

Interventions to Reduce Anxiety & Increase Engagement in Monitoring

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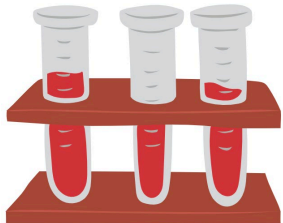


Background

- Benefits of islet autoantibody (IAb) screening cannot be fully realized unless those screened complete additional testing and engage in follow-up monitoring.
- Time from development IAb to clinical diabetes highly is variable.
 - Regular monitoring is currently only option to identify those progressing.
- Need to identify those progressing to:
 - Prevent DKA
 - Offer interventional trials
 - Offer novel therapeutics (e.g., teplizumab)
- There's a growing literature on participant engagement and retention from studies such as TEDDY, ASK, TrialNet.



Summary of Literature on Engagement and Retention



Volume of Screening



Study Satisfaction



Age of Youth



IAb Status



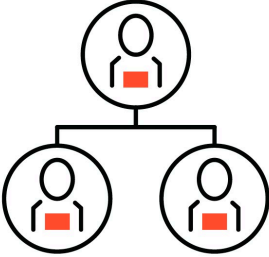
Race & Ethnicity



Only Child Status



Country



FDR Status & Type of FDR



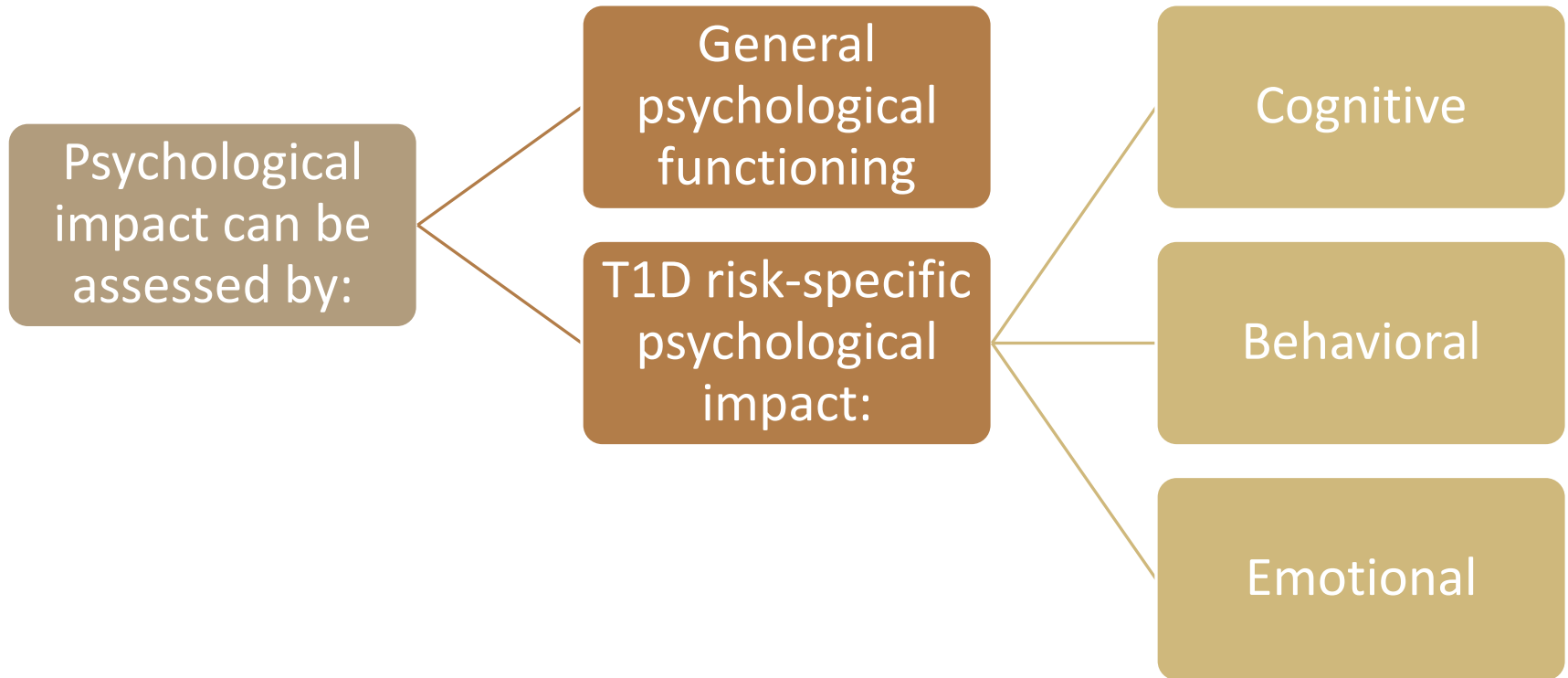
Parental Risk Perception



State Anxiety about T1D



Assessment of psychological impact



General psychological functioning

Many studies have documented the impact of T1D on general psychological functioning in children and parents at T1D diagnosis.

