Harnessing human-centered design for the redesign of psychosocial interventions and implementation strategies within communities: UW ALACRITY Center study protocol

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Abstract

Background: Although substantial progress has been made in establishing evidence-based psychosocial clinical interventions and implementation strategies (CIs/ISs) for mental health, translating this research into practice—especially in more accessible, community settings—has been slow. We outline our protocol for the renewal of the National Institute of Mental Health-funded University of Washington ALACRITY (Advanced Laboratories for Accelerating the Reach and Impact of Treatments for Youth and Adults with Mental Illness) Center, which draws from human-centered design (HCD) and implementation science to improve implementation of CIs/ISs.

Objective: UW ALACRITY Center's second iteration of funding (2023-2028) focuses on using the Discover, Design/Build, Test (DDBT) framework to address three priority CI/IS mechanisms (usability, engagement, and appropriateness), which we identified as challenges to implementation and scalability of CIs/ISs during the first iteration of center funding. Local redesign teams work collaboratively and share decision-making to carry out DDBT. We expect DDBT to result in changes to the CI/IS mechanisms, proximal implementation outcomes (adoption, fidelity, reach, adaptation), and clinical outcomes.

Methods: We will provide research infrastructure to one large effectiveness study and three exploratory pilot studies as part of the center grant. At least four additional small pilot studies will be solicited and funded by the center. All studies will explore the use of DDBT to: (1) Identify CI/IS modification targets to improve usability, engagement, and appropriateness in accessible non-specialty settings (Discover phase); (2) Develop redesign solutions with local teams to address CI/IS modification targets

(Design/Build phase); and (3) Determine if redesign improves usability, engagement, and appropriateness (Test phase), as well as implementation outcomes. Center staff will collaborate with local redesign teams to develop and test CIs/ISs for community settings. We will collaborate with teams on the use of methods and center-wide measures that facilitate cross-project analysis of the effects of DDBT-driven redesign on outcomes of interest.

Results: All four core studies received institutional review board (IRB) approval in February 2023, and each pilot project will pursue IRB approval when awarded.

Conclusions: During the first iteration of the center, we established that DDBT is a useful approach to systematically identify and address chronic challenges of implementing CIs/ISs. In this subsequent grant, we expect to increase evidence of DDBT impact by expanding: (1) a list of common challenges of CIs/ISs that could benefit from modification, (2) a list of exemplary solutions to address these challenges; and (3) guidance on using the DDBT framework. These resources will contribute to broader discourse on how to enhance implementation of CIs/ISs that integrate HCD and implementation science. Clinical Trial: Individual studies are registered upon initiation. At the time of publication, there are two studies registered: ClinicalTrials.gov NCT06494384 and NCT06508515.

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Keywords:
implementation science; human-centered design; evidence-based psychosocial interventions; mental health

Contribution:
All authors contributed to study concept and design. ARL, SAM, MDP are center Co-Directors and created the protocol for the Methods Core with contribution from authors. MDP led statistical analysis planning. TA developed the manuscript outline and ARL, SAM, BNR, and TA drafted the manuscript with contributions from all authors. All authors are contributing to the conduct of the studies and have read and approved the final manuscript for publication.

Introduction

Background

Psychosocial clinical interventions (CIs) such as psychotherapy, counseling, and case management are a preferred mode of treatment by most people seeking care for mental health problems [1–5]. Access to evidence-based CIs remains variable among diverse groups, leading to mental health disparities across racial/ethnic, geographic, and socioeconomic status [6–16]. Furthermore, there is mixed success in implementing CIs in nontraditional and integrated settings (e.g., primary care, virtually, schools), which can serve as a "safety net" for obtaining mental health treatment when traditional settings are inaccessible [17–20]. Addressing barriers to implementing CIs in these settings is vital to promote more equitable access to mental health services for all.

Poor availability of CIs is due to intervention complexity and suboptimal fit with many settings where CIs are deployed [21]. Implementation strategies (ISs)—"systematic intervention process(es) to promote the uptake of evidence-based health innovations into usual care"—have often taken the form of complex tools and processes (e.g., train-the-trainer, booster training, incentive models, and decision supports) [22,23] However, these often fall short because they can be excessively costly and cumbersome [22,24]. Different needs of recipients and settings can lead to high rates of reactive adaptations of CIs/ISs by their intended users in many settings where they are deployed. Reactive adaptations are unplanned or improvised changes during an implementation process in response to unanticipated challenges [25]. While reactive adaptations can compromise clinical potency, those that are proactively tailored to different care settings can improve sustainability and impact [26–29]. A systematic review of cultural adaptations to health and mental health services highlighted how adaptations motivated by cultural sensitivity are not guaranteed to demonstrate increased efficacy [30]. Instead, patient-centered approaches that account for individualized needs and barriers to service are recommended to guide adaptions [30,31].

Human-centered design (HCD) and Implementation Science

Human-centered design (HCD) and the closely related discipline user-centered design offer a suite of methods to develop useful, compelling, intuitive, and enjoyable products, services, and tools based on people's needs [32,33]. HCD relates to the evolution of human-computer interaction (HCI), a multidisciplinary field that incorporates computer science, cognitive science, and human factors engineering as a response to personal computing, collaborative work, and interconnected technologies in everyday life [34]. While HCD's origins are rooted in technology, it has been used beyond the context of digital technologies to address therapeutic elements and implementation supports [35]. HCD has been applied to improve usability, reduce burden, and increase the contextual appropriateness of CIs/ISs [36–40].

The fields of HCD and implementation science share common objectives and offer complementary methods that can support CIs/ISs innovation and redesign [41–44]. HCD techniques are particularly well-positioned to help with redesign, which we define as modifications to CIs/ISs while preserving proven effective components (i.e., fidelity-consistent adaptation) [45]. HCD's traditions of situating problem discovery and solutions in user needs, usability, engagement, innovation, and rapid exploration are core strengths that align with implementation science's goal of translating CIs/ISs into adoption [41]. Combining HCD and implementation science traditions for CI/IS redesign grounds novelty in empirical evidence.

Integrating HCD and IS through the Discover, Design and Build, and Test (DDBT) framework

The University of Washington ALACRITY (Advanced Laboratories for Accelerating the Reach and Impact of Treatments for Youth and Adults with Mental Illness) Center (UWAC), which is funded by a grant from the National Institute of Mental Health (NIMH), is a multidisciplinary team of experts from mental health, implementation science, and HCD focused on improving usability, engagement, and appropriateness of CIs/ISs in diverse and non-specialty settings (e.g., rural, urban, low-income, primary care, schools). Drawing on strengths from different disciplines, UWAC developed the *Discover, Design and Build, and Test* (DDBT) framework (**Figure 1**) at the start of the center ("UWAC 1.0"). The DDBT framework guides teams in redesigning CIs/ISs to improve usability, engagement, appropriateness, and implementation outcomes while preserving CIs' core components [46]. Key to this model: 1) not all CIs/ISs are designed for all settings, 2) "there is no implementation without adaptation" [45], 3) unchecked, reactive adaptations have the potential to exclude essential active ingredients [47,48], and 4) reactively adapted CIs/ISs can negatively impact implementation and clinical outcomes.

