

# **The Efficacy of Just-In-Time Adaptive Interventions in Augmenting Behavioral Health: Protocol for a Systematic Review**

Lauren Marie Henry, Morkeh Blay-Tofey, Clara E Haeffner, Cassandra N Raymond, Elizabeth Tandilashvili, Nancy Terry, Miryam Kiderman, Melissa A Brotman, Silvia Lopez-Guzman

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# The Efficacy of Just-In-Time Adaptive Interventions in Augmenting Behavioral Health: Protocol for a Systematic Review

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## Abstract

**Background:** Just-in-time adaptive interventions (JITAI) use mobile, digital tools to provide individuals with personalized interventions at the optimal time and in the optimal context. Accordingly, JITAI are promising for advancing accessible, equitable, and evidence-based treatment for behavioral health. To guide future work in this space, research is needed to examine the efficacy of JITAI for behavioral health conditions and better understand their mechanisms of action.

**Objective:** In the proposed systematic review, we will investigate the efficacy of JITAI for improving (1) distal outcomes (here, behavioral health) and (2) proximal outcomes (eg, emotion regulation).

**Methods:** This systematic review is being conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta Analyses Protocol. We developed our search strategy and executed the literature search in collaboration with biomedical librarians; five databases (PubMed, Embase, Cochrane Library, Web of Science: Core Collection, and APA PsycINFO) were searched and results were managed using EndNote 20. We are screening all records in duplicate in Covidence according to eligibility criteria; title/abstract screening is complete and full-text screening is ongoing. Data items will be extracted, and risk of bias will be assessed in duplicate from the included articles in Covidence.

**Results:** We will summarize JITAI characteristics in tables and text. We will conduct meta-analyses for the distal and proximal outcomes conditional upon sufficient homogeneity in subgroups. Moderation (conditional upon sufficient heterogeneity of outcomes) and mediation (ie, whether changes in proximal outcomes mediate the relation between JITAI and distal outcomes) will be conducted, as appropriate. We will investigate publication bias and use the Grading of Recommendations Assessment, Development and Evaluation to characterize the quality of evidence of our estimates.

**Conclusions:** Here, we propose a systematic review to assess the state of the literature on JITAI for behavioral health. The insights derived from this study will reinforce JITAI definitions, clarify JITAI components, describe the efficacy of JITAI in augmenting distal and proximal behavioral health outcomes, and inform the next steps in JITAI research.

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## Original Manuscript

# **The Efficacy of Just-In-Time Adaptive Interventions in Augmenting Behavioral Health: Protocol for a Systematic Review**



## Abstract

**Background:** Just-in-time adaptive interventions (JITAI) use mobile, digital tools to provide individuals with personalized interventions at the optimal time and in the optimal context. Accordingly, JITAI are promising for advancing accessible, equitable, and evidence-based treatment for behavioral health. To guide future work in this space, research is needed to examine the efficacy of JITAI for behavioral health conditions and better understand their mechanisms of action.

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**Conclusion:** Here, we propose a systematic review to assess the state of the literature on JITAI for

behavioral health. The insights derived from this study will reinforce JITAI definitions, clarify JITAI components, describe the efficacy of JITAI in augmenting distal and proximal behavioral health outcomes, and inform the next steps in JITAI research.

**Keywords:** just-in-time adaptive interventions; behavioral health; systematic review





## Introduction

Mental illness has devastating consequences for individuals, their families, and society. Those in need of treatment are woefully underserved, with a dearth of professionals relative to patients [1]. Race and ethnicity, geography, and socioeconomic status influence who can, and who cannot, access care [2]. For the subset of individuals who receive treatment, lack of evidence-based care [3] and issues with drop out [4] and nonresponse [5, 6] limit recovery. New solutions are critical for reaching, and equitably and effectively treating, people suffering from mental illness.

Technological advances may provide a pathway to more equitable evidence-based care at scale. While structural barriers (eg, cost, transportation) impede access to in-person healthcare, mobile devices are plentiful and may allow for greater population coverage [7, 8]. Further, while treatment may be perceived as stigmatizing, further reducing service utilization [9, 10], research provides preliminary support for willingness to initiate and maintain engagement with digital interventions (even in severe mental illness) [11]. Beyond accessibility and acceptability, treatment delivered via technology allows for the provision of therapeutic support when and where it is most needed — outside of the clinic and within patients' daily lives [12, 13]. After a prescribed treatment is delivered, technological solutions can be seamlessly integrated and accessed again to boost skills and maintain treatment gains [12, 13].

