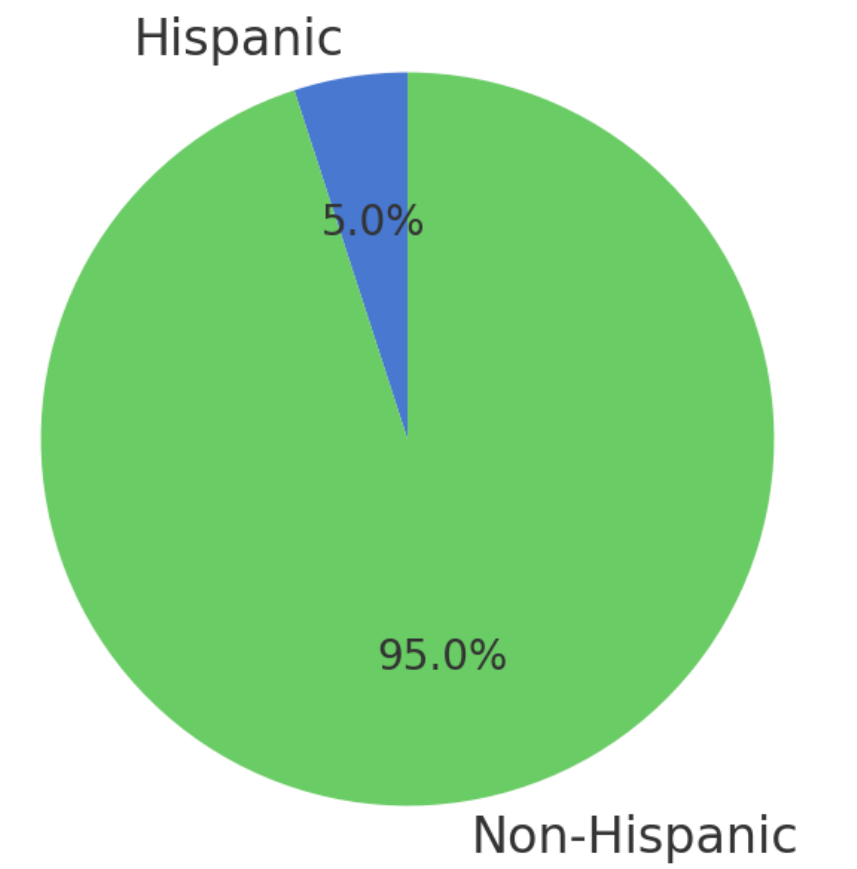
Sex Distribution



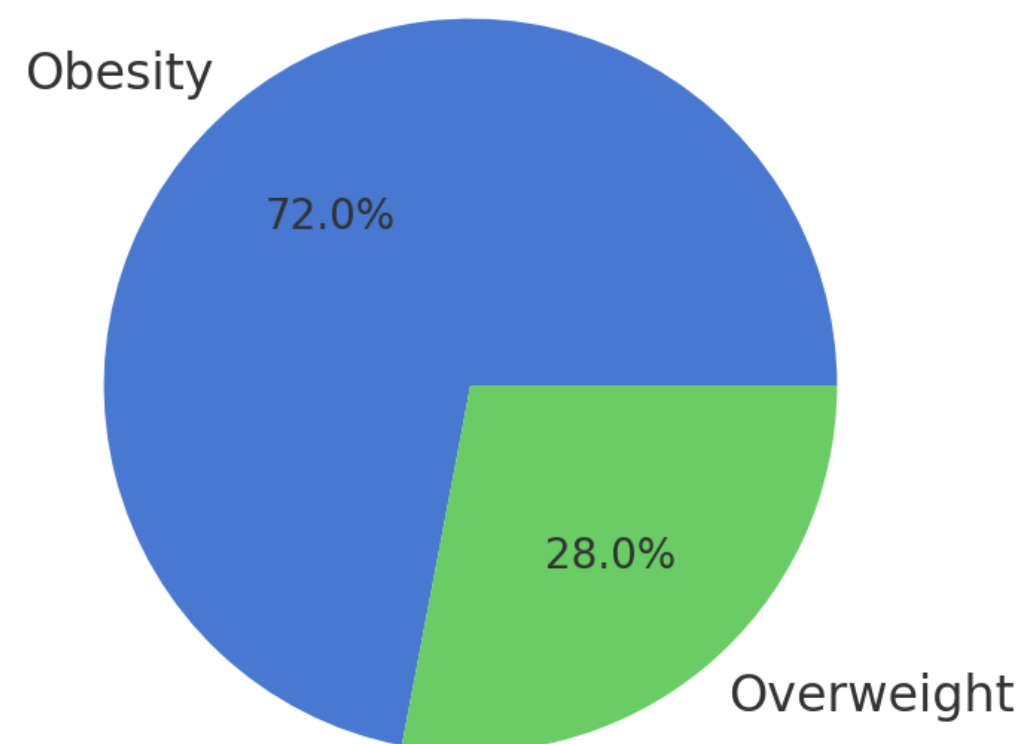
Race



Ethnicity



Weight Status



Baseline Lifestyle

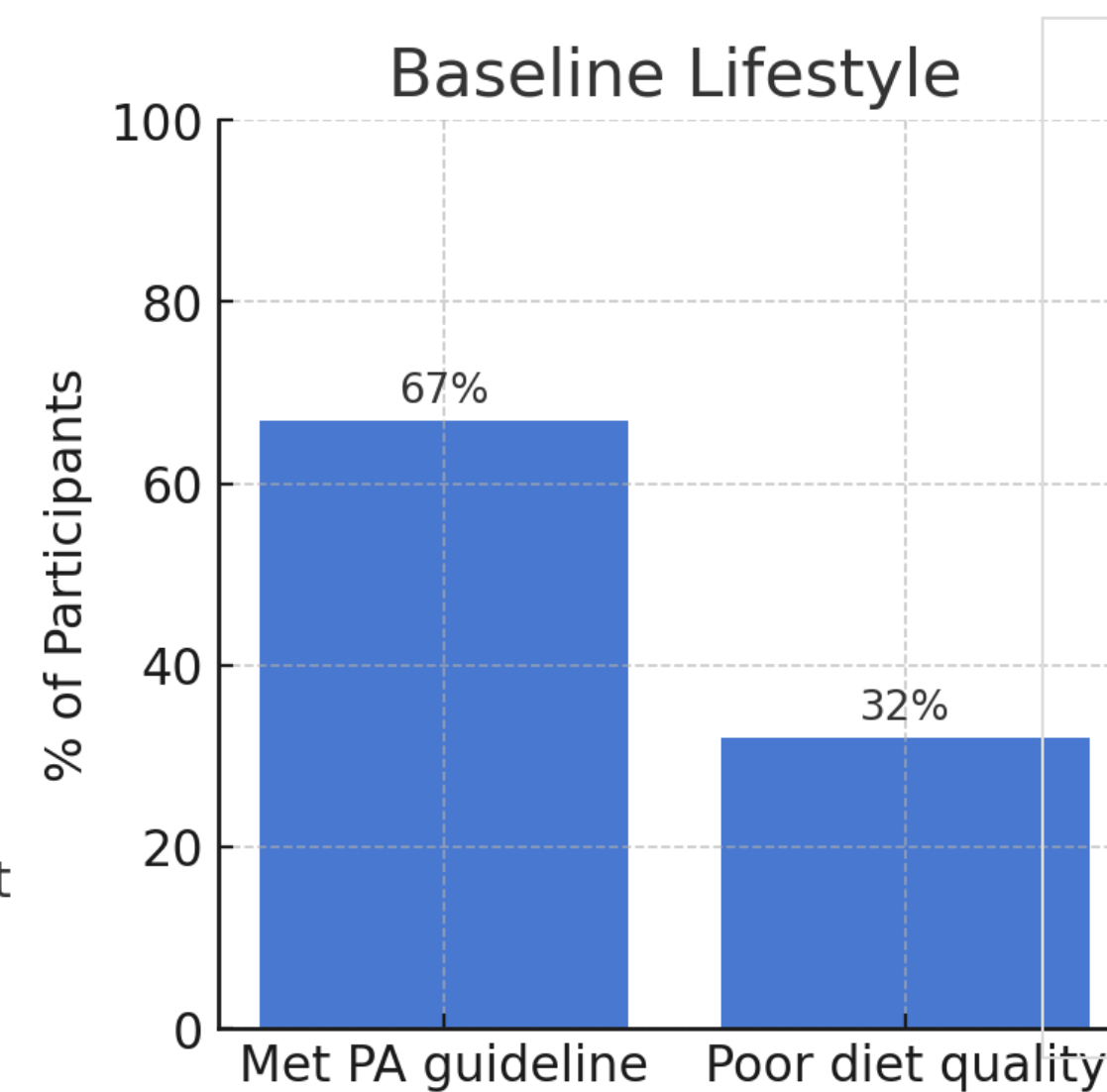
