

BEhavioral Nudges to Enhance Fidelity in Telehealth Sessions (BENEFITS): Protocol for developing and pilot testing a telehealth tool to improve CBT implementation

Emily M. Becker-Haimes, David Mandell, Patty Kuo, Kevin Lynch, Megan Brady, Sophia Young, Torrey Creed

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Abstract

Background: The proliferation of telehealth offers a unique opportunity to integrate strategies from behavioral economics (BE) into the telehealth infrastructure to improve clinician fidelity to cognitive behavioral therapy (CBT).

Objective: We will develop and evaluate “Tele-BE,” a novel telehealth infrastructure that nudges and incentivizes clinicians to use core structural CBT components. We focus on structural CBT components as they align with practices most likely to benefit from BE strategies, are delivered regardless of diagnosis, and represent CBT competencies independently associated with improved patient outcomes.

Methods: We will refine our Tele-BE prototype in collaboration with clinicians and supervisors (target end-users; Aim 1). We will work closely with our web development team to field test and iteratively refine Tele-BE using rapid cycle prototyping to optimize the user experience and refine our specific BE strategies (Aim 2). The revised Tele-BE platform will be tested in a 12-week open trial with 30 community mental health clinicians randomized to Tele-BE or telehealth as usual (Tele-AU). The trial will include 2 patients per clinician (60 patients in total). All sessions will be recorded and coded for CBT fidelity. Clinicians and patients will complete questionnaires at Weeks 1, 5, 9, and 12 and qualitative interviews at post. Primary outcomes will be CBT structural component fidelity, measured through coding of recorded sessions; secondary outcomes include target implementation mechanisms (intentions and their determinants: attitudes, norms and self-efficacy), measured via mixed methods, and overall CBT fidelity (Aim 3). Using data from the trial, we also will examine acceptability and feasibility of Tele-BE from patient and clinician perspectives, as well as any potential ethical issues identified with Tele-BE use (Aim 4).

Results: The study received NIMH funding in June 2024. Recruitment for Aim 1 started in October 2024. As of March 2025, we recruited 6 participants in the initial development stage. Recruitment is ongoing and we anticipate Aim 1 will be completed in May 2025 at which point we will prepare for study activities in Aim 2. We aim to have all study collected by the end of 2026. Per the terms of our grant award, we will submit de-identified study data collected in Aims 3 & 4 to the NIMH Data Archive for participants who consent to data sharing.

Conclusions: Outcomes will provide insight into the utility of a behavioral economics-informed telehealth platform to increase clinicians’ use of core structural components of CBT to improve overall CBT fidelity and patient outcomes. It also will inform future confirmatory trials. Clinical Trial: Clinical Trials Registration Number: NCT NCT06601062. Registered 9/17/2024, <https://clinicaltrials.gov/study/NCT06601062>

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Original Manuscript

BEhavioral Nudges to Enhance Fidelity in Telehealth Sessions (BENEFITS): Protocol for developing and pilot testing a telehealth tool to improve CBT implementation

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Keywords: telehealth; behavioral economics; implementation; cognitive behavioral therapy

Introduction

Background

Telehealth for psychological interventions has existed for decades with historically limited uptake, primarily due to strict regulations [1] and limited reimbursement [2]. COVID-19 facilitated swift global adoption of telehealth [3], and payors have accepted the need to ease regulatory burden and sustain telehealth reimbursement post-pandemic [4–8]. To date, telehealth primarily has been studied as an alternative to in-person care [9–12] and as a means to support access to care for historically marginalized groups [13,14]. Little research has examined how to leverage the platform to support evidence-based practices (EBPs) and patient-centered care.

Telehealth provides a unique opportunity to use behavioral economics (BE) principles to structure therapy encounters in ways that nudge clinicians to deliver high-quality services. BE approaches address psychological biases that drive individual decision-making [15]. BE frameworks acknowledge that human decision-making often is not made under optimal conditions, leading individuals to stray from “rational” decision-making in a myriad of ways. Classic examples of such “bounded rationality” (i.e., the recognition that humans make decisions based on limited cognitive resources and thus rely on heuristics in decision-making [16] include failure of individuals to opt-in to retirement investments that are in their best interest (i.e., due to a status quo or loss aversion bias [17] or make suboptimal or irrational decisions when in situations that are highly cognitively burdensome (e.g., due to decision fatigue or availability heuristics [15]. In healthcare, clinicians may be aware of the right thing to do (e.g., “I should deliver x treatment for y condition”), yet may often choose other, less empirically supported interventions for a range of reasons related to environmental cues (e.g., availability biases), individual cognitive styles (e.g., aggregate heuristics), and other biases [18]. Health care research has shown that structuring environments and nudging clinicians to use recommended practices can increase quality of care [19–21]. Common BE applications have included strategies that guide decision-making by providing information (e.g., social reference points

or peer comparisons, making key information visible), making structural changes (e.g., changing choice defaults, altering options presented to decision-makers to influence attractiveness of some choices over others), and offering cognitive assistance (e.g., reminders) [18,22,23].

While BE holds strong potential to inform cost-effective, pragmatic implementation strategies to support clinicians in delivering EBPs, the role of BE in changing mental health clinicians' behavior has received little attention. The nature of traditional behavioral health sessions, which occur behind closed doors and prioritize privacy, makes it hard to implement supports during encounters. The continuation of telehealth access post-pandemic provides a context ripe for improving treatment delivery. Telehealth has traditionally been viewed as a medium by which treatment is delivered, with content and processes comparable to what would occur in office visits [24]; however, it also offers an *infrastructure* that is well-suited to BE strategies to optimize clinician use of EBPs, track and reward fidelity to EBPs, and make EBP use easier and more motivating.

In this study, BEhavioral Nudges to Enhance Fidelity in Telehealth Sessions (BENEFITS), we will develop and pilot test an implementation strategy that leverages the technological infrastructure of telehealth encounters to nudge and incentivize clinicians to increase fidelity to structural components of cognitive behavioral therapy (CBT). We focus on CBT because it is an EBP for many mental health conditions; increasing clinician fidelity to CBT can improve care quality and patient outcomes [25–27]. Most research suggests that if community clinicians use CBT at all, it is often with poor fidelity [28–30].

We focus on structural components of CBT for two reasons. First, structural components are a core and distinct CBT competency [31,32] and the backbone of CBT practice; they are delivered regardless of diagnosis. A typical CBT session starts with a brief check-in on treatment progress, collaborative agenda, and review of prior homework. The core of the session focuses on intervention techniques and skills, and the session closes with planning a between-session homework practice. Specific clinical content, including which interventions are selected and what will be practiced in the

homework, are tailored to the patient's individual presentation, but use of these structural components remains consistent across sessions. Structural components also support shared decision-making and facilitate selecting and tailoring interventions to patient preferences and symptoms, which improves patient-centered care [33]. Clinical trials suggest that structural components are independently associated with improved clinical outcomes [34–37]. Our work has shown that community clinicians have consistently low fidelity to structural components [32,38], even when clinicians' intentions to deliver them are high [39].