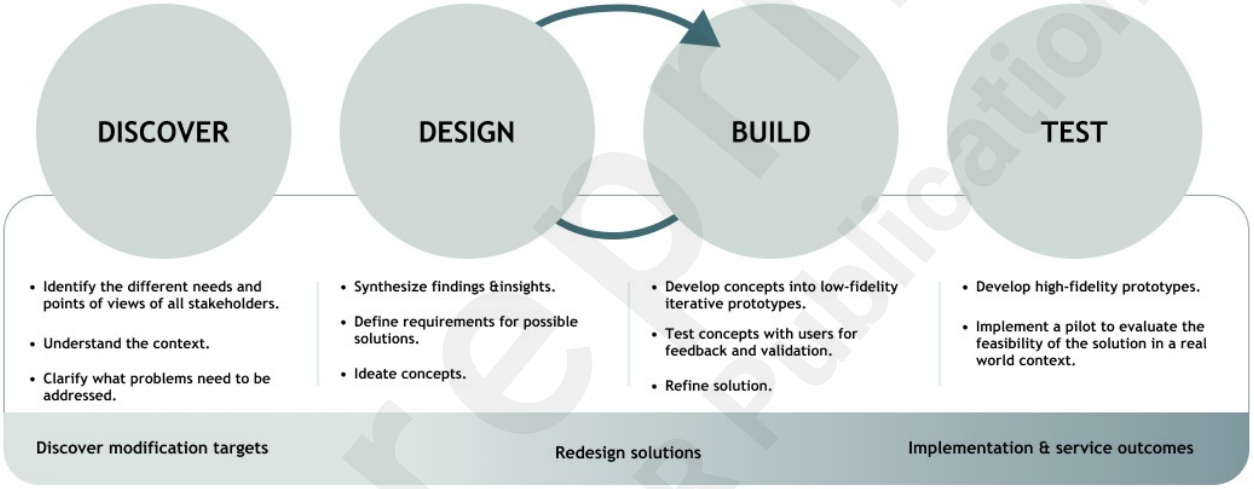

Figure 1. DDBT Redesign Framework

The DDBT framework is modeled after existing HCD frameworks [49] and is an iterative stepped approach to systematically: 1) understand usability constraints of existing CIs/ISs; 2) iteratively design solutions for usability challenges with redesign teams (composed of local community collaborators and researchers) of direct and indirect users; and 3) test and refine prototypes. DDBT starts by identifying multilevel factors that drive CI/IS usability problems, engagement challenges, and problems with contextual appropriateness (**Discover phase**). Once problems and challenges are identified, modifications are iteratively created between the design team and practitioners/clients, until a new version of the CIs/ISs are developed to address crucial issues and enhance usability, engagement, and appropriateness (Figure 2) (**Design/Build phase**). Early prototypes of CIs/ISs are assessed with small samples (e.g., 5 to 25 participants) to answer design questions using paper or other "low-fidelity" (i.e., sufficient to communicate a concept but potentially lacking functionality, some content, and/or look/feel of final materials) versions of modifications, which reduces waste of unnecessary investment in programming and development until as late in the process as possible. Design/Build phase prototypes are then tested against the original version to ascertain if the modified CIs/ISs result in improved implementation (e.g., increased **adoption**, **fidelity**, **reach**, and reduced **reactive adaptations**), and equivalent or better mental and behavioral health outcomes because of the changes to usability, engagement, and appropriateness (**Test phase**). Additional detail on the

DDBT framework is outlined in our UWAC 1.0 protocol paper [46].

All UWAC research uses the DDBT framework, which is applied flexibly based on project needs and allows us to evaluate the extent to which incorporating HCD and implementation science methods impact CIs/ISs. Since 2018, DDBT has been used in over 18 UWAC studies and 16 National Institutes of Health (NIH)-funded awards external to UWAC. During UWAC 1.0, we originally assessed impact of DDBT on three mechanisms: **learnability** (i.e., extent to which users can understand or facilitate use) [46], **usability** (i.e., extent to which users can achieve specified goals of effectiveness, efficiency, and satisfaction) [49], and **sustained quality of care** (i.e., extent of treatment fidelity and impact on target outcomes) [46]. Analysis of UWAC 1.0 projects resulted in a) identification of common usability issues in CIs/ISs that could benefit from modification (i.e., "Typology of Modification Targets") and corresponding heuristics to guide their design [50], b) reflections on potential exemplary solutions to these challenges (i.e., Library of CIs/ISs Redesign Solutions), and c) guidelines for using the DDBT framework [46].

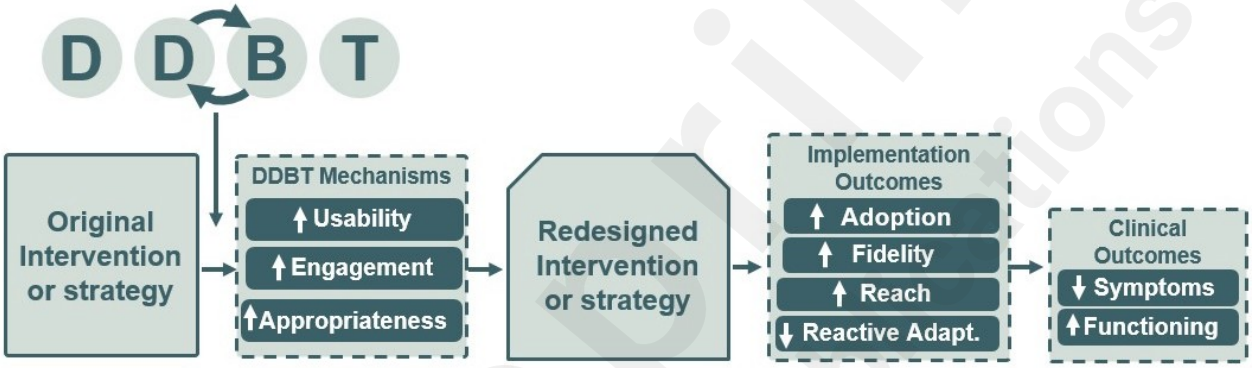

Figure 2. UWAC Theory of Change for CIs/ISs Redesign

Our UWAC 1.0 findings and the implementation literature [21] outline how limited availability and use of CIs/ISs are persistently attributable to organizational and system characteristics (e.g., readiness to adopt, system resources and culture, leadership), clinician/adopter characteristics (e.g., appropriates and perceived efficacy of CIs/ISs for the patients they serve) [28,51,52], and incentives to engage in CIs/ISs [29,53].

As a result, we updated DDBT's underlying theory of change to highlight how adoption of CIs/ISs are largely due to **usability** (e.g., extent to which CIs/ISs can be used by specified users to achieve specified goals of effectiveness, efficiency, and satisfaction) [50], **engagement** (e.g., degree of user participation and enthusiasm for the aspects of CIs/ISs that require user involvement) [54], and **appropriateness** (e.g., perceived fit, relevance, or compatibility of CIs/ISs for a given practice setting, practitioner, and/or consumer) [55] (Figure 2). These mechanisms are direct targets of DDBT-driven redesign and the focus of the new iteration of funding between 2023 and 2028 ("UWAC 2.0"). We ultimately expect DDBT to result in changes to proximal implementation outcomes (**adoption**, **fidelity, reach, adaptation**), and clinical outcomes.