Almost no studies of the impact of an early stage T1D diagnosis on **general psychological functioning**.

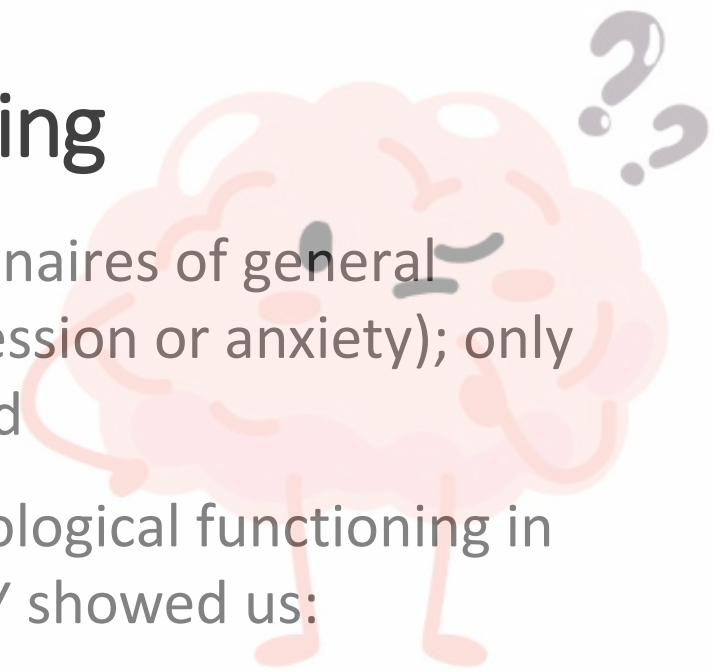
In a study in Bavaria, Germany, mothers of multiple Ab-positive children were given a depression **screening questionnaire**. Their scores:

- Were higher than scores of mothers of Ab-negative children
- Were lower than scores of mothers of newly diagnosed children in a separate study
- Declined over time although follow-up questionnaires were available for <50% of mothers

Ziegler et al., 2020



General psychological functioning



No studies have used validated questionnaires of general psychological functioning (e.g., for depression or anxiety); only screening questionnaires have been used

No studies have assessed general psychological functioning in children with early stage T1D BUT TEDDY showed us:

- No evidence that TEDDY parents are more depressed than general population.
- No evidence that preschool aged children in TEDDY had more behavioral problems than general population.
- No evidence that preschool IA+ children exhibit more behavioral problems than IA- children.



How do parents respond to learning their child is at risk for clinical T1D? What do we know so far?

Most studies have been done with parents

- Mothers are more anxious than fathers.
- Parents with a family history of T1D are more anxious than parents with no family history.
- Repeated IA- test results is associated with a decline in anxiety over time
- IA+ test results increase anxiety.
- Anxiety is greatest in those whose children have multiple IA+ test results; many have significant anxiety which can last for long periods of time.
- Ethnic minorities tend to have higher anxiety than Non-Hispanic Whites.