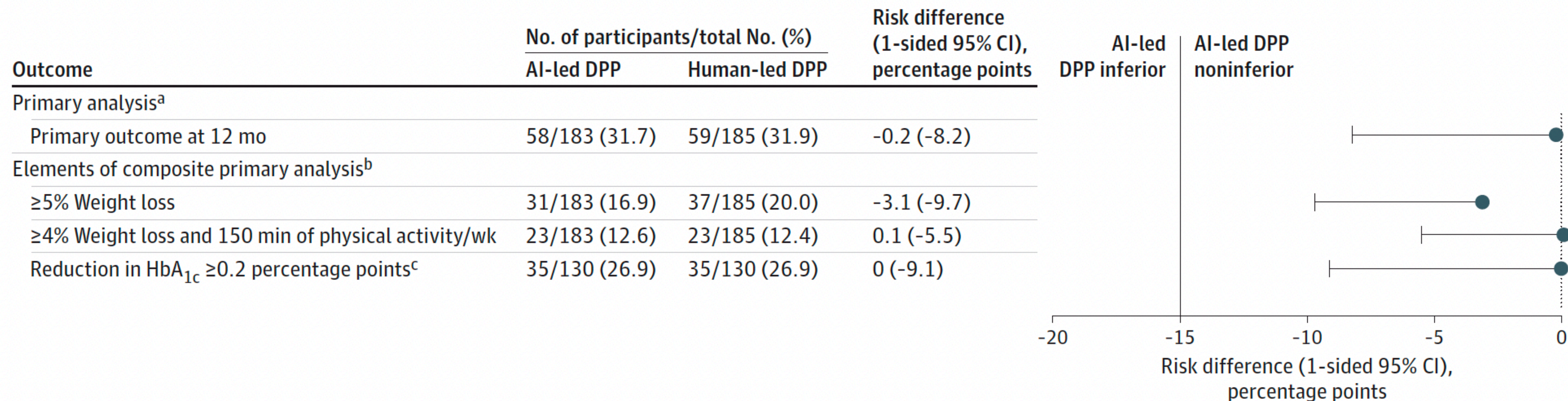


Figure 2. Forest Plot of Binary Outcome Differences

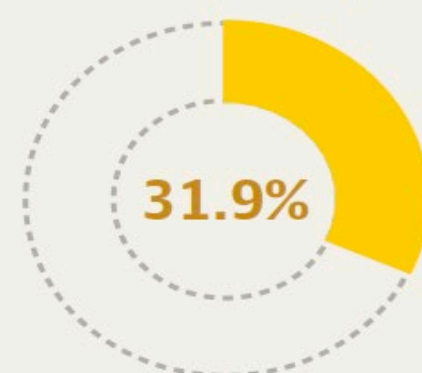
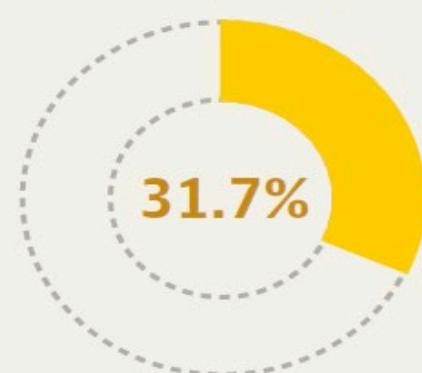


