Presented by

Dr. Inbal Billie Nahum-Shani

Micro-Randomized Trials

MRTs

Outline

What is a Micro-Randomized Trial

Why use an MRT

What do you need to know about MRT data analytic methods?

What do you need to know about MRT sample size planning?

Q&As about MRTs

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What is a Micro-Randomized Trial (MRT)?

- Randomized trial
- Sequential randomizations
- Each participant is randomized between intervention options at each decision point
- Each person may be randomized 100's or 1000's of times and multiple times per day.

Qian, T., Walton, A. E., Collins, L. M., Klasnja, P., Lanza, S. T., Nahum-Shani, I., ... & Murphy, S. A. (2022). The microrandomized trial for developing digital interventions: Experimental design and data analysis considerations. Psychological Methods.

Liao, P., Klasnja, P., Tewari, A., and Murphy, S. A. (2016) Sample size calculations for micro-randomized trials in mHealth. Statist. Med., 35: 1944–1971.

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Why use an MRT?

To answer scientific questions about JITAI construction.

- Should we provide a prompt when the person is stressed?

State of vulnerability:
Heightened risk for lapse

- **Prompt under stress**
- **Prompting would prevent lapse**

State of unreceptivity:
Limited cognitive capacity

- **Don’t prompt under stress**
- **Prompting would be disruptive**

Why use an MRT?

Scientific questions motivating an MRT

1

The selection of intervention options

2

The tailoring of intervention options

Why use an MRT?

Scientific questions motivating an MRT

1 The selection of intervention options

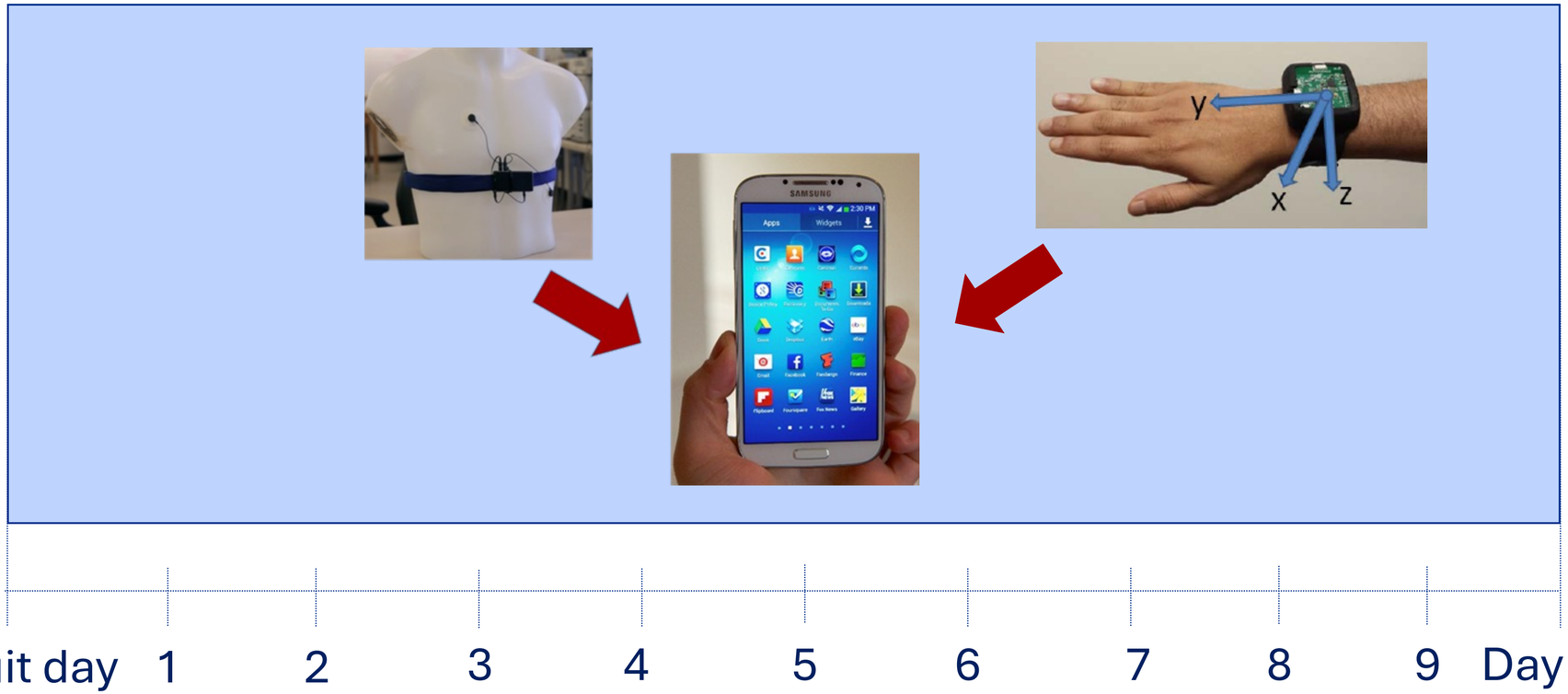
- Do the intervention options impact the proximal outcome?
- Primary: Main effect question
- Example: under stress, is the prompt better compared to no prompt?
- Proximal outcome: probability of experiencing stress in the next 2 hours

2 The tailoring of intervention options

- Under what conditions one intervention option would be better than another in terms of impacting the proximal outcome?
- Secondary: moderation question
- Example: under stress, will the prompt be better than no prompt if the person is at home vs. at work?

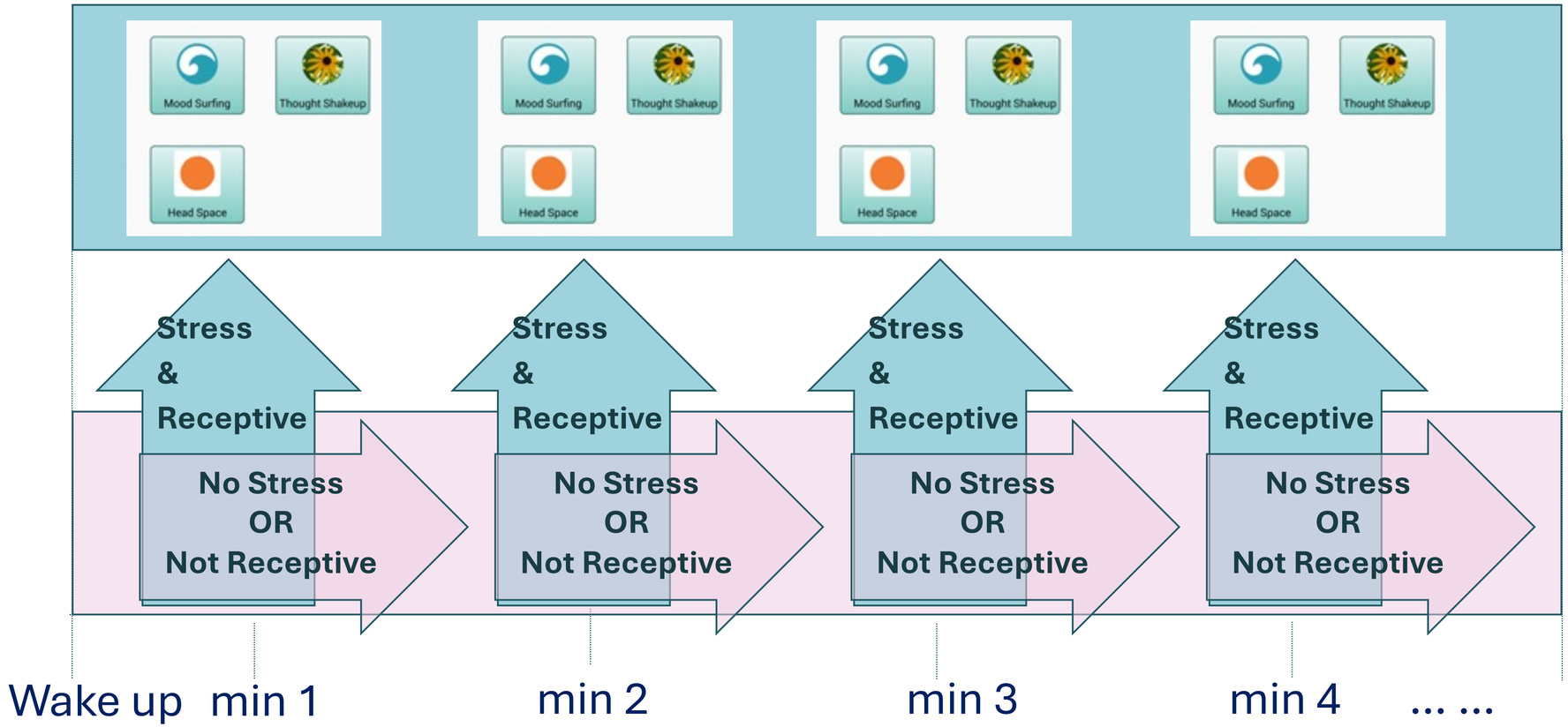
Why use an MRT?

Remember Sense2Stop?



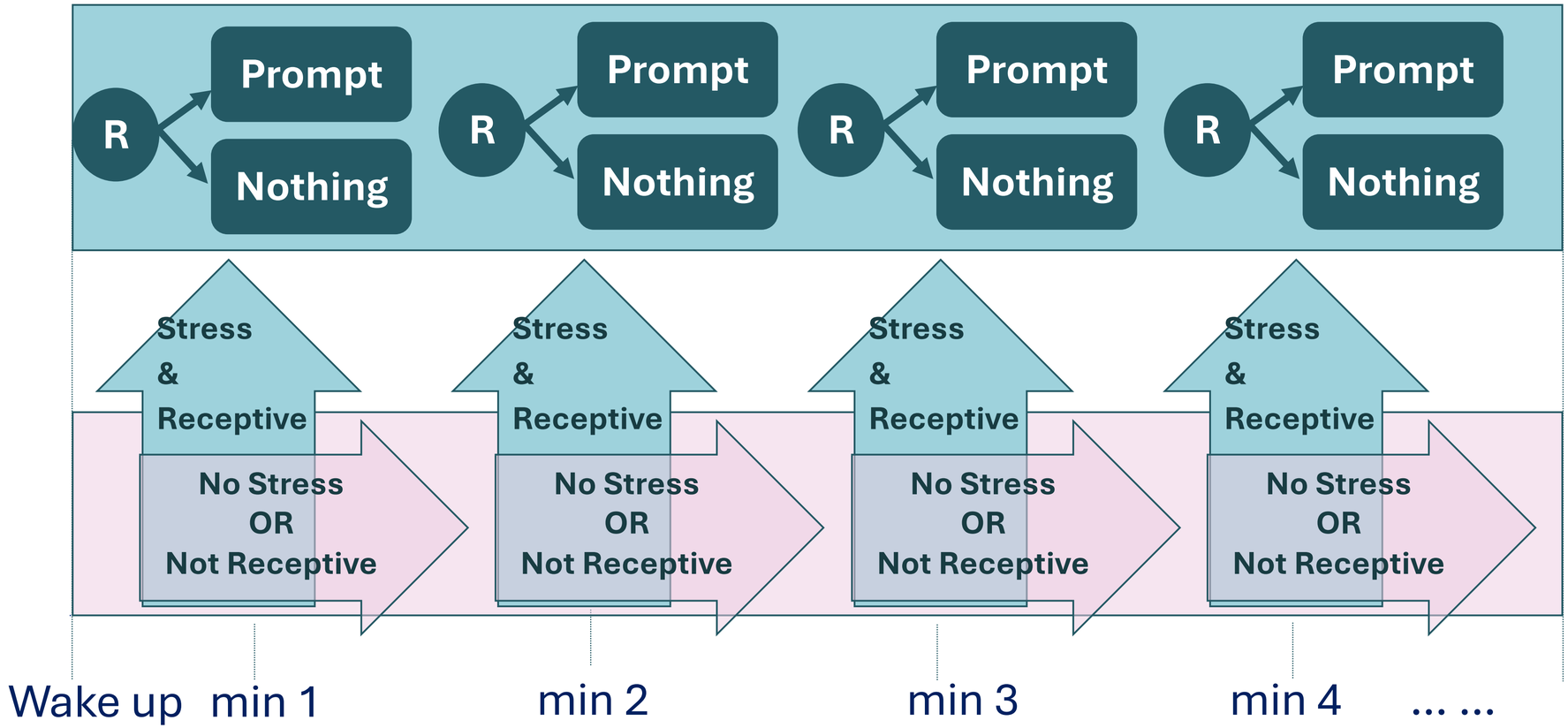
Why use an MRT?

