



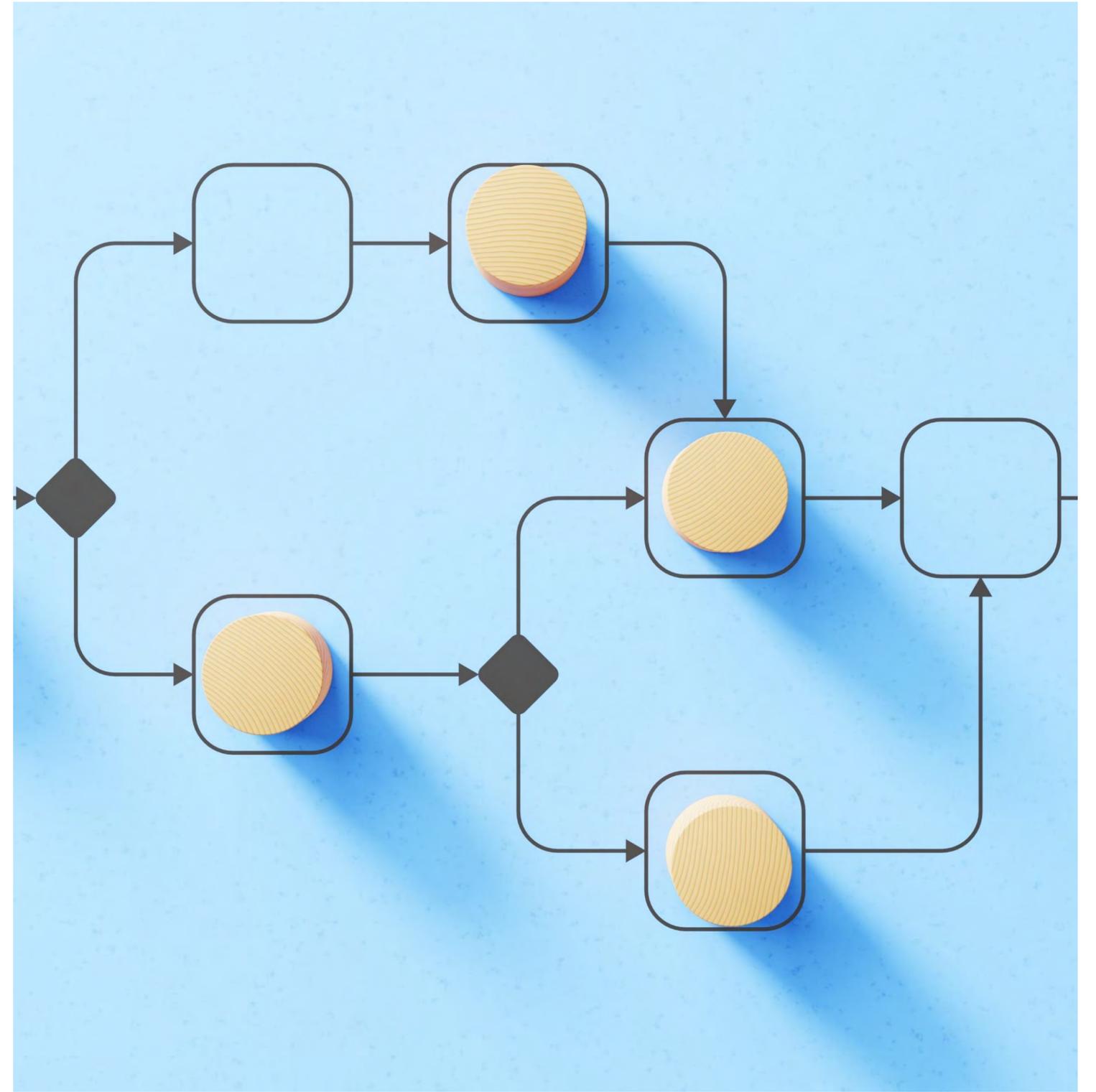
Presented by
Inbal Billie Nahum-Shani, PhD

Grant Writing with MRTs

Tips for writing a JITAI → MRT grant proposal

Learning Objectives

- Learn one way to frame the argument for an MRT
- Learn about the key parts of an MRT grant application
- Learn from your colleagues



Outline

A few ideas for how to craft a grant for one type of MRT with tips for different grant sections

Meant to spur discussion rather than to provide a template!



Before We Begin

- Locate the handout for MRT grant writing Guide

WHAT IS THIS GUIDE ABOUT?

A behavioral intervention scientist can use this guide to kick-start the design of a proposal (e.g., trial protocol, grant application) that aims to construct of an optimized just in time adaptive intervention (JITAI) using a relatively simple MRT.

Author

Inbal Billie Nahum-Shani

Target Primary Audience

Principal Investigator
Lead Methodologist

Type of Intervention

Just in time adaptive intervention

Phase of Research / Types of Scientific Question(s)

Optimization

Trial Design

A relatively simple micro-randomized trial (MRT)

Primary Comparison

Delivering vs. not delivering a mobile-based prompt at decision point

Primary Outcome

A continuous measure, collected following each decision point, and prior to the next decision point

Funding Agency

NIH

Grant Mechanism(s)

R01

Revised

February 6, 2026

Intent

This guide is intended to augment what you currently know about just in time adaptive interventions (JITAI) and micro-randomized trials (MRTs) in order to help you write a grant application proposing a fully powered MRT to optimize a JITAI.