Second, structural components are well-suited for BE strategies, which are ideally used to change discrete, observable, and measurable behaviors. The field of surgery provides a useful example to illustrate the potential benefit of BE strategies to improve patient care. Surgeries are complex and require providers to execute highly specified procedural techniques and learn how and when to deviate from these techniques in response to diverse problems or complications [40]. There is extensive evidence of the effectiveness of structuring surgical environments to minimize risk and optimize outcomes, and nudge surgeons to engage in safety and quality checks (e.g., with surgical checklists) [19,20]. This behavioral infrastructure facilitates delivery of the highest quality care by reducing the cognitive load of remembering routine protocols [21], so that surgeons can focus their efforts on using their clinical skill and judgment to optimally help patients. CBT structural components, when implemented correctly, similarly provide the scaffold to support clinicians in delivering CBT intervention techniques, which can be complex and often require adaptation [41,42] and tailoring [43] in response to patient needs that can change within and between sessions [44]. Unlike surgery, the private, in-person therapy environment historically provided limited opportunities for BE strategies to support clinicians in delivering the structural CBT components that are foundational for intervention delivery; therapy is typically delivered without a support team, like that in an operating room. Leveraging the telehealth encounter to embed checklists and other non-intrusive nudges may lighten the clinician cognitive load, leaving clinicians more able to focus on

selecting and delivering interventions and skills that yield comparable benefits for their patients.

Goal of This Study

In other contexts, BE strategies have raised ethical questions related to coercion to engage in a behavior one otherwise might not [45,46]. Thus, study of BE strategies to support mental health EBP delivery should consider participants and intended end-users' ethical concerns. In BENEFITS, we will develop and evaluate "Tele-BE," a novel telehealth infrastructure that nudges and incentivizes clinicians to use core structural CBT components. Tele-BE is intended solely to support fidelity to the structural components of CBT that should be present in CBT sessions, regardless of where a patient is in active treatment (except for instances where clinicians would be expected to deviate, such as first sessions, termination sessions, or crisis sessions). Tele-BE will be agnostic to intervention content (i.e., clinicians will be encouraged to use *a* CBT skill in session, but not any *specific* CBT skill). We will attend to any concerns clinicians or patients raise to ensure clinicians do not feel undue pressure to deliver therapeutic care they do not think is appropriate. Our specific aims are to:

- Aim 1:** Design the Tele-BE prototype to increase clinician fidelity to CBT structural components, in collaboration with 6 clinicians and 3 supervisors (target end-users) and guided by principles of user-centered design.
- Aim 2:** Adapt and iteratively refine Tele-BE in an open field trial. We will use rapid-cycle prototyping and testing with 5-10 clinicians and 5-10 patients.
- Aim 3:** Test preliminary effectiveness of Tele-BE vs. telehealth as usual (Tele-AU) to engage target mechanisms and enhance clinician fidelity to CBT via a 12-week randomized pilot trial (n=30 clinicians, 60 patients). Primary outcomes will be clinician fidelity to CBT structural components, measured via coded therapy sessions. We will explore mechanisms of action – including intentions and determinants of intentions (attitudes, norms and self-efficacy) – for Tele-BE's effect on fidelity via surveys and interviews.

Aim 4: Evaluate acceptability, feasibility, and ethical issues related to Tele-BE from clinician and patient perspectives via surveys, interviews, and web analytics. We will use qualitative and quantitative methods to analyze Tele-BE's impact on clinician treatment delivery, therapeutic alliance, patient satisfaction, and clinical outcomes.

Methods

Study Setting

All research activities will take place in the City of Philadelphia and capitalize on a strong history of CBT implementation efforts in the region through the Beck Community Initiative (BCI). The BCI represents a partnership with Philadelphia's Department of Behavioral Health and Intellectual disAbility Services (DBHIDS) to implement high-quality CBT in Philadelphia's public mental health system. BCI teaches CBT theory and strategies through intensive workshops, followed by 6 months of weekly case consultation. In the consultation phase, therapists submit recorded therapy sessions and their CBT competence is rated in at least 4 sessions using the Cognitive Therapy Rating Scale (CTRS). Mean competence scores at the end of training ($M = 41.2$) have been just above the criterion threshold by the certification point, suggesting substantial opportunities to improve therapist skills among those who have completed training [47]. Importantly, BCI-trained therapists demonstrated substantial variability in their intentions to use CBT structural components following training [39]. Considerable research also shows that training effects wear off over time without additional support, such as behavioral nudges [48]. Philadelphia's Medicaid behavioral health payor is continuing to support telehealth reimbursement, providing an ideal context in which to test the effects of BE strategies on CBT fidelity. All participants will complete the consent process conducted with research team members prior to engaging in any study activities.

Conceptual Framework

Our intervention design and study measurement are guided by leading theories of clinician behavior change [49–51], and our prior studies [39] suggesting two major reasons why clinicians

trained in CBT do not use CBT structural components. First, some clinicians may have strong motivation (or intentions) to use structural components; however, aspects of their organizational setting or their patients' presentation in treatment may make it difficult to act on their intentions. For example, a patient may present with a lot to share, and the clinician forgets to set the agenda. For these clinicians, effective implementation strategies will either make it easier for clinicians to act on their intentions or bypass intentions altogether by making use of structural components the default (e.g., automatically sending progress monitoring measures to clinicians, rather than asking clinicians to do so). Second, other clinicians may have weaker intentions to use components of CBT due to factors known to affect the strength of one's intentions, such as holding negative attitudes about a specific CBT component (e.g., thinking homework is unhelpful), experiencing limited normative pressure to use CBT components (e.g., feeling as though one's supervisor disapproves of structured sessions), or limited self-efficacy (e.g., not feeling confident in one's ability to plan a homework assignment). For these clinicians, effective implementation strategies will strengthen intentions by improving attitudes, leveraging norms, or increasing self-efficacy to lead to behavior change. Table 1 shows target mechanisms and how Tele-BE is anticipated to map on to each.

Table 1. Proposed Tele-BE design features, target mechanisms, and implicated BE principles.

