



Innovations in measuring
processes of change in
clinical intervention

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Why should we talk about processes of change?

- CBS is process-focused. However, we have not clearly defined our processes and over-relied on self-report.
- Identifying multi-level, multi-dimensional processes of change (defined as “functionally important sequences of contextually embedded biopsychosocial events that can lead to positive or negative outcomes of importance”) may help us select interventions or potentiate treatment effects.
- Technological advances (e.g., mobile devices) allow us to capture multi-level, multi-dimensional events, and gather high-density longitudinal data in the natural environment.



Duke University School of Medicine

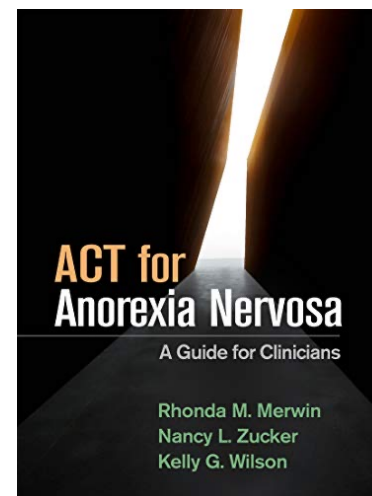
Toward a multi-modal, multi-level assessment of psychological flexibility in maladaptive eating and weight control treatment trials

Rhonda M. Merwin, PhD

Associate Professor

With all my wonderful collaborators, colleagues and labbies

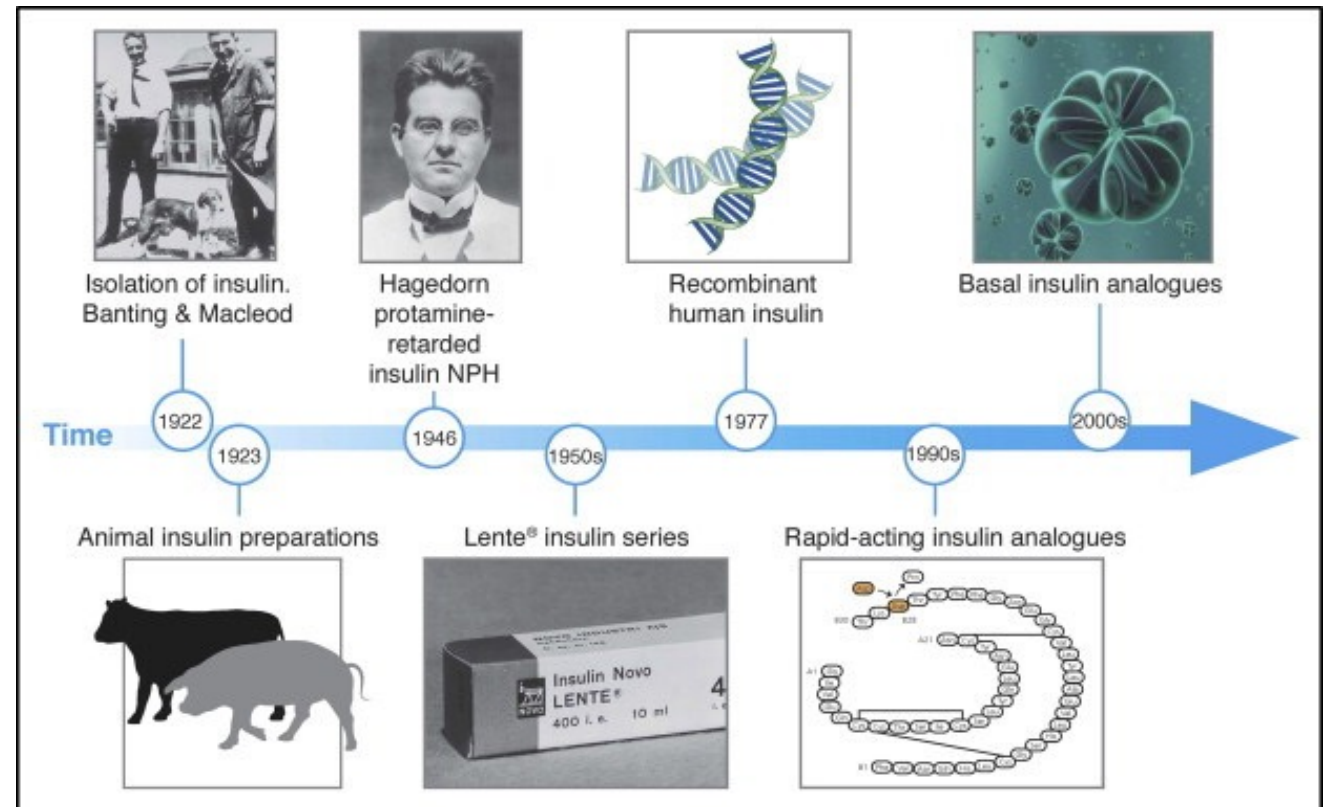
Disclosures



Type 1 diabetes (T1D)



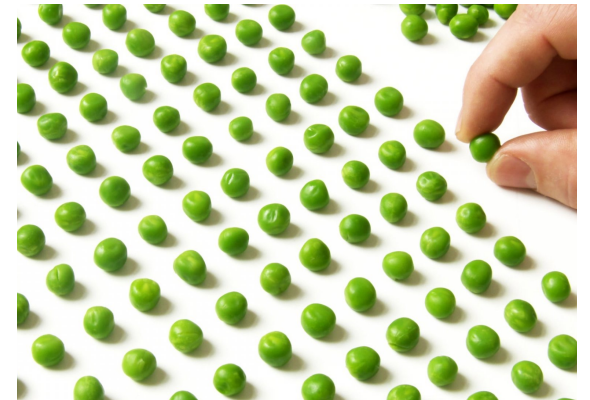
- Autoimmune disorder in which the immune system destroys the beta cells of the pancreas eliminating the body's ability to produce insulin.
- Intensive daily management is required to maintain euglycemia and prevent or delay devastating health consequences.