Instead of delivering a prompt when people are stressed & receptive …



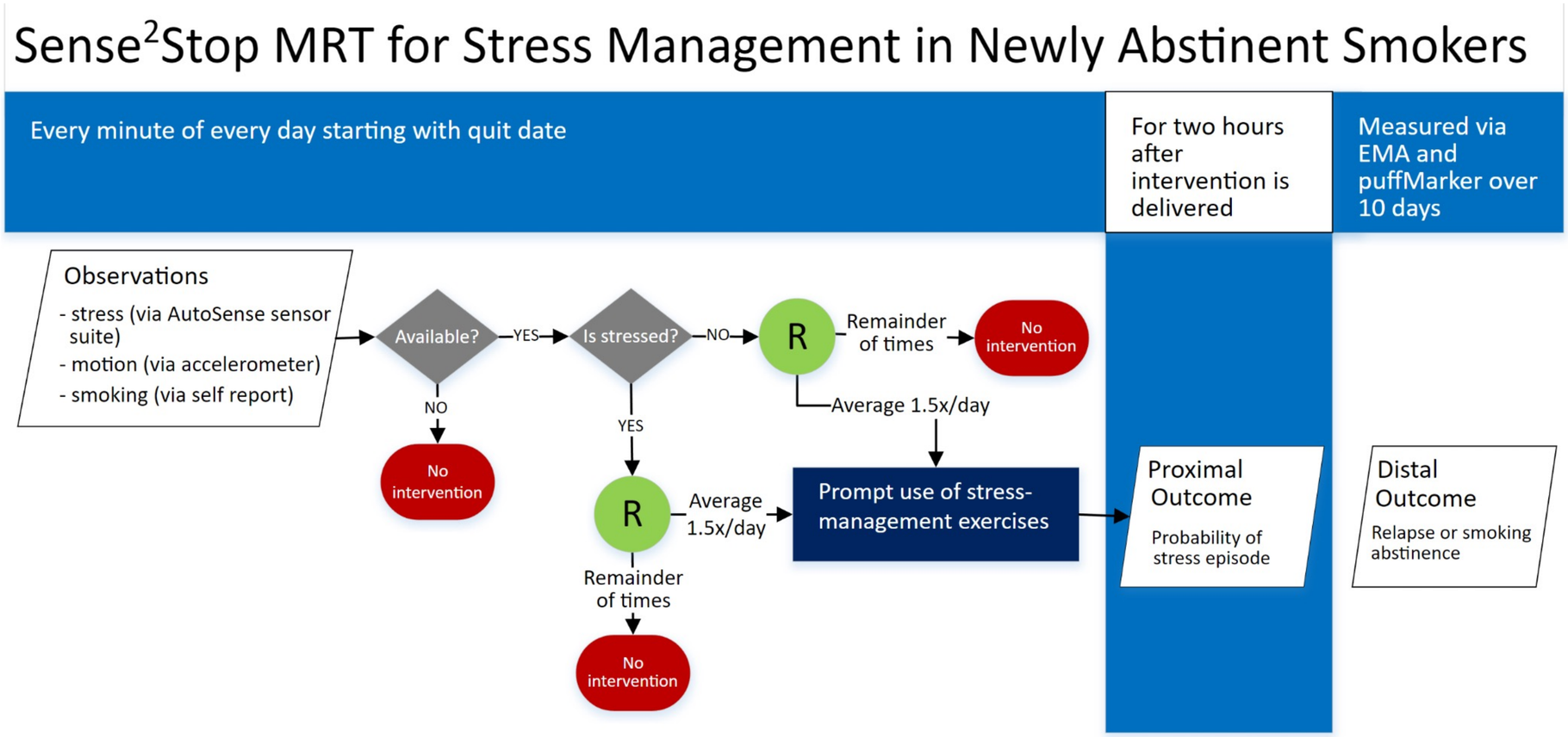
Why use an MRT?

We randomize when people are stressed & receptive …



Why use an MRT?

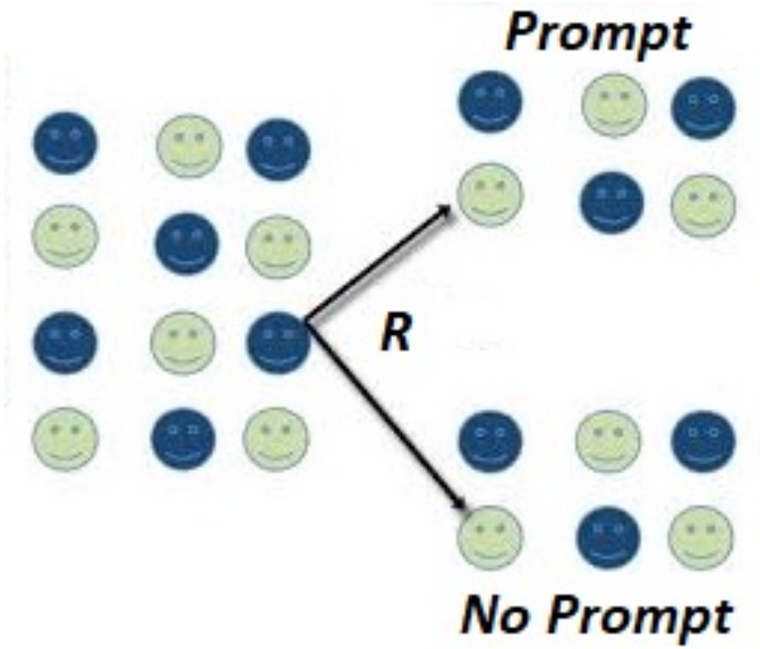
Real version of Sense2Stop available online at **myumi.ch/g3q23**.



Why use an MRT?

Why micro-randomize?

- Randomization (+ representative sample) is a gold standard in providing data to assess causal effects.



Why use an MRT?

Why randomize rapidly?

- Answer scientific questions about the conditions in which an intervention should be delivered
- These conditions may change rapidly

Why use an MRT?

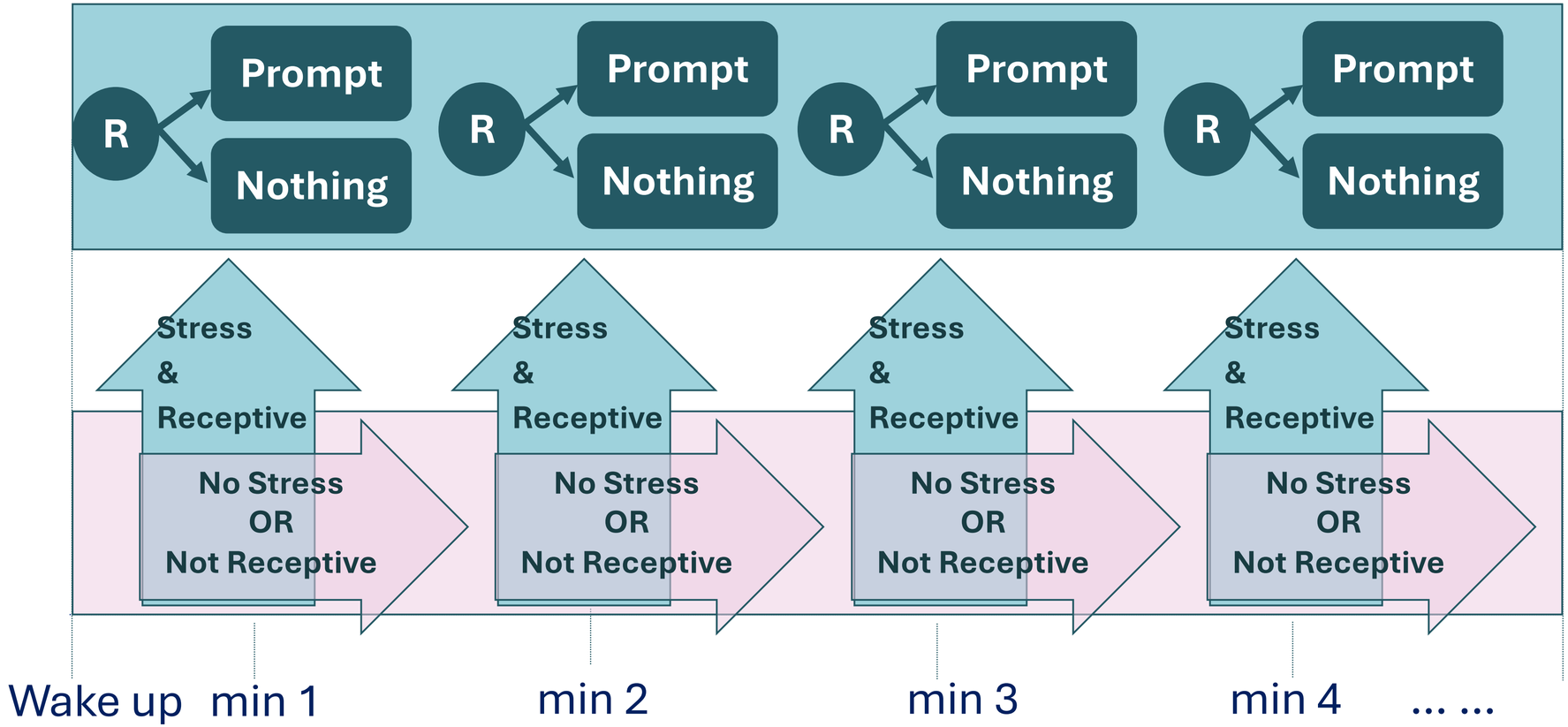
Micro-randomizations may be restricted based on known tailoring variables:

- Tailoring variable: Information used to decide whether and how to intervene
- Similar to SMARTs, investigators may have tailoring variables that are known based on existing evidence and practical considerations
- Known conditions that represent **receptivity** to an intervention
  - The person is not driving a car.
- Known conditions that represent **vulnerability**
  - If the person is experiencing stress
- Known conditions that represent **opportunity**:
  - The person completed a task (opportunity to reinforce future completion).