DDBT Mechanisms: Usability

Usability is an underlying outcome at all stages of the HCD process. Understanding the extent designs are unusable and opportunities to increase an existing solution's usability can inspire innovation and adoption [50]. Deployment of CIs/ISs will continue to be subpar unless usability can be addressed, the historically unidirectional relationship between developers and users can be overcome, and insufficient incorporation of user perspectives can be remedied [56]. Usability is assessed through usability evaluations and usability testing, where prototypes are evaluated using

established heuristics and/or tested user interaction. Usability assessment methods stem from evaluating technologies, however, these techniques have been used to improve usability, decrease burden, and increase contextual appropriateness of non-technological mental health CIs/ISs [5,36,39,50]. As a form of usability evaluation, metrics like the System Usability Scale (SUS) [57] are questionnaires rooted in statements that capture perceived usability from the user's perspective. The SUS is a widely used instrument to measure usability of technologies by industry. Interviews can be particularly insightful if they incorporate observation or demonstrations. Task-based usability testing involves asking participants to complete tasks while using a design. This method can be used to gather baseline usability data for an existing CI/IS and assess usability of CI/IS prototypes [50]. The think-aloud protocol (TAP) involves participants verbalizing thought processes as they use CIs/ISs [39] to complete assigned tasks, including actions they consider taking and reactions to materials as they encounter them. Similarly, the Cognitive Walkthrough for Implementation Strategies (CWIS) is a six-step method for evaluating CIs/ISs usability which can include interviews as part of task-based usability testing [39]

UWAC 1.0 projects assessed usability through usability questionnaires, task-based cognitive walkthroughs [39], and TAP [58,59]. We developed the Intervention Usability Scale (IUS) [37] and Implementation Strategy Usability Scale (ISUS) [39] to better align with measuring CI/IS usability, which are closely aligned with SUS. SUS/IUS/ISUS scores of 70 or greater out of 100 are considered adequate usability. Cross-project usability data informed the Typology of Modification Targets, 12 unique categories of CIs/ISs usability issues of varying levels of severity. These categories help researchers understand common barriers to CI/IS use that can be prevented and addressed during CI/IS redesign [50].

DDBT Mechanisms: Engagement

Engagement—and adaptations to improve engagement—relates to CI fidelity and clinical outcomes [60–63] and is a defining feature of quality of care [64–66]. Engagement describes user connection to CIs/ISs and their capacity to sustain a connection [54]. Engagement is distinct from common health concepts of compliance, adherence, and coverage since it incorporates a dimension of quality, and welcomes the possibility that different people may engage differently with different parts of CIs/ISs based on varying needs. Typical users include the practitioners who deliver them (e.g., clinicians, implementation practitioners, intermediaries) and the individuals who receive them (e.g., clients, practitioners, service system administrators). Our work has found that engagement can be negatively impacted by insufficient buy-in, components that are inaccessible to different users, little support for communication or rapport building, and requirements or constraints that inadvertently shift one user's responsibilities to another (e.g., practitioners completing client tasks) [50].

Engagement is a common focus in HCI literature [54,67–69], where there is an active conversation around how to best assess the quality of interactions rather than quantity of interactions. Multidisciplinary UWAC project teams present an opportunity to incorporate different approaches to improving engagement in translational research [70–72]. We conceptualize engagement as a multifaceted construct focused on interaction quality (participation and enthusiasm) that is enhanced by CIs/ISs that are well-designed and result in improved adoption, fidelity, reach, and adaptations. There are subjectivity-oriented and objectivity-oriented approaches to measuring engagement [54]. Subjectivity-oriented measures are self-reported and include (in order of most documentation of use): questionnaires, behavior logging, observation, task outcomes, and interviews. Objectivity-oriented measures minimize researcher involvement and can include behavior logging, psychophysiological measurements, or telemetry. Within HCI, objectivity-oriented measures like user data—logs, time, number of interactions, and frequency of logins—are commonly used.

DDBT Mechanisms: Appropriateness

Appropriateness captures potential inconsistencies between CIs/ISs and the settings to which they are deployed [55]. Patient needs and therapeutic style drive how mental health practitioners modify CIs/ISs in practice [26]. During UWAC 1.0, we observed how practitioners and recipients felt that exciting innovations can be inappropriate for specific contexts (e.g., schools) or for users facing challenges with identifying and selecting goals or implementation plans. Challenges included CIs/ISs' excessive time demands in their delivery, incompatibility with existing workflows or roles, unavailable system infrastructure requirements, an overreliance on digital technology, and—importantly—practitioner perceptions of the fit of the CIs/ISs to specific client problem types. These issues are well-documented as multifaceted factors that influence CI/IS adaptations [29,73]. During UWAC 1.0, we used the Intervention Appropriateness Measure (IAM) [74] across projects to assess appropriateness.

Study Purpose

Center Aims and Structure

Our goal is to overcome obstacles that prevent quality mental health interventions from reaching historically marginalized groups through addressing critical CI/IS problems with the DDBT framework. Building on learnings during the first iteration of the center, UWAC 2.0 focuses on addressing longstanding problems with *usability*, *engagement*, and *appropriateness* of CIs/ISs that result in high rates of "reactive adaptations" in settings where they are deployed. Within UWAC, the Methods Core team provides methodological and technical support to all projects and maintains cross-cutting project data on UWAC outcomes to determine the impact of DDBT on CIs/ISs. This data will be used to refine and expand UWAC's Typology of Modification Targets and Library of Redesign Solutions. The current iteration of the center emphasizes increased leadership and application of DDBT methods by local project redesign teams (e.g., administrators or champions) that receive methodological training and supports from the Methods Core to work alongside investigators, increasing their decision-making at all stages of the design process. This is a shift from the previous centralized model, where projects engaged users, but project Principal Investigators and center Methods Core team members often led the design process. The Methods Core will address the following aims during UWAC 2.0:

Aim 1: Identify clinical intervention and implementation strategy modification targets to improve usability, engagement, and appropriateness in accessible non-specialty settings (Discover phase)

Known determinants of successful CIs/ISs use exist at several levels, including CI (e.g., complexity), practitioner/client (e.g., training, attitudes, intention to use), and organizational (e.g., climate, leadership, resources, supervision). Historically, adaptations of CIs/ISs have been driven by academics rather than the lived experiences of recipients. Using the Consolidated Framework for Implementation Research (CFIR) [75] as our guide in the Discover phase of each UWAC project, we support project redesign teams to employ HCD methods to identify targets within our Typology of Modification Targets [50]. Qualitative analyses will allow us to compare targets identified via local DDBT (characterized by user involvement in redesign teams and shared decision-making about target prioritization and solutions) with those derived from our original, centralized application of DDBT [46]. Aim 1 outcomes will inform Typology revisions and allow for comparisons between the original, centralized DDBT and the local DDBT. An updated Typology will be broadly disseminated to inform future research.