Tele-BE Features	Target Mechanism	BE Principle	Present in Tele-AU?
Reminder message is sent to prompt clinician to identify skills to review, introduce, or practice prior to session and note identified skill in the web platform	Intentions	Availability Bias: People tend to focus on what easily comes to mind	No, clinician is directed to standard telehealth interface only
Clinicians are prompted to push out brief symptom measures while the patient is waiting for the session to start every 4 weeks	Bypassing intentions; Intention-Behavior Gap	Changing the Default: People will engage in behaviors that are easiest and in front of them	No; to collect patient symptom data for trial purposes, patients will be contacted by research staff directly to complete measures via text or email
Template agenda of structural	Intention-	Reducing Choice	No, clinician is directed

components alongside the embedded video that supports clinician pacing of session by adjusting which component is highlighted (e.g., agenda is highlighted until clinician clicks to indicate that the agenda was set, at which point homework review will highlight, etc.)	Behavior Gap	Overload: People often avoid decisions if there are too many choices	to standard telehealth interface only
Checkmarks indicating component has been completed; display adjusts as goals are reached	Attitudes	Goal Gradients: People try harder when goals are within reach	No, clinician is directed to standard telehealth interface only
Gamification (e.g., badges) for goals met (e.g., agenda completed >90% of the time). Tele-BE will provide automated congratulatory notifications for completing CBT components and delineating them in the Tele-BE platform; exact format (e.g., email vs embedded in the platform) and timing to be determined in development aims. For example, a clinician may get a notification congratulating them for pre-selecting a CBT skill for use three weeks in a row.	Attitudes, Norms	Hyperbolic Discounting: Preference for a small reward sooner over a larger reward later; Injunctive Norms: Perception of whether a behavior is approved	No
Regular feedback about elements completed from clinical supervisor (exact timing to be refined in development). We will identify key benchmarks during our development phase to trigger a congratulatory message (if fidelity benchmark is met) or encouraging message to increase component use (if benchmark is not met), using language refined in our P50 ALACRITY pilot trial	Norms	Social Influence and Injunctive Norms: Perception of whether a behavior is approved	No
Downloadable summary of session activities for the clinical progress note. Information from the template agenda will be downloadable to reduce the time needed to write a session note	Intentions, Self-Efficacy	Integrate Desired New Task into Existing Workflow; Make it Easy and Motivating to Use	No

Aim 1: Designing the Tele-BE prototype in partnership with clinicians and supervisors

Aim 1 will occur in two phases. In Phase 1, we will interview three CBT-trained clinicians and three clinical supervisors who previously received CBT training and either provide telehealth services or supervise a clinician who provides telehealth. Clinicians and supervisors will not be recruited in dyads. We will present each anticipated Tele-BE feature and target mechanism (Table 1), and initial prototypes (see Figure 1), and discuss how to refine our prototype to maximize usability and engagement of target mechanisms (e.g., clinician intentions, intention to behavior gap), minimize unintended negative effects on the patient experience (e.g., perceptions that clinicians are distracted), and ensure that Tele-BE will integrate with clinical, supervision, and administrative tasks and workflows. We do not anticipate changing the structural components targeted but may make small changes to how each is described based on feedback. We also will ask if there are additional features of sessions that would be useful for Tele-BE to target or capture. We will probe for perceived motivators and barriers to adoption of the Tele-BE system, including ethical concerns. For example, therapists might be attracted by the promise of improved session structure and care quality but be concerned about patient perceptions of recording, or the platform infringing on their autonomy to make clinical decisions, which is useful information in the design process and implementation plan (e.g., making it clear that the interface is clinician-facing only and that clinicians can override prompts). Participants also will complete a brief demographics questionnaire. We will share results from this meeting with our technology development team, which will create an initial Tele-BE working prototype. We will reconvene the same group of individuals for a second interview, in which participants will trial the initial interactive Tele-BE platform and suggest refinements before the next design phase. We will compensate participants \$100 for activities and integrate their feedback into the next Tele-BE iteration.

In Phase 2, we will conduct usability testing with three newly recruited CBT trained

community clinicians using the same criteria as Phase 1. Recruited participants will interact one-on-one with a basic version of Tele-BE, with the primary goal of identifying major bugs and usability problems in preparation for Aim 2. Each participant will meet individually with the study team and interact with the current version of the Tele-BE platform for ~45 minutes. During this time, participants will conduct a mock therapy session with a graduate student clinician who has experience providing CBT in the community, with an immediate debrief session to gather participant feedback on the end-user experience, and feedback from the student clinician on the “patient” experience. Participants’ interactions with Tele-BE will be recorded through HIPAA compliant video-conferencing software. Afterward, participants will complete a brief interview on the user experience, including learnability, acceptability, usefulness, overall satisfaction with aesthetics, perceived efficiency, and potential for integration with both clinical and supervision workflows. Semi-structured interviews will include queries about each user-interface element included in the Tele-BE prototype. At the end of the session, participants also will complete brief quantitative measures to assess perceptions of Tele-BE, including the Acceptability of Intervention Measure (AIM) [52], a 4-item, validated measure that measures the extent to which an innovation is perceived as acceptable, the Feasibility of Intervention Measure (FIM) [52], a 4-item scale that indexes the extent to which an innovation is perceived as feasible, and the System Usability Scale (SUS), an established 10-item measure with strong psychometrics and sensitivity to change [53,54]. Participants also will complete a brief demographics questionnaire and be compensated \$75 for activities. Data will highlight places where changes are needed to enhance acceptability, feasibility, and usability; we will incorporate refinements before Aim 2.

Aim 2: Adapt and iteratively refine Tele-BE in an open field trial

We will recruit between 5 and 10 clinician-patient dyads who are already delivering/receiving telehealth therapy services to engage with Tele-BE in an open field trial. The primary aim of this field trial is to identify software bugs, evaluate usability and acceptability issues that emerge over

extended use with Tele-BE, and refine our BE strategies. Secondary goals are to preliminarily examine the extent to which Tele-BE engages target implementation mechanisms and supports clinicians to deliver CBT structural components to inform refinements. Clinicians and patients will be recruited in pairs, with recruited clinicians using Tele-BE with a consenting patient of their choosing for up to 4 consecutive therapy sessions or over 5 weeks of treatment, whichever comes first. After participants' consent, we will provide each clinician-client dyad with a personalized, secure link to use in their regularly scheduled telehealth sessions for up to 5 weeks. Of note, only the clinician will need instructions on how to use Tele-BE. Client participants will not see the actual Tele-BE; their telehealth sessions during the study will appear similar to outside of the study.

We will apply rapid-cycle methods to test and refine the platform itself and the BE features selected in Aim 1, with the goal of optimizing messages and visual displays. We will make rapid adjustments after each dyad completes Aim 2 activities before the next dyad begins, until saturation related to feedback/changes requested is reached and we have a version suitable for formal testing in Aims 3 and 4. To do so, we will rely on "fake back ends" to test our BE strategies whenever possible, to avoid spending time on web programming for features that may need revision. For example, study staff may message clinicians directly to simulate portal-generated messages based on feedback received. The exact content of messages may change over time in response to feedback received. Small changes across enrolled dyads can be tested more efficiently with a fake back end.