These tailoring variables may be embedded in an MRT such that decision points are **eligible** for micro-randomization only under specific conditions.

Why use an MRT?

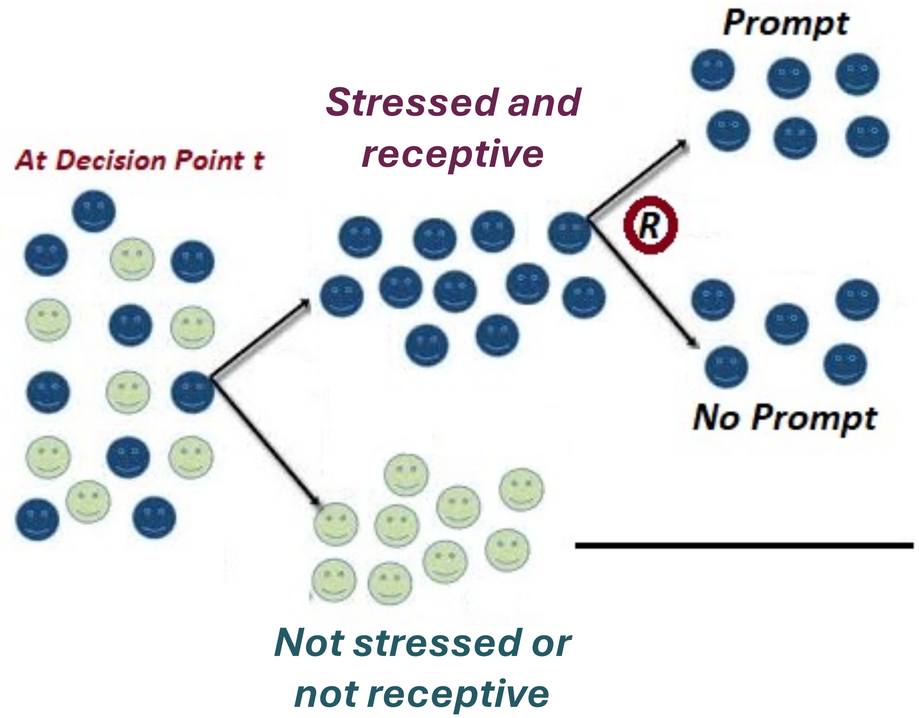
Micro-randomizations may be restricted.



Why use an MRT?

Micro-randomizations may be restricted.

- The main effect of prompt (vs. no prompt), only among decision points in which the individual is stressed and receptive
  - Main effect is conditional on stress and receptivity
  - Only concerns the sub-population of individuals at time t



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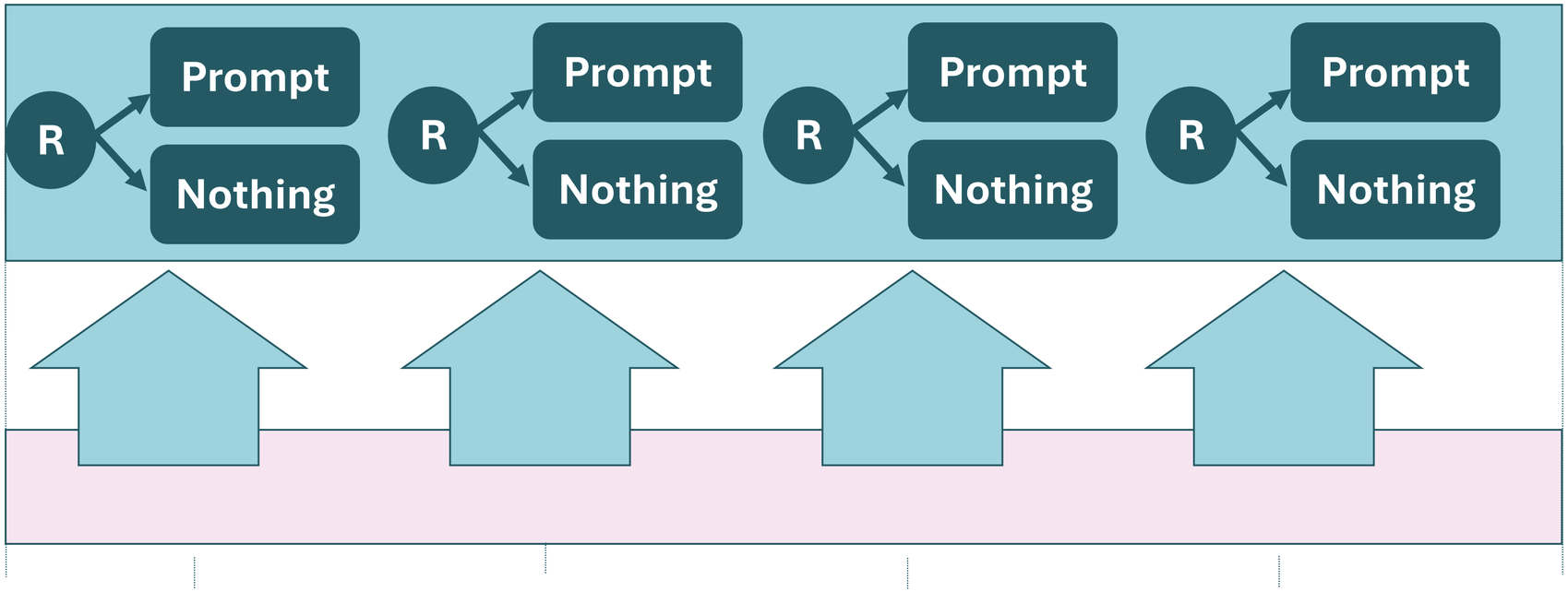
Data Analysis: Intuition

Consider this simplified MRT



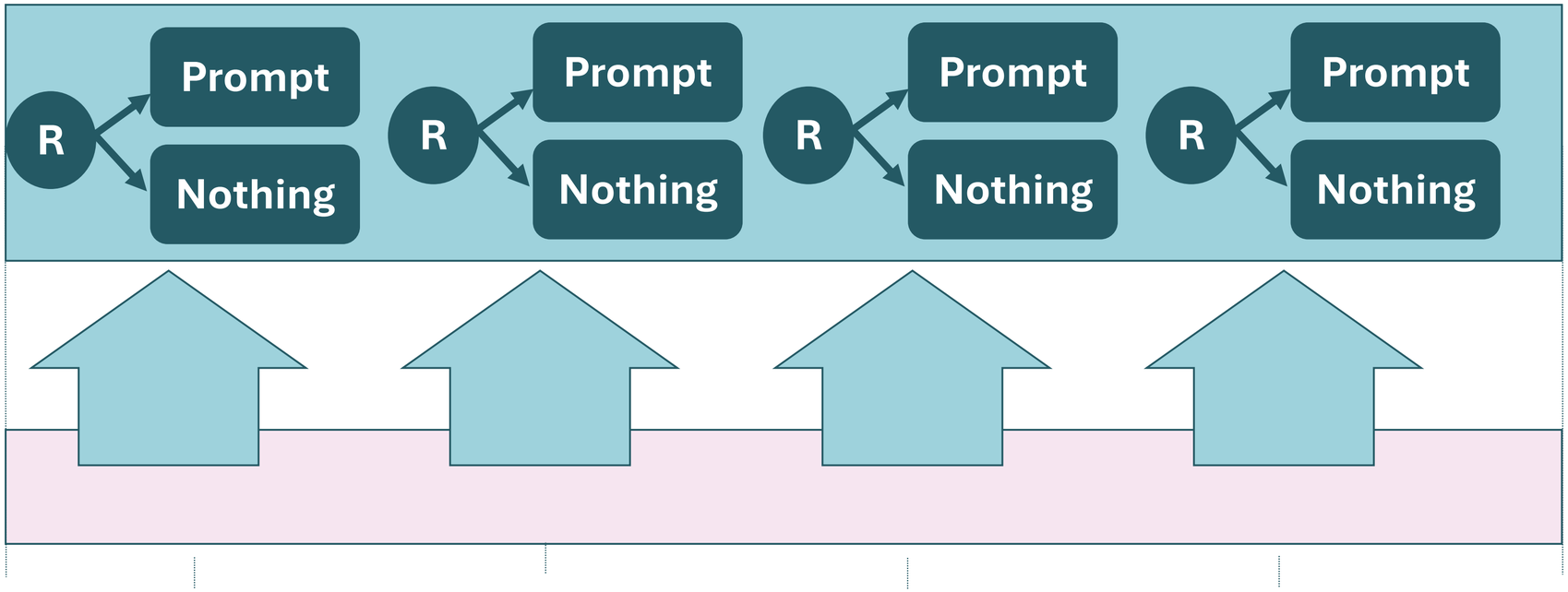
Measure stress continuously with Autosense throughout the day

Scientific Questions:

Main effect: is the prompt better than no prompt?

Moderation: is the prompt better under stress vs. no stress?

Data Analysis: Intuition



Measure stress continuously with Autosense throughout the day

Scientific Questions:

Main effect: is the prompt better than no prompt?