Despite potential benefits of digital treatment delivery, evidence for the efficacy of intervening using standalone mobile applications is limited [14]. Still, just-in-time adaptive interventions (JITAI) are promising. JITAI allow for precise targeting of mechanisms for therapeutic change at the time, and in the context, that is optimal for the individual [15, 16]. JITAI have the potential to capitalize on states of vulnerability and opportunity [16]. That is, JITAI can intervene when individuals are susceptible to negative or positive change, respectively. For example, capitalizing on a state of opportunity might be prompting an adult with social anxiety disorder to approach others while at a public place. JITAI can also intervene when individuals are maximally

receptive, or most likely (willing, able) to accept a specific intervention [16]. To do so, JITAIs leverage real-time data collected passively or actively from smartphones and/or paired wearable devices, in combination with personalized algorithms [15-17]. JITAIs are defined by six components: (1) distal outcome (long-term goal of the JITAI), (2) proximal outcome (short-term goal of the JITAI, which may be a mediator of the distal outcome), (3) tailoring variable (baseline or time-varying information on the individual that informs which interventions to deploy at which decision points), (4) decision point (time frame when an intervention option is, or is not, deployed), (5) decision rule (operationalization of which intervention option should be used, when, and for whom), and (6) intervention options (set of potential components that may be deployed toward behavior change at a given decision point). JITAIs have been developed for a variety of problems, including substance use [18, 19], affective disorders [20], and stress management [21].

The potential impact of an intervention (here, a JITAI) is dependent on the potency of its mechanistic target. Some, but not all, JITAIs that aim to augment behavioral health outcomes describe doing so through purported proximal outcomes [20]. Importantly, to increase the likelihood that JITAIs will be effective, their development must be informed by well-established findings from psychiatric research. Deficits in emotion regulation, or efforts to modify the intensity or duration of an emotion, is a transdiagnostic pathway in the development and maintenance of psychopathology [22, 23]. Importantly, emotion regulation is malleable, in that it can be augmented with intervention [24]. As such, emotion regulation is a key candidate transdiagnostic treatment target for behavioral health. Emotion regulation skills are key components of empirically-supported treatments for psychopathology [25, 26] and have been shown to mediate and moderate effects of interventions on outcomes [24]. Increasingly, emotion regulation skills have been incorporated into digital health interventions [27-30].

There are two major gaps in understanding the potential utility of JITAIs in behavioral

healthcare [31].<sup>1</sup> First, little research has summarized the efficacy of JITAIs for behavioral health conditions. Most commonly, systematic reviews and meta-analyses have examined the impact of JITAIs on the promotion of physical health, providing some early support for JITAIs as a digital health tool [32, 33]. The extant systematic reviews relevant to behavioral health have evaluated JITAIs either within a larger health promotion framework or for a specific psychiatric disorder. In their meta-analysis of JITAIs for physical and mental health (eg, healthy diet, weight loss, diabetic management, addiction, bipolar disorder, anxiety), Wang and Miller [34] found a large effect of JITAIs relative to a waitlist control (Hedges  $g = 1.653$ ). In their systematic review of JITAIs for substance use, Perski et al. [19] found mixed results for efficacy. Second, few systematic reviews [20] have described JITAI proximal outcomes, despite the important role that proximal outcomes play in elucidating intervention mechanisms of action [35]. Further, to the best of our knowledge, no extant systematic reviews on JITAIs have examined the efficacy of augmenting emotion regulation as a proximal outcome. Here, we propose a systematic review (and meta-analysis, as appropriate) of JITAIs targeting proximal outcomes, including emotion regulation, to improve behavioral health outcomes.

## Objectives:

1. Primary objective: Examine the efficacy of JITAIs in improving aspects of behavioral health as distal outcomes. We will examine moderators (eg, sociodemographic variables, symptom severity) conditional upon sufficient heterogeneity in outcomes.
2. Secondary objective: Examine the efficacy of JITAIs in improving proximal outcomes toward the promotion of behavioral health. Given the importance of developing JITAIs incorporating empirically supported intervention targets, we will focus our discussion on emotion regulation as a proximal outcome of interest.

In addition to the aforementioned quantitative objectives, we will qualitatively describe the six

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<sup>1</sup> Henceforth, we use the term “behavioral health” to refer to psychological disorders and symptoms (including substance use disorders), as well as physical symptoms related to life stressors and crises.

