

PARTICIPANTS ACHIEVING HbA1c <8% IN YOUTH STUDY REPORT GREATER TREATMENT SATISFACTION WITH INHALED INSULIN VS RAPID-ACTING ANALOGS

OBJECTIVE

To evaluate treatment satisfaction in youth with type 1 or type 2 diabetes achieving HbA1c <8% between inhaled insulin and rapid-acting insulin analogs (RAAs)

CONCLUSIONS

- In youth with Week 26 HbA1c <8%, inhaled insulin was associated with statistically greater improvements vs RAA in both Teen and Parent-reported treatment satisfaction assessments.
- These findings suggest inhaled insulin may offer quality-of-life benefits beyond glycemic targets compared to RAA.



Authors: Kevin Kaiserman, MD[†]; Joseph Sylvan, BS[†]; Leah-Elena Mycue, MSc[†]; **Joanne Rinker, MS, RDN, BC-ADM, CDCES, FADCES[†]**; Lorena Griparic, PhD[‡]; Jennifer Nguyen, PharmD[†]; Jennifer Rittenberry, MD[†]

[†]MannKind Corporation, Westlake Village, CA; [‡]Biogen Inc., Cambridge, MA

INTRODUCTION

Patient-reported outcomes (PROs) complement glycemic endpoints by characterizing treatment burden, lifestyle flexibility, perceived hypo/hyperglycemia, and overall treatment satisfaction. Integrating PROs with glycemic targets contextualizes patient experience and treatment burden.

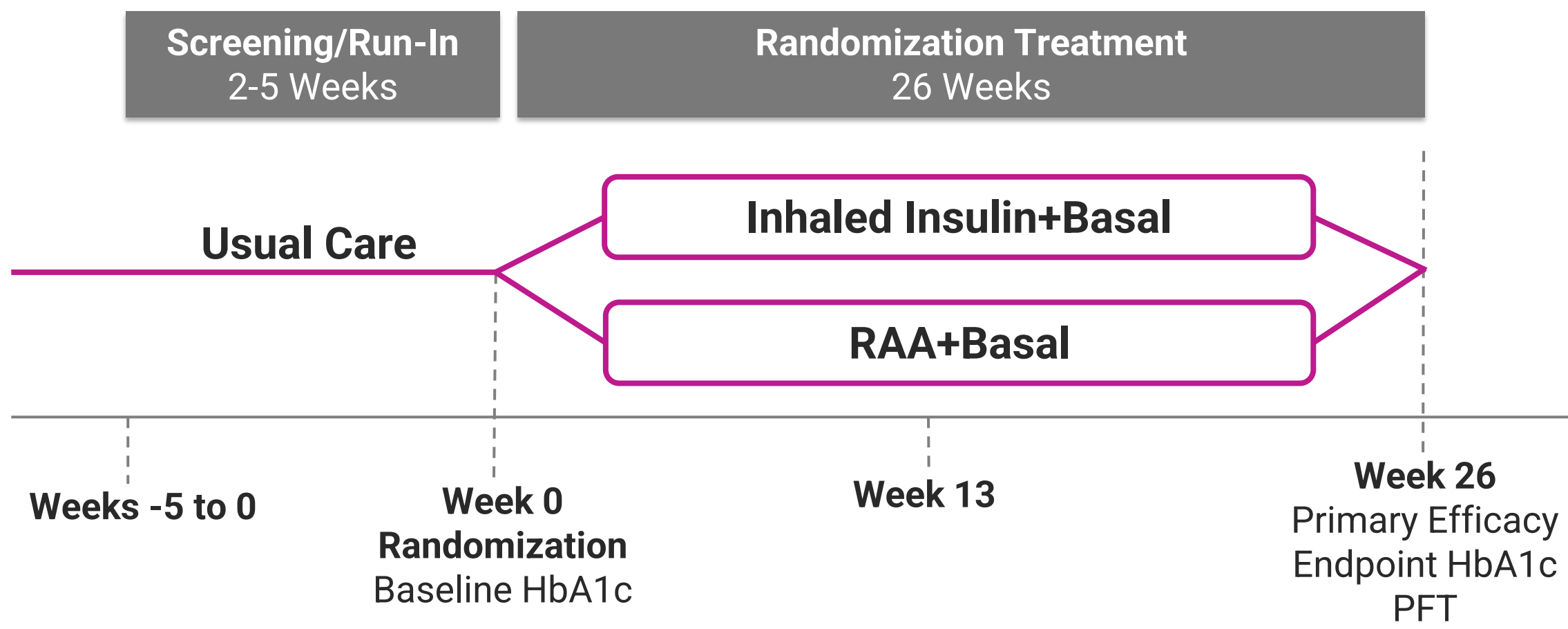
Inhaled insulin (Technosphere[®] insulin, TI) is a dry powder consisting of microscopic carrier particles onto which recombinant human insulin is adsorbed.

This analysis evaluates between group treatment satisfaction among participants who achieved Week 26 HbA1c <8%, comparing inhaled insulin vs RAA delivered by multiple daily injections (MDI) from the INHALE-1 study.