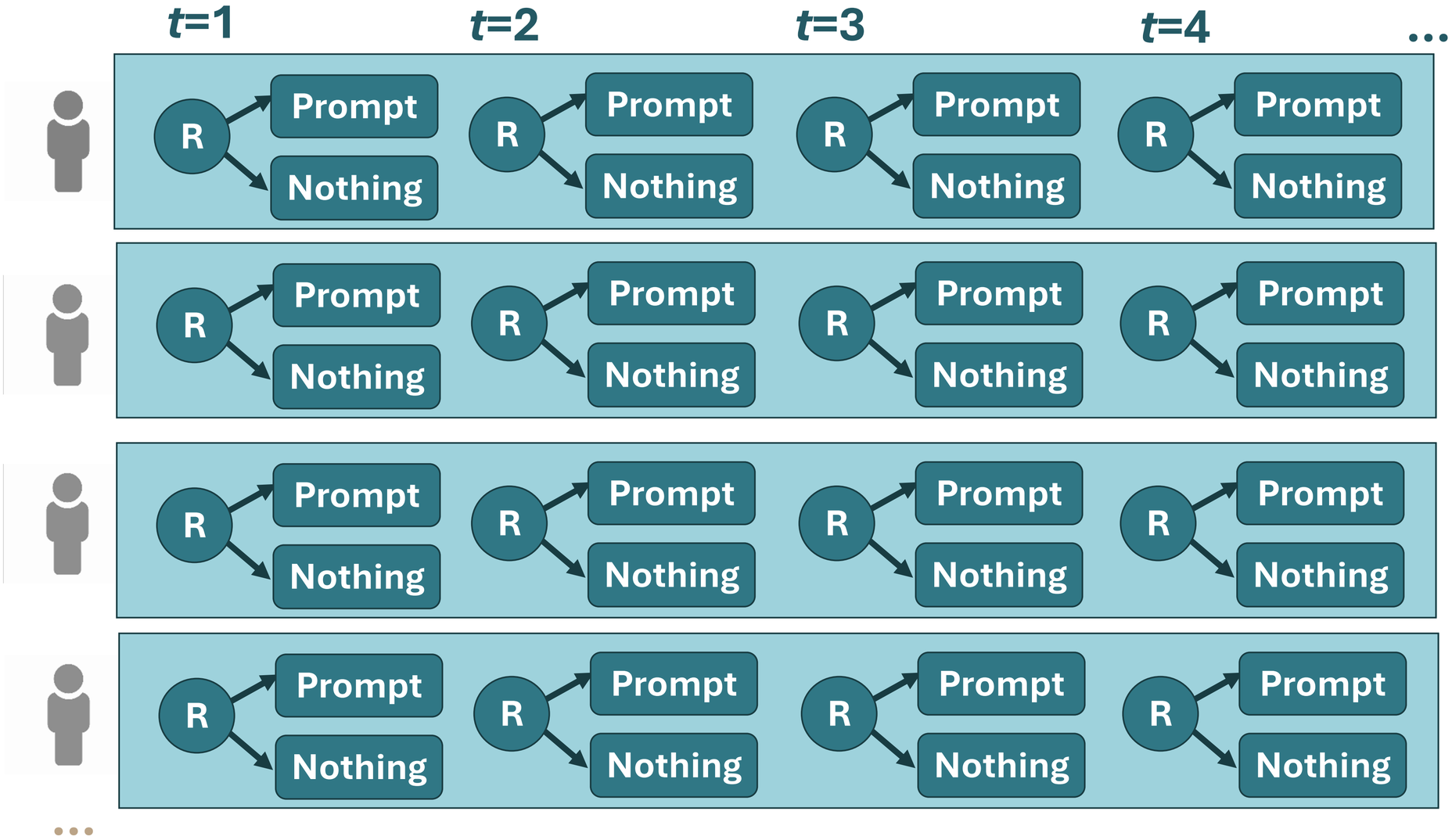
Moderation: is the prompt better under stress vs. no stress?

Data Analysis: Intuition

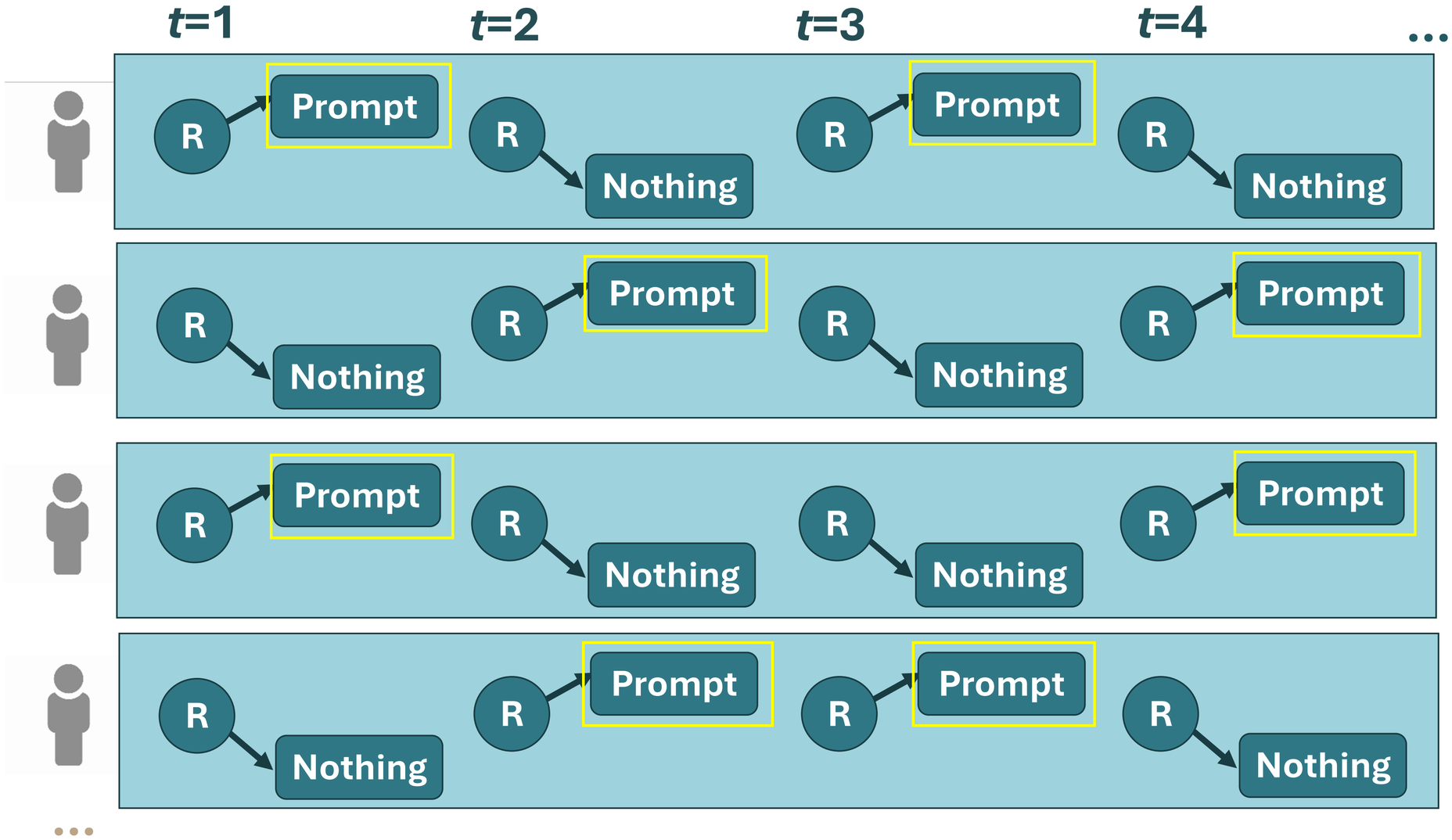
Main effect primary aim:

- The mean difference in the proximal outcome between
- Decision points in which one option was offered and decision points in which another option was not offered,
- Averaged across all decision points in the study and all individuals