JITAI components (ie, distal outcome, proximal outcome, tailoring variable, decision point, decision rule, intervention options) for each of the articles included in our systematic review. In this way, our research will reinforce the existing JITAI framework [15, 16] and provide a roadmap for the development of future JITAIs to improve behavioral health.

## Methods

We used the Preferred Reporting Items for Systematic Reviews and Meta Analyses Protocol (PRISMA-P) checklist to write this systematic review protocol [36].

## Eligibility Criteria

See Table 1 for inclusion and exclusion criteria. After examining a subset of records, it became clear that we were unable to determine with certainty if interventions were JITAIs (ie, just-in-time, adaptive) and if behavioral health outcomes were reported by examining article titles and abstracts. As such, to prevent excluding relevant articles during title and abstract screening, we retained a subset of our inclusion and exclusion criteria for this stage. That is, we focused on identifying articles using digital methods and proposing specific interventions, and articles of the correct format (eg, excluding reviews, case reports, protocols). The full eligibility criteria are being used for full text screening.

**Table 1**

*Eligibility criteria for systematic review*

Category	Inclusion Criterion	Exclusion Criterion
Population	All individuals, regardless of age, sex and gender, race and ethnicity, socioeconomic status, geographic location, and other aspects of identity	None
Study design	JITAIs, that is: <ul style="list-style-type: none"><li>- Just-in-time: deployed when the individual needs it</li><li>- Adaptive: incorporates time-</li></ul>	No JITAI; JITAIs in development (eg, trials to optimize JITAI components, including micro-randomized trials)

	<p>varying and/or contextual information for individualization, leveraged through passively or actively collected data from smartphones or wearable devices</p> <p>- Intervention: activities intended to modify behavior, thoughts, or emotions</p>	
Outcome	Behavioral health	Physical health and wellness outcomes that do not directly focus on behavioral health
Article format	All languages; empirical research studies; publication in a peer-reviewed journal	Reviews, meta-analyses, protocols, case reports, dissertations, theses, and conference abstracts

*Note.* JITAI = just-in-time adaptive intervention.

## Information Sources

Five databases were searched by a biomedical librarian [**BLIND**]: PubMed/MEDLINE (US National Library of Medicine), Embase (Elsevier), Cochrane Library (John Wiley & Sons), Web of Science: Core Collection (Clarivate Analytics), APA PsycINFO (Dialog/Clarivate). To identify relevant articles missed by the search strategy, reviewers [**BLIND**] will scan the bibliographies of included studies and relevant review articles. Protocols, feasibility studies, and acceptability studies were flagged during screening, and reviewers will revisit these records to determine if clinical outcomes were published. The final list of included studies, and additional, relevant studies, will be evaluated by the entire review team, along with relevant unaffiliated collaborators. Articles identified through these supplemental methods will proceed through the full screening process.

## Search Strategy

A biomedical librarian [**BLIND**] with expertise in systematic review searches developed the search strategy. A second librarian [**BLIND**] not otherwise affiliated with the project peer reviewed

the search strategy. The review team provided feedback on the search strategy. The search strategy incorporated keywords and controlled vocabulary terms (ie, Emtree [Embase], MeSH [PubMed], Thesaurus of Psychological Index Terms [PsycNet]) for each concept of interest. The search strategy syntax was adapted for each database searched. See Multimedia Appendix 1 for PubMed search strategy.

## Study Records

### *Data Management*

We used EndNote 20 (Clarivate Analytics) to collect and manage the results of the literature search and identify unique records. We used Covidence (Veritas Health Innovations), an online tool for systematic review data management, for selection and data collection. Prior to selection and data collection, reviewers [**BLIND**] were trained in using Covidence.

### *Selection Process*

Before each stage of screening (title and abstract, full text), a 20-article trial was conducted with all reviewers to pilot and refine the eligibility criteria to increase reliability. All reviewers are conducting screening using the stated eligibility criteria. For title and abstract screening, articles with missing abstracts automatically advanced to full text screening. Following title and abstract screening, included article PDFs were obtained and uploaded into Covidence for full text screening. All articles are being double coded for each stage of screening; that is, each record is independently screened by two reviewers. Screening discrepancies are being resolved during a group consensus meeting. Inter-rater reliability is being recorded in Covidence and will be documented in the final report.