As noted above, the Tele-BE platform is intended to be agnostic to specific CBT interventions and only will nudge use of *an* intervention as part of the standard CBT session structure. A key part of this design phase is to ensure clinicians are clear about how to "override" any recommendation to use a specific CBT structural component so that clinicians retain full autonomy over their clinical decisions for their patients. Aside from being available to support use of the Tele-BE platform in already scheduled CBT sessions, research staff will provide no suggestions or advice for session conduct. Our recruitment from within the BCI-trained pool of therapists ensures that CBT

structure is consistent with routine care. The only restriction we will place is that we will not ask clinicians to use Tele-BE in a first patient encounter or a termination session, as those may not be expected to follow the same session structure as what Tele-BE is intended to nudge clinicians toward.

After each dyad's trial period, staff will interview clinicians and patients separately about their experience. Clinician interviews will query around system usability using the same structured interview employed in Aim 1, including user experience with learnability, acceptability, usefulness, satisfaction with aesthetics, efficiency, and workflow integration. We also will ask semi-structured questions to elicit perceptions of how Tele-BE influenced use of CBT structural elements, explore whether Tele-BE led to any desirable or undesirable perceived effects on the session or therapeutic relationship, and ensure clinicians felt comfortable overriding any recommendations made by the platform. The last portion of the interview will solicit suggestions for improving Tele-BE. Brief patient interviews will query around the patient experience to determine whether use of Tele-BE is perceived as having any desirable or undesirable effects on the therapeutic relationship or patient-centered care processes. Clinicians will be compensated \$75 for these activities and patients will be compensated \$25. We will employ rapid qualitative analysis procedures to synthesize feedback and identify changes needed for the next testing cycle. Feedback will be reviewed with the full research team to clarify any areas where conflicting information is received.

Aim 3 & 4: Test preliminary effectiveness of Tele-BE to engage target mechanisms and enhance clinician fidelity to CBT

Overview

While Aims 3 and 4 are scientifically distinct, study procedures are concurrent and are described together. We will randomize 30 recruited clinicians who already provide individual CBT over telehealth for at least two clients to either Tele-BE or telehealth as usual (Tele-AU), n=15 per condition. We will balance allocation within organizations to ensure that there is equal representation

of clinicians within each condition in each agency. Each participating clinician will deliver treatment to 2 patients for 12 weeks (the standard length of many CBT protocols) and we will track clinician fidelity to CBT structural components in each condition. While our primary goal is to evaluate the feasibility of our design and measurement approach for a fully powered trial, we also include measures of patient symptoms, therapeutic alliance, and patient-centered care to explore clinical effectiveness outcomes and assess any potential concerns with Tele-BE (i.e., distracting to clinicians, detracting from alliance) via mixed methods.

Participants & Procedures

We will identify a minimum of four local agencies that use telehealth and have participated in system-sponsored BCI CBT training from which to recruit [55]. We will employ a cascaded recruitment strategy, which we have used successfully in other studies, to recruit 30 CBT-trained clinicians who treat study-eligible patients (i.e., age 14 or older, in keeping with the local age of consent for mental health services; are already identified as appropriate for CBT, and have already identified telehealth as the preferred mode of therapy delivery). In this cascaded approach, we then will work with clinicians to select 2 patients with whom they plan to use CBT. The clinicians will approach those patients about participating in the study. If a clinician has more than 2 patients with whom they plan to use CBT, we will randomly identify 2 from the larger pool of possible patients for the clinician to approach for study participation. After obtaining informed consent, clinicians will be randomized to either the Tele-BE or Tele-AU condition. All study procedures will be identical for both conditions. The only difference is the Tele-BE condition will be asked to use the new telehealth tool and the Tele-AU condition will use the telehealth methods set by their providing organization. All sessions will be video-recorded via their assigned telehealth platform using encrypted, HIPAA-compliant technology. Clinicians and patients will complete questionnaires at four time points: baseline/week 1, week 5, week 9, week 12, and a qualitative interview at post-trial (Table 2).

Table 2. Aim 3 & Aim 4 trial assessment schedule.

Outcome	Measure	Tele-BE												Post
Aim 3 Primary Outcomes		1	2	3	4	5	6	7	8	9	10	11	12	
Structural Component Fidelity	CTRS, ⁶⁵ Web analytics	*	*	*	*	*	*	*	*	*	*	*	*	
Aim 3 Secondary Outcomes														
Clinician Intentions	Established stems ⁶⁷	*				*				*				*
Clinician Attitudes	Established stems ⁶⁷	*				*				*				*
Clinician Norms	Established stems ⁶⁷	*				*				*				*
Clinician Self-efficacy	Established stems ⁶⁷	*				*				*				*
Aim 4 Primary Outcomes														
Acceptability	AIM, ⁶⁶ Interview	*				*				*				*
Feasibility	FIM, ⁶⁶ Web analytics	*				*				*				*
Usability	SUS	*				*				*				*
Aim 4 Secondary Outcomes														
Patient Symptoms & Functioning	PHQ-8, GAD-7, WHODAS 2.0, DSM Level 1	*				*				*			*	
Therapeutic Alliance	WAI-SF (therapist), WAI-SF (client) ⁶⁹	*				*				*			*	
Additional Constructs of Interest														
Contextual Factors	Qualitative interview													*
Clinician & Patient Demographics	Demographics survey													
Supervision Practices	Adapted SerTIFY-Supervision Form	*												*
Clinician social desirability	Edward's Social Desirability scale	*												
Tele-BE Costs	Qualitative interview, web analytics													*

Note: CTRS = Cognitive Therapy Rating Scale. AIM = Acceptability of Intervention Measure. FIM = Feasibility of Intervention Measure. SUS = System Usability Scale. PHQ-8= Patient Health Questionnaire-8 item. GAD-7: Generalized Anxiety Disorder-7. WAI-SF = Working Alliance Inventory-Short Form. SerTIFY= Self-reported therapist intervention fidelity for youth -supervisor.

Clinicians will be compensated \$150 for completing study measures (\$50 for Week 1 and Post, \$25 for Weeks 5 and 9); patients will be compensated \$5 per session for providing brief self-report data and allowing their sessions to be recorded for research, for a maximum of \$60; those completing qualitative interviews will receive an additional \$25. Clinicians and patients in both

conditions will follow the same study activity schedule, and complete the same assessment battery, except that participants assigned to the Tele-BE condition will also be asked to complete condition-specific qualitative interview questions. Compensation rates are comparable to our prior work.

Quantitative Measures: Aim 3 Primary Outcomes

Aim 3 primary outcomes are clinician fidelity to structural components, which we will measure by coding all recorded therapy sessions (a maximum of 720 coded patient sessions; 60 patients x 12 sessions) for the presence of six structural components: 1) discussion or review of patient symptoms, 2) homework review, 3) agenda setting, 4) skill instruction or review, 5) skill practice, and 6) out-of-session practice (“homework”). We will code using items from the Cognitive Therapy Rating Scale (CTRS), a gold-standard CBT fidelity measure with 11 observer-rated items, including items indexing specific structural components of interest (homework review and planning, agenda-setting, skill instruction, and skill practice [56]). Each item is scored on a 7-point Likert scale, ranging from 0 (*Poor*) to 6 (*Excellent*), which lets us define fidelity in two ways: 1) the presence or absence of each component, and 2) whether each component is present above a competency threshold (i.e., score of 4 or higher). Our primary interest is in the presence/absence of each component; we will calculate the sum of the total binary outcomes indicating presence/absence of each component. We will look at presence above competency threshold as a secondary outcome. The CTRS has strong internal consistency and interrater reliability [56], and strong interrater agreement for the general competency aspect [32]. Importantly, the CTRS has a subscale that assesses structural competency [31], in addition to specific structural components, and an overall competency score.

