

Feasibility, Acceptability, and Preliminary Efficacy of Sleep GOALS: A Pilot RCT Targeting Sleep, Diet, and Physical Activity in the Postpartum Period

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BACKGROUND

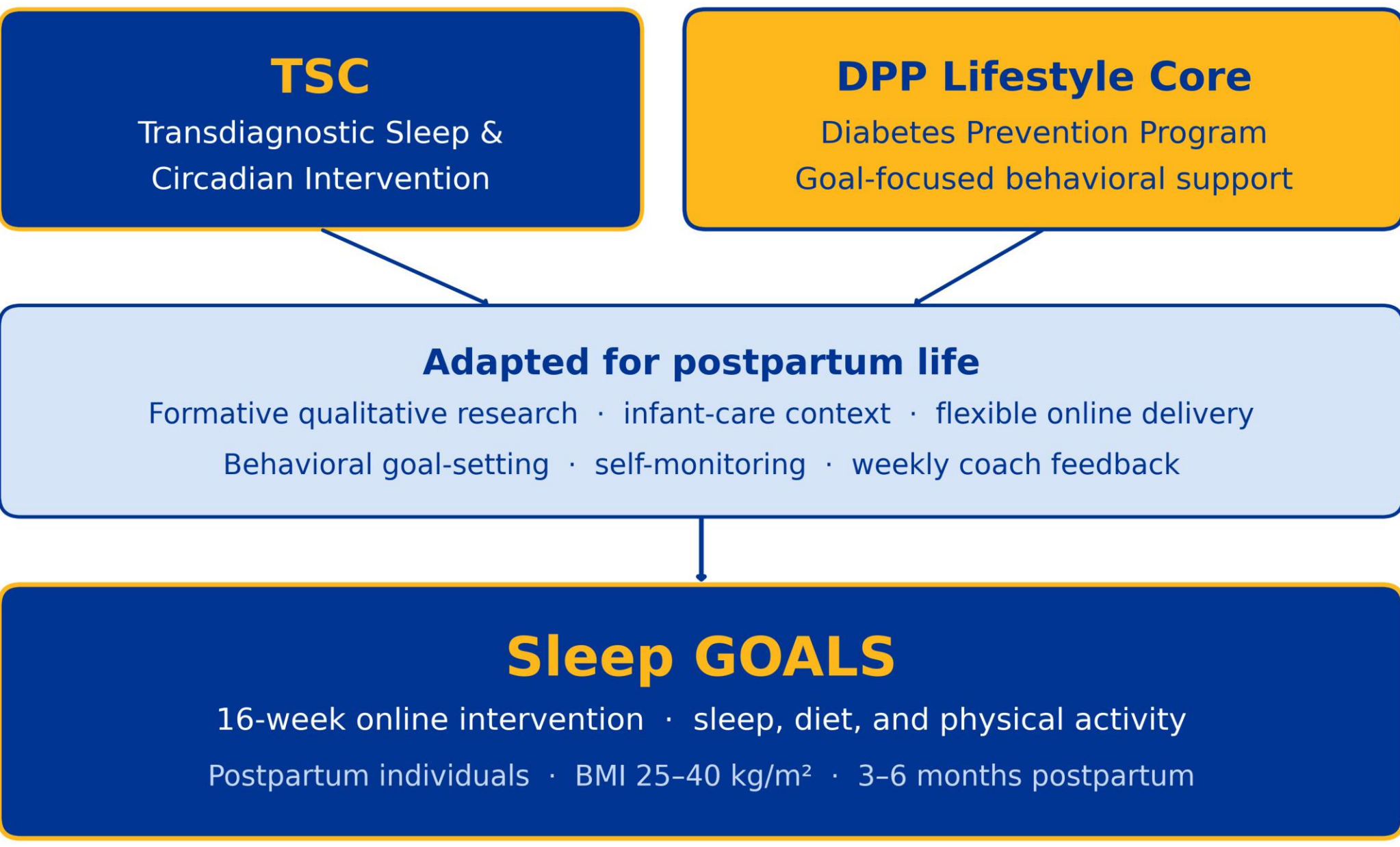
- **Postpartum weight retention (PPWR)** affects 12–31% of postpartum individuals and is a major driver of long-term obesity and cardiometabolic disease.
- **Poor postpartum sleep** exacerbates fatigue, impairs mood, and reduces motivation for healthy eating and physical activity — potentially undermining lifestyle intervention adherence.

OBJECTIVE

This study evaluated the feasibility, acceptability, and preliminary efficacy of Sleep GOALS, an online postpartum intervention integrating strategies to address sleep, diet, and physical activity.