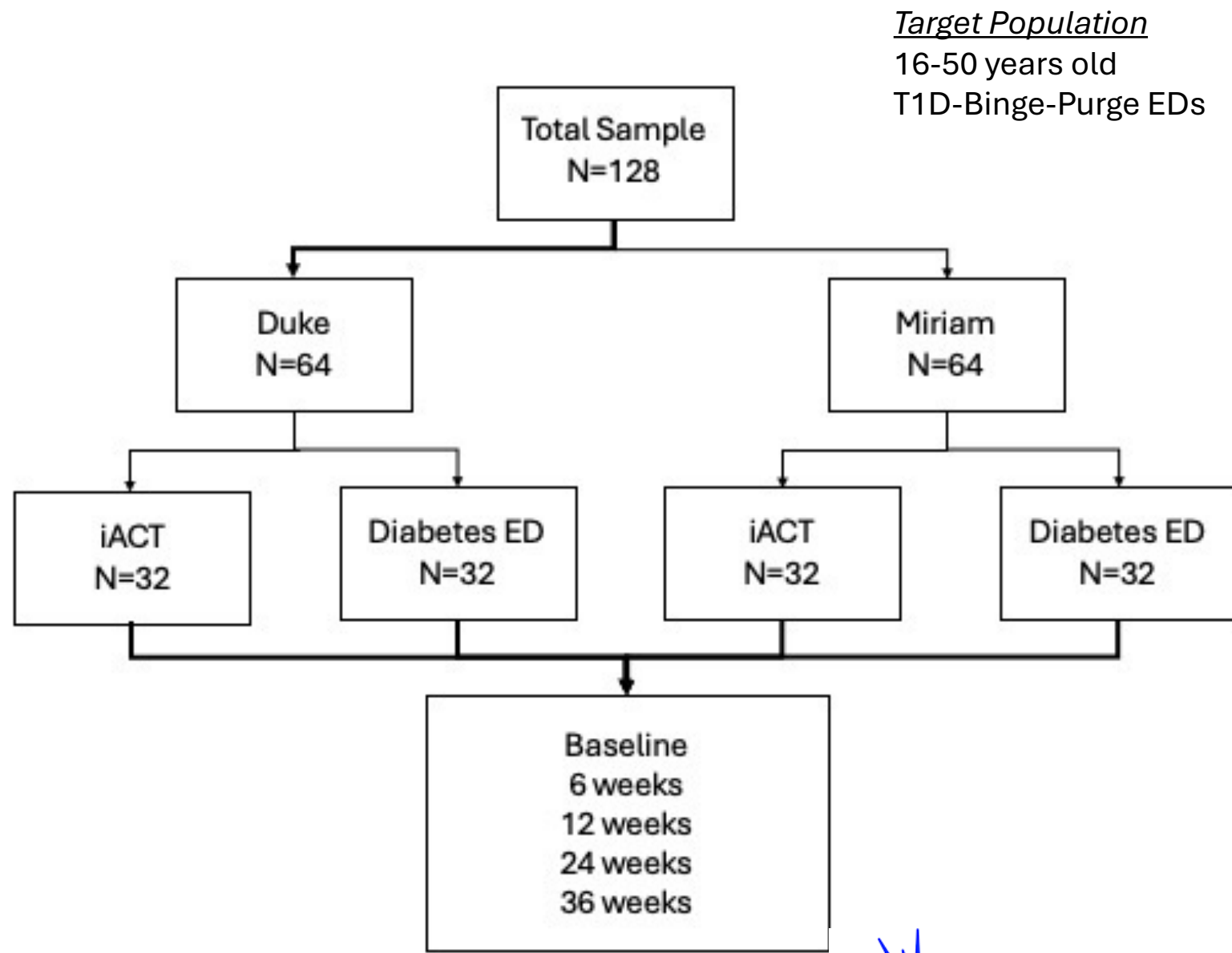
(4-SRA- 2022-1226-M-B, PI: Merwin)

Eating disorders (EDs) in T1D

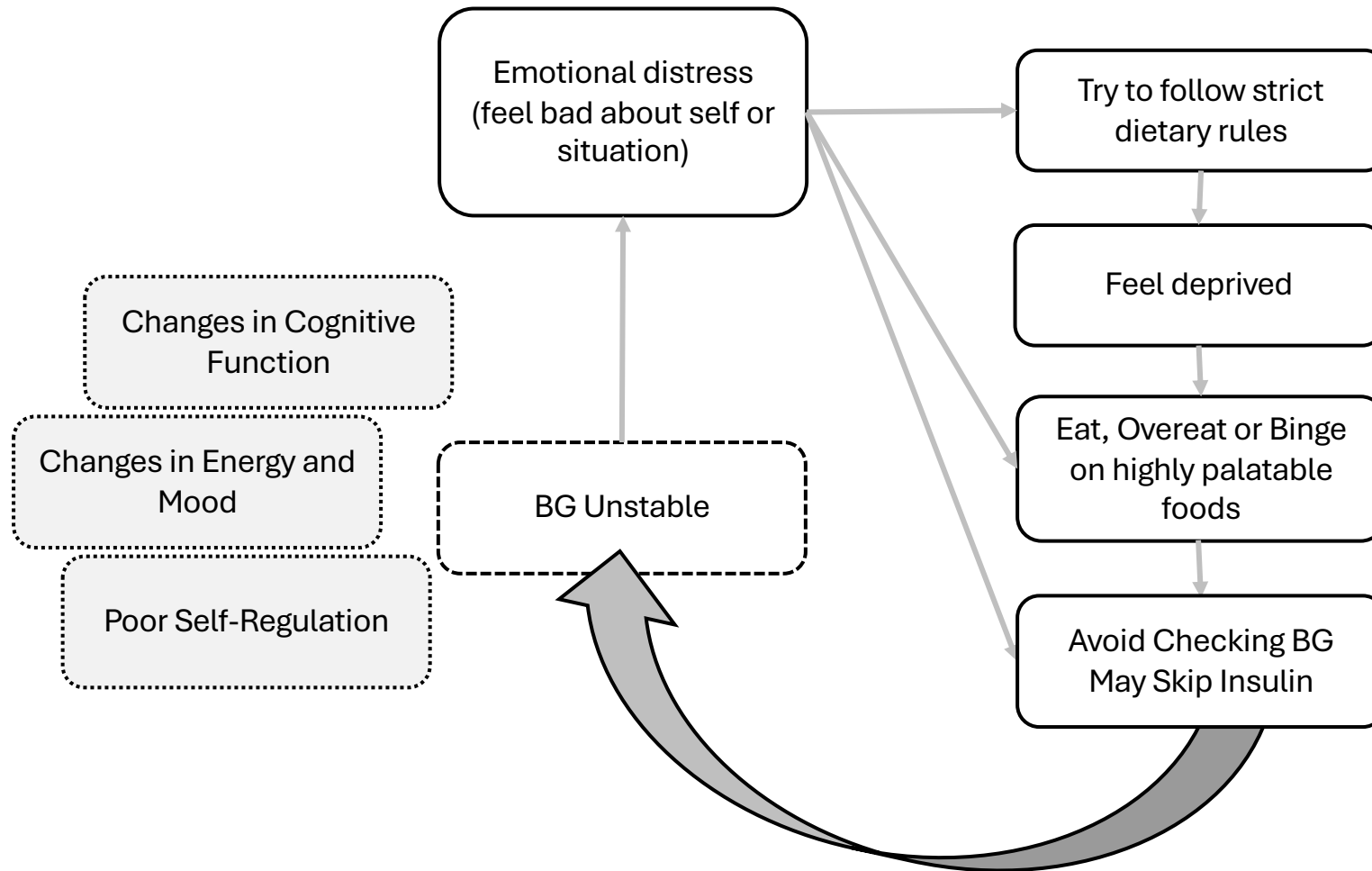
- EDs are common in this population (30% of young women with T1D; 60% cumulative probability by age 25, Colton et., 2015).
- Conventional treatments for AN/BN are less effective for individuals with T1D.
- We've spent the last >10 years studying behavior in this population and developing tailored intervention strategies.