FINDINGS

Participants achieving the composite primary outcome

AI-led DPP group
58 of 183 participants

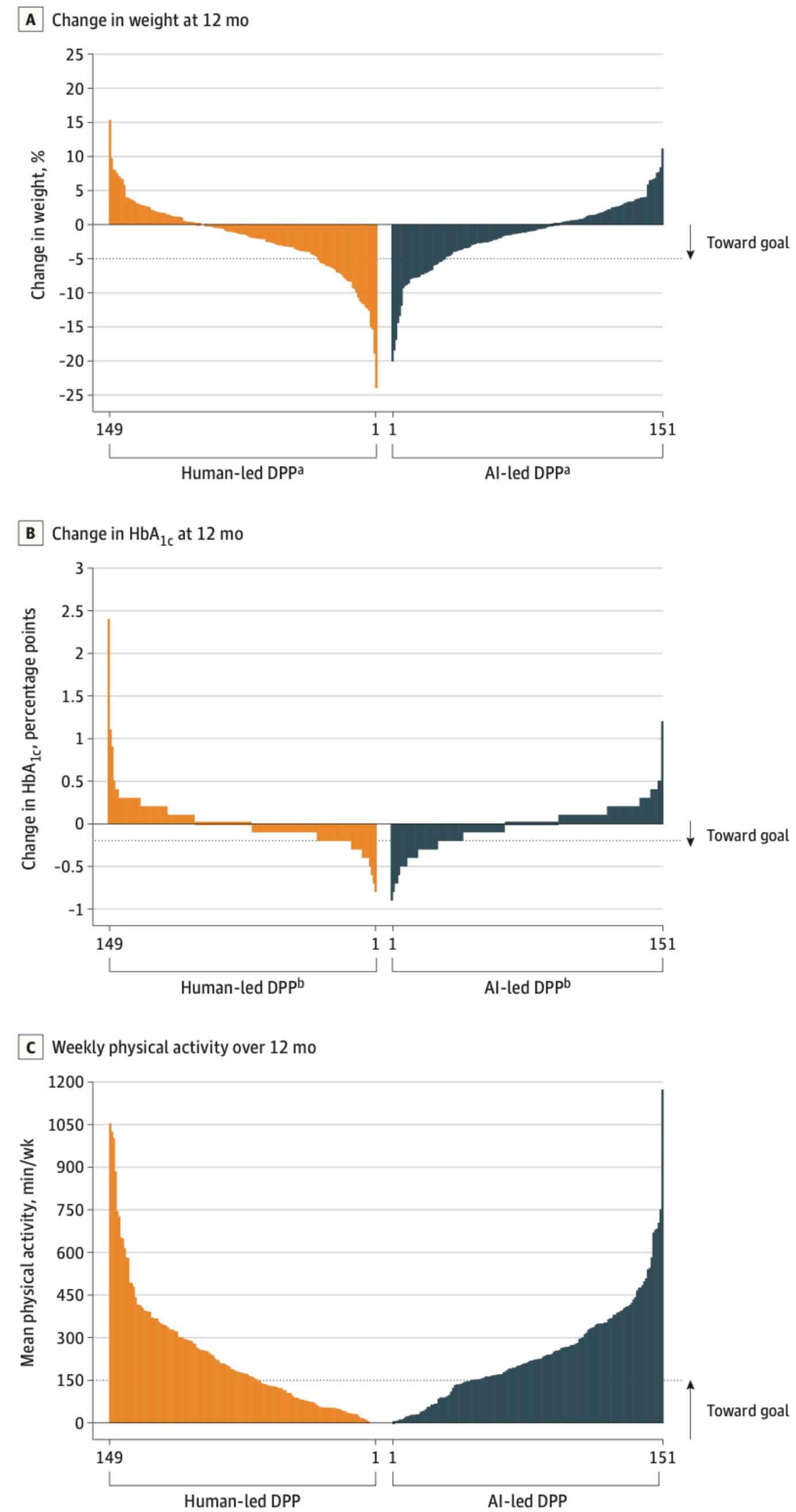
Human-led DPP group
59 of 185 participants



AI-led DPP was noninferior (noninferiority margin, 15%) to a human-led DPP:

Risk difference, **-0.2%** (1-sided 95% CI, -8.2%)

Figure 3. Percent Weight Change, HbA_{1c} Change, and Physical Activity at 12 Months



Results

Outcome vs. Engagement by Group

Figure 4. Outcome Achievement at Varying Levels of Engagement by Group

A AI-led DPP (n=183)

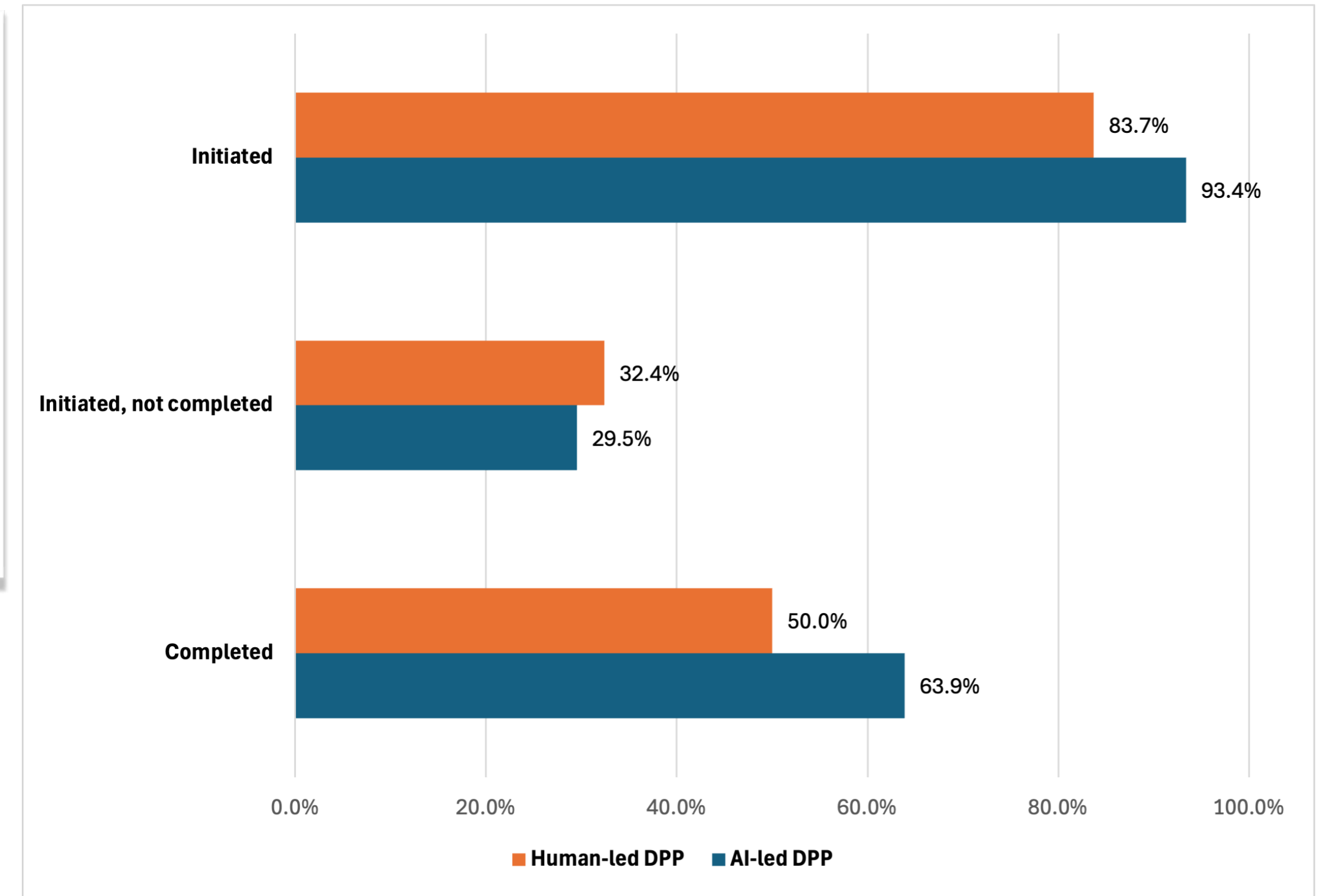
	Referred, not initiated	Initiated, not completed	Completed	Total by outcome achievement status
Did not achieve outcome	9	42	74	125
Achieved outcome	3	12	43	58
Total by engagement level	12	54	117	183