Before We Begin

- Focus is on a relatively simple MRT

Type of Intervention

Just in time adaptive intervention

Phase of Research / Types of Scientific Question(s)

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MARS: One Relatively Simple Example

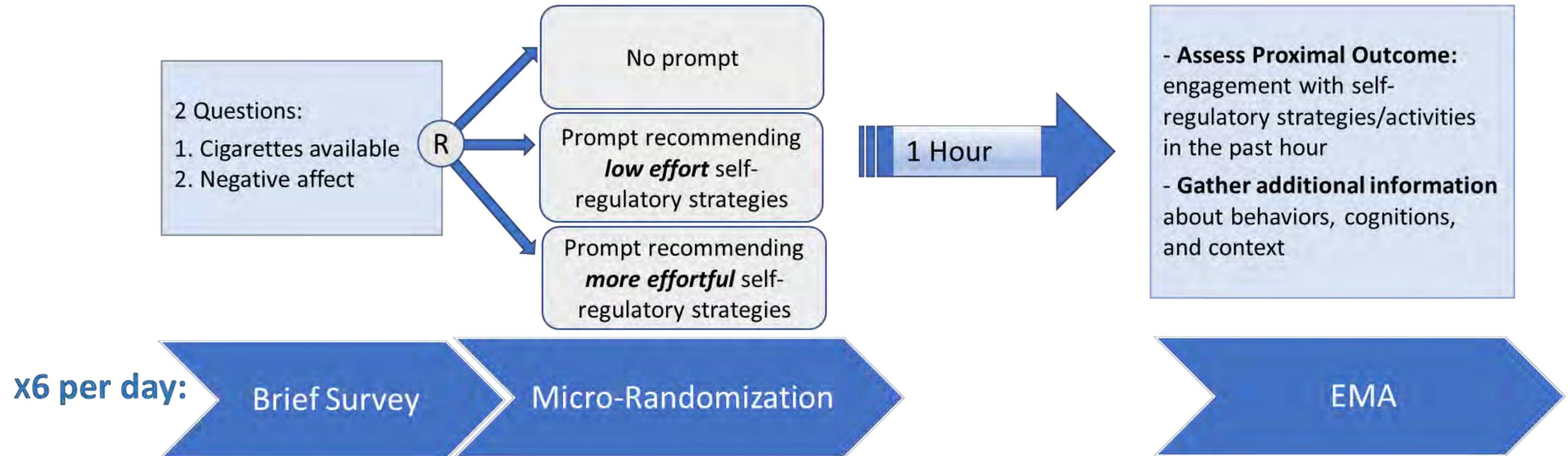
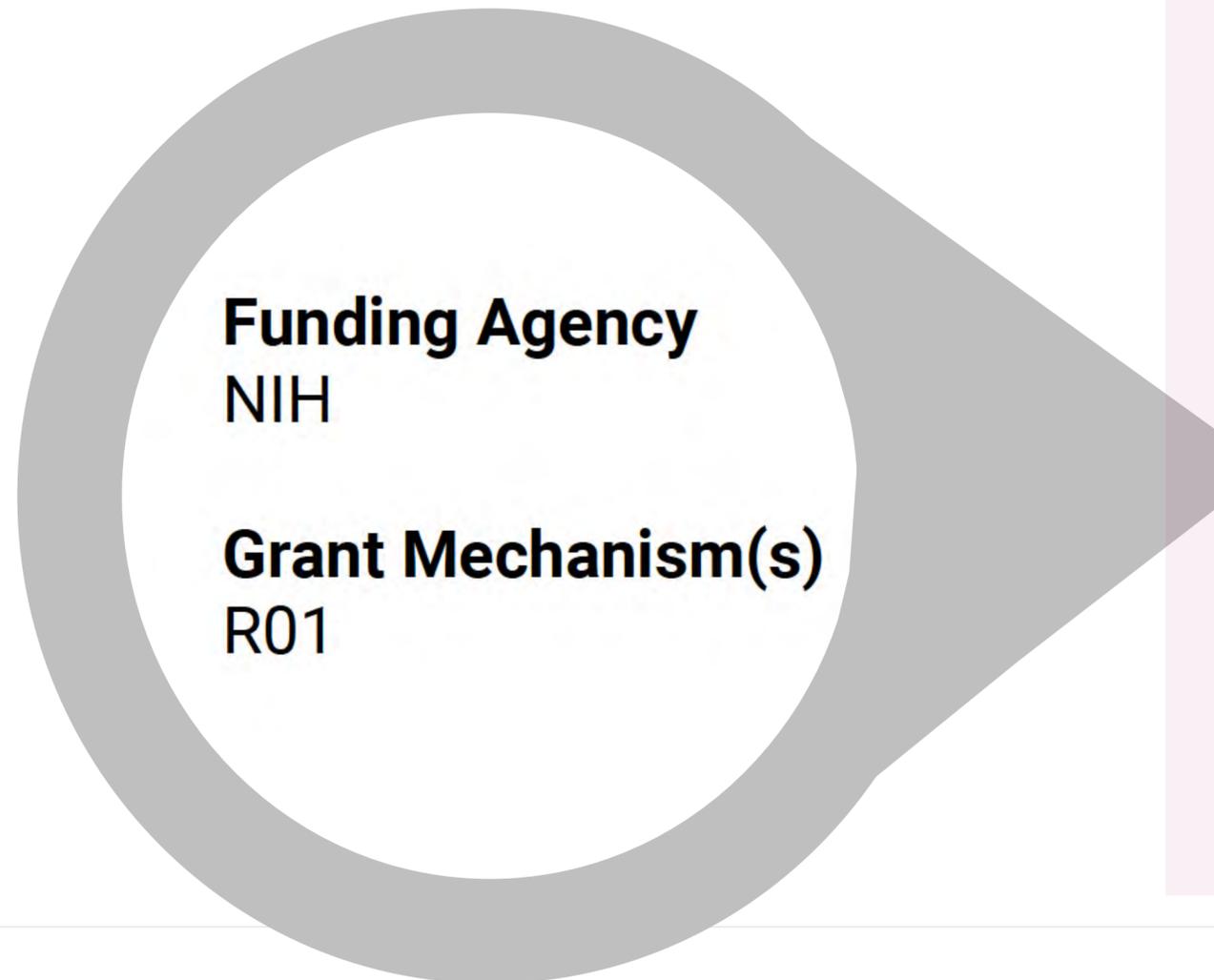


Figure 1: The Micro-Randomized Trial Design

Nahum-Shani, I., Potter, L. N., Lam, C. Y., Yap, J., Moreno, A., Stoffel, R., ... & Wetter, D. W. (2021). The mobile assistance for regulating smoking (MARS) micro-randomized trial design protocol. *Contemporary clinical trials*, 110, 106513.