- Multi-site RCT comparing a tailored ACT intervention to Supportive Diabetes Counseling
- Individualized functional assessment, with a personalized course of treatment
- Hybrid, in-person and virtual sessions, with text messaging between sessions

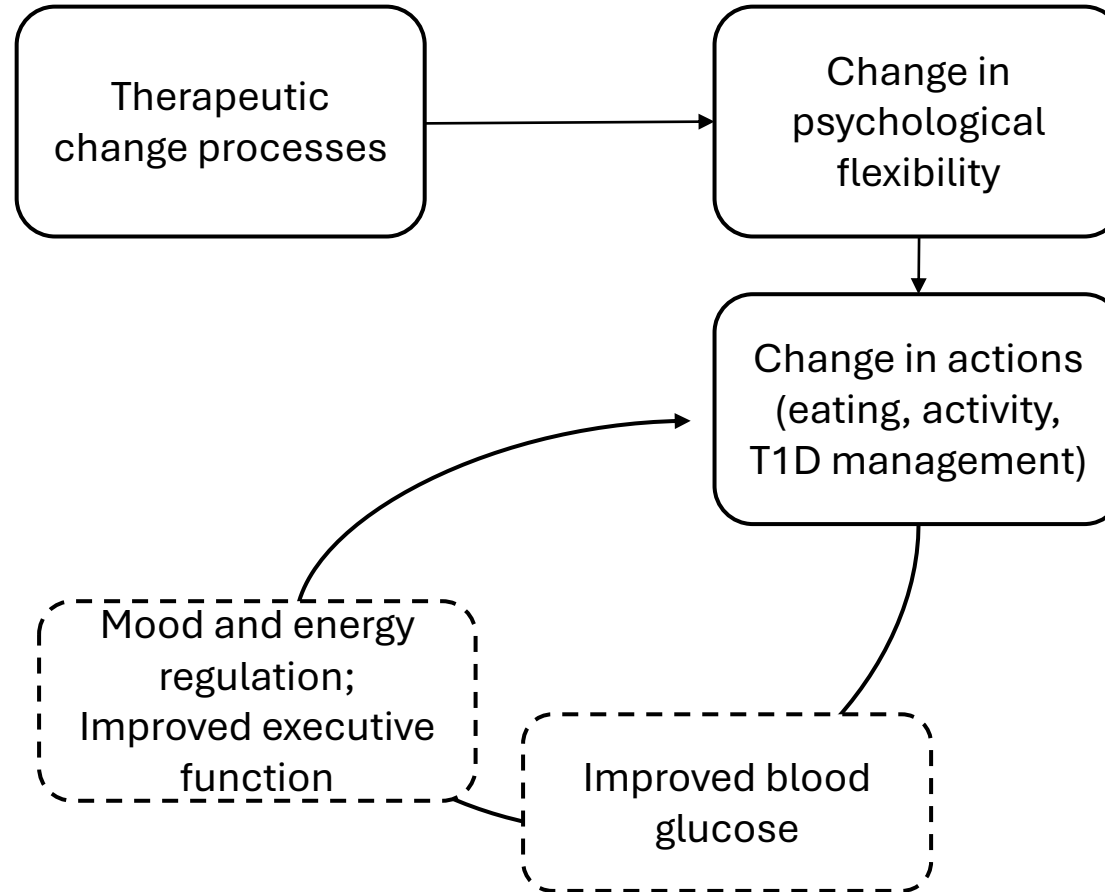


Working model (individualized)



