



The SMARTer Trial: An Adaptive, Technology-Assisted Approach to Behavioral Weight Loss



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ABSTRACT

Behavioral weight-loss programs such as the Diabetes Prevention Program (DPP) are effective but resource-intensive and difficult to scale to meet population-level needs. Adaptive, stepped-care interventions offer a potential solution by using prespecified decision rules to increase treatment intensity only for individuals who do not achieve early weight-loss targets. The SMARTer Weight Loss Management study is a three-arm, randomized controlled non-inferiority trial designed to evaluate whether an adaptive, technology-assisted intervention can achieve weight loss comparable to DPP at lower cost.

Adults with a BMI ≥ 25 kg/m² are randomized to one of three conditions: (1) an adaptive SMARTer intervention that includes app-based self-monitoring, wearable devices, and brief remote coaching with meal replacements for early non-responders; (2) a fixed DPP intervention delivered through structured educational materials and remote coaching sessions; or (3) a self-guided control condition that provides health education resources without ongoing coaching. Body weight is assessed at baseline and at 3-, 6-, 9-, and 12-month follow ups. The primary outcome is change in weight from baseline to 6 months. A micro-costing approach will compare cost and cost-effectiveness across study arms. Recruitment and data collection are ongoing.

INTRODUCTION

- Obesity is a major risk factor for diabetes, cardiovascular disease, and cancer
- Behavioral interventions targeting diet and physical activity produce meaningful weight loss
- Gold-standard programs (e.g., Diabetes Prevention Program – DPP) are effective but:
 - Burdensome
 - Expensive
 - Difficult to scale
- Technology-assisted interventions (apps, wearables) may reduce delivery burden
- Adaptive stepped-care interventions
 - Begin with lower-intensity treatment
 - Increase support only for early non-responders
 - Improve efficiency while maintaining outcomes

SMARTer Trial Objective

- Evaluate whether an adaptive, technology-supported intervention can achieve weight loss non-inferior to DPP at lower cost.