Before We Begin

- Focus on an NIH R01



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This guide is intended to augment what you currently know about just in time adaptive interventions (JITAI) and micro-randomized trials (MRTs) in order to help you write a grant application proposing a fully powered MRT to optimize a JITAI.

Before We Begin

NIH Sections	Focus on the		
	JITAI	Scientific Question	MRT
Specific Aims	✓ ✓	✓ ✓	Maybe Once
Significance	✓ ✓	✓ ✓	Maybe Once
Innovation	✓ ✓	✓ ✓	
Approach	✓	✓	✓ ✓

WHAT IS THIS GUIDE ABOUT?

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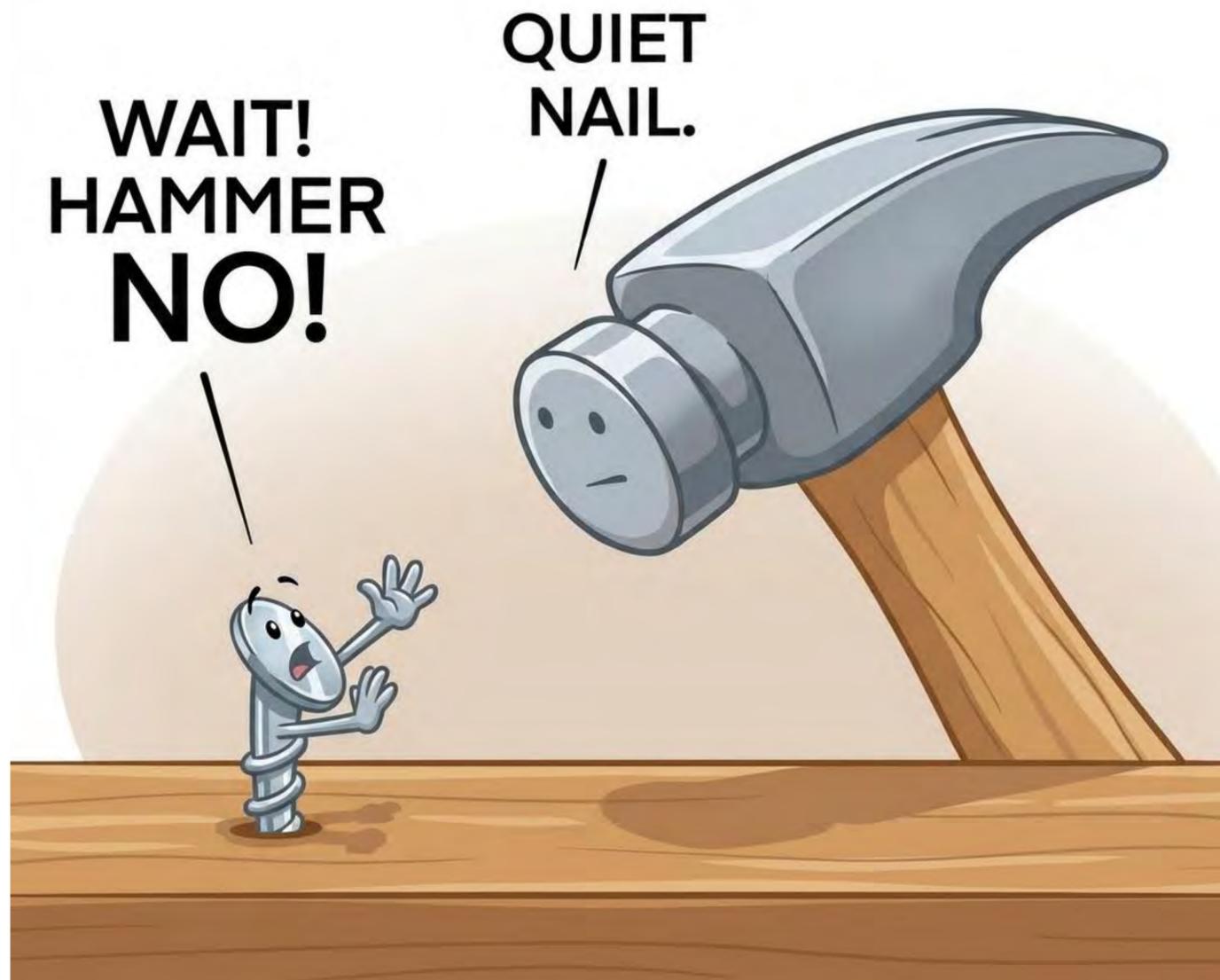
Revised

February 11, 2026

Intent

This guide is intended to augment what you currently know about just in time adaptive interventions (JITAI) and micro-randomized trials (MRTs) in order to help you write a grant application proposing a fully powered MRT to optimize a JITAI.

Not a Hammer



BEFORE USING THIS GUIDE

Prior to using this guide, we recommend that you answer “yes” to these 6 questions:

- I understand the basic principles of a [JITAI](#) design.
- I understand the basic principles of an MRT design.
- I understand that not all research on JITAIs requires an MRT.
- I understand that an MRT is an optimization trial design, not an evaluation trial design.
- I understand that this guide focuses on one, relatively simple MRT, with MRT variants requiring a modified approach.
- I understand that this guide is intended to help me learn one approach to framing and organizing an R01 grant application in a setting where an MRT is a suitable choice for answering scientific questions related to optimizing a JITAI.