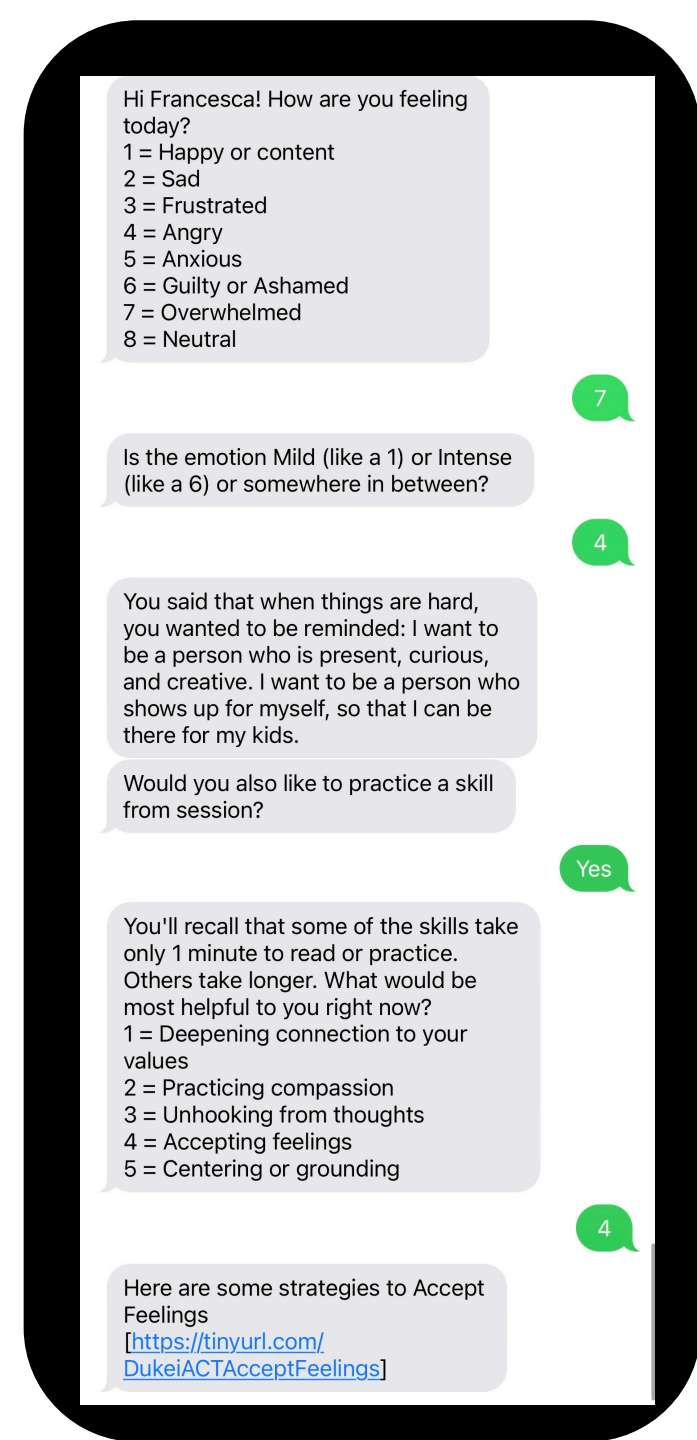
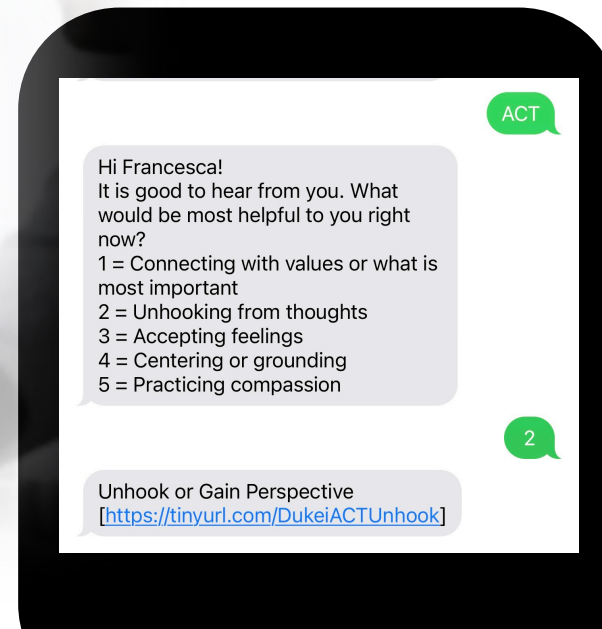
**Complex
Interplay of
multi-level
influences
across
dimensions**

**Affect,
cognition,
physiology,
overt
behavior**



Coding therapeutic process

- In-session behaviors (e.g., contingent responding)
- Text messaging engagement



EMA Bursts (Every 2 hours x 4 days at 0, 6, 12, 24 weeks)

- Psychological flexibility and eating and weight control behaviors

Hello Francesca, it's time for a survey from the Duke Study Team. Over the last couple of hours, what has been your primary emotion?

1 = Happy or Content
2 = Sad
3 = Frustrated
4 = Angry
5 = Anxious or Nervous
6 = Guilty or Ashamed
7 = Overwhelmed
8 = Neutral

5

How intense has the emotion been? Enter a number between 1-6. (1 = Very mild, 6 = Intense).

4

Please tell us how true this has been for you, on a scale from 1-6: Over the last couple of hours...I have been caught up in thoughts or feelings related to food, eating or my body. 1 = Not at All, 6 = Very Much.

4

Over the last couple of hours... I have been trying to avoid or suppress (i.e., get rid of or shove down) emotions. 1 = Not at All, 6 = Very Much.

3

Over the last couple of hours...I have been attached to ideas or beliefs about myself or my body. 1 = Not at All, 6 = Very Much.

3

Over the last couple of hours... I have on autopilot (going through the motions rather than making active choices for my life). 1 = Not at All, 6 = Very Much.

4

Over the last couple of hours...I have been connected to my values and what is most important to me. 1 = Not at All, 6 = Very Much.

3

Thank you!

Did you just finish eating (within the last hour)?

E

Yes

Did you feel a loss of control over eating (or like you couldn't stop eating, even if you wanted to)?

No

Did you overeat (i.e. Do YOU consider what you ate a large amount of food)?

Yes

Do you think OTHER PEOPLE would consider what you ate a large amount of food?

Yes

Did you give less insulin than you needed for this meal because of concerns about your weight? (Report Yes, if you gave less insulin than you needed, and it was AT LEAST IN PART for this reason)

Did you give less long-acting insulin (or adjust your basal insulin) today because of concerns about your weight? (Report Yes, if you gave less insulin and it was AT LEAST IN PART for this reason)

