# Benefits of Early Stage T1D Education

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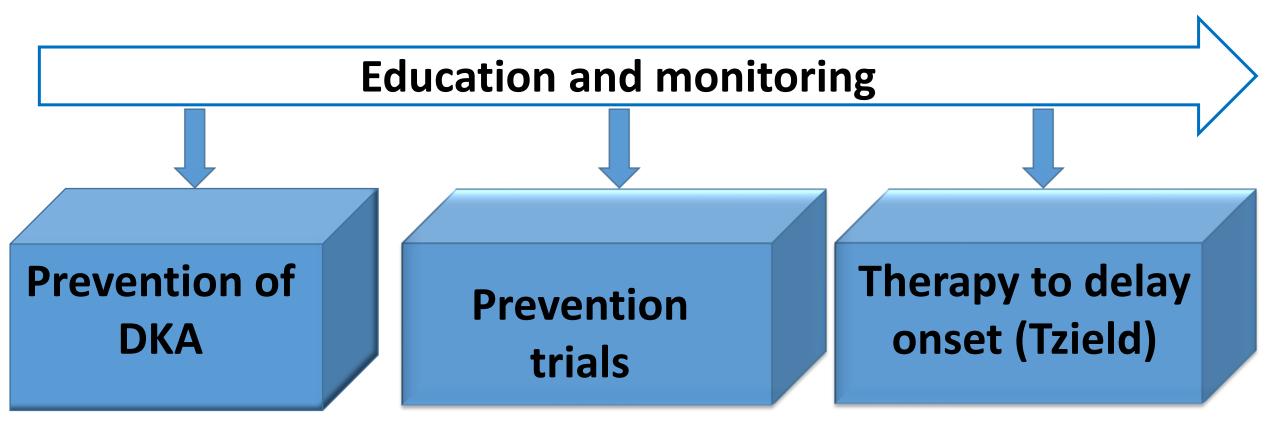
## Disclosures

I have no conflict of interest to disclose

## Goals

- 1. Identify common themes for successful monitoring in the ASK follow-up and TESS cohorts
- 2. Identify reoccurring challenges in early T1D education and monitoring
- 3. Early T1D Monitoring Model
- 4. Next steps

## **Benefits of Early Stage T1D Education and Monitoring**



## ASK Protocol for IA+ Participants

- Every 3-6 months: repeat islet autoantibodies, A1C, blinded CGM
- Every 6 months: OGTT
- •Finger stick blood glucose 2-4 x/month

**ASK Screening** 

**ASK Confirmation**  **ASK Follow-up Education and Monitoring** 

## The Early Start Study (TESS) enrollment

**ASK Screening** 

**ASK Confirmation** 

ASK Follow-up Education and Monitoring

**Dysglycemia** 

**TESS Enrollment** 





## TESS Enrollment Criteria

- Age 2 to 20 years
- •Islet autoimmunity with high risk of progression:
  - Multiple IA positive (>50% 5-year risk)
  - Single high-affinity IA (>30% 5-year risk)
- •Dysglycemia:
  - ADA criteria
  - CGM-based criteria
  - Home glucose testing data

#### **ADA Criteria for Stage 2 T1D**

OGTT (plasma glucose)	
Fasting	100-125 mg/dL
2 hour glucose	140-199 mg/dL
A1c	
At visit	5.7-6.4%
Increase from last visit	<u>≥</u> 10%

#### **Additional TESS Criteria for Stage 2 T1D**

OGTT (plasma glucose)	
<b>30, 60 or 90 min glucose</b>	>200 mg/dL
CGM (worn for <u>&gt;</u> 5 days)	
Average sensor glucose	≥120 mg/dL
% time above 140 mg/dl	≥15%
Peaks ≥200 mg/dl	on ≥2 days
Home glucometer:	
Fasting BG	>110 mg/dL on ≥2 days
2-hour post meal BG	>150 mg/dL on ≥2 days
Single random BG	> 200 mg/dL





## TESS Design

- Case-control intervention trial for participants in stage 2 T1D to assess:
  - Best early education and monitoring strategy
  - CGM-guided insulin start
- 6 months intervention and 6 months follow-up
- 31 participants recruited from ASK study
- Study groups: randomized 2:1 (intervention:control)

#### ➢ Intensive monitoring / education

Every 3 months

A1C

Every 6 months:

**OGTT** 

CGM 20 days/ month unblinded CGM-guided education

Structured education visits with clinical team via telemed

#### Standard monitoring (control)

Every 3 months

A1C

Blinded CGM wear

Every 6 months:

**OGTT** 

2-4x / month FSBG

Education on signs/symptoms





## Early-stage T1D education topics by Telemedicine

#### Pathophysiology of T1D (MD)

- ❖ Why did this happen?
- ❖ Stages of T1D/How blood glucose changes
- ❖ Ketosis, illness and avoidance of DKA

#### **Monitoring education: (CDCES)**

- Symptoms of highs and lows
- Checking glucose
- When/how to check ketones
- CGM placement, alarms, troubleshooting

#### Interventions: (MD)

- Options
- Eligibility criteria

#### **Dietary education: (RD)**

- Diet history
- What foods have carbohydrates?
- ❖ Healthy diet choices, balanced diet
- Exercise: impact on glucose, lifetime health, exercise goals

#### **Emotional and Family impacts (SW)**

- Family strengths/challenges
- Diabetes is a collaboration
- Assessment of depression/anxiety
- Coping with uncertainty
- Resources