Matrix plots illustrating the distribution of participants by program engagement level and 12-month outcome. Between-group engagement categories are based on discrete program milestones and exposure to the program and may not fully correspond to equivalent levels of intensity or effort. A. In the AI-led DPP, outcome achievement was observed in 25% of those referred but did not initiate, 22% who initiated but did not complete, and 37% who completed.

B Human-led DPP (n=185)

	Referred, not initiated	Initiated, not completed	Completed	Total by outcome achievement status
Did not achieve outcome	23	43	60	126
Achieved outcome	9	17	33	59
Total by engagement level	32	60	93	185

Among those who achieved the outcome, 5% were referred but did not initiate, 21% initiated but did not complete, and 74% completed. B. In the human-led DPP, outcome achievement was observed in 28% of those referred but did not initiate, 28% who initiated but did not complete, and 35% who completed. Among those who achieved the outcome, 15% were referred but did not initiate, 29% initiated but did not complete, and 56% completed.



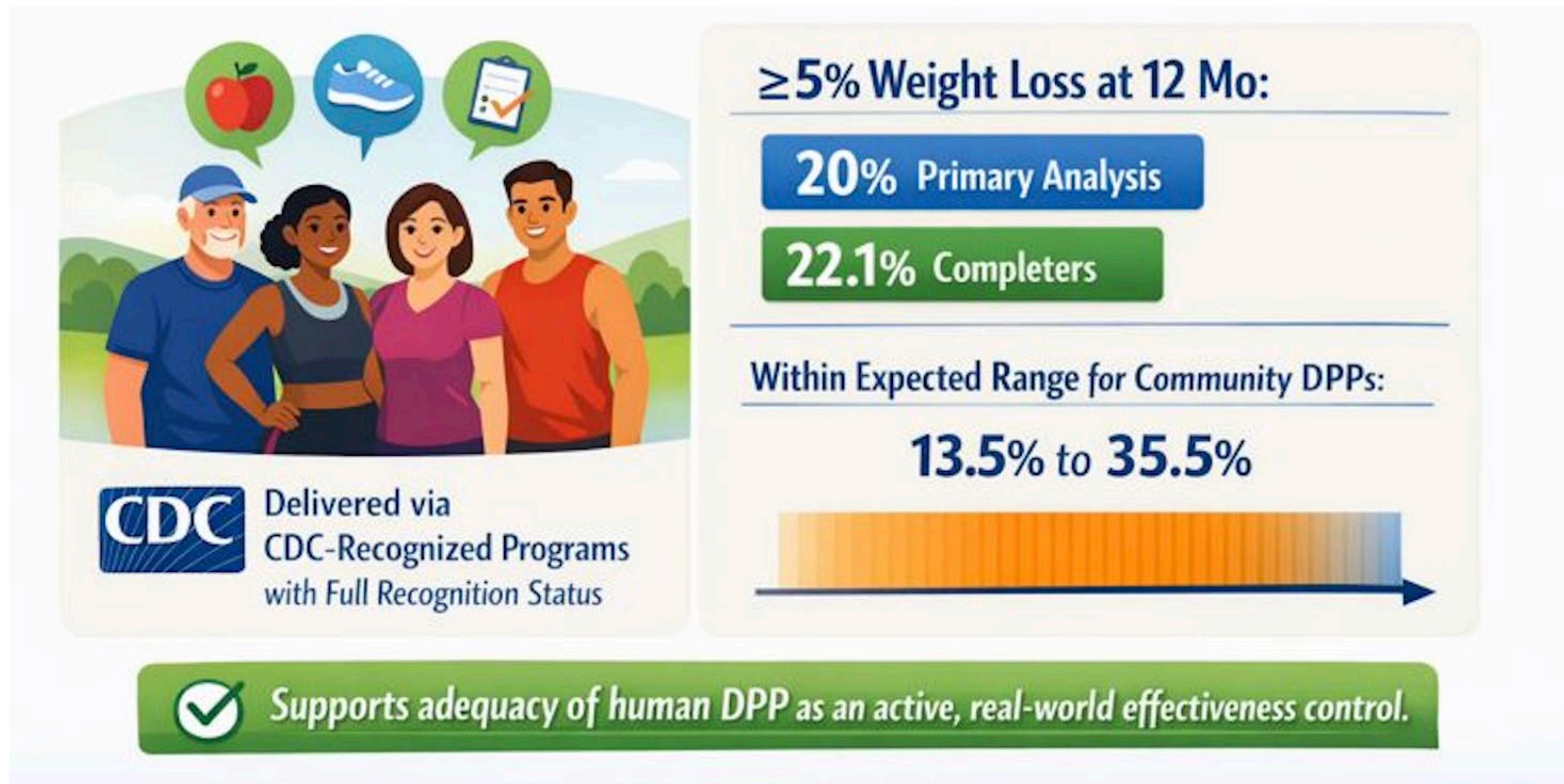
Main Findings

- **AI-driven DPP** delivered without human intervention was **non-inferior** to traditional **human coach-based DPP**
- **First RCT** comparing fully automated vs human DPP
- Adds to **limited evidence evaluating AI interventions** against established standards in medicine



Adequacy of control group

Paralleled the Real-World Community DPPs



Pragmatic Trial Design Features



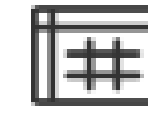
Real-world delivery

Embedded within CDC-recognized programs.