No

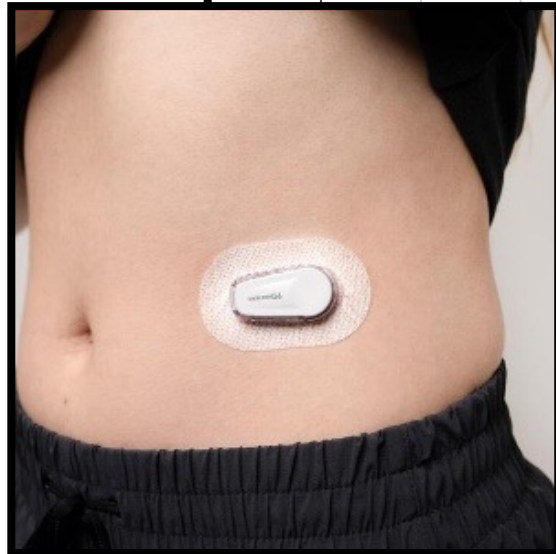
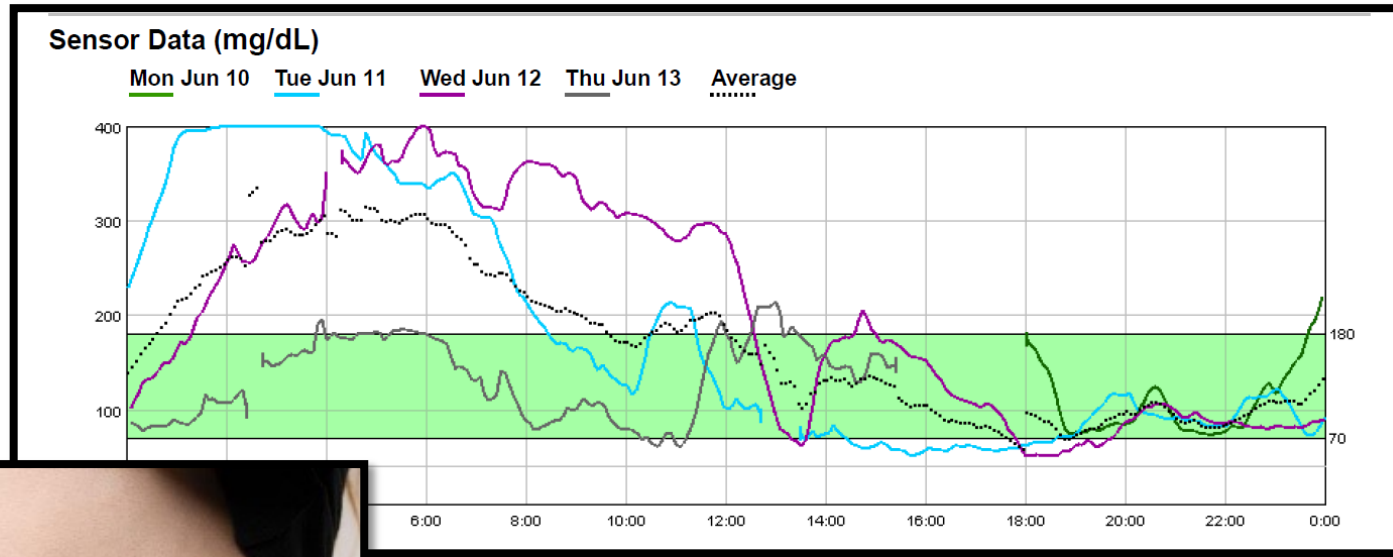
Did you do any of the following today to try to control or change your body weight/shape? (List all that apply, e.g. 1, 2, 4)
1 = Skipped meals or ate very little
2 = Exercised severely
3 = Took diet pills
4 = Took laxatives
5 = Took other medications or drugs (e.g. to suppress appetite, increase energy to burn calories)
6 = No (I did none of these)

6

Was there anything unusual about today (stressful situations etc.)?

I was late to work this morning again, and my boss had to call someone else in to work. Worried I'll get fired.

- Passive collection of glycemic variation, activity and sleep



Flexible responding in an emotional context (physiology) (0, 12, 24 weeks)

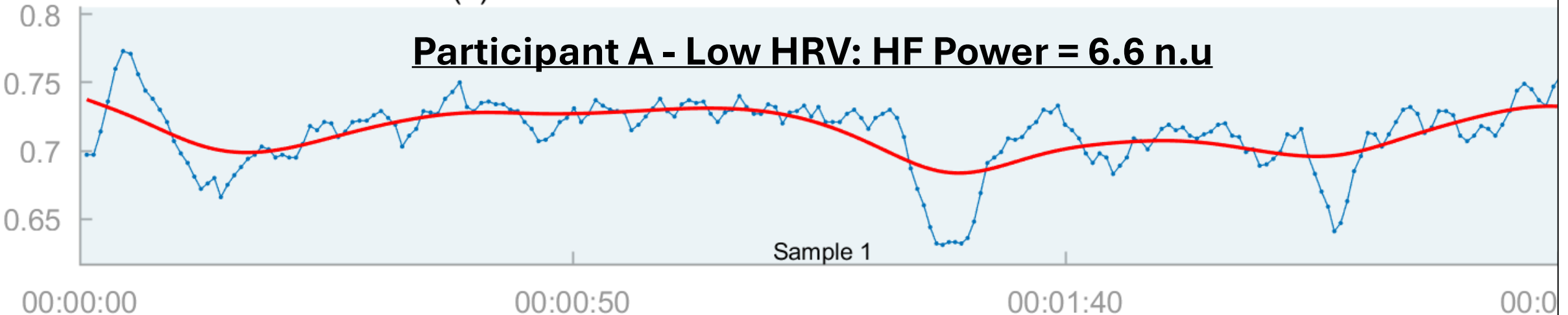
- High-Frequency Heart Rate Variability



HRV during induction

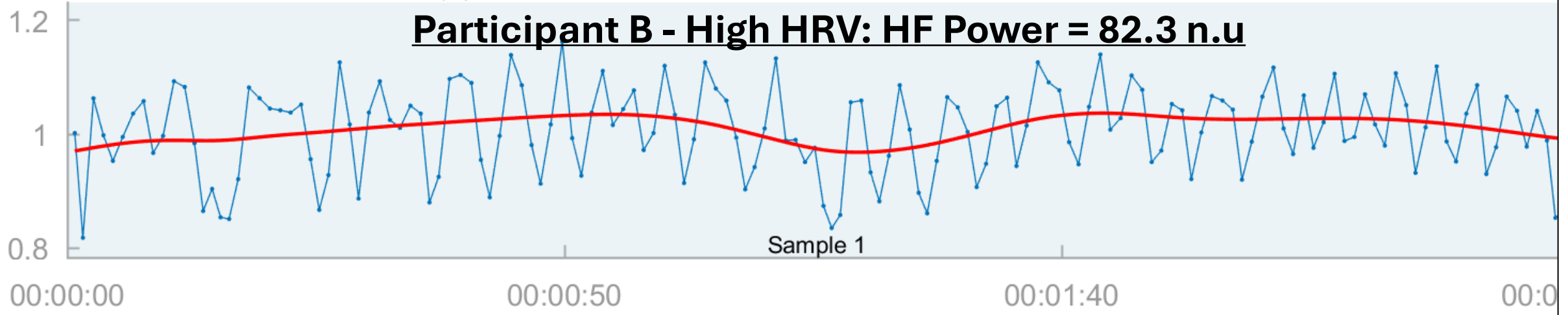
RR Time Series ● RR (s)