Aim 2: Develop redesign solutions with local teams to address clinical intervention and implementation strategy modification targets (Design/Build phase)

Using rapid, iterative design principles, we are supporting research project teams in developing prospective CIs/ISs that enhance usability, engagement, and appropriateness. We will systematically catalog these design solutions using the Framework for Modifications and Adaptations of Evidence-based Interventions/Implementation Strategies (FRAME/-IS) [26,29,73]. We will examine solutions and the populations, organization types or structures, practitioner types, and CIs/ISs in which they work, identifying solutions that transfer across different contexts or are uniquely suited to specific contexts. Aim 2 outcomes will be compared with centralized DDBT outputs, resulting in an updated Library of Redesign Solutions organized by target and redesign method (i.e., localized vs. centralized), and shared with our clinician community.

Aim 3: Determine if redesign affects changes in usability, engagement, and appropriateness (Test phase)

During the Test phase, each project will include a hybrid effectiveness-implementation trial [76,77] with a primary comparison between the original CI/IS and the DDBT-adapted version on theorized mechanisms (usability, engagement, appropriateness), implementation outcomes (adoption, fidelity, reach, adaptations), and client outcomes. Projects will apply FRAME/-IS [29,73] to examine the extent to which DDBT decreases reactive adaptations to the CI/IS (i.e., unplanned/due to unanticipated obstacles) during implementation. We hypothesize that DDBT-informed, prospective adaptation will reduce the number and extent of reactive adaptations. The Methods Core will systematically integrate new data from the UWAC projects with existing data in our continuously updated meta-analysis [46] of how redesign affects theorized mechanisms, implementation outcomes, and patient outcomes. Aim 3 outcomes will be disseminated to the field and inform new projects designed to test which redesign strategies best improve DDBT mechanisms and outcomes.

Methods

Overview

Composed of an interdisciplinary team and advisory board with experience in HCD, implementation science, psychosocial CIs, and research methods/data, the Methods Core supports one large effectiveness study (NIH R01), three exploratory pilot studies (NIH R34s) (Table 1) and at least four pilot projects (NIH R03s) during UWAC 2.0. These projects aim to improve CI/IS access and scale in diverse settings. The R01 Problem Solving Treatment-Aid (PST-Aid) (trial number NCT06494384) will test a DDBT-designed decision support tool for Problem Solving Treatment in a large network of primary care clinics. R34 Research Units on Behavioral Intervention in Educational Settings (RUBIES) (trial number NCT06508515) will create a novel IS to support delivery of evidence-based classroom supports for students with autism. R34 Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) will redesign and test a well-researched CI for youth trauma for use in education settings. R34 Brief Intervention for School Clinicians (BRISC) will adapt an existing set of effective ISs to enhance delivery of a school-based engagement, assessment, brief mental health intervention, and triage strategy. PST-Aid and RUBIES were part of UWAC 1.0 as R34 and R03 projects, respectively, highlighting how UWAC 2.0 activities build on previous accomplishments. UWAC funds pilot projects through a competitive solicitation process, with a particular focus on supporting and mentoring investigators from historically marginalized groups. All projects use the DDBT framework to address CI/IS usability, engagement, and appropriateness in partnership with local community collaborators. We provide projects direct support with integrating methods and

measurement approaches, and professional development that respects Diversity, Equity, and Inclusion (DEI) values. University of Washington's Institutional Review Board granted approval for the four projects (PST: STUDY00017272; RUBIES: STUDY00017261; TF-CBT: STUDY00017262 and STUDY00019451; BRISC: STUDY00017263 and STUDY00019682).

Table 1. Summary of UWAC 2.0 Projects and Methods by Discover, Design/Build, Test (DDBT) Phase

Project & Timeline	Setting	Clinical Intervention	Implementation Strategy	Methods during UWAC 2.0	Methods during UWAC 1.0
Problem Solving Treatment-Aid (PST-Aid) (R01) (2023-2028)	Primary care clinics	PST	PST-Aid	**N/A** (Activities completed during UWAC 1.0 serve as the "Discover" phase for UWAC 2.0)	**Discover**: Interviews, observations of new and experienced PST trainers, affinity diagramming
				Design/Build: Observation, co-design, prototyping, think-aloud protocol	**Design/Build**: Prototyping and co-design of potential products to enhance fidelity when conducting PST
				Test: Randomized hybrid type 3 effectiveness-implementation trial with observation (audio recordings of sessions), interviews, surveys	**Test**: Pilot randomized trial comparing PST training-as-usual to training plus PST-Aid
Research Units on Behavioral Interventions in Educational Settings (RUBIES) (R34) (2023-2026)	Schools	Research Units on Behavioral Interventions (RUBI) protocol	RUBIES -"RUBIES Teams" Team IS	**Discover**: Focus groups, cognitive walkthrough for implementation strategies, think-aloud protocol, interviews, surveys	**Discover**: In-class behavioral observations, retrospective cognitive walkthroughs, interviews, demonstration of the original RUBI intervention paired with behavioral rehearsal, prospective think-aloud, and structured assessment methods to identify targets for RUBI redesign
				Design/Build: Prototyping, user testing	**Design/Build:** Prototyping of RUBI content based on identified targets for redesign
				Test: Randomized hybrid type 3 effectiveness-implementation pilot trial	**N/A**
Trauma-Focused	Schools	TF-CBT for	N/A (adapting	**Discover**: Contextual evaluation,	**N/A**

Cognitive Behavioral Therapy (TF-CBT) (R34) (2024-2027)		schools (S-TF)	intervention only)	think-aloud protocol, behavioral rehearsal, interviews, user testing **Design/Build**: Prototyping, user testing **Test**: Randomized hybrid type 2 effectiveness-implementation pilot trial	
Brief Intervention for School Clinicians (BRISC) (R34) 2025-2028)	Schools	BRISC	BRISC IS package Adapted to local needs (BR-A)	**Discover**: Observation, CWIS, think-aloud protocol, interviews, focus groups, surveys **Design/Build**: Co-design, user testing **Test**: Randomized hybrid type 3 effectiveness-implementation pilot trial	**N/A**

DDBT Constructs

Projects collect common data on DDBT mechanisms and constructs to determine the impact of modifying CI/IS targets. The Methods Core maintains a list of recommended and required measures for projects to gather at each DDBT phase ("Center Measures and Guidance") (Table 2). We developed Center Measures and Guidance to facilitate DDBT hypothesis testing and data management across UWAC, help teams select methods based on project design objectives, and satisfy NIMH reporting requirements. Center Measures and Guidance include 15 constructs with 26 quantitative and qualitative measures across DDBT phases. The Methods Core provides teams support with integrating and adapting these measures for projects through a consultation model. This is a shift from our approach in UWAC 1.0, where Methods Core investigators and staff provided more project-specific measurement support to teams. Outlined below is each construct with a description of related measures and activities, and relevance to each DDBT phase. The Methods Core team provides data management for all projects, maintains survey instruments in REDCap, and conducts cross-project analyses. Individual projects are responsible for their own project analyses. The Methods Core provides guidance on ensuring recruitment, data analysis, and dissemination practices incorporate diverse perspectives and accurately represent the lived experiences of participants to inform CI/IS re-design.