Recruitment and Optimization Strategies

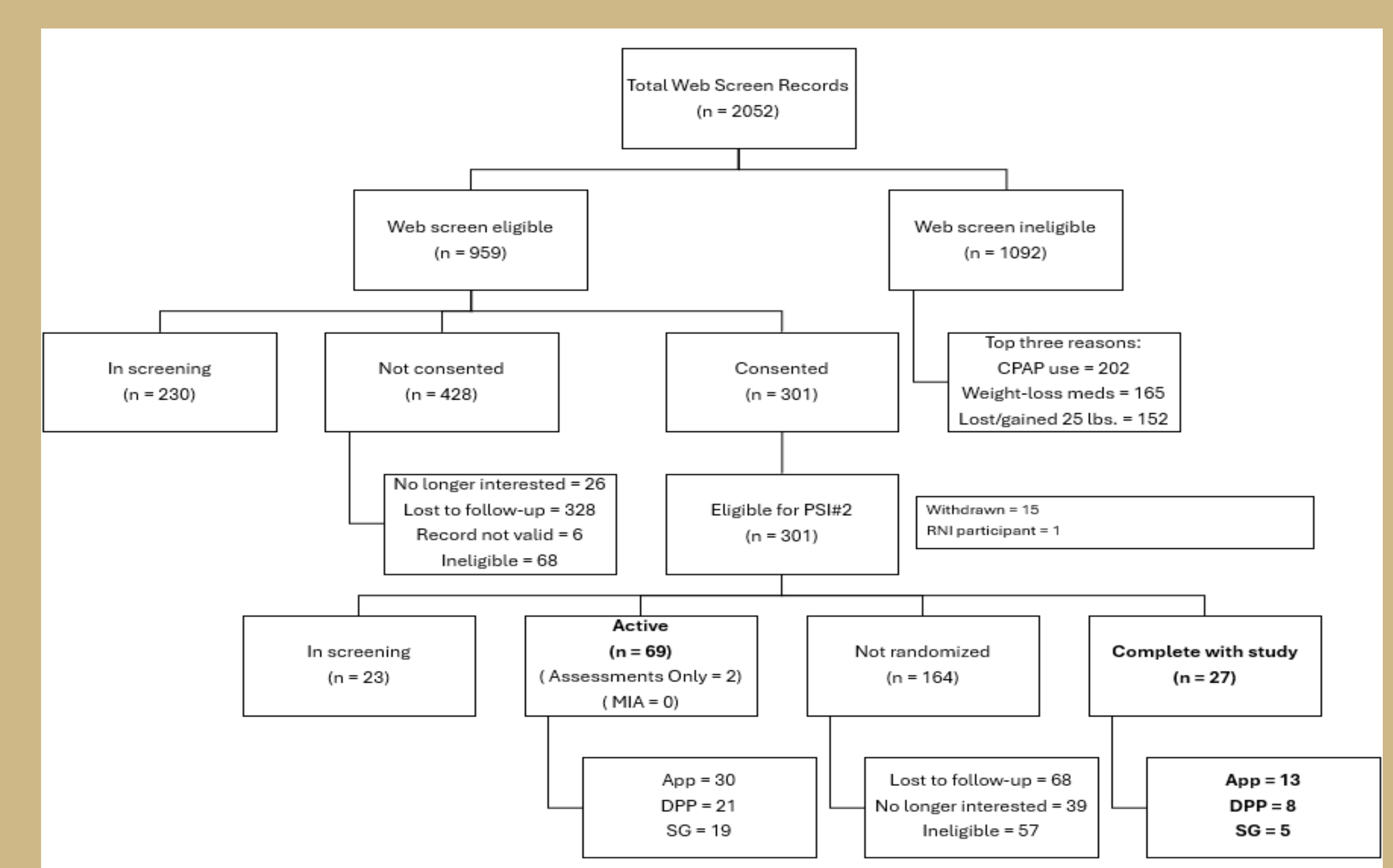


Figure 1. CONSORT diagram depicting participant flow from web screening through randomization and study completion across SMARTer, DPP, and Self-Guided conditions.