METHODS

INHALE-1 was a Phase 3, open-label, randomized study evaluating the efficacy and safety of inhaled insulin plus basal insulin versus RAA in youth (4-17) with type 1 or 2 diabetes. The primary endpoint evaluated noninferiority for change in HbA1c from baseline to Week 26 between treatment groups, which was not met in the intent-to-treat population.

Figure 1. INHALE-1 Study Design



Post hoc descriptive analyses evaluated the change from baseline in Diabetes Treatment Satisfaction Questionnaire status (DTSQs).

DTSQs-Teen survey and -Parent survey (for children <13 years) were administered at baseline and Week 26 among participants.

The DTSQs is a validated patient-reported outcome measure assessing satisfaction with diabetes treatment. Example treatment satisfaction specific items are shown below for the teen survey, with a parallel parent version substituting “your child” for “you.”

- How satisfied are you with your current treatment?
- How easy or difficult is your diabetes treatment?
- How flexible is your diabetes treatment?
- How satisfied are you with your diabetes treatment during the school/college day?

Changes from baseline in DTSQs treatment satisfaction were summarized descriptively by treatment group for the subset of participants with Week 26 HbA1c <8%. Between-group comparisons were conducted using a two-sample, two-sided t-test.

RESULTS

Table 1. Baseline Characteristics

	Inhaled Insulin N=45	RAA N=49
Mean Age, yrs (SD)	13.4 (2.9)	12.6 (3.0)
Female, n (%)	15 (33.3)	20 (40.8)
Mean HbA1c (SD)	7.62 (0.5)	7.60 (0.5)

Previously reported primary glycemic outcomes indicated similar HbA1c responses between inhaled insulin and RAA in the overall cohort.

Within the Week-26 HbA1c <8% subgroup, mean improvement in DTSQs treatment satisfaction from baseline was greater with inhaled insulin than with RAA for both Teen (p<0.05) and Parent (p<0.01) versions, **Figure 1 and 2.**