Table 2. Center Measures and Guidance.[a]

Construct	**Measure/Activity**	**Phase**		
		Discover	**Design/Build**	**Test**
DDBT Mechanisms				
Usability	Usability issues grounded in participant data and reported using UWAC's standard structure	Yes (if existing CI/IS[b])	Yes (if further issues identified)	Yes (if further issues identified)
	System/Intervention/ Implementation Strategy Usability Scale (SUS/IUS/ISUS)	Yes (existing CI/IS)	Yes (redesign CI/IS)	Yes (redesign CI/IS)
Engagement	User Responsiveness Scale	Yes (existing CI/IS)	Maybe (redesign CI/IS)	Yes (redesign CI/IS)
	Coding of qualitative interactions	Yes (existing CI/IS)	Maybe (redesign CI/IS)	Yes (redesign CI/IS)
Appropriateness	Intervention Appropriateness Measure (IAM)	Yes (existing CI/IS)	Maybe (redesign CI/IS)	Yes (redesign CI/IS)
	Revised Goodness of Fit interview	Yes (existing CI/IS) Optional	Maybe (redesign CI/IS) Optional (R03)	Yes (redesign CI/IS) Optional

		(R03)		(R03)
Proximal implementation outcomes				
Adoption and reach	User Report	Yes (existing CI/IS)	No	Yes
Intervention and Implementation Strategy Fidelity	Fidelity of Practice	Yes (existing CI/IS)	No	Yes
Adaptations (i.e., redesign solutions)	Framework for Reporting Adaptations and Modifications to Evidence-based Interventions and Implementation Strategies (FRAME/-IS)	No	Yes	Reactive/ Unplanned adaptations
Distal Service Recipient Outcomes				
Client outcomes	Quality of Life in Neurological Disorders (Neuro-QOL)	No	No	Yes
	Top Problems Assessment	No	No	Yes
	DSM-5 Level 1 Cross-Cutting Symptom Measure	No	No	Yes
	Revised Children's Anxiety and Depression Scale-25 (RCADS-25)	No	No	Yes
	Patient Health Questionnaire - 9 (PHQ-9)	No	No	Yes
	General Anxiety Disorder-7 (GAD-7)	No	No	Yes
	WHO Disability Assessment Schedule (WHODAS 2.0)	No	No	Yes
Demographic & Process Measures				
Demographics	Participant Demographics	Yes	Yes	Yes
User Needs & Experience	User Interviews	At least one	At least one	At least one
	User-Centered Design Activities			
	Other methods for understanding and probing user needs			

Participant research burden, incentive appropriateness, and research satisfaction	Three study-specific items, based on insights from the CREATIV Lab's ADAPT study pilot trial [78]	No	No	Yes
Costs of DDBT	Fidelity and Cost Survey, Budget	Yes (optional R03)	Yes (optional R03)	Yes (optional R03)
Adherence to DDBT process	Survey	Yes	Yes	Yes
Team collaboration, trust, and respect	Transdisciplinary Tobacco Use Research Center (TTURC) Satisfaction Measure of Team Collaboration and Transdisciplinary Integration (productivity and satisfaction sections only/process quality and outcomes)	Yes Optional (R03)	Yes Optional (R03)	Yes Optional (R03)
Community participation in research	Modified Ladder of Participation Measure	Yes Optional (R03)	Yes Optional (R03)	Yes Optional (R03)
Investigator satisfaction with the support they receive from the center	UWAC Satisfaction Measure	N/A	N/A	N/A

[a]Not all teams may complete all phases (especially among smaller-scale pilot projects), and some pilot projects may begin with design/build when prior work by the project team or in literature sufficiently informs the design phase.
[b]CI/IS = clinical intervention and/or implementation strategy

DDBT Theory of Change Mechanisms

Usability

Usability is a fundamental HCD outcome, and our experiences have confirmed that it is a core barrier to CI/IS adoption and redesign [50]. All projects are expected to report usability issues on existing or redesigned CIs/ISs and standardized usability metrics to the Methods Core. Since interviews alone can be limiting for identifying usability issues because of issues with recall and/or challenges with describing behavior, UWAC projects are encouraged to combine interviews with other methods like CWIS and TAP. This helps projects learn what a participant is considering doing next and why, better understand their in-the-moment goals, and identify

misconceptions. For example, members of R34 project BRISC will use TAP and present to users components of an existing IS embedded in a cognitive walk-through methodology to identify opportunities for redesign to improve implementation based on user needs [39].The Methods Core supports teams with adapting surveys (e.g., SUS/IUS/SUS) and implementing cognitive walkthroughs and usability testing for projects.

Engagement

We expect all projects to assess engagement quantitatively using the User Responsiveness Scale and qualitatively (thematic findings from observation or other chosen methods) during Discover and Test phases of existing and redesigned CI/IS. The Methods Core developed the User Responsiveness Scale based on the Patient Responsiveness Scale [60] to create a subjectivity-oriented questionnaire that could be modified for each study. The User Responsiveness Scale has ten statements that cover participation and enthusiasm for an CI/IS that participants rate on a Likert scale. The original Patient Responsiveness Scale has demonstrated strong reliability (α = .86) and construct validity.

Appropriateness

R01 and R34 projects are expected to administer the Intervention Appropriateness Measure (IAM) [74] and/or revised goodness of fit interview [79] during Discover and Test phases of existing and redesigned CIs/ISs to probe areas of alignment and misalignment on goals and expectations, roles, etc. IAM is a 4-item survey and the leading instrument for measuring CI/IS contextual fit with good internal consistency (α =.87) and test–retest reliability (α =.87). The goodness of fit interview is particularly well-suited to probe on CI/IS appropriateness issues identified through IAM. We will use a content analysis to analyze goodness of fit interview data. For example, R34 project RUBIES will conduct goodness of fit interviews to explore the appropriateness of the RUBIES IS (“RUBIES-Team”) for the school environment, using the CFIR domains to drive questioning.

Proximal Implementation Outcomes

Adoption and Reach

Adoption and reach are implementation outcomes specified in the CFIR [55] and Reach, Effectiveness, Adoption, Implementation, and Maintenance [80] frameworks. We expect projects to report on adoption and reach as part of the Design (if feasible) and Test phases. The approach to measuring adoption and reach depends on the project. For example, R34 Project RUBIES defines adoption as educators’ first use of the RUBIES-Team at any point during the study and will measure reach in two ways: 1) the number of autistic students with whom trained educators use RUBIES-Team; and 2) the number of other educators with whom trained educators share RUBIES-Team.

Intervention and Implementation Strategy Fidelity

Fidelity is a core implementation outcome [55]. We expect projects to report on fidelity as part of the Design (for existing CIs/ISs) and Test phases, and teams choose an approach to measuring fidelity based on redesign goals. For example, R34 Project RUBIES rates paraeducator fidelity to treatment (e.g., weekly ratings of the paraeducator’s homework completion and behavior support plan implementation). R34 Project TF-CBT will code session recordings using the Therapy Process Observational Coding Scale (TPOCS) [81] and the TPOCS-Self-Reported Therapist

Intervention Fidelity for Youth [82] at baseline, 3 months, and 6 months.