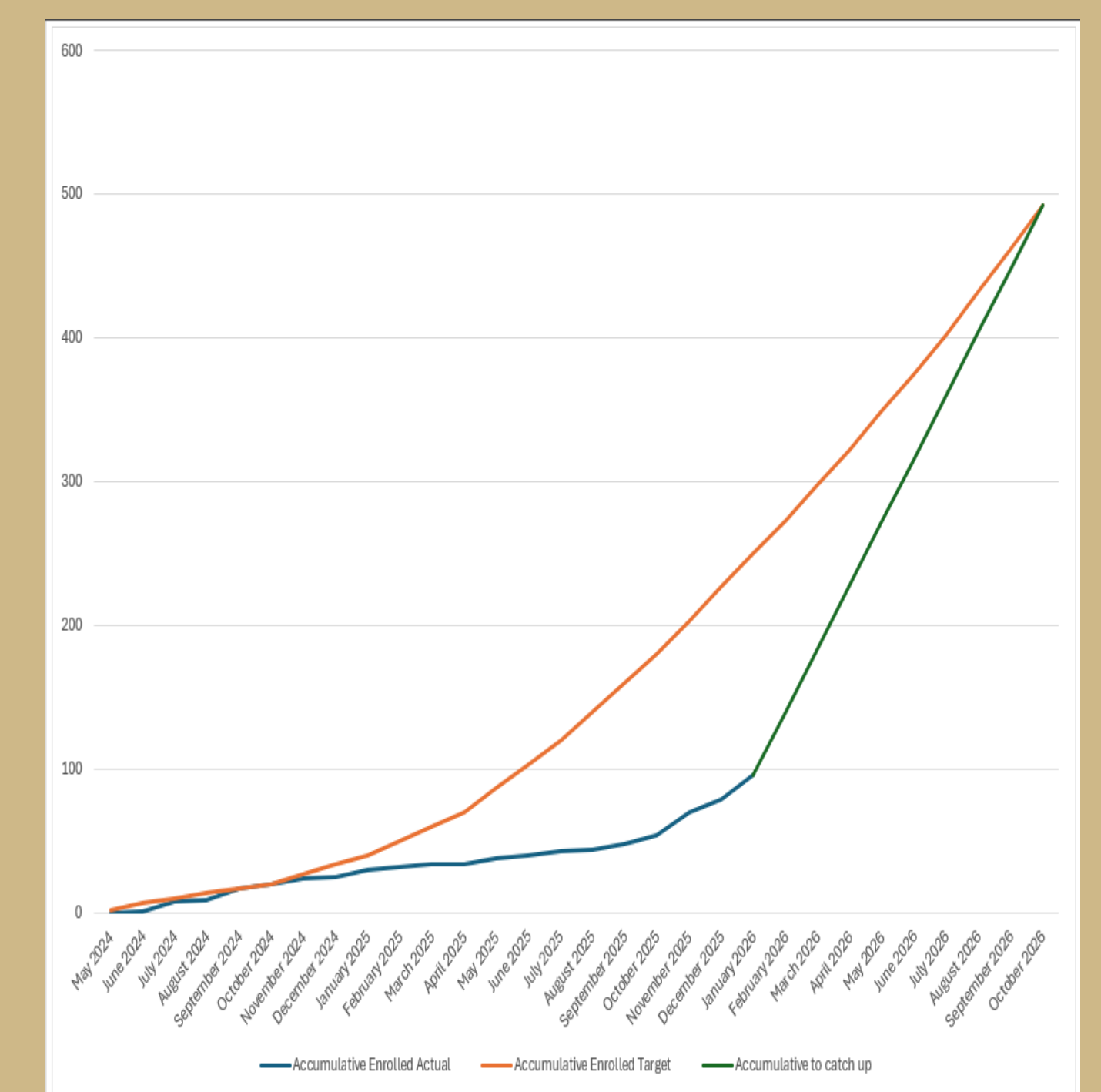


Figure 2. Cumulative enrollment relative to recruitment targets, illustrating current enrollment trends and projected rates required to meet the planned sample size.