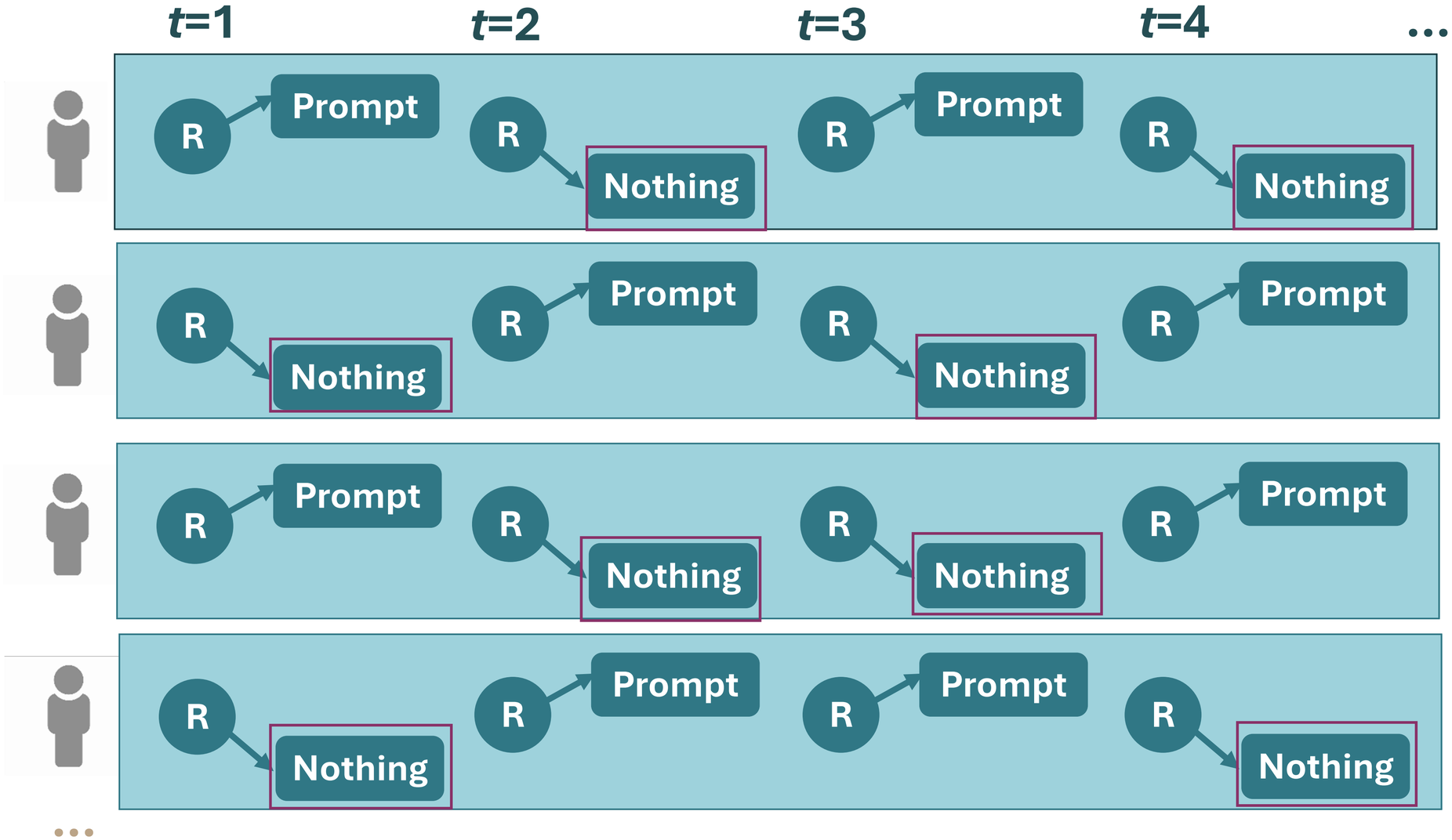
Data Analysis: Intuition



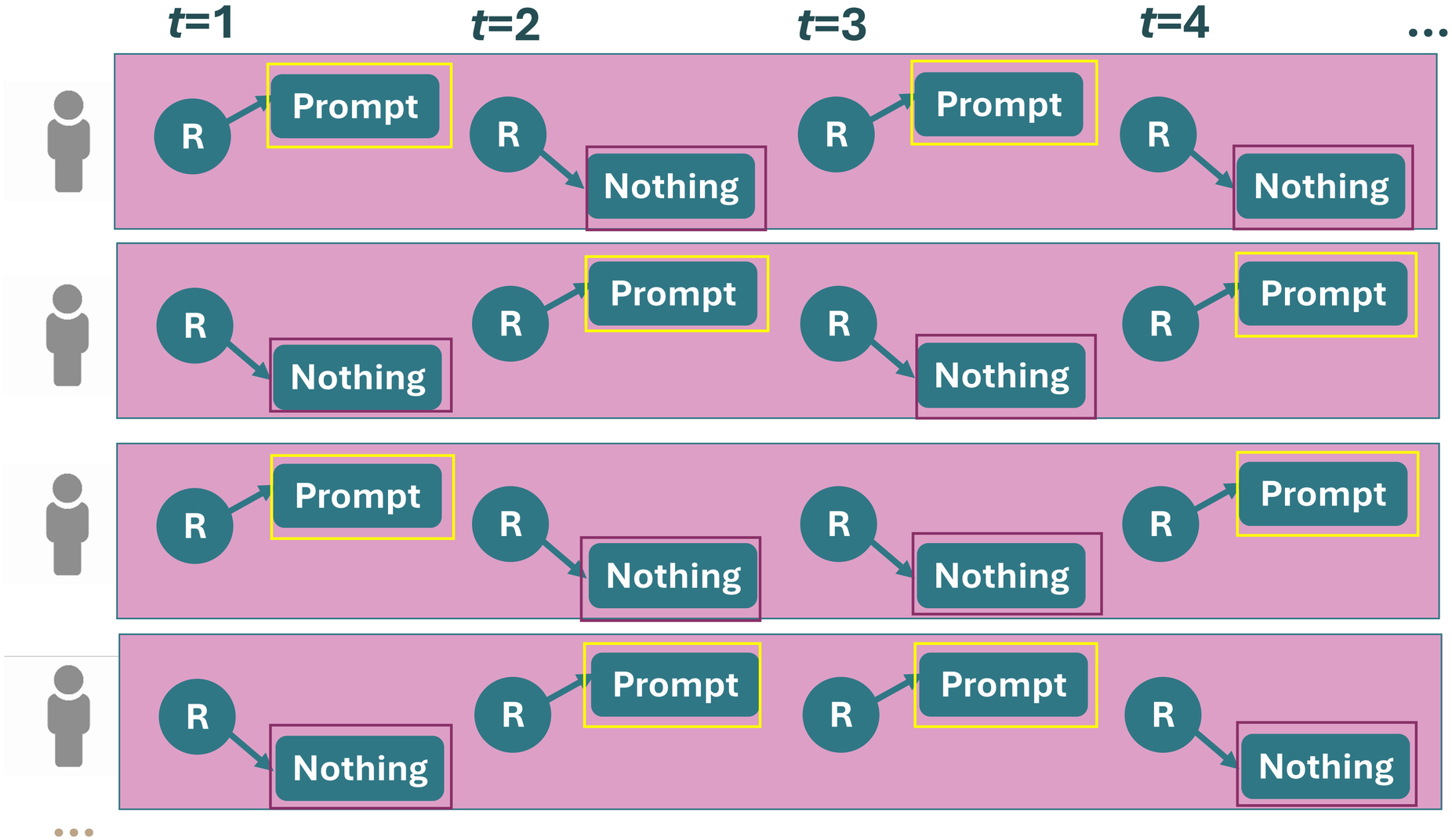
Data Analysis: Intuition



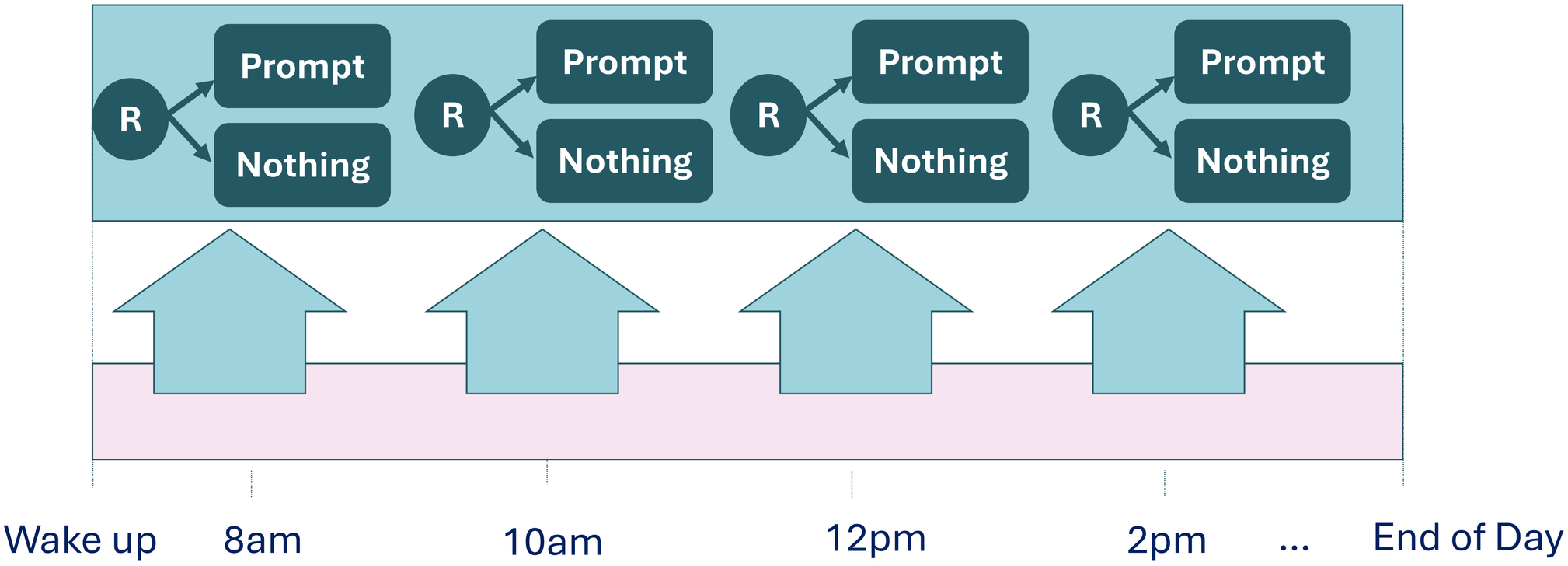
Data Analysis: Intuition



Data Analysis: Intuition



Data Analysis: Intuition



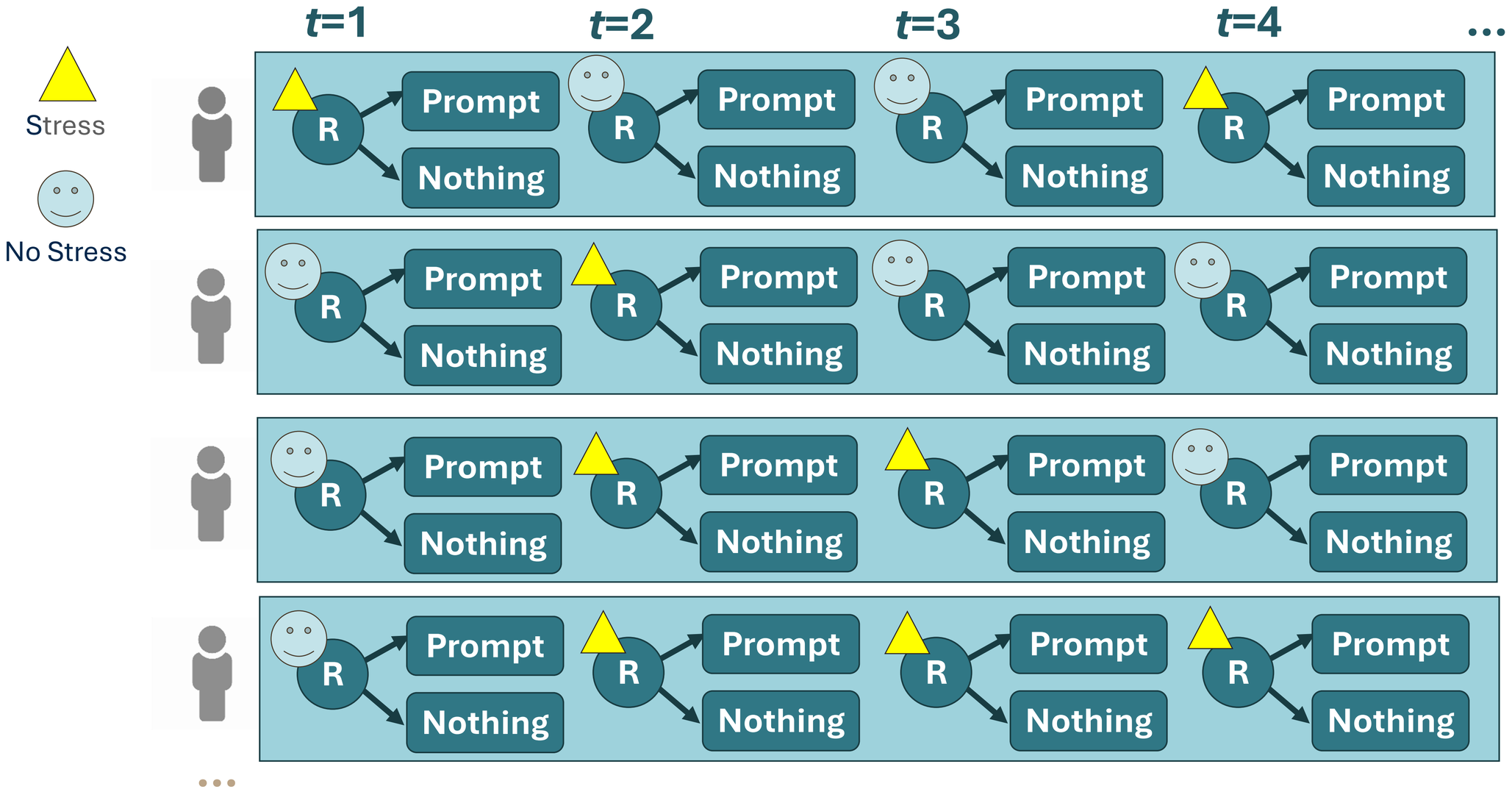
Measure stress continuously with Autosense throughout the day

Scientific Questions:

Main effect: is the prompt better than no prompt?

Moderation: is the prompt better under stress vs. no stress?