Adaptations (i.e., redesign solutions)

Measuring adaptations is key to all three Methods Core aims to better understand and address challenges to CIs/ISs. We expect projects to measure adaptations with FRAME/-IS [29] as part of the Design/Build phase and for reactive/unplanned adaptations during the Test phase. For example, R34 BRISC will analyze recorded intervention sessions using FRAME/-IS. The R01 PST-Aid will code randomly selected session audio recordings per client for fidelity and reactive adaptations using FRAME/-IS. Projects will submit to the Methods Core adaptations and describe whether these adaptions were made proactively (e.g., as part of the design process) or reactively (e.g., unplanned/due to unanticipated obstacles). Across projects, the Methods Core will systematically categorize adaptations to examine proven solutions and the populations, organization types or structures, practitioner types, and CIs/ISs in which they work. Our objective is to identify transferable and unique solutions to different contexts and CIs/ISs. This information will ultimately inform an updated version of the Library of Redesign Solutions.

Distal Service Recipient Outcomes

Client Outcomes

During the Test phase, projects are expected to collect clinical and functional outcomes. Teams will administer condition-specific standardized assessments (e.g., Patient Health Questionnaire [PHQ-9] [83], Quality of Life in Neurological Disorders (Neuro-QOL) [84], Satisfaction with Social Roles for adults [85], and the Neuro-QOL Social Relations Scale for youth [86]) based on CI/IS primary focus. These measures are widely used and capture functioning in usual social roles, activities, and responsibilities. Item development of these scales included factor analyses and item response theory to ensure broad information parameters without differential item functioning. The scales have been validated with thousands of participants from the U.S. general population and in clinical inpatient and outpatient settings who have a wide variety of presenting problems [84–86]. All projects will also employ idiographic (i.e., individualized) client outcome monitoring based on the Top Problems Assessment (TPA) [87], an approach informed by goal attainment scaling [88,89] that has been found to be highly sensitive for monitoring CI outcomes and thus is preferred over standardized/nomothetic assessments by both practitioners and clients [90].

Demographic & Process Measures

Demographics

All projects are expected to collect participant demographic data mandated by the NIMH at all phases. Teams collect additional demographic data based on project needs. For example, the R34 Project RUBIES collects required educator and student demographics (e.g., age, gender, race) and additional data on school characteristics (e.g., school size, % eligible for free/reduced lunch, racial/ethnic composition, % English Language Learners, % in special education, annual funding for external resources, per capita number of community-based organizations). Data will be tabulated to satisfy federal demographic and data reporting requirements as well as cross-project meta-analyses and comparisons.

User Needs & Experience

All projects are expected to clearly identify direct and indirect users and incorporate methods that address user needs. We define *direct users* (also known as "primary users") as people who directly interact with the CI/IS. We define *indirect users* (also known as "secondary users") as people affected by the CI/IS. HCD places a strong emphasis on explicitly identifying relevant community collaborators and users to ensure that new products effectively meet their needs [91,92]. Explicit user identification produces more usable products and ensures that the design team does not underestimate user diversity [93] or create designs based on the team's own needs [36,94,95]. CI/IS users should include the deliverers (e.g., practitioners for CIs) and recipients (e.g., clients, and IS targets such as administrators or practitioners). Identification of users for a CI/IS includes: 1) generating a preliminary user list, 2) articulating the most relevant characteristics that reflect anticipated users, 3) describing and prioritizing main user groups, and 4) selecting typical and representative users [93]. For example, in R34 Project TF-CBT, direct users are school counselors and social workers who provide mental health services, as well as public school students with histories of traumatic stress (e.g., posttraumatic stress disorder). Potential indirect users in this project include caregivers of students. We include users who are diverse with respect to characteristics such as age (students), race/ethnicity (students and practitioners), culture (students and practitioners), and clinical domain experience (practitioners), which are features known to impact experiences of usability, engagement, or appropriateness [50,96–98].

Projects will use interviews to identify key challenges end users might face when applying CIs/ISs. Interviews consist of questions derived from HCD principles such as organizational and community culture, values, and challenges in applying CIs/ISs. For example, in R34 Project RUBIES, the team will interview educators about their existing opportunities to learn behavioral management strategies for students with autism who exhibit challenging behavior. Interviews will identify promising professional development approaches and areas to improve the existing RUBIES multifaceted IS. Additional interviews with school administrators or lead special educators are likely to surface critical organizational factors that can serve as design constraints for any subsequent redesign solution [99,100].

As described above, interviews can be supplemented through observation methods to better understand interactions in real-world settings. Projects can use an adapted form of TAP, known as retrospective think-aloud, where participants (e.g., clinicians or clients) and researchers watch recordings of sessions while the participant explains what they were thinking in the moment. This approach can offer additional suggestions for improvement on the design of a CI or offer ideas for tools that could support the clinician during implementation. Interviews can also supplement comparative testing (e.g., A/B testing) to explore and evaluate a broader landscape of design options and reach more robust solutions. A/B testing is an evaluation method in which two or more versions of a prototype are compared sequentially or in parallel to determine which version is easier to use and better meets the needs of the end user [101]. For example, R34 Project BRISC will build prototypes of digital asynchronous learning modules for novel users as well as post-training support tools; initial prototypes will undergo comparative testing to finalize solutions to be evaluated in the Test phase. The pragmatic applicability and match of potential designs to the targeted service environments and resource constraints will be systematically addressed.

Participant Research Burden, Incentive Appropriateness, and Research Satisfaction

At the end of the Test phase, projects are expected to measure the burden of participation in the study. This instrument includes six questions to understand participants' perceived burden of participating in the study, appropriateness of the level of compensation offered, and overall satisfaction with the study experience. This information will be used to help improve future protocols. Response frequencies will be tabulated for the four close-ended responses and themes will be summarized from open-ended responses.

Costs

We will measure costs of applying DDBT to help understand the resource requirements involved in its use, which can be a major challenge of HCD and coproduction methods [102]. Projects are expected to report total costs of redesign, reported through a Fidelity and Cost Survey in REDCap at the end of each phase (this is optional for R03 projects). We will aggregate activity-based costs (e.g., time to create, complete, and analyze each activity; participant payments or time) across individuals, and use budgets or other institutional records to assign hourly costs by role, then add in any fixed costs (e.g., materials, activity-specific software). We will calculate total DDBT costs, as well as phase-specific and activity-specific DDBT costs. Analyses will follow best practices by placing all dollar values onto the same metric, including an index year to account for inflation; local or national average cost-of-living values to account for geographic variation in prices; and discounting of costs from different years due to preferences for delayed over immediate costs. We will conduct sensitivity analyses to examine the robustness of our cost estimates [103,104] by identifying areas of uncertainty in measuring units and prices for our ingredients, and then calculating costs across a range of plausible values (e.g., we can substitute limits of 95% confidence intervals for uncertain prices).

Adherence to DDBT process

All projects are expected to complete a Fidelity and Cost survey in REDCap about their application of HCD techniques at the end of each DDBT phase. We are developing the survey to systematically collect data on how the DDBT framework guides CI/IS redesign, and link design activities with project goals. To facilitate teams in drawing on a range of methods, the Fidelity and Cost survey focuses on understanding which goals of each DDBT process teams completed (Figure 1) and the methods they used to support each goal. We will conduct descriptive statistical analyses and content analysis of data to understand the frequency of goals completed and HCD strategies used, links between strategies and goals, and modifications made to strategies during their use.