Learning you or a loved one has early stage T1D can be stressful

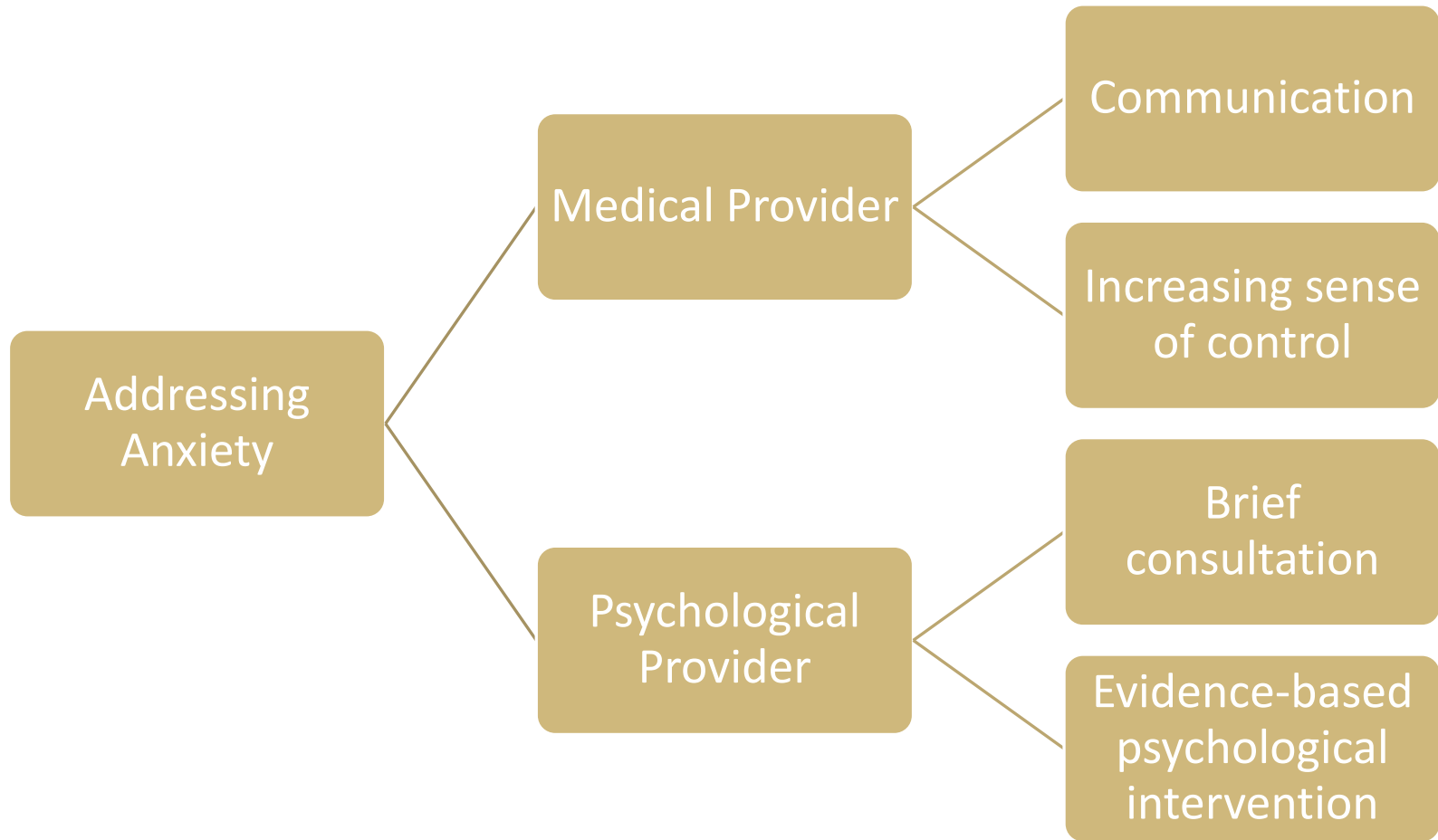
Humans are stressed when faced with events that are

- Threatening
- Unpredictable
- Uncontrollable

Learning you or a loved one has early stage T1D is an event that is

- Threatening
- Unpredictable
- Uncontrollable





What can medical providers do?

Empathy is helpful when individuals are highly stressed



Empathy statements help show the individual that their emotions are normal and harmless, and that they can share these emotions with you

Empathy does not involve fixing a problem

Guess how they're feeling — it is okay if you are wrong; they will correct you

Validate *their* reality; the goal is to show you understand

Pause and leave time for them to respond

Avoid statements that may be perceived as negating the patient's experience, such as:

"It's not a big deal; lots of people have T1D"

"You look a bit overwhelmed"

"I wonder if you're feeling overwhelmed"

"It makes sense that you would be feeling this way after all the information you just learned"

"I totally understand that this is a lot of information to process"



What can medical providers do?

HCPs should ask children who have screened positive for IAbs* and/or their family members/caregivers about **how they feel about the news**¹

“What are your feelings about this news?”



What can medical providers do?

Specifically assess **anxiety, risk perception, and behavior changes**¹

Guided questions should be used, such as

"Have you noticed any changes in your or your family's **level of stress**?"