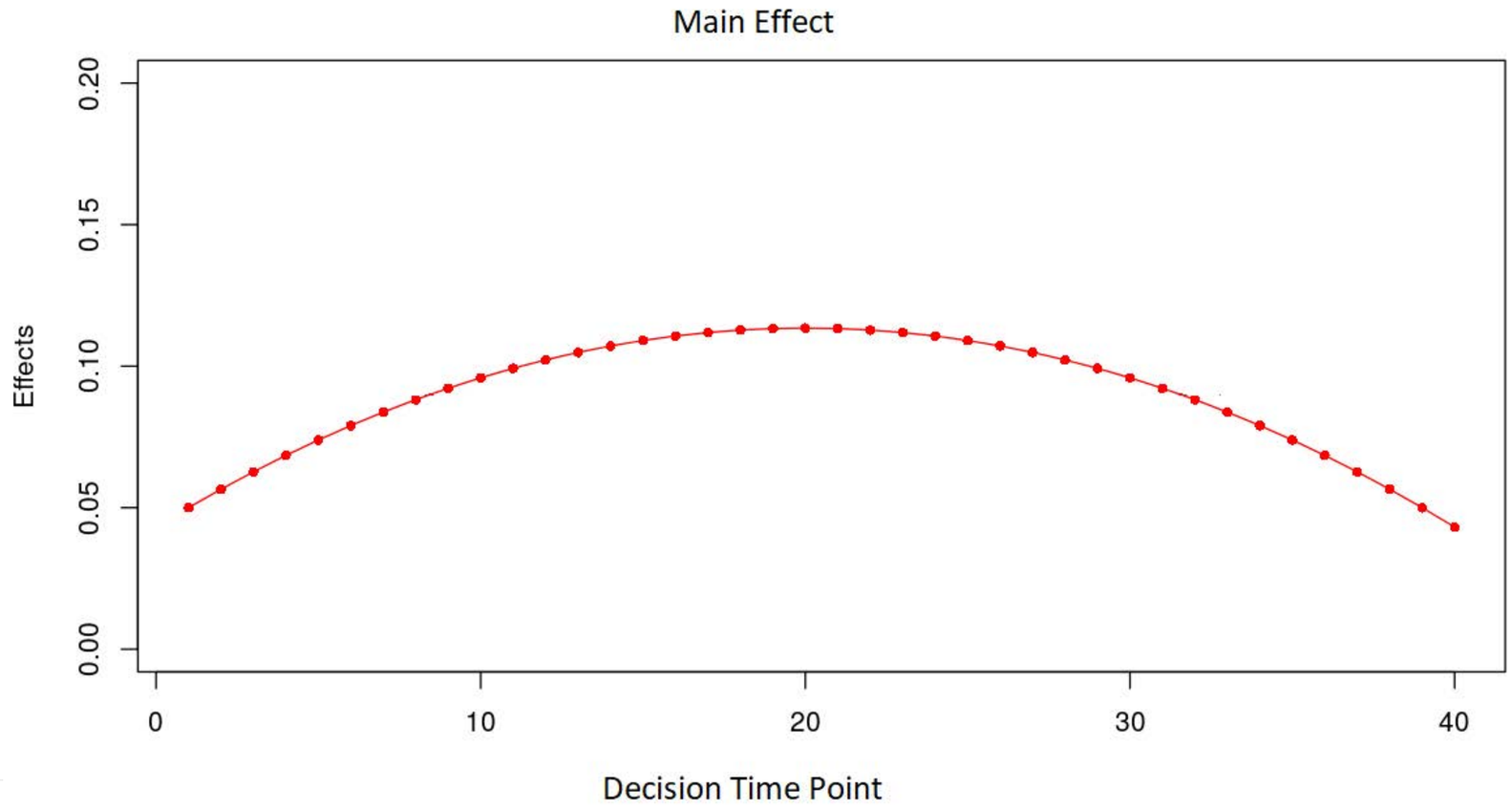
Data Analysis: Intuition



Data Analysis: Intuition

Time as a candidate moderator: Main effect can be time-varying

- Potentially due to habituation or accumulation of burden



More technical details about data analysis

- Standard multi-level models (random effects) can lead to biased estimates of intervention effect when endogenous time-varying covariates are included in model (Qian et al., 2022)
  - ❑ Endogenous -- depend on previous outcomes or previous interventions (e.g., prior app engagement)
- Weighted and Centered Least-Squares (WCLS; Boruvka et al., 2018)
  - ❑ Special type of regression analysis for longitudinal data
  - ❑ Uses an independent working correlation structure to avoid bias
  - ❑ Account within-person correlation via robust SE
  - ❑ **Centers** intervention indicator around randomization probability so that you can correctly interpret intervention effect coefficient even if incorrect model was specified for control covariates
  - ❑ **Weights** used if scientific question assumes probabilities that differ from those used in MRT.

Qian, T. et al. (2022). The microrandomized trial for developing digital interventions…. *Psychological methods*, *27*(5), 874.

Boruvka, A., et al, (2018). Assessing time-varying causal effect moderation in mobile health. JASA, 113 (523), 1112-1121.

More practical details about data analysis

d3center Code Library - **d3c.isr.umich.edu/code-library**

Code Library

Browse our library of open-source statistical software for the design, conduct, and analysis of intervention optimization trials.

Micro-Randomized Trials [MRT]

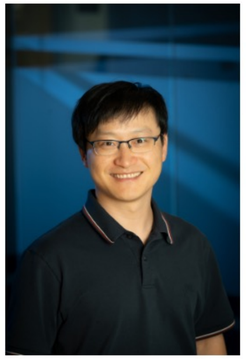
- MRT Sample Size & Power Calculations
- MRT Data Analysis

Estimate the proximal and distal causal effects of a JITAI on a continuous outcome

NEW Primary and secondary analyses for MRT w/continuous or binary proximal outcome

- MRT Case Studies

Tianchen Qian



Welcome! Current and prospective PhD students, if you are interested in learning more about my research, feel free to reach out — I am always happy to chat.

About me.

My name is Tianchen Qian (钱天琛). I am an Assistant Professor in the Department of Statistics at University of California Irvine. I am also affiliated with UCI's Alzheimer's Disease Research Center (ADRC) and Institute for Future Health (IFH).

- Google Scholar
- Github

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MRT Sample Size Considerations

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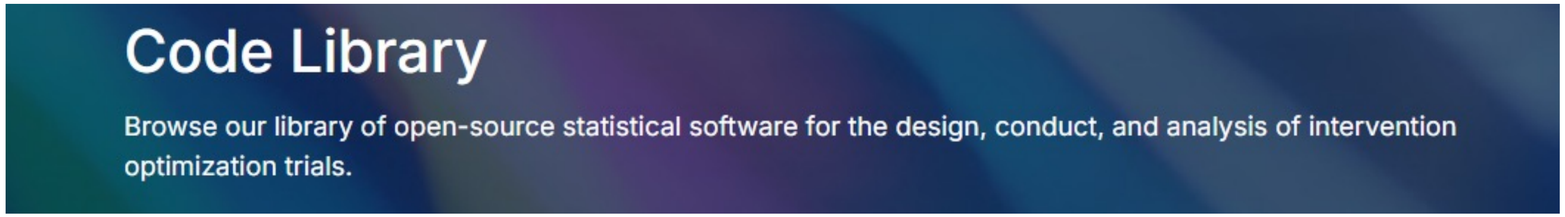


Micro-Randomized Trials [MRT]

- **MRT Sample Size & Power Calculations**

Sample size & power for an MRT with a continuous proximal outcome

Sample size & power for an MRT with a binary proximal outcome

NEW Causal excursion effect for multi-treatment data with a continuous outcome

- **MRT Data Analysis**
- **MRT Case Studies**

MRT Sample Size Considerations

MRT sample size is a function of 3 key aspects:

*In addition to the standard aspects, such as power and type I error rate

1. Study set-up

- Study duration
- Number of decision points
- Randomization probability

30-day study

1 decision point per day

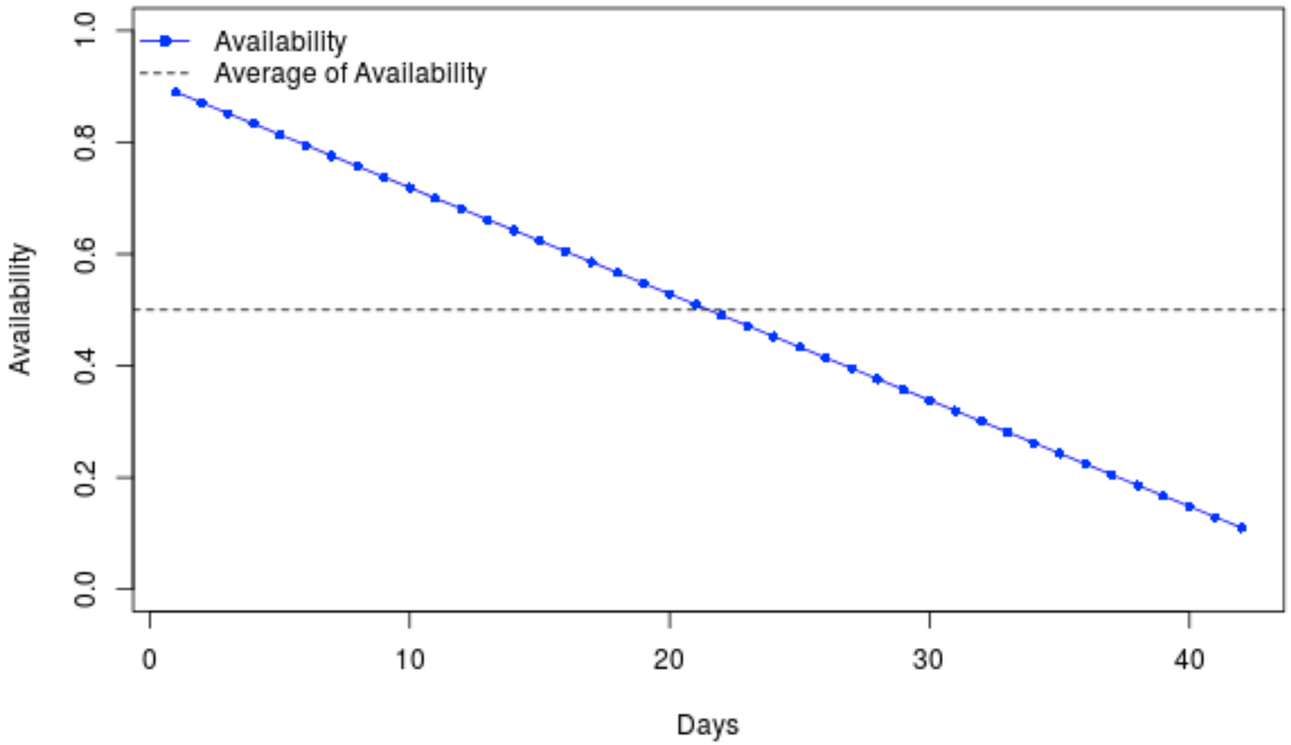
0.5 probability

MRT Sample Size Considerations

MRT sample size is a function of 3 key aspects:

2. Restriction to micro-randomizations

- On average, what is the proportion of decision points that are eligible for micro-randomization?
- Does this proposition change over time & if so, how?