Team Collaboration, Trust, and Respect

At the end of each DDBT phase, R01 and R34s team members are expected to complete a survey that assesses satisfaction with the collaboration, impact of collaboration, trust, and respect. This survey is modelled after the Transdisciplinary Tobacco Use Research Center's (TTURC) measure of Team Collaboration and Transdisciplinary Integration, which assesses satisfaction with the collaboration, impact of collaboration, trust, and respect [105]. Ongoing review of outcomes will allow for critical assessment and course correction as needed and recommended by these bodies. Participation is confidential and teams will receive an aggregate report of the number of team member participants and average scores for each item. Any free response

comments are additionally summarized. We will encourage teams to discuss results to improve their projects.

Community Participation in Research

The collaboration survey questions described above will be administered with additional questions to characterize the extent to which redesign teams engage users in a localized DDBT process. This instrument is based on an existing measure of community participation in research [106,107], which has been modified to target design of CIs/ISs across six dimensions: identification of design issues, design activities, use of resources, design methods, indicators of success, and sustainability. Redesign teams will complete the measure at or near the end of each DDBT phase and then explain ratings in an interview.

Investigator satisfaction with the support they receive from the center

At the conclusion of projects, we will require investigators to share their level of satisfaction with support from UWAC through a five-item Likert survey adapted from a survey used by the University of Washington IMPACT Center [108]. We intend to use this data to improve how the Methods Core provides projects technical support.

Data Analysis

The Methods Core provides data management and guidance on all DDBT constructs. For Aim 3, fundamental comparisons are the differences in DDBT mechanisms (usability, engagement, appropriateness) and implementation outcomes (adoption, reach, adaptation, fidelity [and sustainment for the R01 PST]) for the original (un-adapted) CI/IS versus the DDBT-informed (localized) CI/IS. We will conduct a: 1) qualitative multiple case study analysis and 2) quantitative meta-analysis across projects. Case studies will examine each project's context, implementation, mechanisms, and outcomes.

For each project, we will also develop analytical summaries to facilitate between-project comparisons. Using the constant comparative method [109], we will compare projects to group common and divergent themes. The meta-analytic synthesis will increase our inferential ability by combining results from the underpowered R34s. For the meta-analysis, each project's mechanism and outcome will be summarized as a Cohen's d effect size comparing localized DDBT with original CI/IS and corresponding 95% confidence interval, using random effects weighting by the inverse of the within- and between-studies variance. Standard data screening and adjustments will be made to the data (e.g., to limit the effect of outliers, they will be Winsorized). Each project will be additionally advised on how to address possible confounders in analysis and reporting. For instance, projects will be encouraged to use naive participants in design/build and test phases, recognizing that adaptations of smaller elements of complex CIs may require the participation of experienced participants during design/build. Additionally, randomization will occur at appropriate levels to avoid contamination by intra-level communication. Non-monotonic missing data will be addressed via inverse probability weighting or multiple imputation, as appropriate [110]. The Methods Core will aggregate these data across projects into a series of working meta-analyses of the effectiveness of DDBT on each mechanism and outcome.

Finally, determining whether a DDBT-modified CI/IS leads to better implementation and clinical

outcomes is ultimately a question of mediation. Although the initial R34 and R03 studies are not likely to yield large enough sample sizes to meaningfully test such an implementation mechanism question, the R01 PST will provide a direct test of the DDBT theory of change (Figure 2). Aggregating project data over time will allow us to eventually test a range of mediation-focused hypotheses via multivariate network meta-analyses.

Incorporating Diversity, Equity, and Inclusion (DEI)

During UWAC 2.0, we are improving integration of DEI initiatives throughout Center activities. Projects selected for UWAC 2.0 and pilots must demonstrate potential for clinical or public health significance, especially for historically marginalized communities. The Methods Core team provides mentorship on incorporating and adapting methods so that teams are positioned to conduct research that respects diverse populations and maximizes community benefits. Project teams will be provided training and consultation on the ASPIRE method, a 3-step process for adapting implementation science to promote equity, and expertise in methods for explicitly incorporating equity into the measurement of implementation outcomes [111]. We will also collaborate with projects to ensure diverse representation and decision-making during the DDBT phases, crucial stages where diverse viewpoints and demographically representative samples are essential. To facilitate diverse engagement, we will offer resources on building equitable research-practice partnerships, contextualizing implementation science to specific communities, and enhancing community collaborator capacities for community-engaged research. Consultation on Quantitative Critical research [112] will be provided to critically examine the treatment of race within quantitative methods and support equity testing through disaggregation, moderator exploration, and mixed-method triangulation.

UWAC additionally supports faculty and staff as part of its DEI work. The center team engages with historically marginalized investigators in planning and conducting center activities so that DEI efforts are integrated throughout center mentoring, pilot funding, methods support, and support for investigators planning future proposals. These measures include enhancing communication strategies based on team science [71] and avoiding a "minority tax", which refers to additional responsibilities on minorities as an act of promoting diversity [113,114]. The Methods Core also advises investigators on using patient-centered and non-stigmatizing language when reporting findings.

Results

UWAC 2.0 received funding in June 2023 and the University of Washington Institutional Review Board (IRB) granted approval for the R01 and three R34s in February 2023. The Methods Core provides support to pilot project teams on IRB applications after studies are funded.

Discussion

Charting New Research Directions

Our vision is to address persistent issues with usability, engagement, and appropriateness that are barriers to CI/IS use by drawing from the fields of HCD and implementation science. The first iteration of the center advanced our understanding of how DDBT can guide CI/IS adaptations for uptake in historically marginalized communities. During UWAC 2.0, we aim to continue serving as a multidisciplinary incubator to find viable solutions for improving implementation of CIs/ISs

using DDBT through the R01, R34s, and pilot projects. We believe that our expected outputs of 1) an updated Typology of Modification Targets; 2) a Library of CI/IS Redesign Solutions; 3) a meta-analysis of modification impacts on usability, engagement, appropriateness; and 4) findings for implementation outcomes will help build the case for DDBT as a tool for improving CIs/ISs in public health more broadly. Focusing on usability, engagement, and appropriateness and providing and testing ways to measure engagement in a CI/IS context is particularly novel.

Our experiences underscore a benefit of developing additional resources for DDBT, HCD, and implementation science. UWAC 1.0 outputs contributed to foundational conversations on the intersection of HCD and implementation science, and produced potential pathways to address conceptual overlap and distinctions [43] and terminology [42]. We additionally developed resources such as CWIS [39], IUS [37], the ISUS [39], and a Typology of Modification Targets/Usability Issues [50]. We plan to build on these foundational methodological advancements, which have been used by a broader research community interested in HCD and implementation science methods and measurement. This includes additional resources for UWAC project teams and the broader research community on specific methods, team science, equity-oriented design practices, and grant writing. Developing additional resources aligns with the Methods Core shifting to a consultation model on using the DDBT framework during UWAC 2.0. UWAC teams receive technical support from the Methods Core with greater emphasis on building local capacity to carry out DDBT and specific methods rather than conducting analyses.