Study team as proxy PCP

Utilizing the study team to act as a surrogate Primary Care Provider.



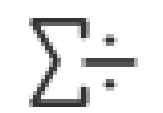
Remote low-burden data collection

Employing methods like actigraphy with remote upload and automated surveys.



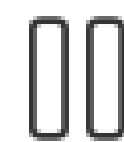
Surrogate primary outcome

Aligned with existing policy for relevance.



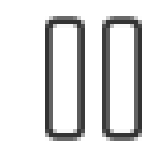
Noninferiority framework

Reduce sample size and timeline.



Intentional delay of AI kit deployment

Strategically delaying the introduction of AI kits.



Pausing randomization

Temporarily halting randomization to ensure comparability across groups. Balancing effectiveness /



COVID-19 adaptations

Incorporating home visits and Point-of-Care A1C Now+ testing.

Strengths



**Randomized
design**



**Criterion-
standard
active control**



**High
retention**



**Objective
physical
activity
assessment**



**Pragmatic
approach to
DPP delivery**

Limitations



Not masked



Surrogate outcomes



Human DPP delivery may have varied



Impact of app updates



Study visits + actigraphy



Referrals not from PCP



COVID-19 impact on in-person DPP



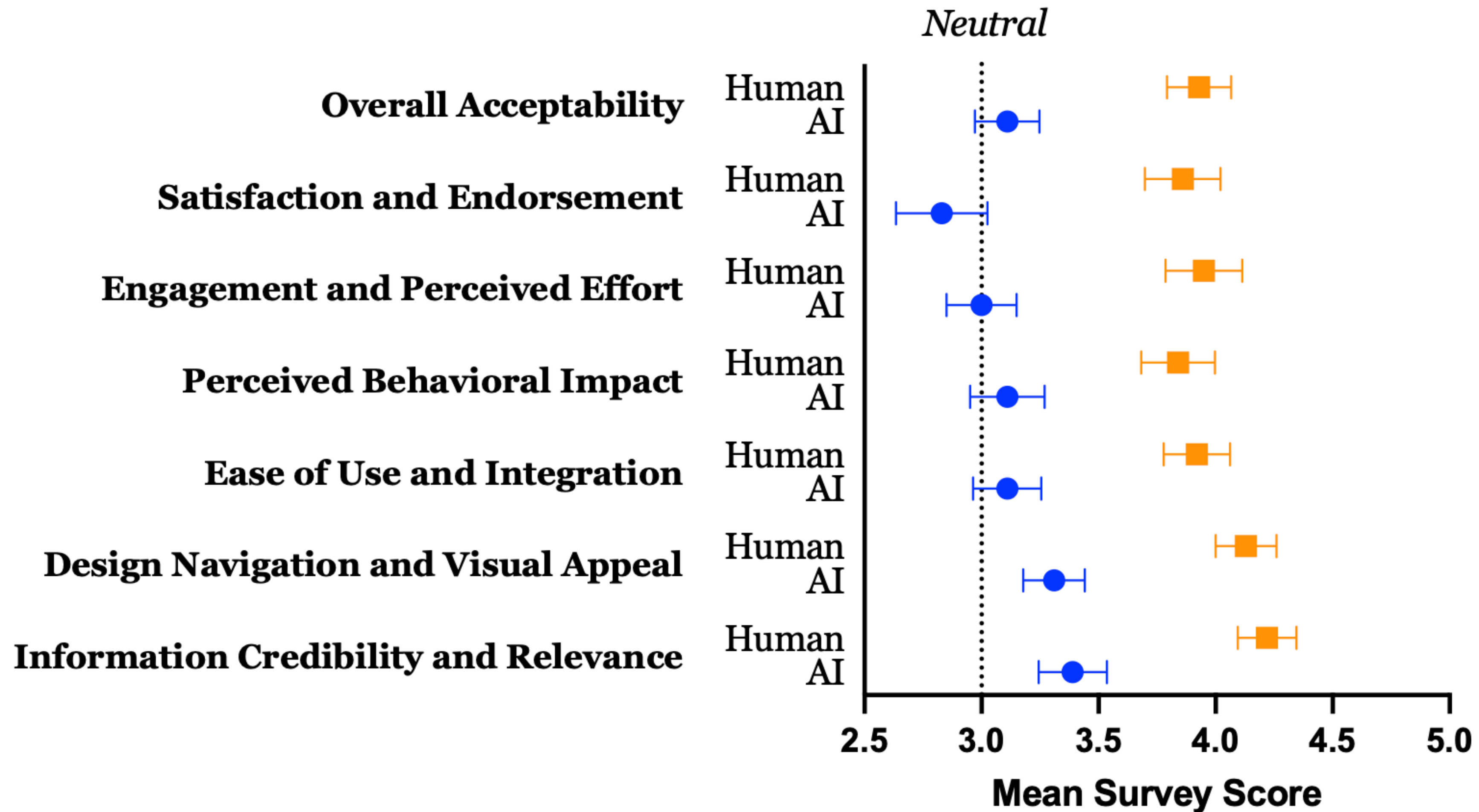
Missing 12-month data



Motivated and active participants

Acceptability

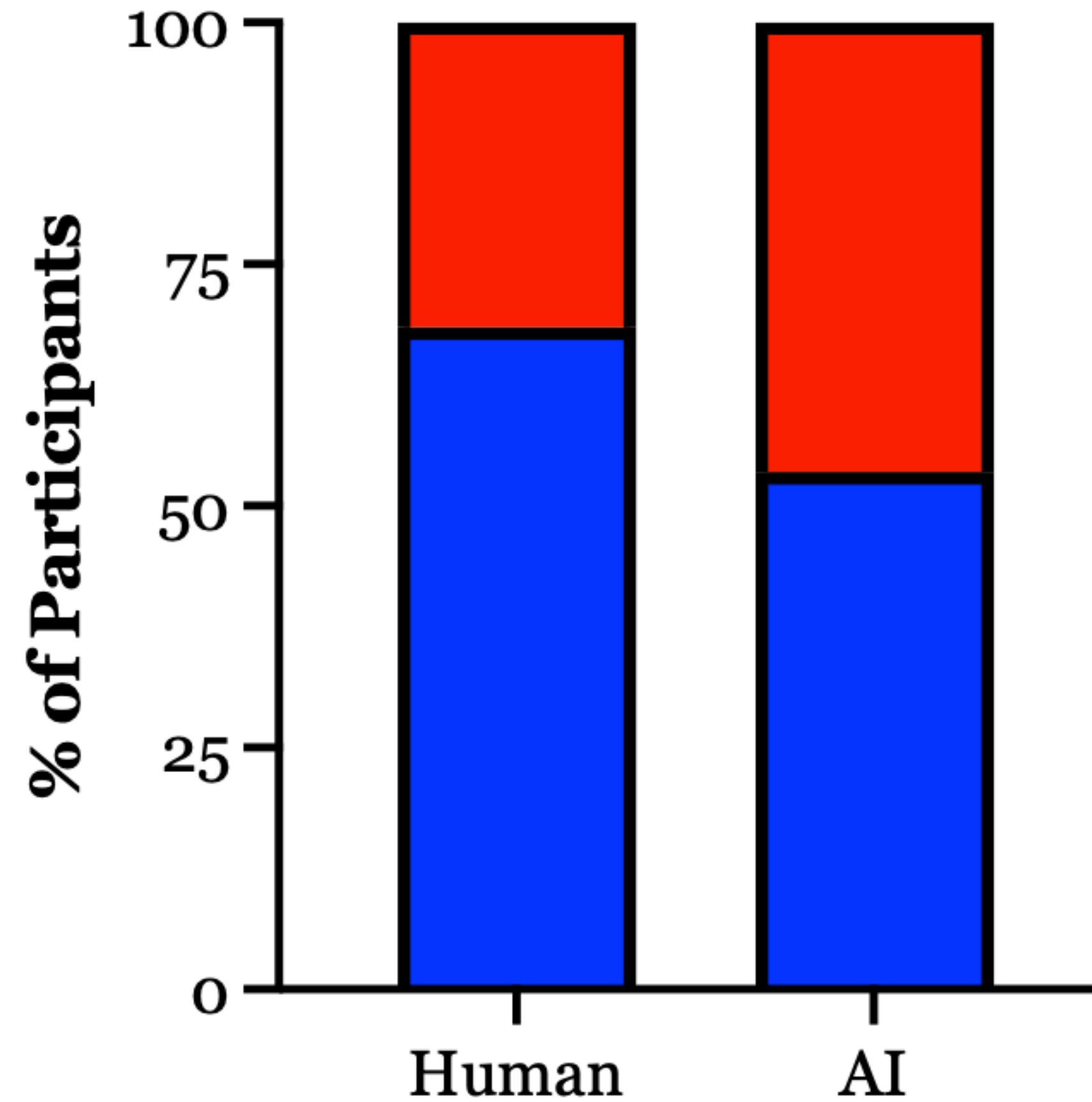
AI vs. Human DPP



Preference

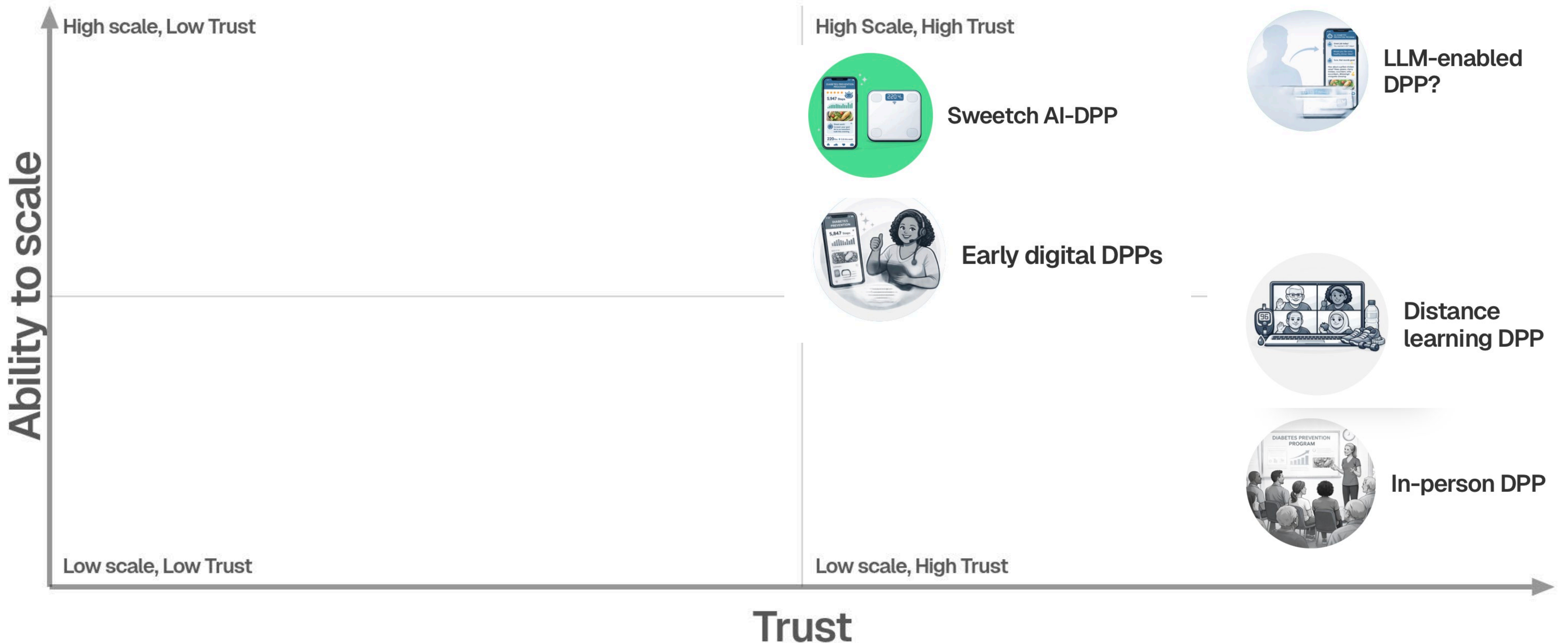
AI vs. Human DPP

- Preference Concordant with Assigned Intervention
- Preference Discordant with Assigned Intervention