### *Data Collection Process*

Before data collection, a 15-article trial will be conducted with all reviewers [**BLIND**] to increase reliability. All reviewers [**BLIND**] will independently extract data items from records included after full text screening. Each data item from each study record will be extracted in

duplicate. Coding discrepancies will be discussed and resolved via dyadic consensus meetings including the two relevant reviewers for each article. Discrepancies that cannot be resolved during dyadic consensus meetings will be resolved at a group consensus meeting. Data extraction forms will be published.

### **Data Items**

See Table 2 for data items that will be collected.

**Table 2**

*Data items for systematic review*

Category	Criteria
Article	Authors, Title, Journal, Year
Sample	demographics Where the study took place, Sample size, Age, Gender and/or sex, Race and/or ethnicity
JITAI characteristics	Tailoring variable, Decision points, Decision rules (including static or adaptive status), Intervention options, Proximal outcomes (eg, emotion regulation), Distal outcomes (eg, depression)
Study design	Study type (eg, randomized controlled trial), Where the JITAI was developed (eg, university, industry), Was the JITAI delivered alongside other support (eg, in-person intervention), Was the JITAI delivered alongside biological sensors/ambulatory device, Types of sensors used, JITAI delivery service (eg, iPhone, personal device), Number of intervention days, Payment structure (eg, flat fee), User engagement, User compliance (eg, response to prompts and/or frequency of JITAI use), Usability

*Note.* JITAI = just-in-time adaptive intervention.

### **Outcomes and Prioritizations**

Our primary outcome of interest is the distal outcome of the JITAI. Here, we focus on JITAIIs that target behavioral health outcomes. Examples of potential distal outcomes include affective, substance

use, disruptive behavior, eating, trauma-related, personality, psychotic, and neurodevelopmental disorders; psychological symptoms (ie, not meeting criteria for disorder); pain; and well-being. See Multimedia Appendix 1 for full list of search terms related to behavioral health. Our secondary outcome of interest is the proximal outcome of the JITAI. While we are particularly interested in emotion regulation, all proximal outcomes will be collected. We will calculate effect sizes for both the distal and proximal outcomes.

## **Risk of Bias in Individual Studies**

Tools appropriate to the study design of individual records will be used to determine risk of bias. For example, Version 2 of the Cochrane risk-of-bias (RoB 2) tool for randomized controlled trials will be used for randomized controlled trials [37]; the Risk Of Bias In Non-Randomized Studies - of Interventions (ROBINS-I) will be used for non-randomized studies comparing the effects of two or more interventions [38]; and Risk Of Bias In Non-randomized Studies - of Exposure (ROBINS-E) will be used for observational studies [39]. Risk of bias will be evaluated by two reviewers for each study. Disputes will be resolved during dyadic consensus meetings, and discrepancies that cannot be resolved during dyadic consensus meetings will be resolved during group consensus meetings.

RoB 2 includes five domains: bias due to randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result [37]. Each domain will be classified as low risk of bias, some concerns, or high risk of bias. ROBINS-I includes seven domains: bias due to confounding, bias in selection of participants into the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of the outcome, and bias in selection of the reported result [38]. Each domain will be classified as low, moderate, serious, or critical risk of bias or no information. ROBINS-E includes seven domains: risk of bias due to confounding, risk of bias arising from measurement of exposure, risk of bias in selection of



participants into the study, risk of bias due to post-exposure interventions, risk of bias due to missing data, risk of bias arising from measurement of outcome, and risk of bias in selection of the reported result [39]. Each domain will be classified as low risk of bias, some concerns, high risk of bias, or very high risk of bias.

## Data Synthesis

Characteristics (eg, tailoring variable, decision points) for each JITAI will be presented in tables and summarized in text. Data synthesis will be explored based on outcomes, and a summary of findings table will be presented, as appropriate.

We will categorize studies by design type (eg, randomized controlled trial, observational). If studies in each subgroup are sufficiently homogeneous, meta-analyses will be conducted for the distal and proximal outcomes. Features of the studies collected will inform selection of the measure of effect size (eg, Cohen's  $d$ , Hedge's  $g$ ). Subgroup analyses will be considered based on characteristics, including age, gender, type of psychopathology, and type of JITAI. Additionally, sensitivity analysis will be carried out, excluding studies of low methodological quality, if necessary.

$I^2$  statistic will be used to quantify heterogeneity across effect sizes, and  $Q$  statistic will be used to test heterogeneity reduction through the inclusion of moderators. To address potential heterogeneity, meta-regression will be used to assess clinical characteristics (eg, severity of symptoms), individual JITAI features (eg, type of emotional regulation strategies used in the intervention), study quality, and demographic characteristics (eg, age, gender, race/ethnicity) that might influence the effect sizes.