Conclusion and Impact

There is a pressing need to ensure that CIs/ISs are easily implementable and meet the needs of the communities they aim to help. Integrating HCD and implementation science offers promising approaches to tackle this challenge. UWAC 2.0 expands and strengthens our efforts to ensure that accessible community service settings and marginalized communities see the benefit of decades of research on effective CIs/ISs.

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Conflicts of Interest

None declared

Abbreviations

BRISC: Brief Intervention for School Clinicians
CFIR: Consolidated Framework for Implementation Research
CI: clinical interventions
CWIS: Cognitive Walkthrough for Implementation Strategies
DDBT: Discover, Design/Build, Test
DEI: Diversity, Equity, and Inclusion
FRAME/-IS: Framework for Modifications and Adaptations of Evidence-based Interventions/Implementation Strategies
GAD-7: General Anxiety Disorder-7
HCD: human-centered design

HCI: human-computer interaction
IAM: Intervention Appropriateness Measure
ISUS: Implementation Strategy Usability Scale
IUS: Intervention Usability Scale
IRB: institutional review board
IS: implementation strategies
Neuro-QOL: Quality of Life in Neurological Disorders
NIMH: National Institute of Mental Health
PHQ-9: Patient Health Questionnaire - 9
PST-Aid: Problem Solving Treatment-Aid
RCADS-25: Revised Children's Anxiety and Depression Scale-25
RUBIES: Research Units on Behavioral Intervention in Educational Settings
SUS: System Usability Scale
TAP: think-aloud protocol
TF-CBT: Trauma-Focused Cognitive Behavioral Therapy
TPCOS: Therapy Process Observational Coding Scale
TTURC: Transdisciplinary Tobacco Use Research Center
UWAC: University of Washington Advanced Laboratories for Accelerating the Reach and Impact of Treatments for Youth and Adults with Mental Illness Center
WHODAS 2.0: WHO Disability Assessment Schedule

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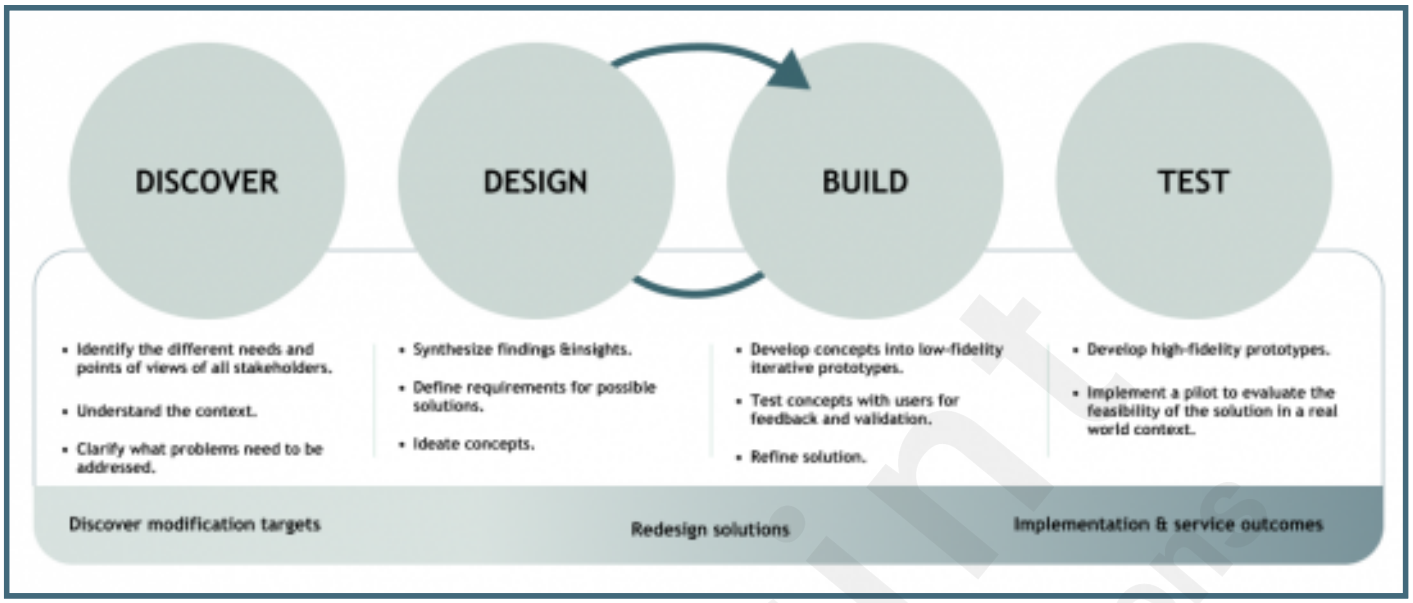
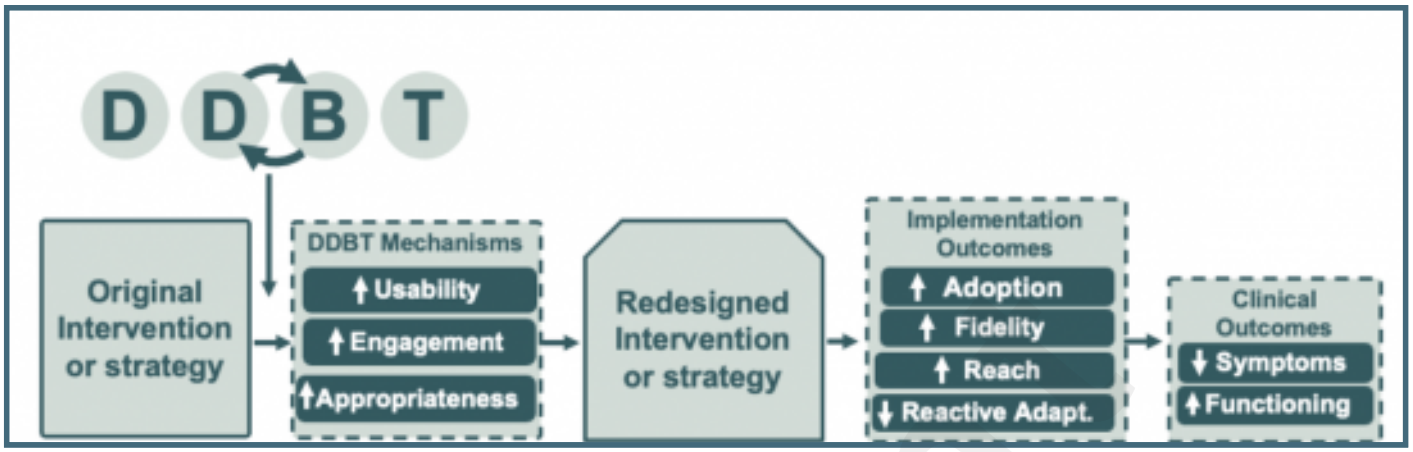
Supplementary Files

Figures

DDBT Redesign Framework.



UWAC Theory of Change for CIs/ISs Redesign.



Multimedia Appendixes

NIH review.
URL: http://asset.jmir.pub/assets/f21578e70a1a56df7ed4e6070726d1a6.pdf