METHODS

- **Design:** 2-arm, 16-week parallel-group pilot RCT (ClinicalTrials.gov: NCT05942326)
- **Population:** Primiparous; 3–6 months postpartum; BMI 25–40 kg/m²; physically inactive (<150 min MVPA/wk); ≥1 RU-SATED poor sleep indicator
- **Intervention:**



- **Control:** One-time email with evidence-based brochures (AASM, AHA, USDA, HHS)
- **Measures:** Actigraphy (7-day ActiGraph GT9X, 24-hr dietary recall (HEI-2015), depressive symptoms, perceived stress, overall maternal functioning, weight.

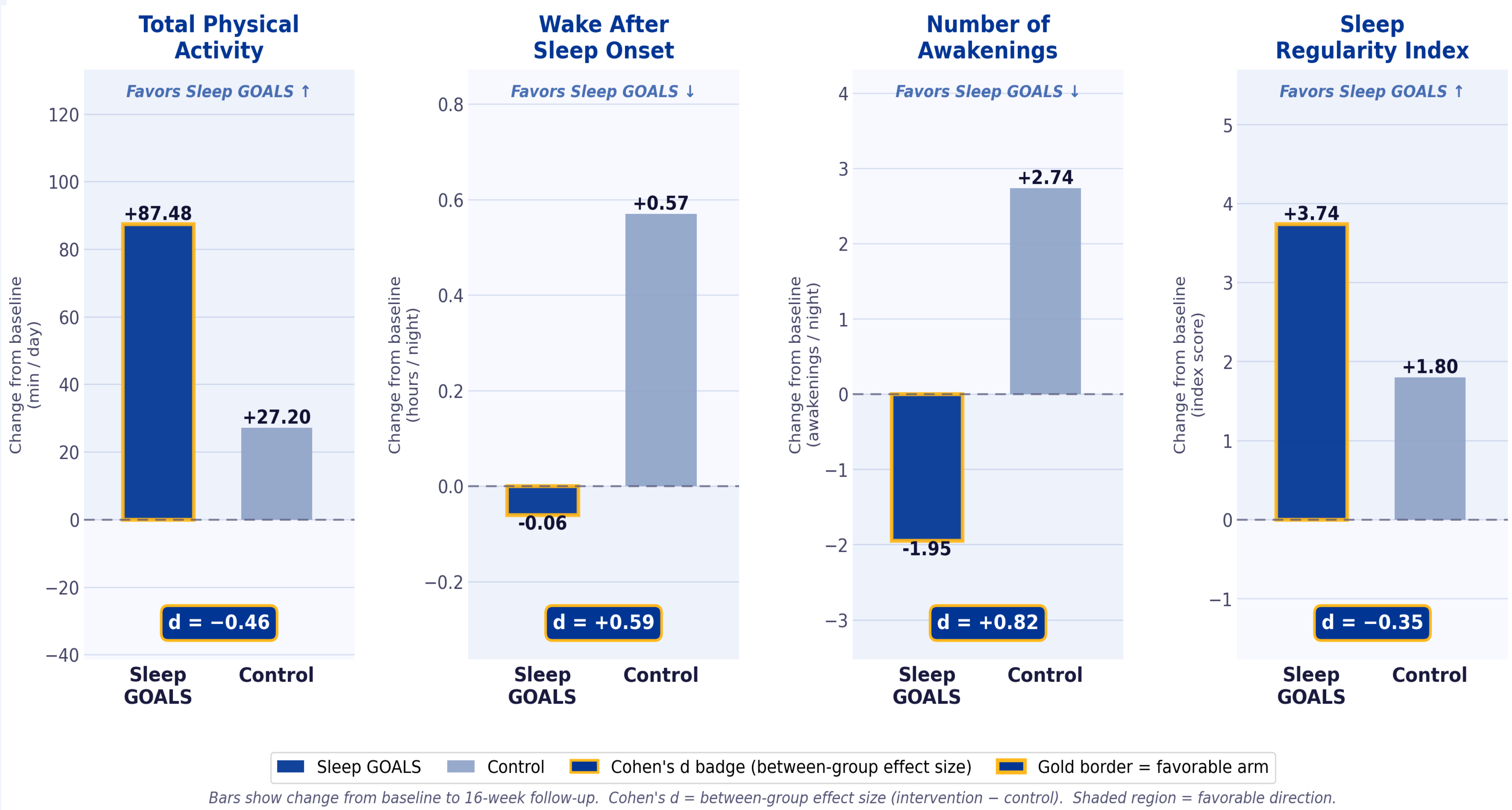
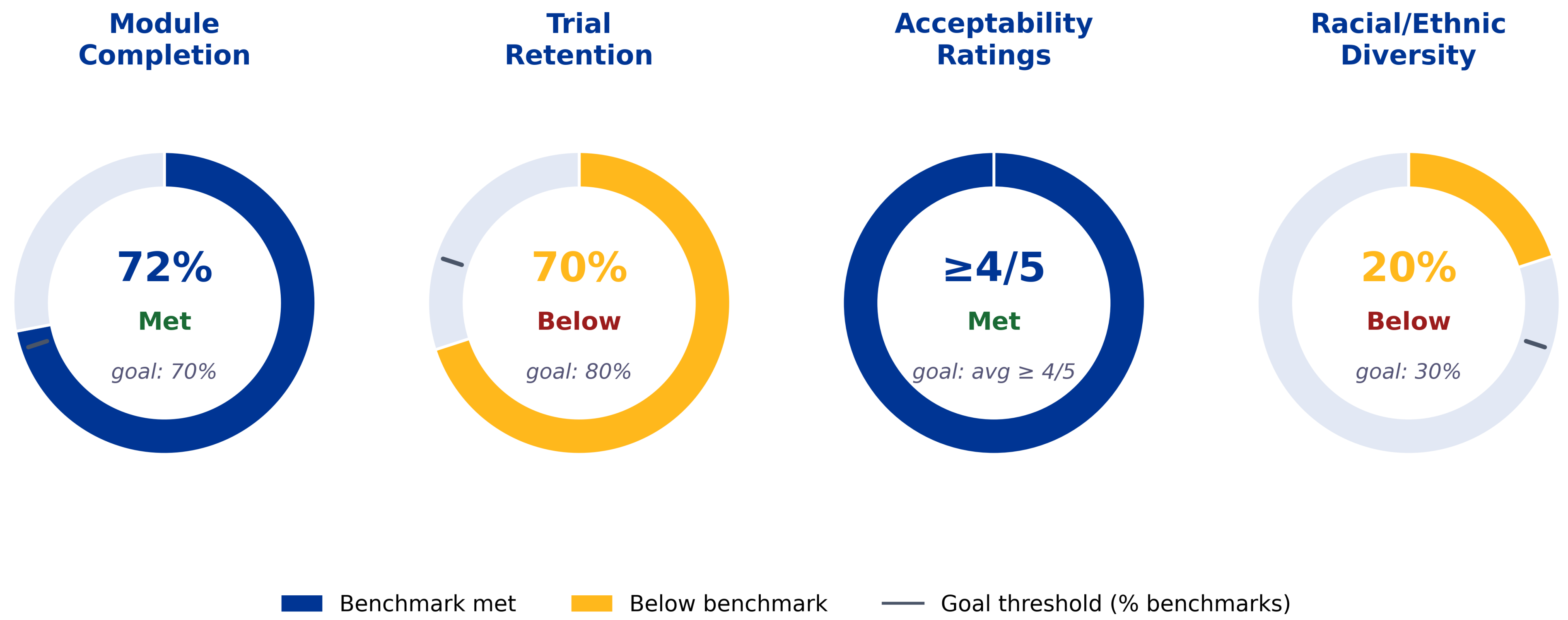
STATISTICAL ANALYSIS