Participant A - Low HRV: HF Power = 6.6 n.u



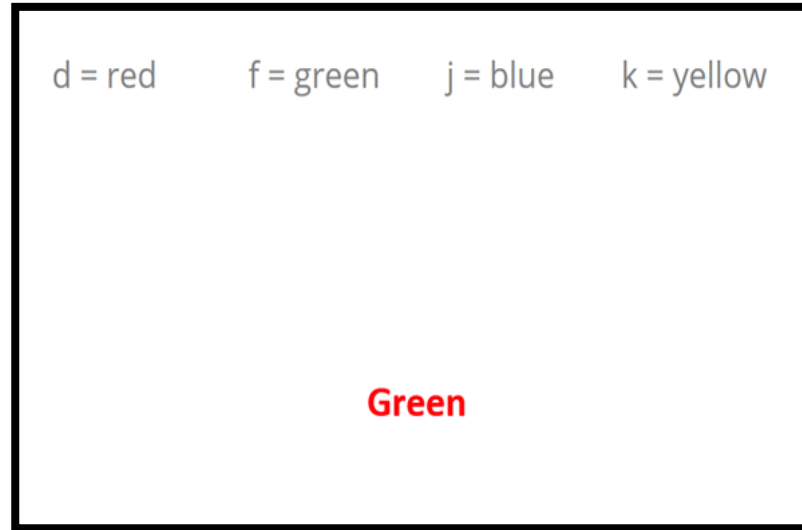
RR Time Series ● RR (s)

Participant B - High HRV: HF Power = 82.3 n.u

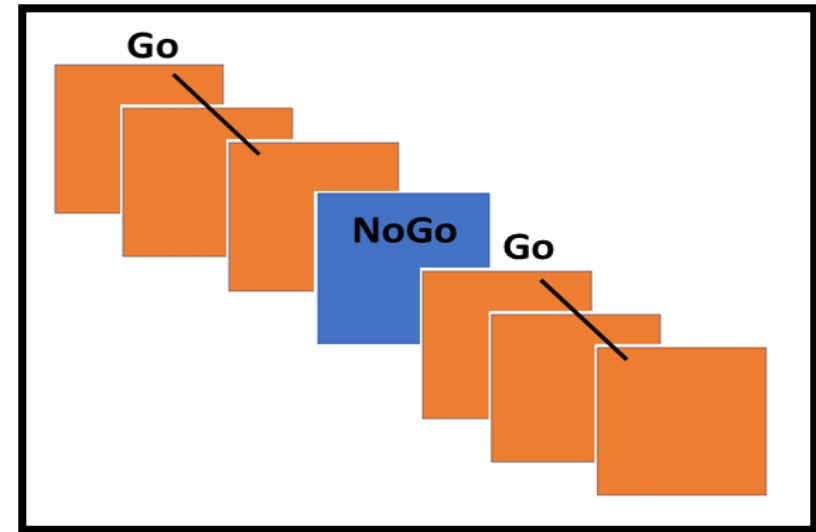


Flexible responding in nonemotional context (neurocognitive-behavioral) (0, 12, 24 weeks)

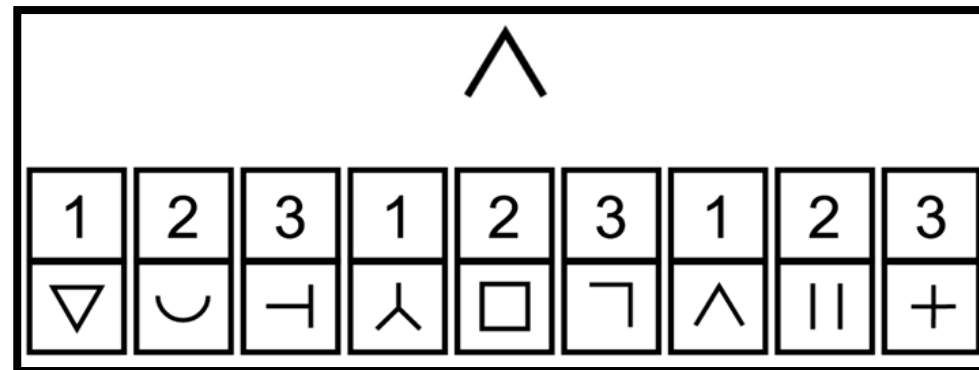
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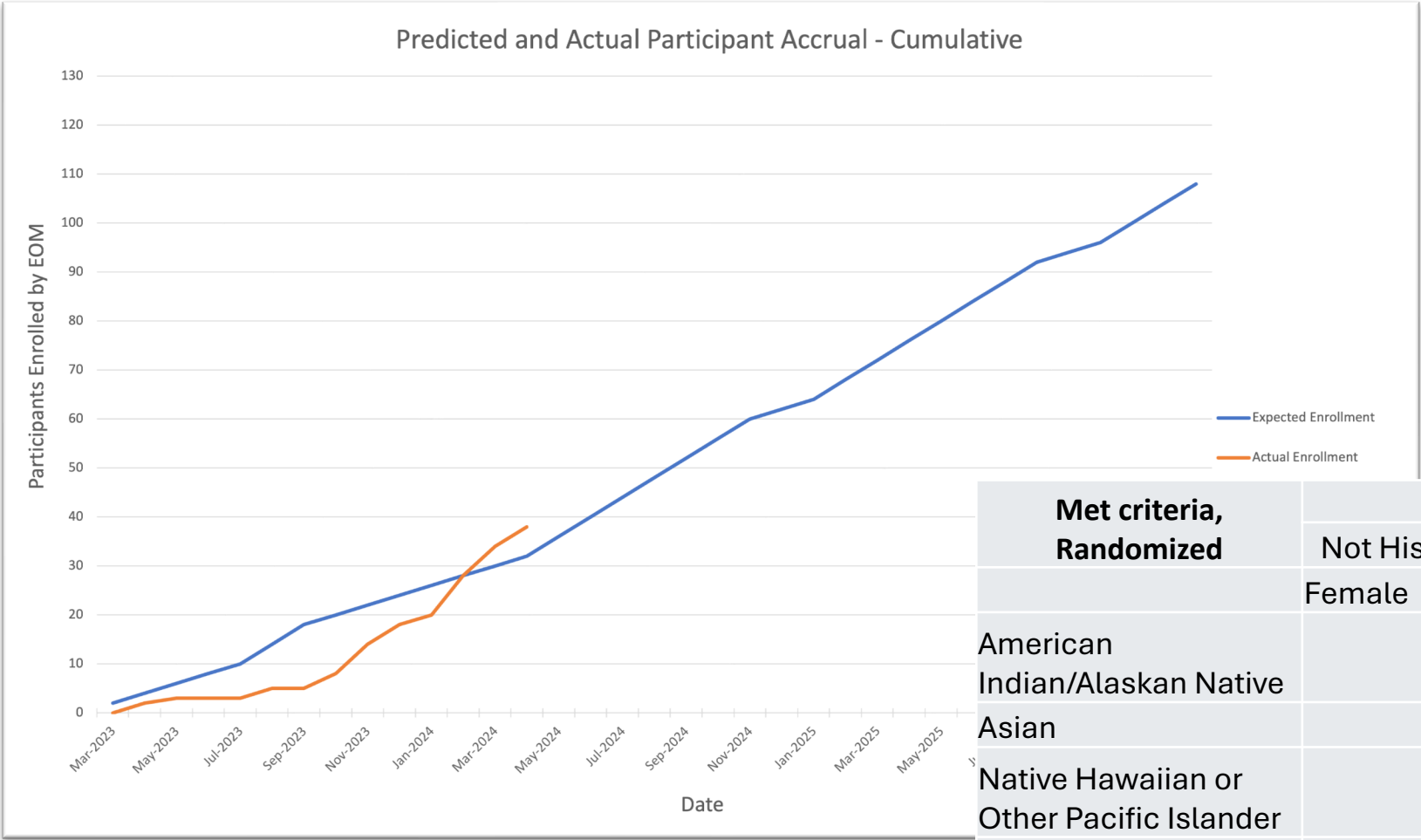
Go/No-Go Task