If appropriate, mediation analyses will be considered to investigate whether changes in proximal outcomes mediate the relation between JITAIs and distal outcomes.

## Meta-bias(es)

Publication bias, resulting from selective publication or reporting, will be investigated through visual inspection of funnel plots. Statistical tests for assessing symmetry (eg, Egger's test) will be

explored if 10 or more studies have evaluated the same outcome. Trim and fill analyses will be conducted, as necessary.

## Confidence in Cumulative Evidence

The quality of evidence of estimates will be rated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework [40]. GRADE characterizes the quality of evidence according to publication bias, study limitations, inconsistency, imprecision, and indirectness [40]. Evidence of efficacy outcomes will be rated from high to low quality by two reviewers. Disputes will be resolved during dyadic consensus meetings, and discrepancies that cannot be resolved during dyadic consensus meetings will be resolved during group consensus meetings. Results from GRADE ratings will be included in the summary of findings table.

## Results

We finalized the search strategies and began the literature search in November 2023. We retrieved 1,243 records from our literature search. We excluded 91 duplicate records, leaving 1,152 records for the selection process. Of note, we performed a preliminary literature search for systematic reviews related to this topic and found no review identical to the one proposed.

## Discussion

### Principal Results

In our systemic review, we aim to examine the efficacy of JITAIs for (1) distal outcomes (here, behavioral health) and (2) proximal outcomes (eg., emotion regulation).

### Strengths and Limitations

Our systematic review has numerous strengths, including a comprehensive search strategy, double coding in each stage of screening and data extraction by trained reviewers, assessment of risk of bias of the included studies by reputed tools, evaluation of publication bias, and ratings of quality of evidence of estimates derived from the review.

There are also potential limitations of our work. Primarily, some ambiguity exists in

the use of the term “JITAI;” the definition of JITAI has evolved since it was first coined in 2015 [15]; the term has been used inconsistently (eg, an intervention with all the characteristics of a JITAI being characterized as a “momentary intervention” or related term) and imprecisely (eg, an intervention labeled as a JITAI despite the lack of adaptive components); and there is overlap in the definitions of JITAIs and similar tools (eg, ecological momentary interventions). As such, we have developed a robust search strategy, including not only the term JITAI but also related terms (eg, ecological momentary intervention, real time intervention; see Multimedia Appendix 1). Further, we developed and implemented detailed eligibility criteria for screening. We also clearly describe the six components that constitute a JITAI in the current protocol and will describe each component for each included JITAI in the final report. Accordingly, the current systematic review may provide the field with further clarity on the definition and characteristics of JITAIs. Another limitation is that due to the iterative design process that characterizes JITAIs (and interventions, in general), JITAIs included in this report may not reflect their finalized form. Future scholarship will be needed to capture further JITAI innovations and evaluations. Finally, although we did not limit our search to English language articles, most of our articles are written in English and so the samples and populations represented may be similarly homogeneous. Additional work may be needed to increase representation of studies published in languages other than English in JITAI efficacy research.

## Comparison with Prior Work

Previous research has typically evaluated JITAIs as digital health tools for the promotion of physical health [32, 33]. While a select few reviews have examined JITAIs for specific psychiatric disorders [13], research has yet to robustly summarize the impact of JITAIs for behavioral health conditions.

## Conclusions

The current systematic review will summarize the evidence on the efficacy of JITAIs in improving distal (ie, behavioral health) and proximal (eg, emotion regulation) outcomes. Results will provide clarity on JITAI definitions and components, describe the efficacy of JITAIs for behavioral health, elucidate targeted proximal outcomes, and inform the development of future JITAIs.

## Acknowledgements

None.

## Conflicts of Interest

The authors have no conflicts of interest to declare.

## Abbreviations

**GRADE:** Grading of Recommendations Assessment, Development and Evaluation

**JITAI:** just-in-time adaptive intervention

**PRISMA-P:** Preferred Reporting Items for Systematic Reviews and Meta Analyses Protocol

**RoB 2:** Version 2 of the Cochrane risk-of-bias tool for randomized controlled trials

**ROBINS-E:** Risk Of Bias In Non-randomized Studies - of Exposure

**ROBINS-I:** Risk Of Bias In Non-Randomized Studies - of Interventions

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## Supplementary Files

## Multimedia Appendixes

Search Strategy.

URL: <http://asset.jmir.pub/assets/33baca48f53463795e08eba6d395639a.docx>