"What do **you** think the chances are that you will develop T1D?"

"Are you **doing anything different** since you learned of this information?"

"Has this news caused you to make **any major changes** lately?"

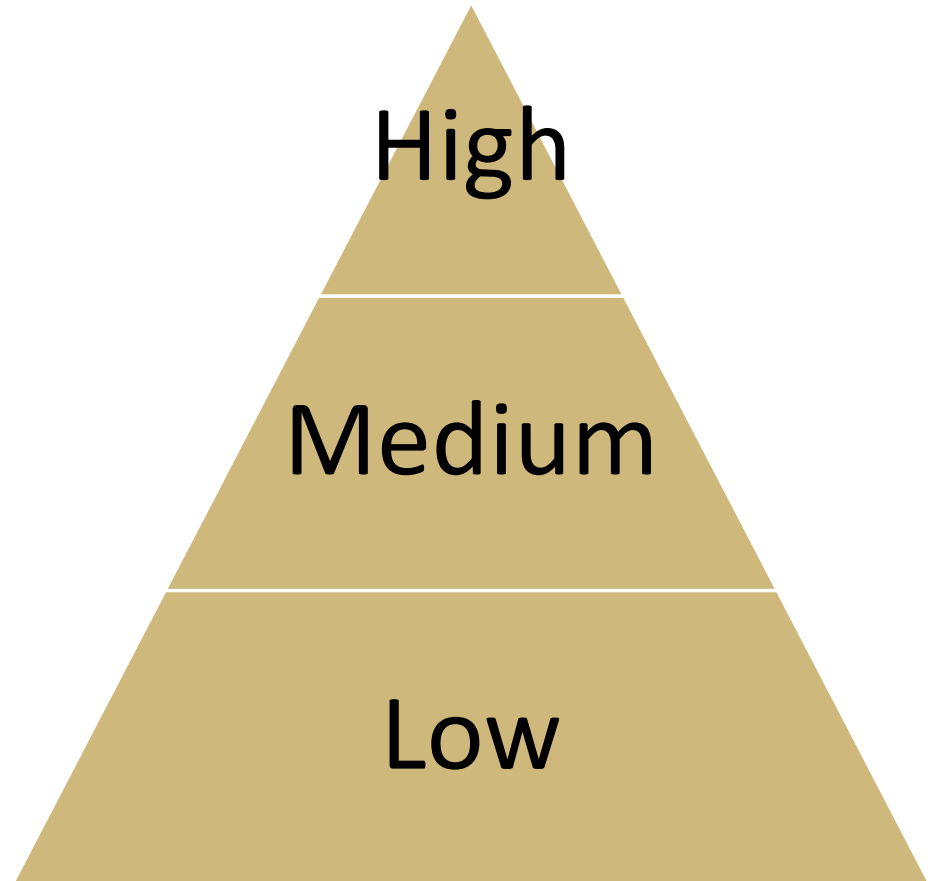
"**How much space** is diabetes taking up in your brain?"