Number Symbol Coding Task



Trial progress



EMA completion rate: Most >70%

Meals reported per burst: 8 (on average)

Met criteria, Randomized	Not Hispanic or Latinx		Hispanic or Latinx		Total
	Female	Male	Female	Male	
American Indian/Alaskan Native	0	0	0	0	0
Asian	1	0		0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	4	0	0	0	4
White	12	4	2	0	18
More than one race	2	1	0	0	3
Total	19	5	2	0	26

FlexED: A digital, gamified early intervention for eating disorders

- EDs associated with significant morbidity and mortality (2nd highest following opioids)
- 70% of affected individuals do not receive treatment
- Digital interventions may be easily disseminated and engage adolescents and young adults most at risk
- FlexED - teaches skills in psychological flexibility in the context of body image distress (character, storyline, games and rewards)

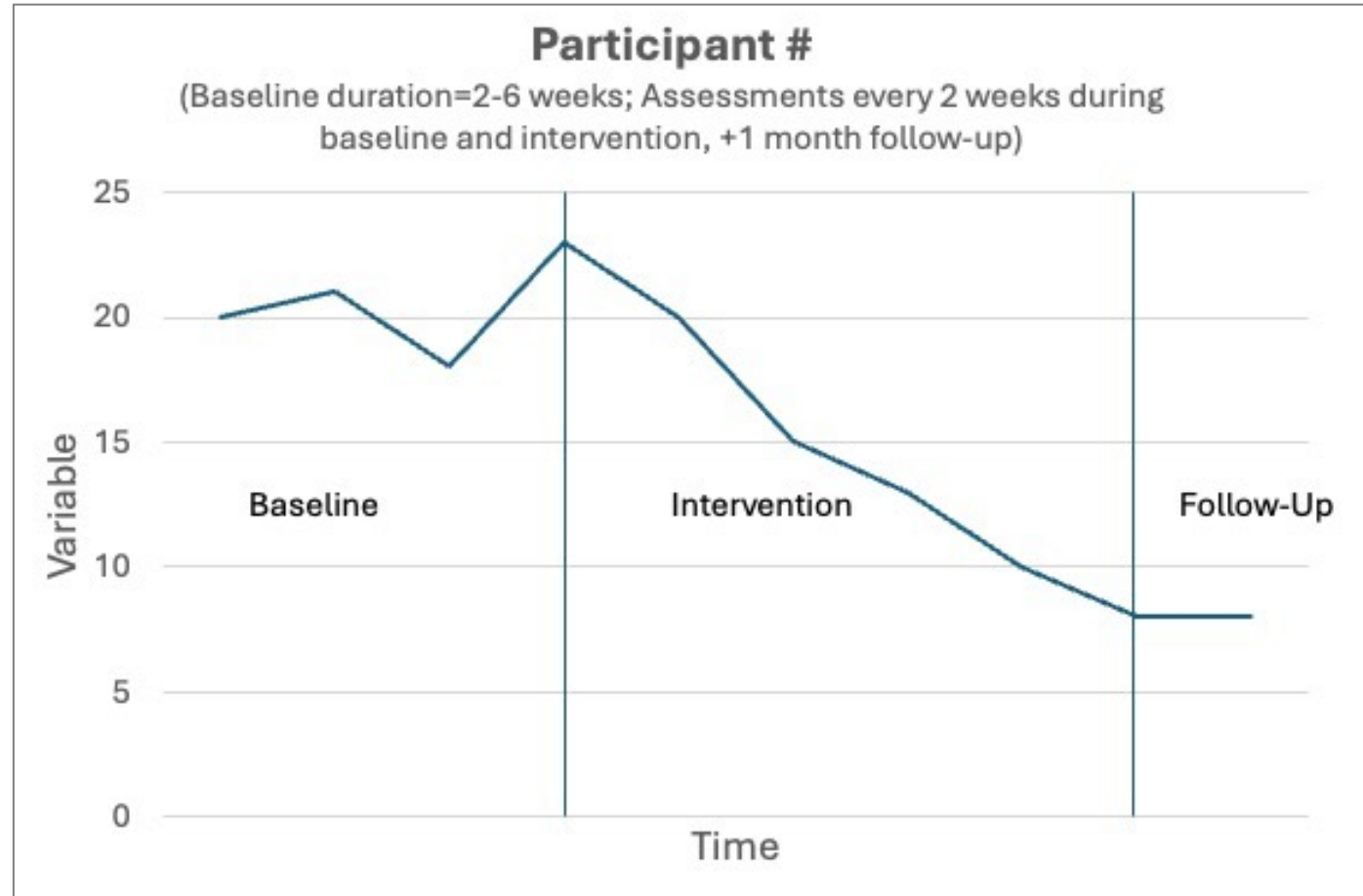


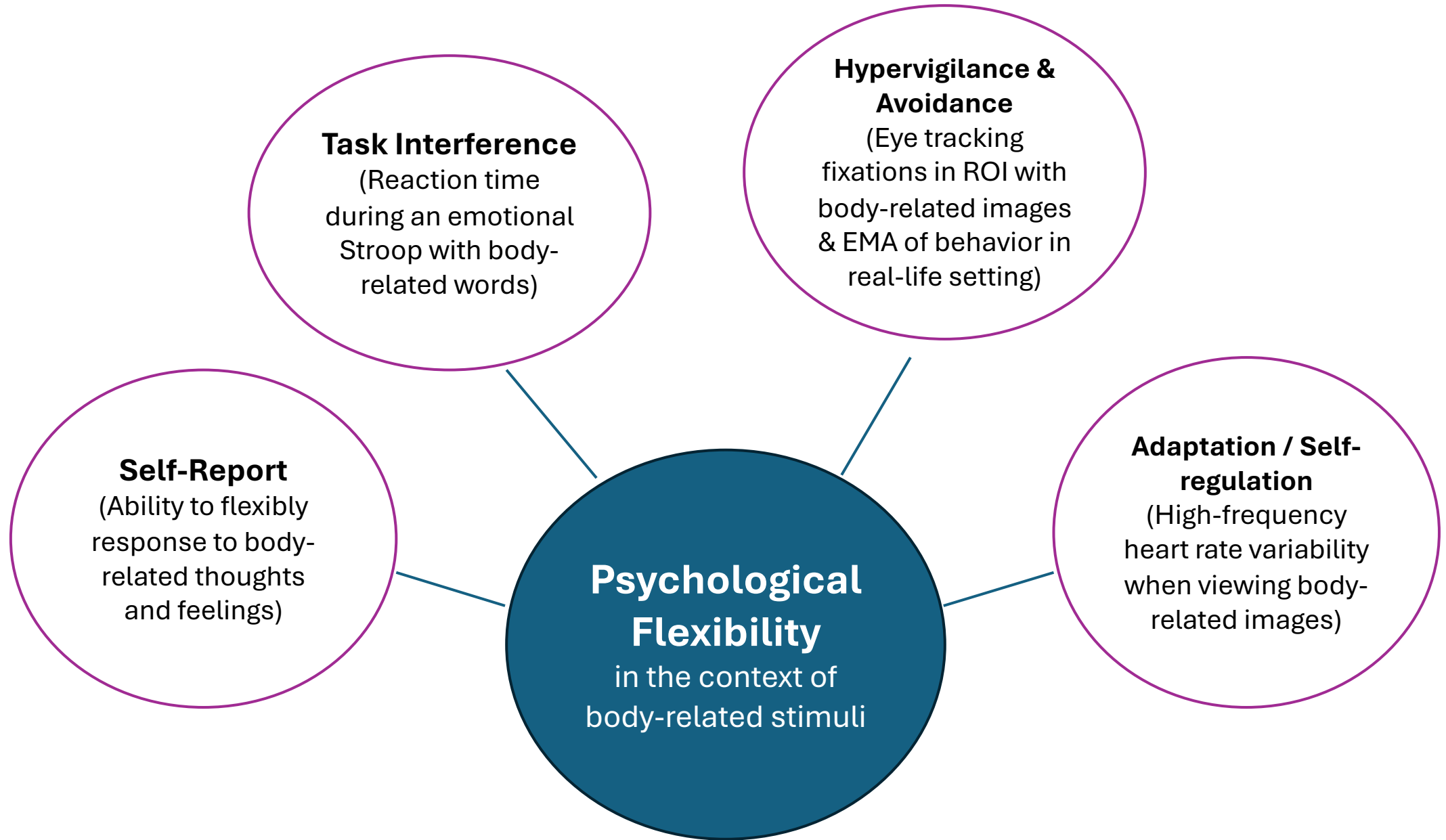
(R61MH127137, PI: Merwin)

Multiple baseline experiment

Target Population
15-25 years old
Female-identifying
Early signs of an ED

- Developed and beta tested with extensive end user engagement and beta-testing
- Sessions are ~20 minutes, completed on mobile phone
- Multiple baseline experiment to test mechanism engagement and determine dose





BI-AAQ-5

Never True	Very Seldom True	Seldom True	Sometimes True	Frequently True	Almost Always True	Always True
1	2	3	4	5	6	7

1. Worrying about my weight makes it difficult for me to live a life that I value.
2. I shut down when I feel bad about my body shape or weight.
3. My thoughts and feelings about my body weight and shape must change before I can take important steps in my life.
4. I will have better control over my life if I can control my negative thoughts about my body.