Given the volume of recorded sessions, CTRS scores will be generated for each recorded session using the Lyssn platform. *Lyssn.io* (or Lyssn, pronounced ‘listen’) is a technology start-up deploying artificial intelligence (AI) technologies to support training, supervision, and quality assurance of EBPs. Lyssn’s established cloud-based platform includes a) user management and organization of sessions, clinicians, and supervisors; b) recording, playback, and annotation of audio

or video from therapy sessions; c) speech-to-text transcription; d) AI-generated fidelity and quality metrics; and e) data summaries and visualizations for feedback. Session recordings are automatically transcribed via Lyssn's speech recognition algorithms, which was trained on over 4,000 sessions [57–59]. Using transformer-based, deep neural networks [60], Lyssn developed AI-generated models for the 11 CTRS codes specifically using 2,494 sessions and related CTRS ratings (within a cross-validation framework of test and training partitions [61,62]). Based on a 30% test set of sessions that were distinct from the training set where models were originally developed and fit, results demonstrated very strong signal and prediction. In all but one instance (Understanding, which is not a structural component of interest for this study), AI-generated predictions crossed the 80% of human reliability threshold. Using AI-generated metrics, the tools achieved 100% of human reliability on the total score and also demonstrate highly accurate individual item reliability. Lyssn has a standing in-house coding team that continuously provides new validation and calibration data to assess the ongoing performance of the AI algorithms.

While CTRS scores will serve as our primary fidelity metric, we also will examine self-reported fidelity to CBT structural components within the Tele-BE condition only, using web analytic data collected through the developed platform. As clinicians engage with the Tele-BE platform, they will be asked to check off each structural component as they complete it in session or indicate that they intentionally chose to override the checklist and not administer a specific component (see Figure 1). We thus will have self-reported data of structural component use for every recorded patient session for clinicians in the Tele-BE condition through web analytic data. This will enable us to compare self-reported data to the CTRS scores Lyssn generates and gather specific data on how and when clinicians override the Tele-BE infrastructure to inform Aim 4 acceptability.

Quantitative Measures: Aim 3 Secondary Outcomes

Secondary outcomes are our target implementation mechanisms that align with our theorized mechanisms of action: intentions to use structural components of CBT and determinants of intentions

(Table 1). We will measure the strength of intentions separately for each structural component of interest using established item stems from social psychology designed to be adapted to any behavior of interest [63]. Intentions are measured with two items on a 7-point scale that ask how willing and likely one is to use each component. Higher scores represent stronger intention. For each component, the two items will be averaged. To assess determinants of intentions, attitudes towards each component will be measured by four standard semantic differential scales [49,64] (e.g., a 7-point scale ranging from “extremely unpleasant” to “extremely pleasant” or from “extremely wise” to “extremely foolish”). The total scale score will be computed by averaging all z-standardized items within each structural component (higher score indicates more favorable attitude). *Norms* will be measured via two standard item stems regarding the perception that “other people like me” will use the component, and that other people who are important to them (e.g., supervisors) will approve of them using it, rated on a 7-point scale of degree of agreement. *Self-efficacy* will be measured via responses to three statements on a 7-point scale about clinicians’ perceptions of themselves as having the ability to perform each component (e.g., degree of agreement with the statement, “If I really wanted to, I could use an agenda”). All items will be asked separately for each structural component and aggregated for primary analysis; exploratory analyses will examine variation by component.

Quantitative Measures: Aim 4 Primary Outcomes

Primary outcomes for Aim 4 include Tele-BE acceptability, feasibility, and any potential ethical concerns held by clinicians and patients about the Tele-BE platform. Tele-BE acceptability will be assessed via the Acceptability of Intervention Measure (AIM) [52]. We will use a combination of the Feasibility of Intervention Measure (FIM) [52] and web analytics to examine feasibility. We also will examine Tele-BE usability via the System Usability Scale (SUS) [53]. Psychometric support for these measures is described above under Aim 1 activities. Each of these measures will be administered to clinicians in both conditions to facilitate comparison of quantitative scores of acceptability and feasibility between conditions. Measures of acceptability and feasibility

will be supplemented by clinician and patient interviews; interviews also will assess for potential ethical concerns related to any pressure from the platform clinicians felt to deviate from care they felt was in the best interest for their patients.

Quantitative Measures: Aim 4 Secondary Outcomes

Aim 4 secondary outcomes include patient-level outcomes, including therapeutic alliance, symptoms and functioning, and treatment satisfaction. During the trial, we will measure therapeutic alliance every 4 weeks from the patient and clinician perspective for all patients, using parallel versions of Working Alliance Inventory-Short Form (WAI-SF), a validated measure that asks respondents to rate 12 items about their perceptions of their therapeutic relationship using a 5-point Likert scale [65]. Patient symptoms will be measured with the DSM Level 1 Cross-Cutting Symptom Adult Measure [66] (23 questions rated on a 5-point scale, 0=None, Not at all to 4=Severe, Nearly every day, covering 13 domains), the Patient Health Questionnaire [67] (PHQ-8, 8-item measure on a 4-point scale from 0=Not at all to 3=Nearly every day, which measures patient's depressive symptoms), and the General Anxiety Disorder Scale (GAD-7, 7-item measure on a 4-point scale from 0=Not at all to 3=Nearly every day, which measures patient's anxiety symptoms) [68]. These measures are completed by patients at 4-week intervals. We will use the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) [69], a 12-item measure on a scale from 1 (None) to 5 (Extremely or cannot do) that measures a patient's health and mental health difficulties across 6 domains (cognition, mobility, self-care, getting along, life activities, participation), to describe patient functioning. This measure is completed at weeks 1, and 12. Questionnaires will be sent electronically for patients to complete at the established intervals by research staff. Patient satisfaction, including any potential perceived ethical concerns with their clinician using Tele-BE, will be assessed qualitatively in a subsample of patient participants.