Outline

A few ideas for how to craft a grant for one type of MRT with tips for different grant sections

Meant to spur discussion rather than to provide a template!



Specific Aims

- An iterative process
- Top 1/2 to 2/3: Setting up entire project
- Bottom 1/3 to 1/2: List of specific aims

[1 page]

	<p><i>what?</i> target population, problem, desired outcome, context</p> <p><i>goal:</i> frame the problem and its significance,</p> <p><i>point to:</i> JITAI optimization as a solution</p>	<div style="border: 1px solid black; padding: 5px;">1. the problem</div>
<div style="border: 1px solid black; padding: 5px;">2. set-up & rationale</div>	<p><i>goal:</i> rationale for a JITAI:</p> <p><i>what?</i> address rapidly changing risk factors in daily life; take advantage of in-the-moment opportunities for positive change in daily life; promote intervention engagement; minimize participant burden; minimize habituation; resource efficiency</p> <p><i>how?</i> describe business-as-usual; prior work; current clinical gaps</p> <p><i>point to:</i> JITAI as a promising solution</p>	
	<p><i>goal:</i> the promise of a JITAI!</p> <p><i>what?</i> close-the-loop; help reader envision future practice using a JITAI</p>	<div style="border: 1px solid black; padding: 5px;">3. your vision</div>
<div style="border: 1px solid black; padding: 5px;">4. scientific questions</div>	<p><i>goal:</i> set-up your scientific questions</p> <p><i>what?</i> explain what we need to know so we can achieve the vision you put forth above</p> <p><i>point to:</i> innovation of the scientific questions</p>	

The [insert study name] will use a micro-randomized trial to address the following specific aims:

Aim 1 (Primary). To test [insert the primary aim: e.g., average proximal main effect of delivering vs. not delivering a prompt] on [insert primary proximal outcome] (primary outcome), and on [insert list of secondary outcomes] (secondary outcomes).
Hypothesis: [insert the study's primary hypothesis]

Aim 2 (Secondary). To investigate [insert a secondary aim: e.g., what type of prompt is most beneficial by comparing two or more types of prompts] in terms of the primary and secondary outcomes.
Hypothesis: [insert secondary aim hypothesis]

Aim 3 (exploratory). To explore whether (i) baseline [insert candidate baseline moderators]; and (ii) time-varying information [inset time-varying variables collected prior to a given decision point] moderate the effect of [insert the effect of interest: e.g., delivering vs. not a prompt; one type of prompt vs. another type]

Impact. [summarize how this study leads to answers that solve the health problem you started with; summarize how this study is aligned with strategic aims and priorities set out by the funding agency.]

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Specific Aims

- Top half: Setting up entire project
 - Problem, population, desired outcome
 - Rationale for JITAI
 - Your JITAI vision
 - Scientific questions
 - Summarize the solution

[1 page]

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Specific Aims

- Top half: Setting up entire project
 - Problem, population, desired outcome
 - Rationale for JITAI
 - Your JITAI vision
 - Scientific questions
 - Summarize the solution

1. SPECIFIC AIMS

Smoking continues to take an enormous toll on society. Tobacco use is the leading preventable cause of death and disability in the U.S.,^{1,2} with 30% of all cancers directly attributable to tobacco.^{3,4} Smoking cessation decreases morbidity and mortality and is a cornerstone of cancer prevention. Although most smokers would like to quit, over 90% of quit attempts are unsuccessful.⁵ Empirical evidence suggests that engaging in evidence-based self-regulatory activities (e.g., behavioral substitution, mindful attention) can improve the ability to resist temptations and build self-regulatory skills.⁶⁻⁹ As a result, self-regulatory activities are key components in many smoking cessation interventions.¹⁰⁻¹² However, poor engagement represents a major barrier to maximizing the impact of self-regulatory activities.^{6,13} Enhancing real-time, real-world engagement in evidence-based self-regulatory activities has the potential to improve the efficacy of smoking cessation interventions.

[1 page]

SPECIFIC AIMS		1. the problem
<i>what?</i>	<i>target population, problem, desired outcome, context</i>	
<i>goal:</i>	<i>frame the problem and its significance,</i>	
<i>point to:</i>	<i>JITAI optimization as a solution</i>	
<hr/>		
2. set-up & rationale	<p><i>what?</i> <i>address rapidly changing risk factors in daily life; take advantage of in-the-moment opportunities for positive change in daily life; promote intervention engagement; minimize participant burden; minimize habituation; resource efficiency</i></p> <p><i>how?</i> <i>describe business-as-usual; prior work; current clinical gaps</i></p> <p><i>point to:</i> <i>JITAI as a promising solution</i></p>	
<hr/>		
	<p><i>goal:</i> <i>the promise of a JITAI!</i></p> <p><i>what?</i> <i>close-the-loop; help reader envision future practice using a JITAI</i></p>	3. your vision
<hr/>		
4. scientific questions	<p><i>goal:</i> <i>set-up your scientific questions</i></p> <p><i>what?</i> <i>explain what we need to know so we can achieve the vision you put forth above</i></p> <p><i>point to:</i> <i>innovation of the scientific questions</i></p>	
<p>The [insert study name] will use a micro-randomized trial to address the following specific aims:</p>		

Tip: Avoid using the term JITAI, appeal to the desired outcome

Specific Aims

- Top half: Setting up entire project

- Problem, population, desired outcome
- Rationale for JITAI
- Your JITAI vision
- Scientific questions
- Summarize the solution