Use clinical judgement to decide when to **refer to a mental health specialist**

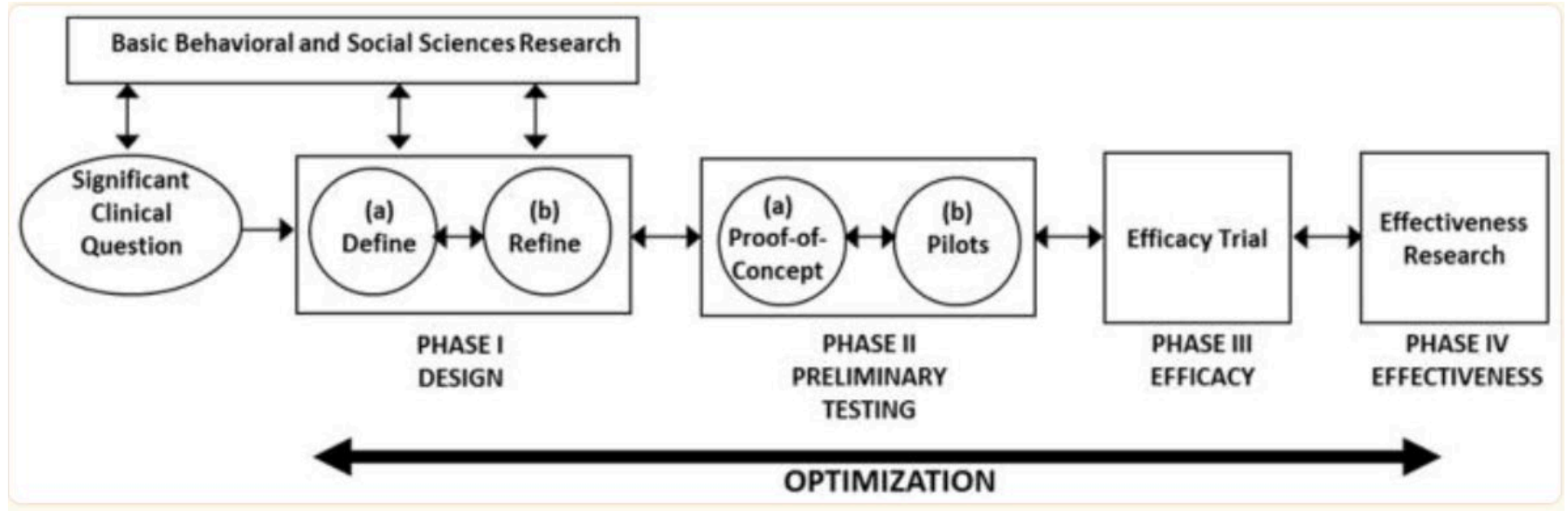


How might psychological providers help?

- Despite detecting high rates of anxiety in multiple studies (e.g., TEDDY, ASK, etc.), we have **no evidence-based interventions for this problem.**
- Cognitive-Behavioral Therapy for Pre-Symptomatic Type 1 Diabetes (CBT-PreT1D; funded by Breakthrough T1D)



NIH ORBIT Model



Czajkowski et al., 2015



Phase 1a: Define the Problem

Define the problem.



Develop hypothesized mechanism for how treatment will address the clinical problem.



Provide basic behavioral science rationale for treatment.



Identify appropriate participants.



Cognitive-Behavioral Therapy 101

Think-Feel-Do

Situation (what was happening):

My mom asked me if I had checked blood glucose yet.

She never trusts me. She thinks I am a failure.

Think

Do

Feel

Lie and tell her I did.

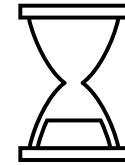
Tell her to leave me alone.

Worthless

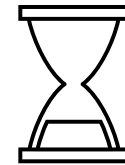
Sad

Phase Ib: Refine

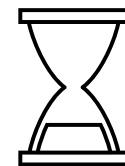
Refine treatment intervention to identify treatment components, appropriate dose, duration, method of delivery.



Assess if further refining is needed for specific populations.



Treatment manual ready for testing.



Teens

Want to connect with peers who already live with T1D

- *"...I think if I was really worried about it I'd just want to know from people who were in the same position as me that it's gonna be fine." ID 4*
- *Oh, I'm gonna get it," or, "Oh, well, if I'm gonna get it, at least I join the community, get to know other people who have it." ID 15*

Learning about T1D management

- Symptoms, ways to decrease getting T1D

-Support

- -Talking about how you feel and what you're going through
- -Strategies and ways to help cope with anxiety and improve confidence
- *"Saying that it'll be okay, because most anything that we go through, we can probably go through." ID 5*



Caregivers

Seeing other parents, teens, and families dealing with type 1 diabetes and their experiences and how they are managing it, others going through the same thing

- How to manage from a parent's point of view
- *"Okay, I'm going to the program," and there you meet other people who are going through the same thing, you lean on them, you can talk to people who understand what you're going through, and that, in a way, makes the stress feel less overwhelming. ID 16*

Learning about T1D management

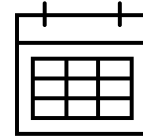
- Explaining what the antibodies mean, what type 1 diabetes is in general, symptoms
- Wanting to learn about developments in T1D

Information about anxiety in general, how to feel less anxious, and how to deal with it, more information about coping, common emotions people feel, how to stay positive and hopeful

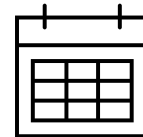


Phase IIa: Proof of Concept Testing

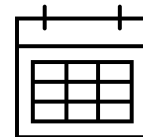
Determine whether treatment can achieve clinically meaningful change on behavioral target.



Prepare intervention for fidelity monitoring.



Iterative testing to maximize acceptability/perceived benefit and signal for clinical outcome improvement (i.e., decreased anxiety) are optimized.



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