- **Primary comparisons:** Linear mixed-effects models (LME); fixed effects for group, time, and group × time interaction.
- **Effect sizes:** Cohen's d (between-group); MD = intervention – control.
- **Sample size:** N=40 (20/arm) — designed to estimate feasibility with precision (95% CI ±13–14 pct. pts. around 75% retention); not powered for efficacy.
- **Actigraphy processing:** GGIR v3.3-0; validated autocalibration, non-wear detection, and sleep detection algorithms.

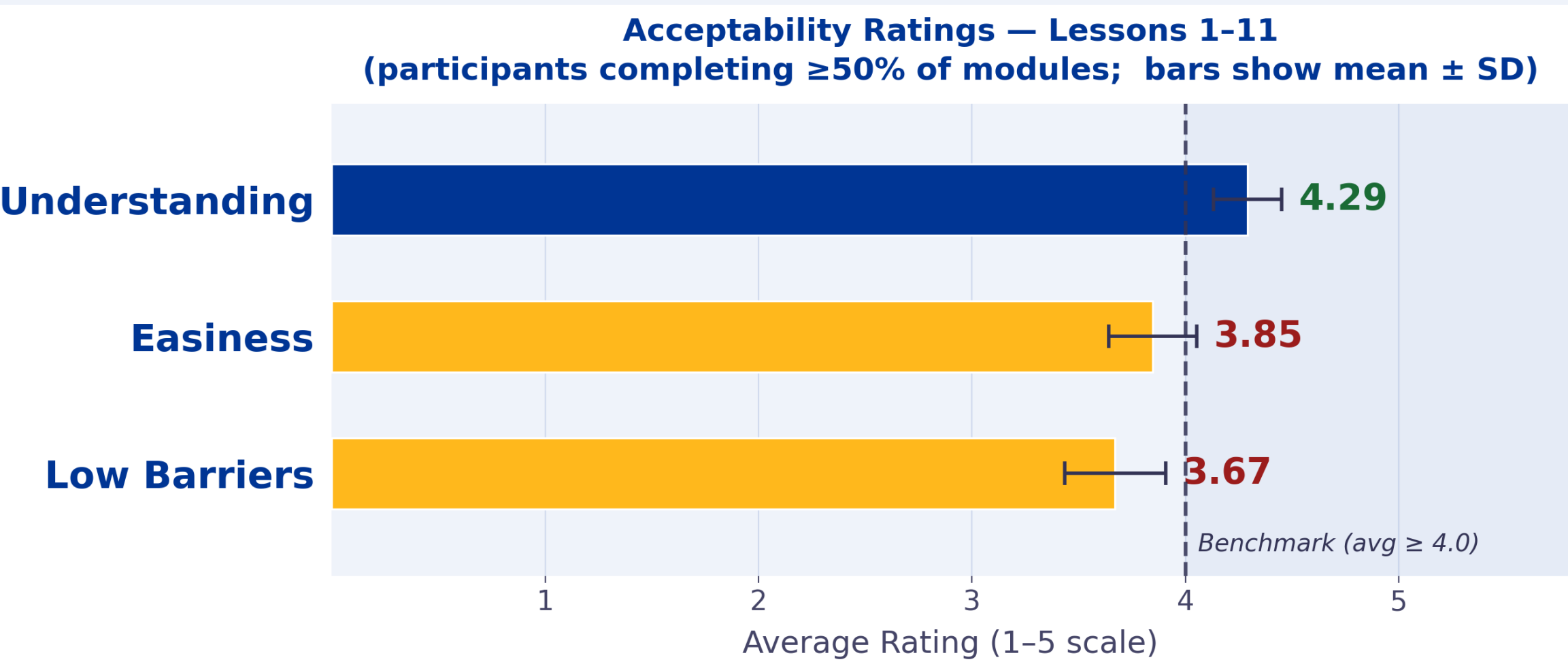
TAKEAWAY MESSAGE

Sleep GOALS demonstrated strong acceptability and produced encouraging signals of efficacy for sleep continuity and physical activity in postpartum women with overweight/obesity.

FEASIBILITY & ACCEPTABILITY BENCHMARKS



RESULTS



Domain	Outcome	Sleep GOALS Δ from BL	Control Δ from BL	Cohen's d	Favors
Physical Activity	Light-Intensity Activity	+62.5 min/day	+19.5 min/day	-0.32	← Tx
	MVPA	+13.0 min/day	+7.7 min/day	-0.17	~
Sleep	Daily Steps	+1,175 steps/day	+408 steps/day	-0.29	← Tx
	Sleep Duration	-0.74 hr/night	+0.77 hr/night	+0.33	→ Ctrl
Weight	Weight Change	-3.08 kg	-2.88 kg	—	~
	≥5% Weight Loss	36%	23%	—	← Tx
Diet	PPWR ≥5 kg	36%	39%	—	~
	Diet Quality (HEI-2015)	+3.66 pts	+4.18 pts	+0.04	~

Δ = change from baseline to 16 wks. Cohen's d = between-group effect size. ← Tx = favors intervention; → Ctrl = favors control; ~ = similar.

DISCUSSION

- Feasible & acceptable: 70% retention, 72% module completion, and high content-usability ratings.
- Promising efficacy: more reached ≥5% weight loss (36% vs 23%) with large activity gains (+44 min/day, d=−0.46).
- Sleep signals: improved continuity and regularity (awakenings d=0.82; WASO d=0.59) despite new-parent sleep disruption.

FUTURE DIRECTIONS

- Launch a fully powered RCT comparing standard diet-plus-activity care with the integrated sleep-inclusive model.
- Improve recruitment diversity (~20% vs >30% goal) and retention (30% attrition) to strengthen generalizability.
- Strengthen the dietary component and test whether sleep mediates gains in physical activity and weight.



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Scan to learn more about the Hawkins Lab and the Sleep GOALS intervention development and protocol