SPECIFIC AIMS		[1 page]
what?	target population, problem, desired outcome, context	1. the problem
goal:	frame the problem and its significance,	
point to:	JITAI optimization as a solution	
2. set-up & rationale	goal:	rationale for a JITAI:
	what?	address rapidly changing risk factors in daily life; take advantage of in-the-moment opportunities for positive change in daily life; promote intervention engagement; minimize participant burden; minimize habituation; resource efficiency
	how?	describe business-as-usual; prior work; current clinical gaps
	point to:	JITAI as a promising solution
goal:	the promise of a JITAI!	3. your vision
what?	close-the-loop; help reader envision future practice using a JITAI	
4. scientific questions	goal:	set-up your scientific questions
	what?	explain what we need to know so we can achieve the vision you put forth above
	point to:	innovation of the scientific questions
The [insert study name] will use a micro-randomized trial to address the following specific aims:		

Tip: Avoid using the term JITAI, but make sure you point in this direction

1. SPECIFIC AIMS

Smoking continues to take an enormous toll on society. Tobacco use is the leading preventable cause of death and disability in the U.S.,^{1,2} with 30% of all cancers directly attributable to tobacco.^{3,4} Smoking cessation decreases morbidity and mortality and is a cornerstone of cancer prevention. Although most smokers would like to quit, over 90% of quit attempts are unsuccessful.⁵ Empirical evidence suggests that engaging in evidence-based self-regulatory activities (e.g., behavioral substitution, mindful attention) can improve the ability to resist temptations and build self-regulatory skills.⁶⁻⁹ As a result, self-regulatory activities are key component in many smoking cessation interventions.¹⁰⁻¹² However, poor engagement represents a major barrier to maximizing the impact of self-regulatory activities.^{6,13} Enhancing real-time, real-world engagement in evidence-based self-regulatory activities has the potential to improve the efficacy of smoking cessation interventions.

Specific Aims

- Top half: Setting up entire project
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SPECIFIC AIMS		[1 page]
<i>what?</i>	<i>target population, problem, desired outcome, context</i>	1. the problem
<i>goal:</i>	<i>frame the problem and its significance,</i>	
<i>point to:</i>	<i>JITAI optimization as a solution</i>	
2. set-up & rationale	<i>goal:</i>	rationale for a JITAI: <i>address rapidly changing risk factors in daily life; take advantage of in-the-moment opportunities for positive change in daily life; promote intervention engagement; minimize participant burden; minimize habituation; resource efficiency</i>
	<i>what?</i>	
	<i>how?</i>	
	<i>point to:</i>	<i>JITAI as a promising solution</i>
<i>goal:</i>	<i>the promise of a JITAI!</i>	3. your vision
<i>what?</i>	<i>close-the-loop; help reader envision future practice using a JITAI</i>	
4. scientific questions	<i>goal:</i>	set-up your scientific questions <i>explain what we need to know so we can achieve the vision you put forth above innovation of the scientific questions</i>
	<i>what?</i>	
	<i>point to:</i>	

The [insert study name] will use a micro-randomized trial to address the following specific aims:

- Tip 1: Clearly define a JITAI here
- Tip 2: Avoid jargon;
- Tip 3: Define new key terms

Just-In-Time Adaptive Interventions (JITAI) delivered via mobile devices have been developed for preventing and treating addictions.¹⁴⁻¹⁶ JITAI adapt over time to an individual's changing status and are optimized to provide appropriate intervention strategies based on real time, real world context.^{17,18} Vulnerability (e.g., risk for lapse) and receptivity (i.e., ability and willingness to utilize a specific intervention) are two theoretical constructs that play a critical role in the formulation of effective JITAI. Conceptual models of JITAI emphasize the importance of minimizing disruptions to the daily lives of the individual by tailoring strategies not only to vulnerability, but also to receptivity.¹⁹⁻²¹ Although both vulnerability and receptivity are considered latent states that are dynamically and constantly changing based on the constellation and temporal dynamics of emotions, context, and other factors,^{19,20} no attempt has been made to systematically investigate the nature of these states, as well as how knowledge of these states can be used to decide when and how to intervene. For ex-

Specific Aims

- Top half: Setting up entire project

- Problem, population, desired outcome
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SPECIFIC AIMS		[1 page]
what? goal: point to:	target population, problem, desired outcome, context frame the problem and its significance, JITAI optimization as a solution	1. the problem
2. set-up & rationale	goal: rationale for a JITAI: what? address rapidly changing risk factors in daily life; take advantage of in-the-moment opportunities for positive change in daily life; promote intervention engagement; minimize participant burden; minimize habituation; resource efficiency how? describe business-as-usual; prior work; current clinical gaps point to: JITAI as a promising solution	
goal: what?	the promise of a JITAI! close-the-loop; help reader envision future practice using a JITAI	3. your vision
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The [insert study name] will use a micro-randomized trial to address the following specific aims:

Tip: whether, how, when to intervene

- **Whether:** should a prompt be delivered
- **How:** what type of prompt
- **When:** under what conditions

Specific Aims

- Top half: Setting up entire project
 - Problem, population, desired outcome
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 - Your JITAI vision
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poral dynamics and interactions of emotion, self-regulatory capacity (SRC), context, and... used to detect states of vulnerability and receptivity. We will also investigate how knowledge of these states can be used to optimize real-time engagement in self-regulatory activities by conducting a Micro-Randomized Trial (MRT)²² enrolling 150 smokers attempting to quit. Utilizing a mobile smoking cessation app, the MRT will randomize each individual multiple times per day to either (a) no intervention prompt; (b) a prompt recommending engagement in brief (low effort) strategies; or (c) a prompt recommending a more effortful practice of self-regulation strategies. The specific aims are:

Aim 1: Identify states of vulnerability for lapse: Self-reported and sensor-based measures will be used to identify empirically-based and theoretically-grounded features across multiple time scales that are

SPECIFIC AIMS		[1 page]
what? goal: point to:	target population, problem, desired outcome, context frame the problem and its significance, JITAI optimization as a solution	1. the problem
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The [insert study name] will use a micro-randomized trial to address the following specific aims:		

- Tip 1: First time MRT should be mentioned
- Tip 2: Define MRT + references
- Tip 3: Provide a clear and brief description

Specific Aims

- Bottom half: List of specific aims

Tip: End with an impact statement

The [insert study name] will use a micro-randomized trial to address the following specific aims:

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Hypothesis: [insert the study's primary hypothesis]

Aim 2 (Secondary). To investigate [insert a secondary aim: e.g., what type of prompt is most beneficial by comparing two or more types of prompts] in terms of the primary and secondary outcomes.