Quantitative Measures: Additional Constructs

We additionally will quantitatively assess: (1) supervisory practices, (2) clinician social

desirability, and (3) cost of Tele-BE. We will measure clinician report of CBT-specific supervisory practices at weeks 1 and 12 to identify any between condition differences in CBT supervision. We adapted the Self-reported Therapist Intervention Fidelity for Youth Supervision (SeRTIFY), a supervisor-report of supervisory practices, to be inclusive of clinicians who see adult clients and to prompt about supervision practices as they relate to CBT structural components. The resultant 14-item measure is rated on a 7-point scale for the extent to which supervisory techniques are used (1=not at all; 7=extensively). The 17-item Edward's Social Desirability scale will be included in the baseline clinician survey battery as a possible covariate of clinician reported engagement with the Tele-BE platform [70]. Finally, we will track the following cost metrics that will allow us to conduct more formal cost evaluations in subsequent studies: (1) anticipated annual cost per clinician user to use Tele-BE and how anticipated costs vary based on number of patients with whom Tele-BE is used; we will calculate this in collaboration with our web development team to ensure cost estimates account for ongoing web maintenance in addition to base subscription estimates, (2) amount of time needed to train clinicians to use Tele-BE; while anticipated to be minimal, we will track this per clinician and calculate an average at the conclusion of the study period, and (3) time clinicians spend logged into the Tele-BE interface, via web analytics.

Qualitative: Clinician Interviews (Aim 3 and 4)

All clinicians, regardless of condition, will complete interviews after their patients complete the trial period. The first portion of the interview will be identical for all clinicians and will query about perceptions of intentions and determinants of intentions to use structural components of CBT over the trial period; this will address Aim 3 questions related to engagement of target mechanisms. We will adapt questions from an established theory-guided qualitative interview [71] that includes questions about attitudes toward an EBP of interest, self-efficacy, norms, and motivation. Questions will be asked separately for each structural CBT component of interest (see Table 1). We also will ask all clinicians about barriers they faced over the trial period to using structural components,

including specific probes about how perceived cognitive burden influences use (e.g., “To what extent, if at all, did factors like forgetting due to competing demands make it easier or harder for you to set an agenda?”). Asking these questions to all clinicians will allow us to examine themes by condition to see if Tele-BE better engaged target mechanisms of interest and led to fewer barriers related to structural component delivery. The second portion of the interview will be administered to clinicians randomized to Tele-BE only to address Aim 4. This portion will query about acceptability of Tele-BE and any feasibility issues that arose. Questions may include, “How was your experience with Tele-BE? What aspects were easy/hard to use?” We also will examine self-reported fidelity collected via web analytics to ask specific questions of all clinicians about how clinicians made decisions to act on or override Tele-BE nudges (e.g., indicated that they elected not to review a planned homework) and their rationale for doing so, along with any ethical concerns they feel themselves, their colleagues, or their patients might raise (e.g., any undue inducement to deliver structural CBT components or concerns Tele-BE will negatively impact treatment processes). Finally, we will query clinicians about any unanticipated resources required to engage with Tele-BE and ask them to estimate the extent to which Tele-BE influenced their time required to prepare for or document a therapy session to inform our cost estimates.

Qualitative: Patient Interviews (Aim 4)

We will randomly select one patient per therapist to participate in a qualitative interview at the end of the 12-week trial period. Should a patient decline, we will select the second patient per therapist, with the goal of having one patient per therapist complete an interview. In the first half of every interview, research staff will begin by querying patients about their perception of the therapeutic relationship during the trial period (including any changes from prior to the trial), their satisfaction with services received over the preceding 12 weeks, and perceived effectiveness of psychosocial treatment. This will allow us to look by condition to examine whether themes related to treatment processes vary by whether the clinician used Tele-BE or Tele-AU. In the second half of the

interview, staff will query patients about their awareness and perception of Tele-BE or Tele-AU on clinician behavior. Then, staff will present information about Tele-BE and ask patients about their perceived likes and dislikes associated with their clinician utilizing an enhanced telehealth interface to deliver care.

Preliminary Analyses

Data screening and missing data analysis will be conducted in accordance with best practices. We will examine the psychometric properties of all scales used to assess constructs of interest (e.g., coefficient alpha) to confirm adequate psychometric performance. We will conduct analyses of baseline variables as a randomization check to ensure comparable baseline characteristics for clinicians in Tele-BE and Tele-AU. We will examine the sensitivity of our main comparisons to medium-to-large effect size imbalances between the randomized groups

Quantitative analyses

Aim 3 primary analyses will examine structural component scores on the CTRS generated through the Lyssn platform dichotomized as present/absent, with an aggregate fidelity metric for each session that sums the number of components present. We will use a linear mixed effects regression model to estimate the time course of completion scores across the 12 weeks of treatment. For fixed effects, we expect linear and quadratic time trends will capture the overall trajectory over the 12 weeks, but we will examine more flexible specifications if necessary. To accommodate correlations induced by patients nesting within clinicians, we will include a random intercept for clinician, and we will include correlated residuals to account for further within-patient correlations across time. The model will use data from all 12 sessions and will provide estimates of time trends and of session means and standard errors for all 12 sessions; in addition, it will also provide monthly estimates to facilitate comparison with the monthly participant responses. As described above, we can also create a separate overall structural component sum score for each session by summing the total structural components “completed at/above satisfactory threshold” on the CTRS. If there is

sufficient variability in responses, we will model time course using mixed effects models like those described above. If the range on this score is too narrow, we will use mixed effects ordinal regression models, with fixed and random effects specified as described above. All analyses will include patient demographics as covariates (i.e., age, diagnosis). In addition to these CTRS-based measures of fidelity, we will also have measures of self-reported fidelity for the intervention group, based on web analytic data. The primary response will be a continuously distributed measure that parallels that obtained by the CTRS (i.e., sums the number of structural components rated as present); we will use a bivariate-response mixed effects model, with the CTRS and web-based measures as responses for each of the 12 weeks, to compare the measures in terms of overall levels and trend across time.

To examine secondary outcomes (intentions and determinants of intentions), we will examine monthly trends in clinician measures of intentions, attitudes, self-efficacy, and social norms, using similar models to those described for the fidelity measures. The main distinction between the models will be that we will use a categorical variable for time, as there are now three time points instead of 12.

Missing Data Considerations

Based on our ongoing prospective community mental health studies of comparable length of follow-up [72], we anticipate a clinician dropout rate of 20% over 12 weeks, with a low rate of patient dropout from retained clinicians as patients are part of the clinicians' established caseloads. The mixed effects models described above will yield valid estimates and standard errors if the dropout is ignorable (e.g., depends only on observed outcomes and participant characteristics). We will perform additional analyses to assess the sensitivity of our main results to this ignorability assumption. Given the sample size, we will focus on overall completion of the 12 weeks. We will use logistic regression models to examine whether prior outcomes, or baseline variables, are individually related to completion, and will combine variables that show strong relationships with completion into a multiple logistic regression model predicting completion. Based on the participant-level estimates

of dropout from this model, we will perform exploratory, inverse probability weighted versions of the main mixed effects models and compare the estimated intervention effects from the two sets of models.