Scale + Human Experience

Efficacy → Delivery Science → Population Prevention Systems



Future Directions

Research Priorities

- Improve acceptability of AI
- Identify essential coaching components
- Evaluate **complementary AI + human models**



Patient Perspectives

- Address concerns about trust and reliability
- Preserve human connection in digital care



Sweetch 2.0 (LLM-enabled)

The Sweetch D.R.E.A.M.® Framework

A psychologically-grounded AI model for self-motivated transformation

Daily resolution

Setting personal daily resolutions triggered by one's CGM data

Motivation formation

Connecting positive experiences to agency and transformation



Reflection

Building awareness through assisted reflection

Emotional Acceptance

Reframing and manage resistance and setbacks as learning

Action

Achieving small personal wins

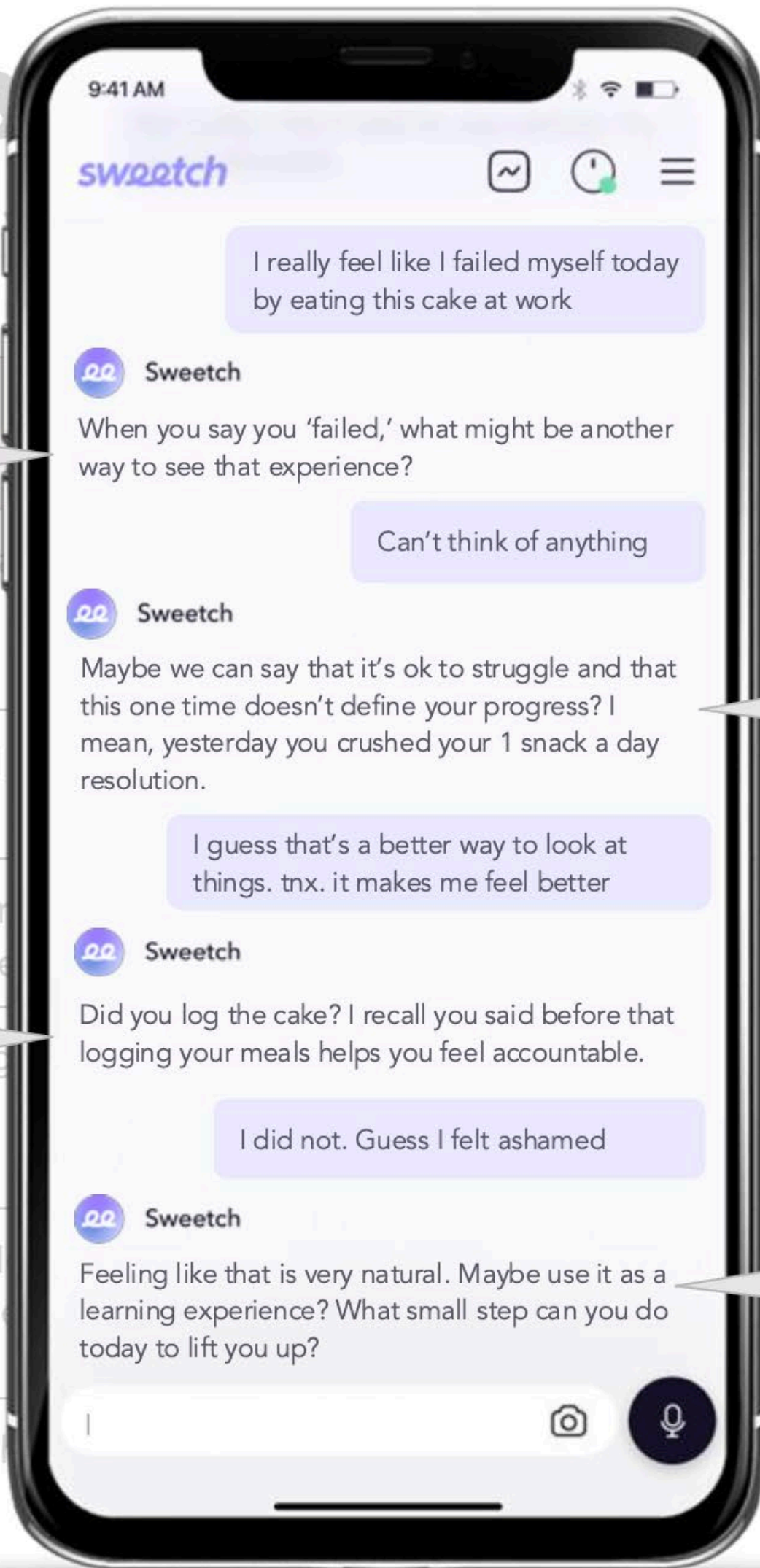
D.R.E.A.M.® - The AI Companion

Change Toolkit

The DREAM companion uses a range of evidence-based frameworks to build connection and to dynamically adapt to the context of specific conversations

uses to achieve emotional well-being in the context of specific conversations

Framework	Core Purpose	Example Prompt or Interaction
Motivational Interviewing (MI)	Engage and elicit motivation to reduce resistance	"When you say you 'failed,' what might be another way to see that experience?"
Relational Agent Model (Bickmore)	Build long-term trust and human-like rapport	"You sound determined even though it's hard — what feels most important right now?"
Self-Compassion Framework (Neff)	Reduce shame and self-criticism, strengthen emotional safety	"It's okay to struggle — this doesn't define your progress."
Self-Determination Theory (SDT)	Support autonomy, competence, and connection	"You choose what works for you — how can we make this goal feel doable?"
Acceptance & Commitment Therapy (ACT)	Cultivate acceptance while focusing on personal values	"Feeling like that is very natural. Maybe use it as a learning experience? What small step can you do today to lift you up?"
Cognitive Behavioral Coaching (CBC)	Reframe unhelpful thoughts, build coping patterns	"When you say you 'failed,' what might be another way to see that experience?"