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Impact. [summarize how this study leads to answers that solve the health problem you started with; summarize how this study is aligned with strategic aims and priorities set out by the funding agency.]

Specific Aims

- An elaboration of Specific Aims Page + Preliminary Research

A. SIGNIFICANCE

[approximately 2-3 pages]

A.X. The Problem. This is a detailed and more elaborate version of part “1.punch with the problem” of the specific aims.

...

A.X. XXXX.

A.X. The Clinical Practice Gap. This is a detailed and more elaborate version of part “2.additional set-up and rationale” of the specific aims.

...

A.X. XXXX.

A.X. The promise of a just-in-time adaptive intervention approach which.... This is a detailed and more elaborate version of part “3.the future we envision” of the specific aims.

...

A.X. Conceptual Model. Include a schematic/figure with your working theory of change/conceptual model, including the distal outcome, proximal outcomes, and other pathways through which the JITAI is expected to produce a desired change in the distal outcome.

A.X. Rationale for each Aim. Explain why it is necessary for the field to construct an optimized JITAI. This is the most important part of the Significance section. In one approach to writing grants, you intersperse your preliminary data throughout this section. In a different approach, you include a stand-alone preliminary studies section (shown below).

A.X. Project Overview. Some investigators provide a brief outline of the intervention procedures and experimental design in the Significance Section to anchor reviewers. This is where you will mention the MRT for the first time in Research Strategy, explain that this trial design is suitable for optimizing JITAIs and describe the randomization scheme and data collection procedures briefly. Consider including a figure describing the design.

A.X. Preliminary Studies. Some investigators use a stand-alone section of Significance to explain the preliminary work that prepared the investigators to propose/conduct this study.

A.X. Investigative Team. Explain why the investigators on this team are the perfect ones to be conducting this research.

A.X. Summary of Significance. You can end with a summary: “The proposed project is significant in the following key respects [*insert 3-5 key aspects, ordered based on importance based on the text above; 1-2 sentences each*]

Specific Aims

- An elaboration of Specific Aims Page + Preliminary Research
 - Significance dives into two key aspects:
 - The gap: “what is known” vs. “not known”
 - The solution: your approach to gaining knowledge
 - Scientific questions are the key– explain what they are and why they are important

A. SIGNIFICANCE

[approximately 2-3 pages]

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...

A.X. XXXX.

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**Tip 1: The significance section can be organized around these two key titles:
The gap and the solution**

Tip 2: Explain that the goal is to inform an optimized JITAI

Tip 3: If you use the term “optimized” -- clearly define it

Significance

Tip 1: Avoid giving the impression that you are planning to test a specific conceptual model or mechanisms.

How? Use the conceptual model to justify (a) the proposed JITAI (e.g., intervention options, tailoring variables) and (b) proximal outcome(s)

Tip 2: Present multiple mechanisms– each intervention option can target more than one mechanism

Tip 3: Balance completeness with simplicity

Tip 4: Leave room for other possible models

A. SIGNIFICANCE

[approximately 2-3 pages]

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A.X. The promise of a just-in-time adaptive intervention approach which.... This is a detailed and more elaborate version of part “3.the future we envision” of the specific aims.

...

A.X. Conceptual Model. Include a schematic/figure with your working theory of change/conceptual model, including the distal outcome, proximal outcomes, and other pathways through which the JITAI is expected to produce a desired change in the distal outcome.

A.X. Rationale for each Aim. Explain why it is necessary for the field to construct an optimized JITAI. This is the most important part of the Significance section. In one approach to writing grants, you intersperse your preliminary data throughout this section. In a different approach, you include a stand-alone preliminary studies section (shown below).

A.X. Project Overview. Some investigators provide a brief outline of the intervention procedures and experimental design in the Significance Section to anchor reviewers. This is where you will mention the MRT for the first time in Research Strategy, explain that this trial design is suitable for optimizing JITAIs and describe the randomization scheme and data collection procedures briefly. Consider including a figure describing the design.

A.X. Preliminary Studies. Some investigators use a stand-alone section of Significance to explain the preliminary work that prepared the investigators to propose/conduct this study.

A.X. Investigative Team. Explain why the investigators on this team are the perfect ones to be conducting this research.

A.X. Summary of Significance. You can end with a summary: “The proposed project is significant in the following key respects [*insert 3-5 key aspects, ordered based on importance based on the text above; 1-2 sentences each*]

Significance

Tip: Providing a project overview in the significance section, including a Figure describing the design to orient the reviewer

A. SIGNIFICANCE

[approximately 2-3 pages]

A.X. The Problem. This is a detailed and more elaborate version of part “1.punch with the problem” of the specific aims.

...

A.X. XXXX.

A.X. The Clinical Practice Gap. This is a detailed and more elaborate version of part “2.additional set-up and rationale” of the specific aims.

...

A.X. XXXX.

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Significance

Tip 1: Provide a brief description of preliminary evidence in Significance and a more elaborate section in the Approach

Tip 2: Show that key components of the future JITAI you envision are feasible acceptable

Tip 2: You can present data from your own studies or others

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[approximately 2-3 pages]

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Significance

Tip: towards the end of Significance, provide a summary with a few sentences summarizing why this project is significant

A. SIGNIFICANCE

[approximately 2-3 pages]

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Innovation

B. INNOVATION

[approximately 1/2 to 2/3 page]

Insert a bulleted list of prioritized innovation statements and 1-2 supporting sentences for each.