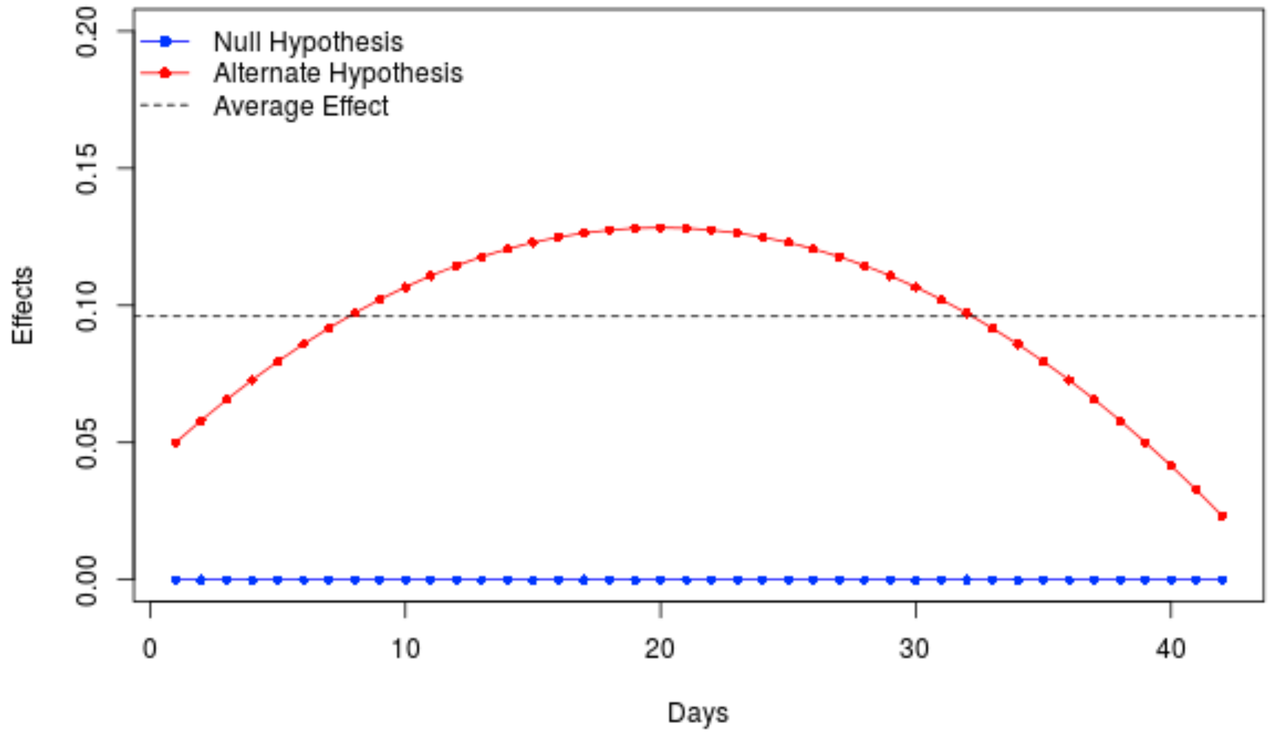


MRT Sample Size Considerations

MRT sample size is a function of 3 key aspects:

3. Expected proximal treatment effect

- Average treatment effect
- Trend (constant, linear, quadratic)

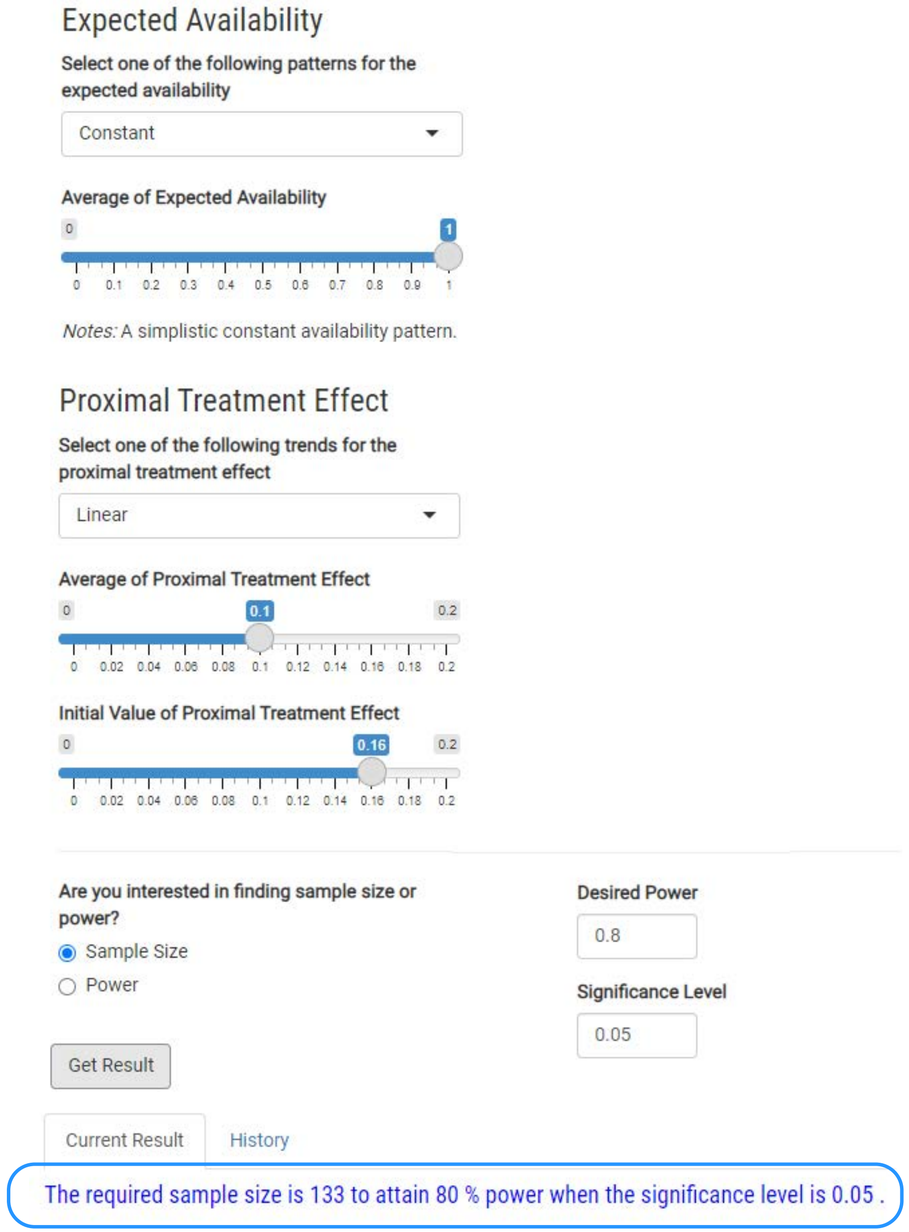


MRT Sample Size Considerations

30-day study

0.5 probability

Decision points per day	Required N
1	133
2	69
3	46
4	37



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Frequently Asked Questions & Answers

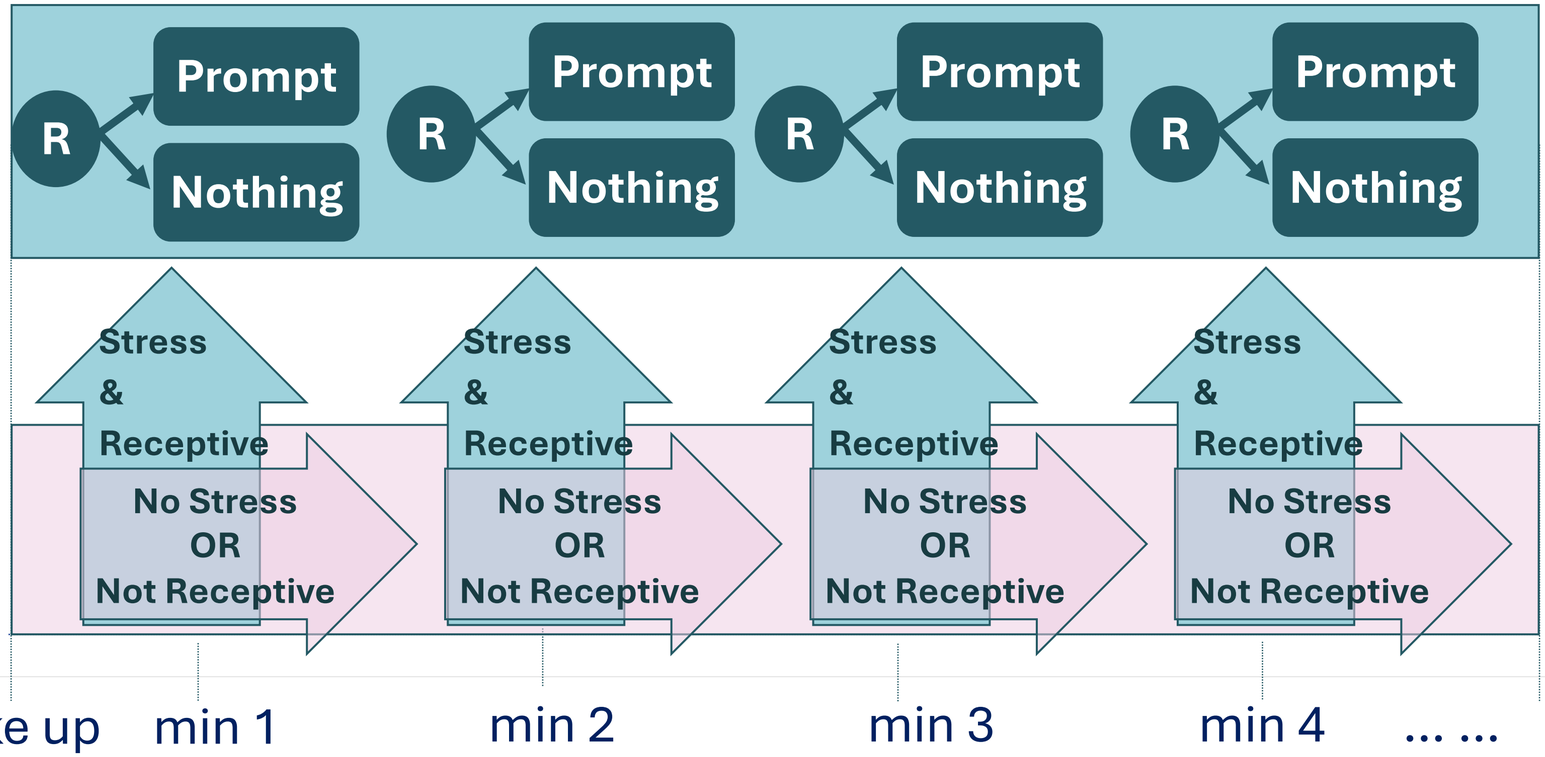
The goal: engage you and help you generate additional questions

1. Go to Kahoot.it (we recommend using your phone)
2. Type the PIN
3. Select a nickname (not your real name)
4. Let’s play

Q1: In MRTs all participants should be randomized at each decision point

A1: No.