Qualitative and Mixed-Methods analyses

All interviews will be audio-recorded and transcribed for thematic analysis to complement quantitative data to examine engagement of target mechanisms (Aim 3), acceptability and feasibility of Tele-BE, and any concern for ethical issues with Tele-BE (Aim 4). Given our specific interests in understanding how clinicians and patients respectively experience Tele-BE, clinician and patient interviews will be analyzed separately. Qualitative coding for both clinician and patient interviews will be divided into six stages. First, the coding team will familiarize themselves with the data by reading transcripts of all interviews and noting reactions to interviews. Coding team members will debrief and share their notes after reading all transcripts. Second, the coding team will create an initial set of codes by engaging in line-by-line open coding of two randomly selected transcripts. Coding team members will separately code transcripts, then reconvene to compare codes, and reach consensus on codes from the two transcripts. Consensus coding facilitates trustworthiness in data analyses and helps to account for values and biases that impact the coding process [73]. As coding team members are reviewing the two transcripts, they will create a codebook documenting code descriptions to facilitate organization and reflection of codes. We anticipate that the codebook will be guided by a mix of both *a priori* areas of interest (e.g. impact of Tele-BE on motivation to use structural components, acceptability of Tele-BE, impact of Tele-BE on reducing cognitive burden associated with CBT delivery) and those themes that emerge from the data. Following codebook creation, the coding team will separately code all remaining transcripts line-by-line, compare codes, and reach consensus on all codes. The coding team will iteratively update the codebook as new codes arise to reflect new clinician and patient experiences that arise in interviews. Third, the coding team will cluster codes together based on shared patterns in content and generate themes that describe

these patterns. Fourth, the coding team will compare the themes with quotes from the coded data to ensure that the themes accurately reflect participant experiences. The coding team will also refine themes by consolidating similar themes and separating broader themes into subthemes. Fifth, the coding team will finalize names and descriptions associated with themes and subthemes. Finally, the coding team will present findings from themes and subthemes using examples from the coded data. To further promote trustworthiness in qualitative findings, coding team members will keep analytic memos on thought processes surrounding codes, subthemes, and themes to facilitate conversations about how values and biases, particularly about Tele-BE, may have informed their codes.

We then will conduct mixed methods analyses in accordance with best practice recommendations to contextualize findings from our quantitative analyses and facilitate interpretation of our quantitative data [74–76]. We will compare qualitative themes among therapists with low, medium, and high fidelity in Tele-BE surrounding any overriding of the Tele-BE nudges, ease of use, and any ethical concerns that arise. Furthermore, we will examine how patient ratings of therapeutic alliance are informed by patients' qualitative experiences with working with therapists using Tele-BE and differences in themes in patients' qualitative experiences among therapists with low, medium, and high fidelity to structural components in Tele-BE.

Progression Criteria

We will examine acceptability and feasibility data, as well as trends in observed fidelity to determine whether pilot trial results support the notion of progressing to a larger, confirmatory trial. For acceptability and feasibility, we will descriptively compare mean AIM and FIM scores between Tele-BE and Tele-AU clinicians; comparable scores between conditions would indicate the utility of progressing. If Tele-BE scores are significantly lower than those within the Tele-AU condition, this would raise concerns about its acceptability and feasibility. With respect to fidelity, we will be looking to see: 1) trends toward greater use of structural components as measured by the CTRS in the Tele-BE condition relative to Tele-AU, or 2) increased motivation to use CBT structural

components in Tele-BE relative to Tele-AU emerge in our qualitative analysis.

Data Safety and Monitoring

We will convene a three member DSMB that consists of an independent group of experts with no professional or financial conflict of interest with the research project or study investigators. The DSMB will be charged with reviewing study data for data quality and integrity, adherence to the protocol, participant safety, study conduct and progress, and making determinations regarding study continuation, modifications, or suspensions/terminations. The DSMB will meet before any patients are enrolled in the study (i.e., prior to Aim 2) and annually thereafter for the duration of the project.

Results

The study received NIMH funding in June 2024. Recruitment for Aim 1 started in October 2024. As of March 2025, we recruited 6 participants in the initial development stage. Recruitment is ongoing and we anticipate Aim 1 will be completed in May 2025 at which point we will prepare for study activities in Aim 2. We aim to have all study collected by the end of 2026. Per the terms of our grant award, we will submit de-identified study data collected in Aims 3 & 4 to the NIMH Data Archive for participants who consent to data sharing.

Discussion

Contribution to Existing Work

The rapid expansion of telehealth [3] presents opportunities to directly address the infrastructure of the therapy environment via technology in a way that was previously unavailable due to the “closed door” and solitary nature of therapy. This pilot randomized hybrid effectiveness-implementation clinical trial will develop and evaluate the initial acceptability and feasibility of a novel telehealth tool intended to improve clinician fidelity to CBT structural components. Telehealth has long been touted as a way to enhance patient access to CBT by expanding access to CBT providers, but the associated technology has not yet been leveraged to increase clinicians’ use of EBPs. To our knowledge, this is the first attempt to leverage the infrastructure of telehealth platforms

to enhance clinician delivery of EBPs, rather than conceptualize telehealth primarily as a medium that approximates traditional face-to-face therapy. This is also one of the first efforts to apply and evaluate the success of BE strategies for a psychosocial EBP. Our focus on the cross-cutting, transdiagnostic structural elements of CBT, rather than diagnosis-specific protocols or intervention techniques (e.g., exposure therapy) is also unique. BE strategies are best suited for changing discrete provider behaviors (e.g., changing medication prescriptions for specific disorders, increasing depression screening rates) that are observable and measurable [15,77], and CBT structural components (e.g., agenda setting) share these attributes. This enables us to directly target clinician behaviors through Tele-BE that are theoretically aligned with BE-informed implementation strategies and will set the stage for future research that layers implementation strategies targeting specific interventions on top of those addressing structural components.

Design Considerations

First, we considered linking our trial phase to sessions attended, rather than weeks; but most outpatient sessions are designed to occur weekly and no-show rates are lower over telehealth [78]. No-show rates will inform future trial design. We considered focusing on a broader set of EBPs that include structural components (e.g., dialectical behavioral therapy) but focused on CBT due to its rollout within our partner public health system and to maintain more specificity in our patient population. We will examine other EBPs in future work. We considered including supervisors in Aims 2-4; however, we chose to prioritize initial testing with our direct end-users (therapists and patients). We ensure supervisor representation in Aim 1 design and ask clinicians to report on supervisory practices in the clinical trial; our follow-up trials will more formally include supervisors. We also considered limiting inclusion criteria to certain patient diagnoses in our clinical trial; however, given our focus on transdiagnostic CBT, we felt this was better suited to subsequent trials. Finally, we considered more formally measuring organizational constructs (e.g., organizational culture and climate) during our pilot trial; however, our focus in this pilot project is to address our

target mechanisms of action via the BE strategies. Ultimately, we imagine that Tele-BE will be rolled out as part of larger organizational quality improvement efforts as an organizational-level implementation strategy; as such, these constructs will be important in larger confirmatory trials of Tele-BE.