We recommend the innovative statements focus on the (i) nature/novelty of the JITAI (e.g., a JITAI designed to address innovative mechanisms of change, a JITAI that deploys new intervention options, a JITAI that leverages sensor-based assessments to adapt the delivery of interventions), and/or (ii) nature/novelty of the scientific questions.

We recommend not listing (or de-prioritizing the extent to which you list) research methods (e.g., the MRT) as a purported innovation unless this really is the first time such a method is used to answer this type of question.

 - The rationale for this suggestion is that *the choice of trial design or data analysis method always is in the service of the scientific questions (never the other way around)*.
- By listing the research method as the first innovation statement, you have the potential to communicate the wrong message.

Approach

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7. Statistical Analysis Plan
8. Missing Data
9. Sample Size and Power
10. Alternative Study Designs

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C. APPROACH

[approximately 8 pages]

C.X. Overview of Study Design. Provide an overview of the MRT design. This is also a useful place to define key terminology that you plan to use later, such as “decision points” (times at which randomizations will occur in the proposed study) and “proximal” (next hour in the proposed study). You can use a schematic, such as the one shown in Figure 1 here.



Figure 1: The Micro-Randomized Trial Design

Nahum-Shani, I., Potter, L. N., Lam, C. Y., Yap, J., Moreno, A., Stoffel, R., ... & Wetter, D. W. (2021). The mobile assistance for regulating smoking (MARS) micro-randomized trial design protocol. *Contemporary clinical trials*, 110, 106513.

C.X. Participants. Briefly describe the study’s inclusion and exclusion criteria and other study eligibility information. Point to the supplementary appendices, i.e., the Human Subjects and Clinical Trial Information section where you will provide additional details concerning the following: inclusion/exclusion criteria; the research recruitment and retention plan; and study timeline.

Tip: Try to distinguish between intervention assessments and research assessment

Approach

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Tip 1: Explain the role of assessments that are part of the intervention:

- Self-reflection/feedback
- Tailor content/framing
- Tailor intervention delivery

Tip 2: This section is about engagement with intervention components, not research assessments

Tip 3: Monetary incentives should be minimal

C.X. Intervention Components. Provide details concerning all of the intervention components to be considered in the JITAI you are constructing. Remember that interventions are what you offer the targets of intervention, not what they do. The following subsections are specific to the MRT described in Figure 1.

C.X.X. Monitoring Intervention. Describe assessments that are part of the intervention, including:

- (1) Monitoring designed to be therapeutic (e.g., facilitate self-reflection);
- (2) Monitoring designed to provide information for use in tailoring intervention delivery (e.g., using information about self-reported affect to modify the framing of the messages; using information from GPS to restrict the randomization to times in which the person is not driving); these are tailoring variables that you have already identified based on existing preliminary evidence and/or practical considerations, so they are part of the JITAI you are proposing to deploy in the current study.
- (3) Monitoring designed to inform future tailoring of intervention delivery (to test moderators of intervention effect in order to identify additional ways to tailor intervention delivery in the future). These are tailoring variables that you are considering to include in a future JITAI and you seek evidence to inform whether and how they should be used to tailor intervention delivery.

C.X.X. Intervention Engagement Plan. Describe the intervention components designed to engage the targets in the components of the intervention. This intervention engagement plan can include “proactive” components designed to

prevent intervention drop-out, as well as “reactive” components designed to re-engage those showing early signs of intervention drop-out (within the constraints of the proposed intervention). The proposed intervention engagement plan may include human-delivered components (e.g., phone contact from an intervention coach) and/or digital components (e.g., an automated text message). From the perspective of your intervention targets (e.g., patients), the engagement plan should be viewed as part of the intervention, rather than as part of the research/study. For example, if the engagement plan includes human-delivered contact, make sure that it is delivered by your intervention staff, not your research staff.

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C.X.X. Restriction to Randomizations. Describe the tailoring variables you will use to restrict the randomizations at each decision point (e.g., participants will not be randomized to intervention options at a decision point if they are driving a car or if they turned on the sleep mode on the phone, or if they received a prompt in the past 2 hours). These are tailoring variables that you have decided to include in the proposed JITAI based on existing evidence and practical considerations. The justification for these tailoring variables should be included here as well as in the preliminary evidence section.

C.X. Fidelity and Quality Assurance.

Describe fidelity and quality assurance protocols for (i) intervention procedures; and (ii) study procedures.

Tip 1: Make this section part of the intervention components

Tip 2: Provide a clear justification for these embedded tailoring variables, even if you have already done so in other parts of the proposal (e.g., preliminary evidence)

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C.X. Fidelity and Quality Assurance.

Describe fidelity and quality assurance protocols for (i) intervention procedures; and (ii) study procedures.

Tip: separate fidelity/quality assurance for

- (a) intervention procedures (e.g., monitor and improve clinical staff fidelity to the engagement protocol), and
- (b) study procedures (e.g., dashboard to monitor randomization probabilities and completion of research assessments)

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C.X. Research Measures. Describe all of the research measures or assessments. A table is strongly recommended. Each row of the table is a measure. (Collections of rows could be sectioned off by measurement domains: e.g., demographics, diagnoses, time-varying assessments, by different constructs in the proposed theory of change or conceptual model, research outcomes). The columns of the table could indicate: the name of the measure, who is being assessed with that measure (e.g., child or parent), time points at which measure is collected, and which of the specific aims will use this measure. Some investigators include a column denoting the amount of time it takes to fill out each research assessments from the perspective of study participants. The primary research outcome should be denoted clearly (e.g., shade the row denoting the study's primary research outcome). Explain how the rater collecting the primary research outcome is blind to treatment assignments.