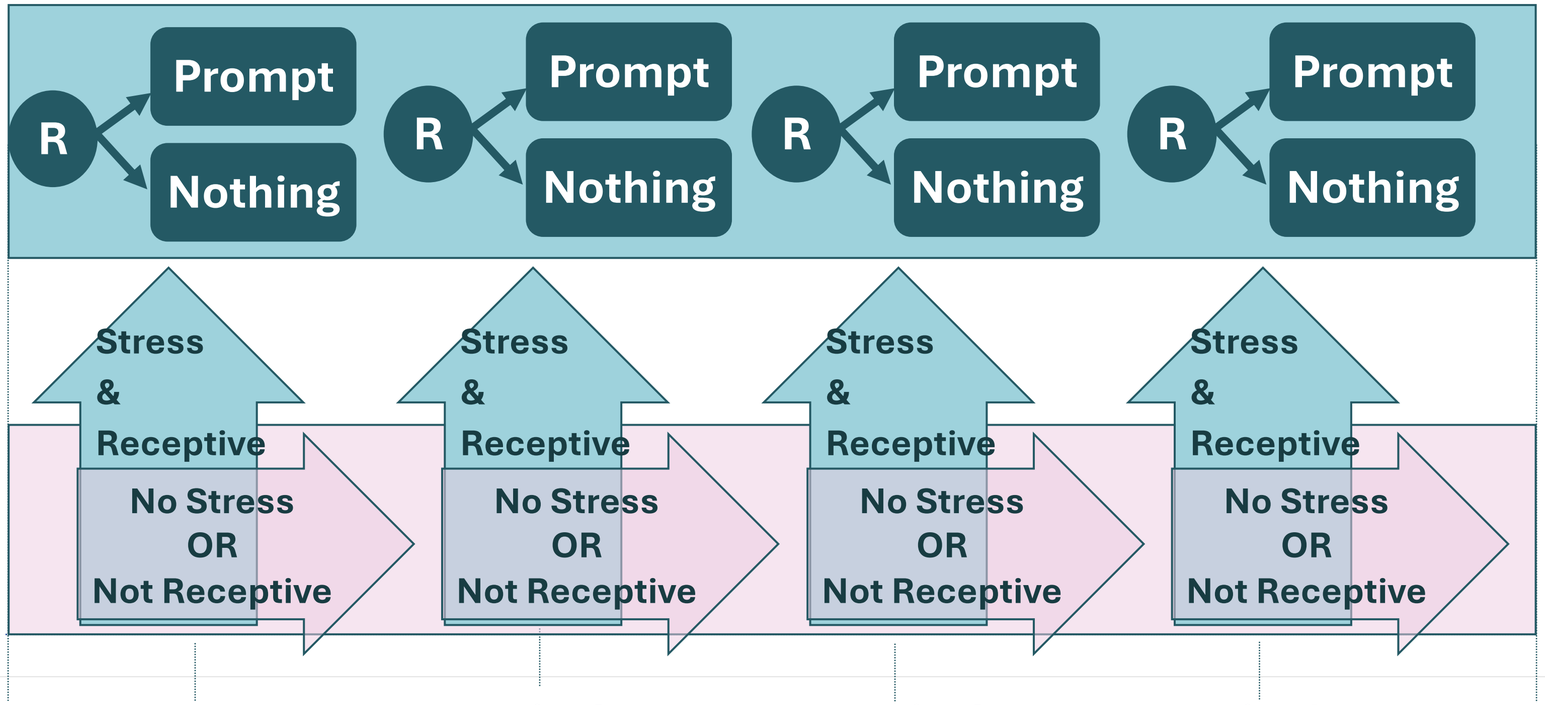
- **Randomization can be restricted such that participants are randomized only under specific conditions based on pre-specified tailoring variables**



Q2: If I restrict the randomizations based on pre-specified tailoring variables, it means that I cannot investigate additional tailoring variables

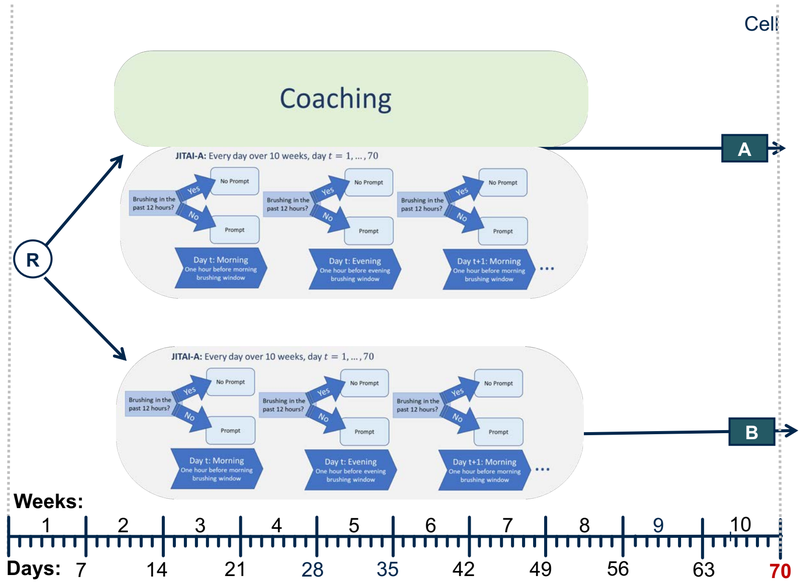
A2: No.

- You can collect baseline and time-varying information and investigate whether this information can be useful to tailor interventions among those who were (re)randomized



Q3: My primary aim is to compare a JITAI with vs. without coaching on a distal outcome: Do I need an MRT?

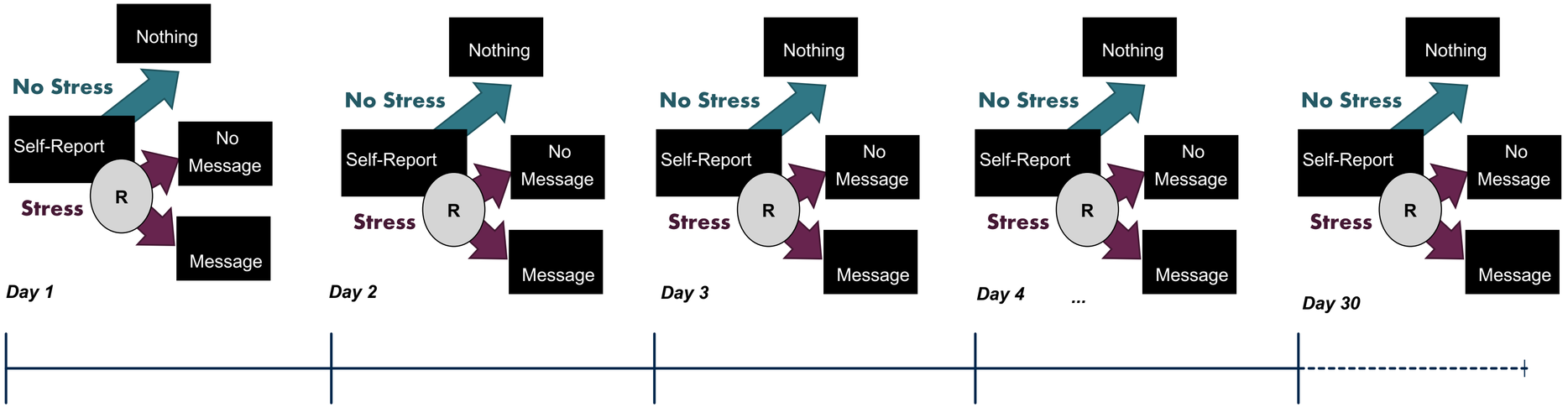
A3: No. I will probably need a 2-arm trial



Q4: In an MRT where self-reported information (e.g., stress) is used to restrict the randomization, how should I plan for missing self-reported information?

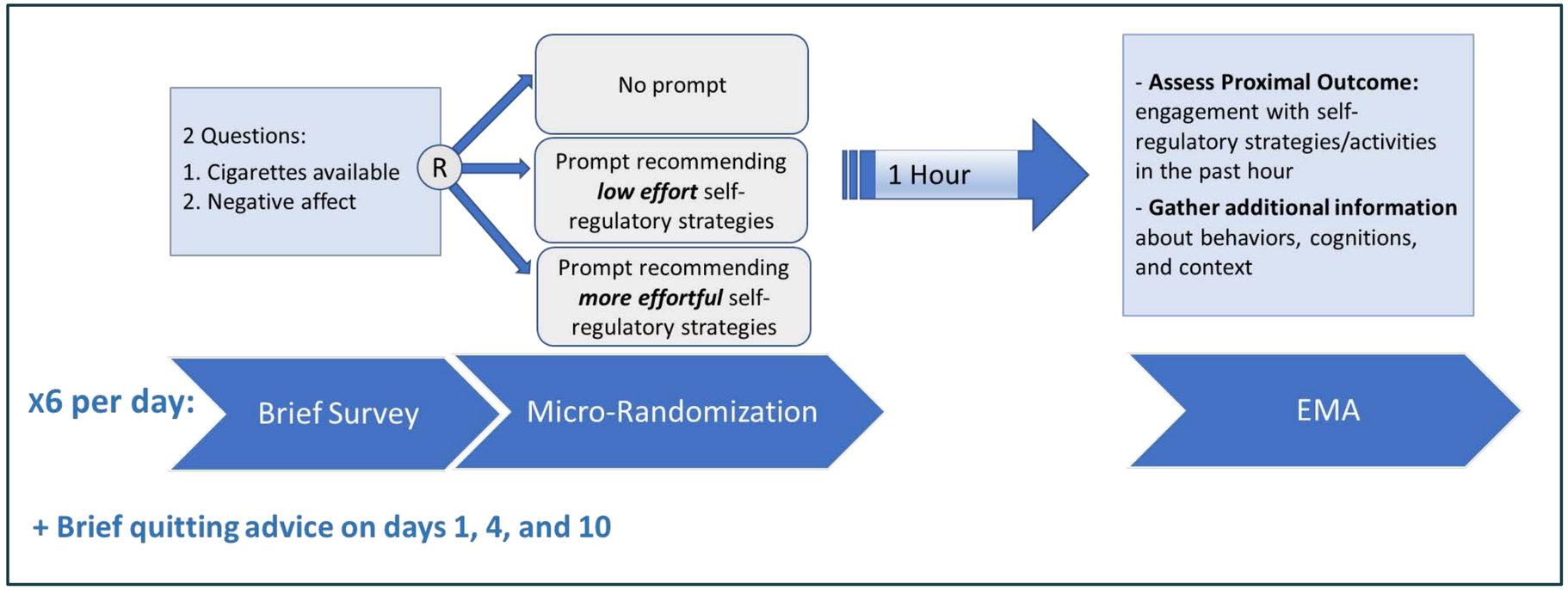
A4: Plan strategies to increase completion of self-report + plan what to do if self-reported information is missing.

This issue is about the intervention design, not the experimental design.



Q5: MRTs should always randomize with equal probability to 2 intervention options

A5: No. They can randomize to more than 2 options, with different probabilities.



Q&A

🕐 10 min