Motivational Interviewing

Self-Compassion Framework

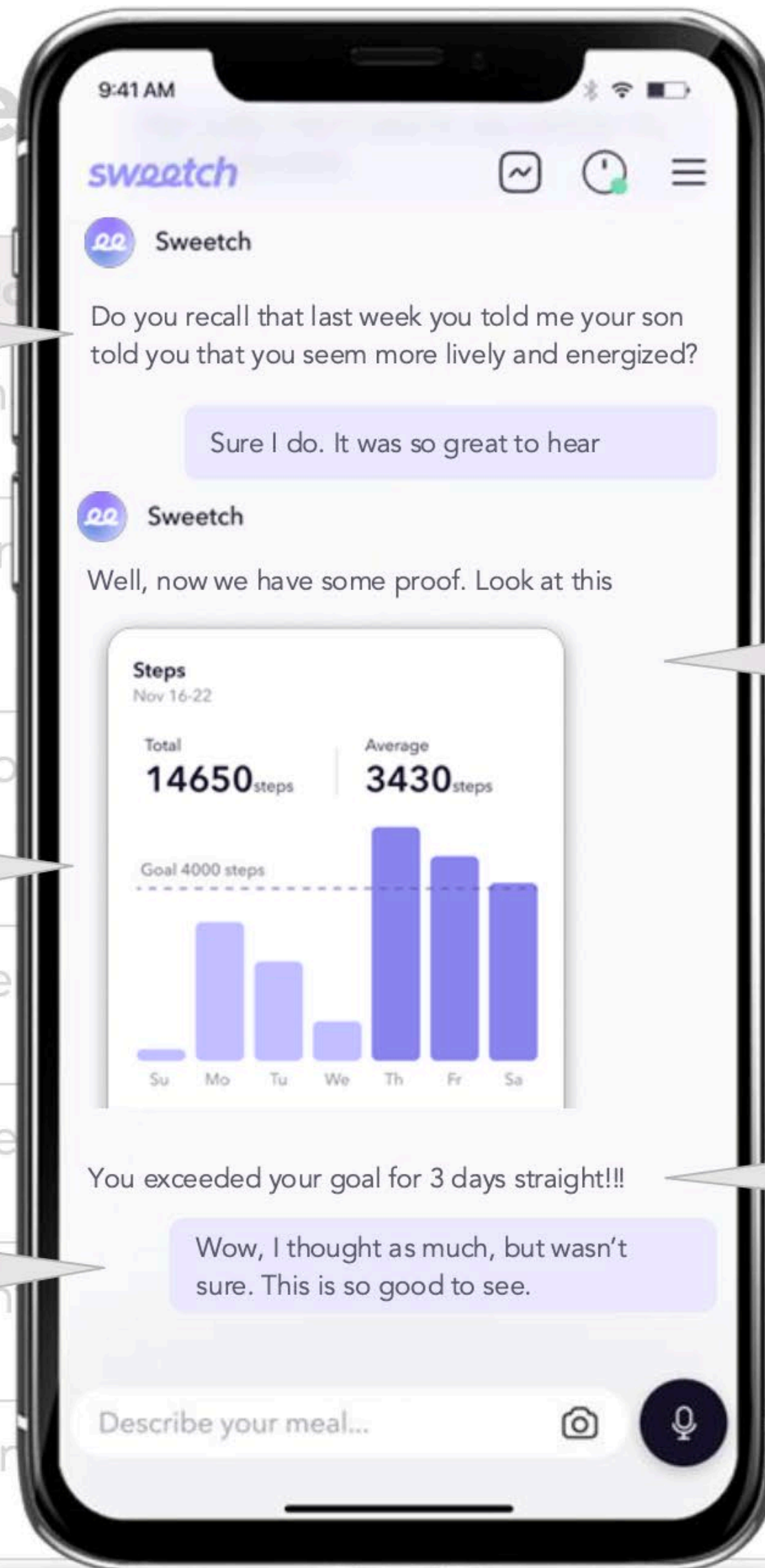
Relational Agent Model

Acceptance & Commitment Therapy

D.R.E.A.M.® - AI-Driven

Change Drivers

Lever	Retention Effect
Emotional agentic Companion	2-3x longer retention
Emotional Memory	↑ Return probability
Data visualization	↑ Daily stickiness
Micro-Reinforcement	↑ Comeback rates
Biometric Feedback	
Adaptive Insights	
Fail-Safe Re-Engagement	



Conclusions

- **Prevention remains an implementation challenge, not an efficacy problem.**
 - High prevalence; low reach and retention
 - Need scalable models
- **AI-driven DPP:**
 - Comparable outcomes
 - Adequate engagement
 - Lower stated preference vs human coaching

Acknowledgements



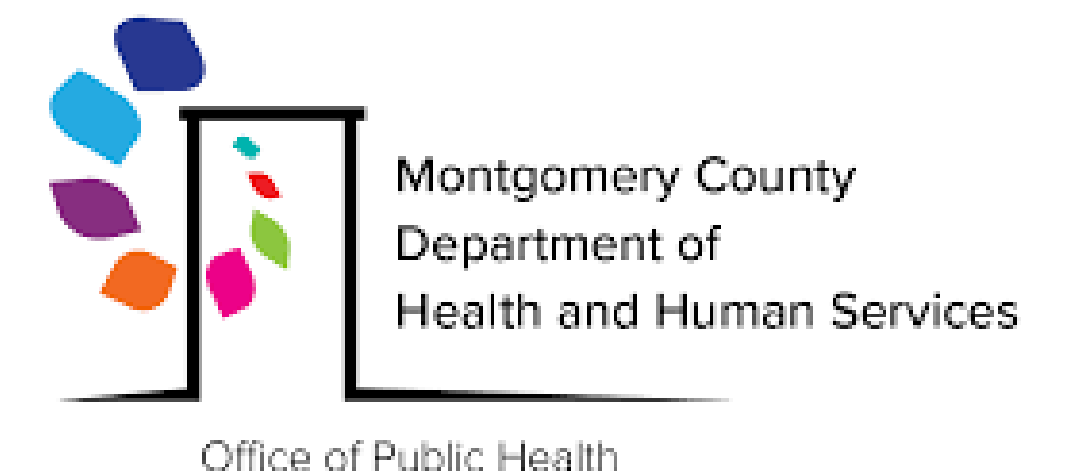
National Institute of Diabetes and Digestive and Kidney Diseases

R01DK125780



ChatGPT 5.0: Image creation

Human-led DPPs



Office of Public Health

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Diabetes Technology Meeting 2025

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