## Use of CGM-Guided Education (MD and NP)

- Practical CGM use (CDCES)
  - Troubleshooting problems
  - When to double-check with glucometer
- Observation of patterns (reviewed at 5 visits)
  - Impact of diet and exercise on glycemic excursions
  - Trends with illness / hormones / changes in activity level
- Recognition of need for insulin
  - Discussion of when and how to start insulin

### Behavioral Health Measures

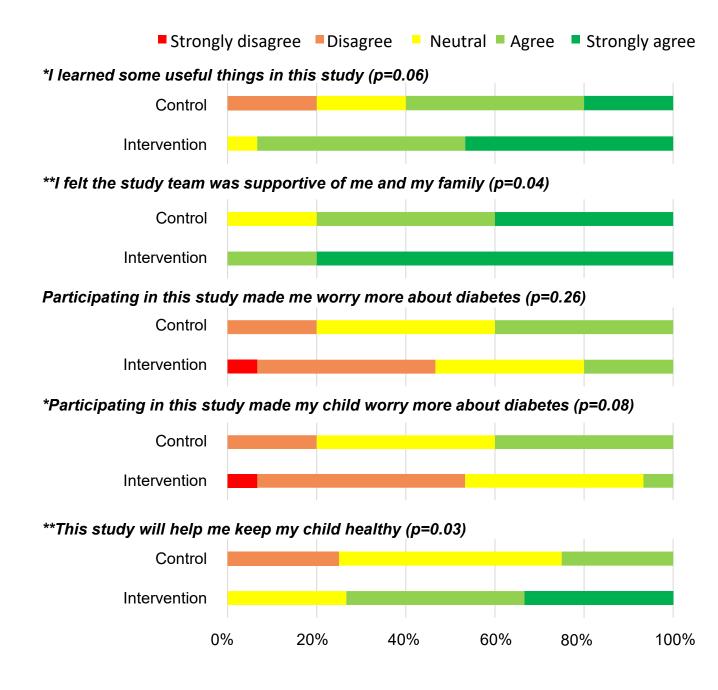
#### No differences by arm or from baseline to follow-up

- PedsQL-Family Impact
- PHQ8 depression scale (parent)
- Tolerance of Uncertainty
- Diabetes Attitude Survery (adapted)

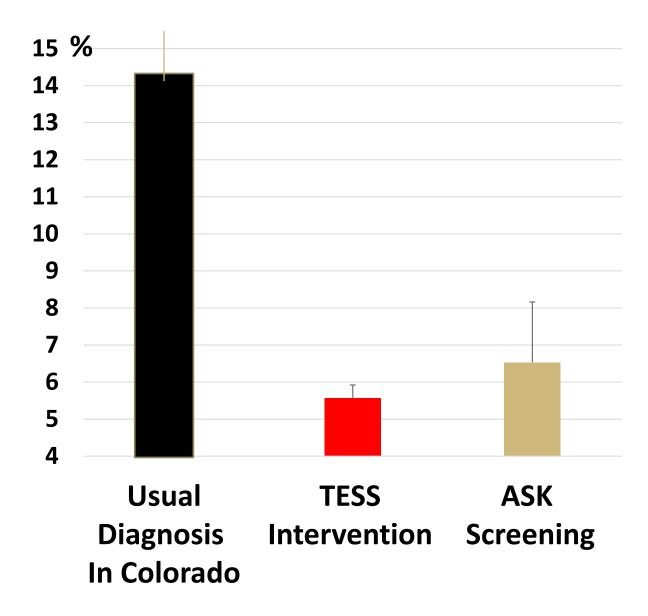


# Unblinded CGM and Education vs Control (standard follow-up)

- Intervention did not increase worry for parents or children (by parent report
- Parents felt study would keep child healthy



## Comparison of HbA1c at Diagnosis



### Benefits from TESS and ASK

- 1. Prompt identification of stage 3 (No DKA in either arm of TESS)
- 2. Increase family confidence with English and Spanish materials
- 3. Increased confidence in CGM technology use
- 4. Unblinded CGM does not appear to negatively impact quality of life.
- Unblinded CGM allowed parents to participate in conversation around timing of starting insulin

## Challenges in TESS and ASK monitoring

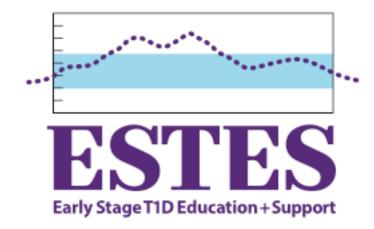
- Time demand on families and clinical staff.
- 2. Needlephobia
- 3. CGM technology issues
- 4. Lack of trust in research
- 5. Complex family dynamics

## Keys for successful education and monitoring

- Continuity
- Establishment of rapport/building trust
- Engagement of participant's healthcare providers
- Design of culturally appropriate educational content

## Next Steps

- Continue exploring different avenues for educating people in early stages of T1D.
- Early stage Education and Support Study (ESTES)
  - ❖BDC, Colorado
  - Mercy Children's Hospital (Missouri)
  - University of Florida
  - ❖Sanford Health (ND, SD, MN)
- ❖Online education tailored to stage 1, 2 and 3 T1D
- Group zoom classes
- Bilingual curriculum (English/Spanish)
- ❖ Partnership with local PCP/Endo
- Focus on accessibility and retention for historically marginalized communities
- Incorporate community feedback



## ASK/TESS Study Group at the University of Colorado

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