C.X.X. Research Engagement Plan. Describe how you plan to collect the research outcomes, especially the primary research outcome, even if (i) a participant does not adhere to, or engage with, intervention; or (ii) a participant elects to drop out of treatment. This is where you describe the incentives you are going to pay for obtaining the primary research outcome. This research engagement plan includes both "proactive" tactics to prevent study drop-out (e.g., offering incentives for showing up to study assessment sessions or for

Tip 1: include a clear plan to increase engagement with research components

Tip 2: Here, it's reasonable to consider monetary incentive

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Tip 1: Clear plans for data curation and integration given that the data likely comes from multiple sources

Tip 2: Explain that the analyses will pool time-varying, longitudinal data across all study participants

Tip 3: Explain the order of randomizations relative to the proximal outcomes

C.X. Statistical Analysis Plan.

C.X.X. Data Management and Processing Plan. Describe how the data will be managed, inputted into the data base(s), and processed.

C.X.X. Intent-to-Treat. Propose that all participants, once randomized at XX, will be included in the intent-to-treat sample for all data analyses described below. Every effort will be made to collect the study's primary outcome (first priority) and secondary outcomes (second priority), even if: (i) a participant does not adhere to, or engage with the intervention; (ii) a participant elects to drop out of the intervention. See the C.X.X. (Research Engagement Plan) above.

C.X.X. Primary Aim Analysis. Describe how you are going to estimate the causal effects associated with the primary aim.

Statistical Inference: Describe the primary aim test statistic and all necessary details (e.g., the null and alternative hypotheses, type of test statistic (e.g., Wald test), Type I error rate (e.g., 5%), degree of freedom adjustments (if any), probability distribution you are going to reference, which multiple comparisons procedure (if applicable).

Control covariates: describe variables you plan to add to the analysis as control covariates to reduce error variance. The list can include baseline variables as well as time-varying variables assessed prior to decision point.

Secondary Outcomes: Most primary aims have a primary outcome and various secondary outcomes. Here, you can explain how, if at all, the proposed analysis above changes when it comes to the secondary outcomes. For example, if your primary outcome is continuous and one of your secondary outcomes is binary, then you will have to explain how the proposed analysis changes.

C.X.X. Secondary Aim Analyses. Describe the secondary aim analyses. If there is insufficient space to provide details related to this aim, it is quite acceptable to provide them in an Appendix to the grant. The important thing is to prioritize the primary aim analysis; that is, strive to pre-specify all details related to the primary aim analysis in the proposal's main narrative.

C.X.X. Exploratory Aim Analyses. Similar to the above.

tings.^{269,270} These analyses pool time-varying, longitudinal data across all study participants. Details: t_1 denotes time points at which an individual may or may not receive a prompt; t_1 ranges from 1 to 60 (10 days*6 times per day). H1 focuses on the marginal effect of delivering (vs. not delivering) a prompt at t_1 on self-reported engagement at the next hour t_2 (proximal effect). H2 focuses on whether the low effort prompt is more

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C.X. Missing Data. Provide an educated guess about the rate of missingness or research drop-out that you expect to see given your other studies in this or related areas. Remind the reviewer why you expect to see minimal missing data (e.g., <10%) in your primary research outcome because of the strong efforts you've detailed above in the Research Engagement Plan. Describe how you plan to impute missing research data, if any.

Tip 1: Focus on missing data in research assessments, not intervention assessments

Tip 2: Refer to preliminary evidence section where you provide evidence of minimal missingness in your prior studies

Tip 3: Clear plan to impute data

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C.X. Sample Size and Power. There are two parts. The second part is optional, but is considered a best practice.

C.X.X. Sample size and Power for the Primary Aim. Describe how you went about choosing the study's total sample size. Recall that the sample size is selected based on having sufficient statistical power to detect a minimum effect size based on a pre-specified hypothesis test associated with the study's primary aim. Based on custom: power is often set to 80% or higher, and the p-value is often set to 5% for the primary aim.

C.X.X. Statistical Power for All Other Pre-specified Comparisons. [Optional.] *[It is a best practice (if you have the space) to provide estimates of the statistical power for any other comparisons/hypothesis tests that are not primary. If this distinction is made clearly, as we recommend you do, then it is accepted (and sensible) for you to explain that may be willing to tolerate greater Type-I error rates and/or lower statistical power for these secondary comparisons. This practice/concept is not specific to MRTs, but it ends up being particularly important in MRTs because there are often multiple interesting scientific questions (comparisons) that rely on randomizations in a MRT. For hypothesis tests related to the primary aim comparison but on a secondary outcome, we recommend setting the p-value to between 5% and 10%. For hypothesis tests related to comparing different types of prompts that are nested within one of the primary intervention options under consideration, or for hypothesis tests related to interaction terms, we recommend setting the p-value to 10-15%. For hypothesis tests related to moderators analyses, we recommend setting the p-values to 10-20%.*

- Some best practices:
1. inflate the total study sample size by estimated rate of missingness (or study drop-out)
 2. The minimum detectable effect size is based on a clinical rationale, not a statistical one. Pilot data could be useful here, but only in a supplementary fashion.
 3. Multiple comparisons procedures are necessary only if you have multiple/co primary aims.

Tip 1: Get Sample Size (N) based on Power to detect a Minimum Clinical Diff for Primary Comparison [necessary]

Provide Power (P) for other Aims based on Sample Size [useful]

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C.X. Alternative Study Designs Considered. Summarize the process that led to this particular pair of scientific questions and trial design. Do this by drawing contrast between your proposed trial design versus others you may have considered. *[We considered XXXX. However, XXXXX. In contrast, the proposed trial design XXXXX. We also considered using a XXXXX trial, where the goal is to XXX. However, we ultimately decided not to XXXXX because XXXXX].*

C.X. Impact. Remind the reviewer why this work is both important, innovative, and aligns with the priorities of the funding agency.

- Tip 1: At minimum, explain why not use a standard 2-arm RCT**
Tip 2: End with reminding reviewers why this work is important

Outline

A few ideas for how to craft a grant for one type of MRT with tips for different grant sections

Meant to spur discussion rather than to provide a template!