5. Feeling fat causes problems in my life.

Emotional Stroop

d = red f = green j = blue k = yellow

Fat

Eye Tracking



- High-Frequency Heart Rate Variability



EMA items (1/day X 7 days)

Thinking back over today...

- Distressing thoughts/feelings about body
- Avoiding seeing body
- Checking body weight/shape
- Avoiding activities or people because of body
- Maladaptive behaviors to change body weight/shape

Hello Francesca, it's time for your end of day survey.

Thinking back over today, how often did you have distressing thoughts and feelings about your body?
Enter a number between 1-6, 1 = Not at all, 6 = Very Frequently

Thinking back over today, how often did you avoid seeing your body (e.g., avoid mirrors, bathing, undressing etc.)?
Enter a number between 1-6, 1 = Not at All, 6 = All the Time

Thinking back over today, how often did you check your body weight/shape (e.g., weigh yourself, pinch or measure your body, scrutinize your body in the mirror, etc.)?
Enter a number between 1-6, 1 = Not at All, 6 = Very Frequently

4

3

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Thinking back over today, how much did you try to restrict your food (whether or not you succeeded)?
Enter a number between 1-6, 1 = Not at All, 6 = A lot

Thinking back over today, how much have you avoided activities or people because of concerns about your body weight/shape?
Enter a number between 1-6, 1 = Not at all, 6 = A lot

Did you vomit, use laxatives, diet pills, or diuretics today because of concerns about your body weight/shape?
1 = No, 2 = Yes

Did you exercise compulsively today because of concerns about your eating or body weight/shape?
1 = No, 2 = Yes

4

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2

2

- Challenges in preparation