Figure 2. DTSQs Treatment Satisfaction Score in Teens

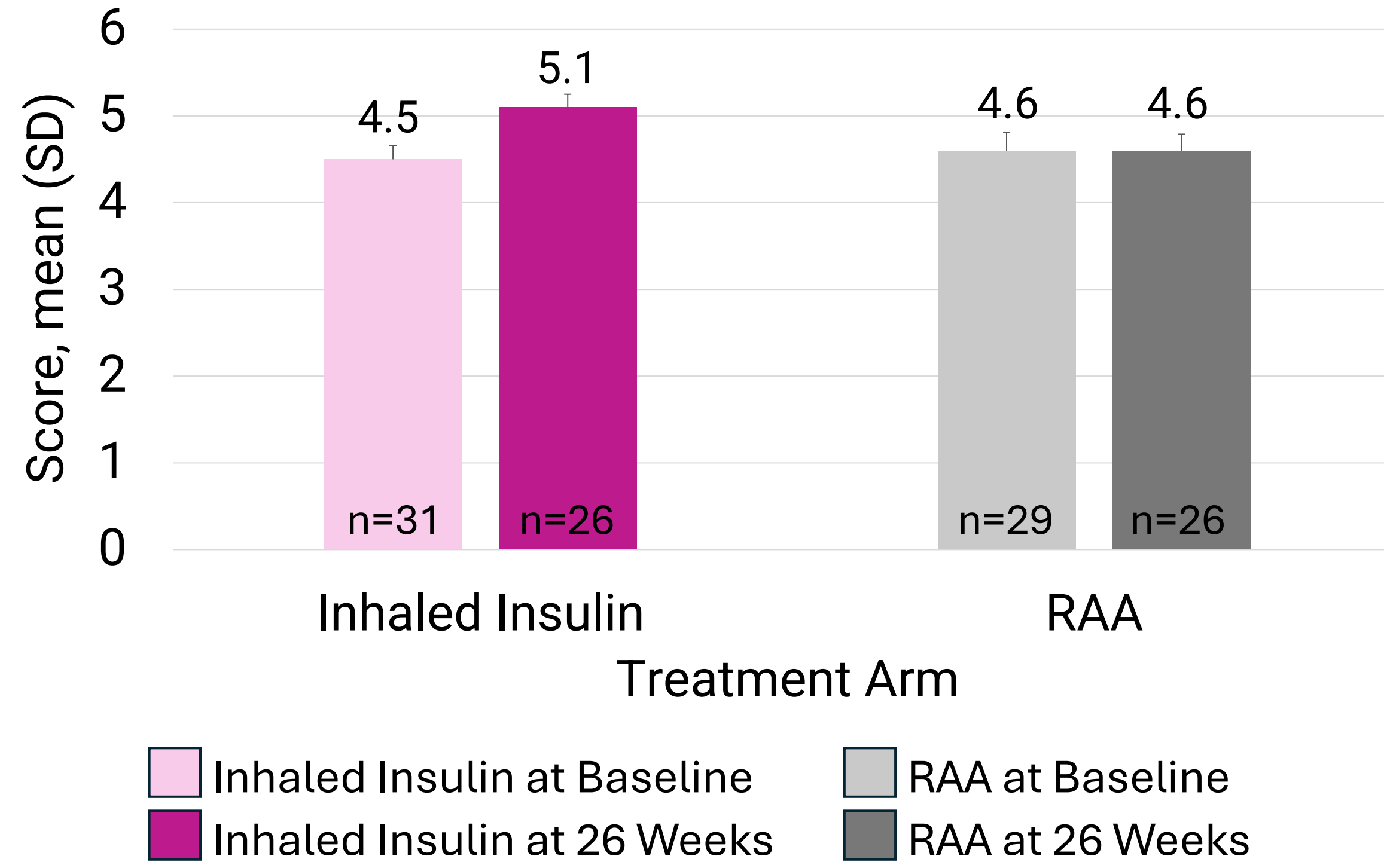


Figure 3. DTSQs Treatment Satisfaction Score in Parents

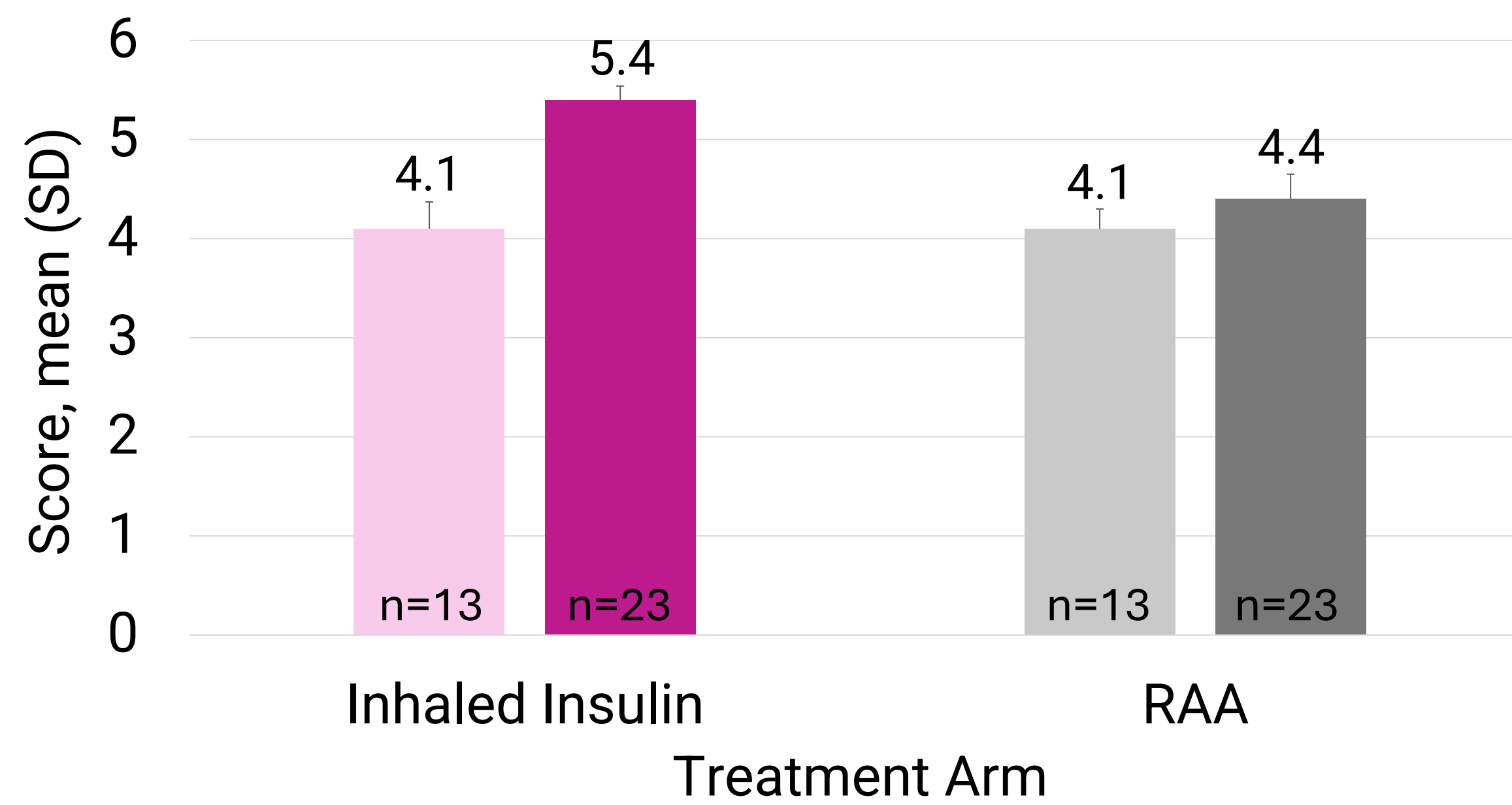


Table 2. Between-Group Comparisons of DTSQs Treatment Satisfaction

	Mean Difference (TI-RAA)	p-value
Teen Treatment Satisfaction, Change from Baseline	0.57	0.02
Parent Treatment Satisfaction, Change from Baseline	1.03	0.01

Safety

No new safety signals were identified, and reductions in HbA1c were achieved without an increased risk of hypoglycemia.