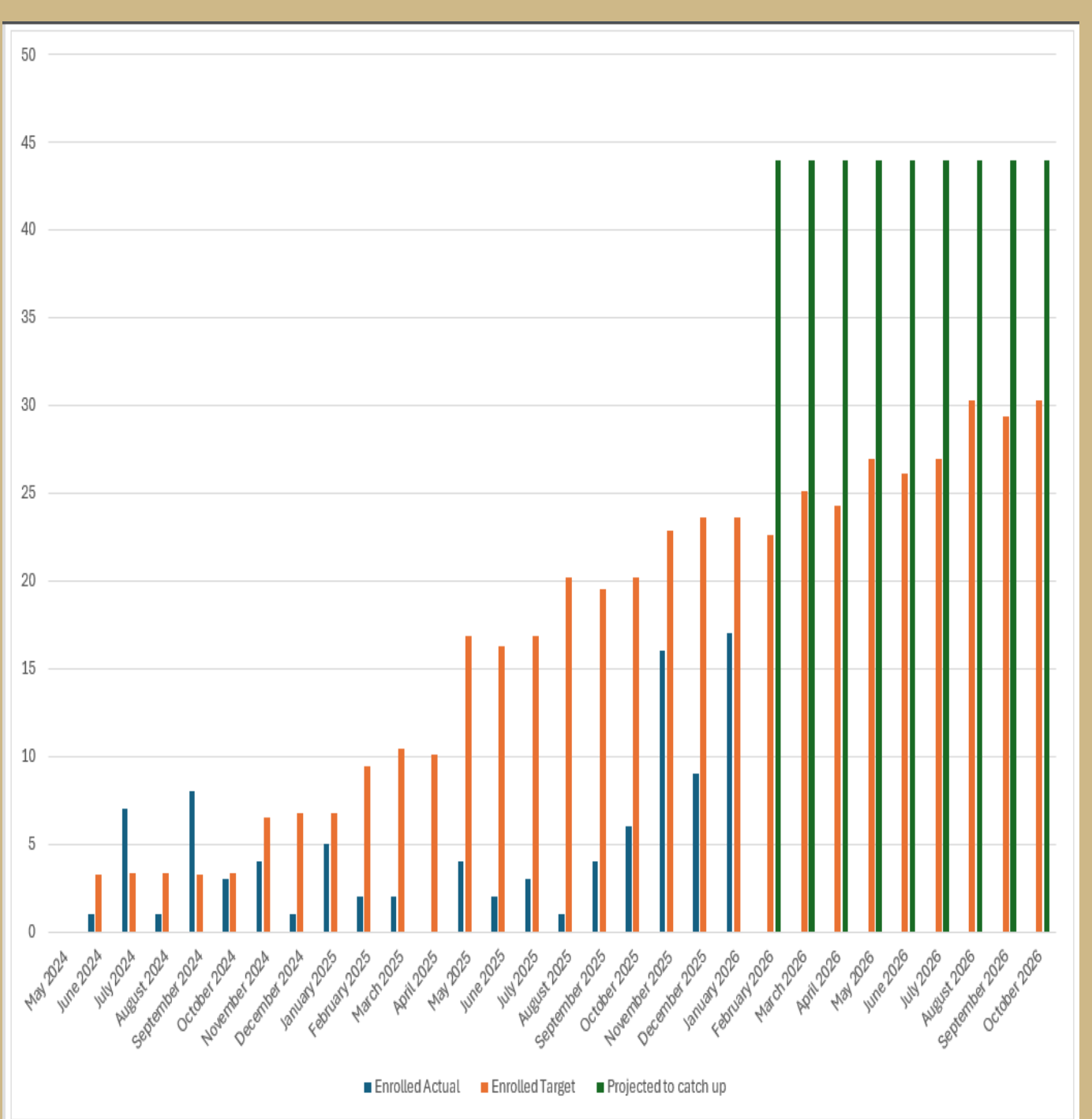


Figure 3. Monthly recruitment performance relative to planned enrollment targets and projected catch-up rates needed to achieve full sample size.

Strategies

- Deploy national recruitment service (Trialfacts)
- Increase screening and scheduling Efficiency
 - Streamline workflows
- Expanded Recruitment and Coaching Capacity
 - Onboard additional staff to assist with screening, enrollment, coaching
- Extend trial end date to October 2027

METHODS

Study Design:

- Three-arm randomized controlled non-inferiority trial
- Parallel assignment
- 24 weeks intervention + 12 months follow-up

Participants:

- Adults ≥ 18 years with BMI ≥ 25 kg/m²
- Key exclusions include insulin-treated diabetes, current weight-loss medication use (e.g., GLP-1 agonists), participation in another weight-loss program, pregnancy, or recent cardiovascular events

Procedures:

- Complete telephone and online screening followed by baseline assessment via Zoom
- Baseline measures include height, weight, and blood pressure.
- Follow-up assessments occur at 3, 6, 9, and 12 months

Interventions:

Adaptive SMARTer:

- App-based self-monitoring with Fitbit and Bluetooth scale, online behavioral lessons, and brief bi-weekly coaching calls
- Early non-responders (<0.5 lb/week) are stepped up to receive additional support (e.g., meal replacements)

Fixed DPP:

- Standard Diabetes Prevention Program (DPP) curriculum including behavioral lessons, self-monitoring logs, and scheduled coaching

Self-Guided Control:

- Receive lifestyle education materials but no coaching support

Outcomes:

- Primary outcome: weight change from baseline to 6 months.
- Secondary outcomes: intervention cost and cost-effectiveness
- Exploratory analyses: weight maintenance at 12 months

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