Future Directions

In addition to next steps including a fully powered evaluation of Tele-BE, future studies will extend Tele-BE use to other EBPs that employ structural components and examine the durability of BE strategies (i.e., do effects persist over time), the generalizability of effects (e.g., will increases in fidelity generalize to in-person sessions conducted by the same clinicians, will use of Tele-BE ultimately improve patient outcomes), and test strategies to scale-up Tele-BE, should it prove effective. This work also will set the stage for future research to test whether targeting structural components, rather than CBT broadly, is a more efficient way to improve fidelity across CBT protocols (and eventually, other EBPs that contain structural components, such as dialectical behavior therapy). Such work also has potential to advance the CBT and implementation science field by enabling disaggregation of treatment effects associated with structural component from intervention technique fidelity. We also will explore other strategies to leverage the telehealth infrastructure to make it easier and more motivating for clinicians to deliver evidence-based care, such as embedding links to CBT worksheets or tip sheets/session guides for common CBT skills delivered in session. Of note, Tele-BE is intended to address some, but not all, of the barriers clinicians face in delivering CBT. The nudge approach proposed here represents a low-cost, low-barrier method with substantial potential to increase clinician fidelity to a point that it will meaningfully improve clinical outcomes.

Conclusions

This study will yield insight into the potential of leveraging the telehealth infrastructure to improve CBT fidelity by integrating BE strategies into the telehealth interface. Should this study

produce promising results, this work will lead to large-scale testing of Tele-BE to improve clinician CBT fidelity and patient outcomes across mental health settings providing telehealth services.



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Author Contributions

EBH, TC, DSM, and KL conceptualized the study. PK, MB, and SY provided meaningful contributions to study design. EBH and TC wrote the initial draft of this manuscript. All others reviewed the manuscript, provided input, and approved the version submitted for publication. Funders were not involved with the writing of this report.

Conflicts of Interest

Torrey Creed is an advisor with an equity stake in Lyssn.io. All other authors have no competing interests to report.

List of Abbreviations

AIM: Acceptability of Intervention Measure

BE: Behavioral Economics

BENEFITS: BEhavioral Nudges to Enhance Fidelity in Telehealth Sessions

CBT: Cognitive behavioral therapy

DSMB: Data and Safety Monitoring Board

EBP: Evidence based practice

FIM: Feasibility of Implementation Measure

Tele-AU: telehealth as usual

Tele-BE: Behavioral economics informed telehealth platform

RCT: Randomized controlled trial



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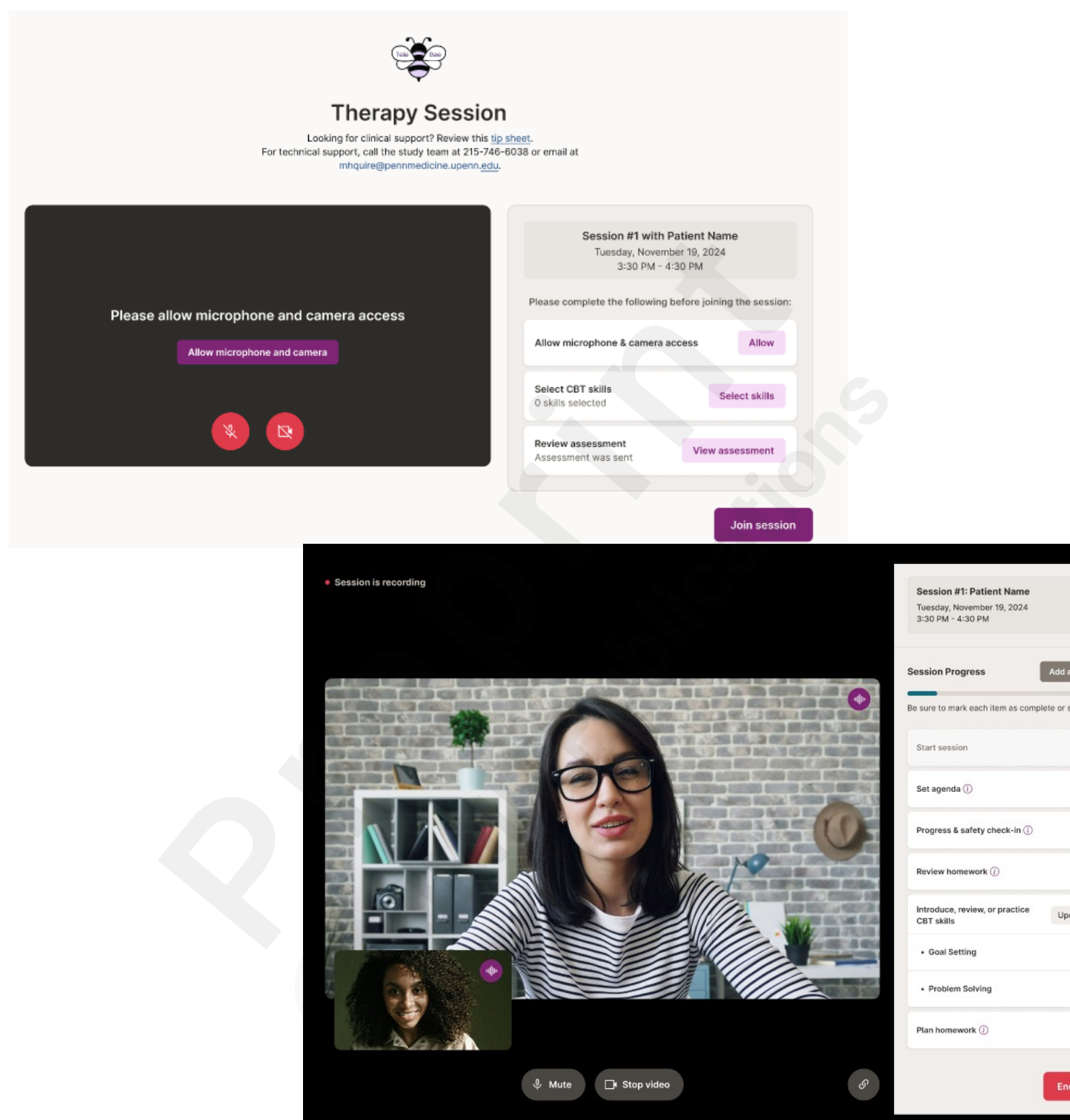
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Figure 1. Prototyped Mock-Up of Tele-BE

Supplementary Files

Multimedia Appendixes

Documentation of peer review through NIMH - privileged communication, not to be published.

URL: <http://asset.jmir.pub/assets/3a6fc4a25716b3c68a974fc052505ace.pdf>

CONSORT (or other) checklists

SPIRIT Checklist.

URL: <http://asset.jmir.pub/assets/118ba02d736ac362477cc58366f5b2cc.pdf>