



Design process and protocol description for a multi-problem mental health intervention within a stepped care approach for adolescents in India



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ABSTRACT

This paper documents the collaborative design of a mental health intervention for adolescents in India with anxiety, depression, or anger-related concerns. The process was characterized by three phases of formative activities: (1) an intensive review of the service context, (2) selection of an overall design strategy (e.g., whether to choose existing evidence-based treatments or build new treatments in context), and (3) a period of prototyping, testing, and refining. Each phase resulted in specific outputs, which were, respectively, (1) a detailed articulation of values and preferences (setting expectations for what the ideal protocol should be), (2) a set of build parameters representing a blueprint that managed strategic compromises for this context, and (3) a working protocol. We outline the steps of this design process, summarize data from an open-trial clinical case series, and illustrate the resulting working protocol, which will be tested in a future larger trial. We conclude with insights and observations likely to be relevant to protocol design activity in a variety of contexts, most particularly those in low-and-middle-income countries such as India.

1. Introduction

1.1. Significance and scope

The scope of meeting adolescent mental health concerns on a global scale is truly extraordinary. Of the more than 1.2 billion adolescents aged 10–19 in the world (United Nations Children's Fund, 2011), at least 10% experience significant mental health challenges at some time, placing the number of adolescents in need of mental health care at more than a hundred million. Even more challenging is the fact that approximately 90% of these adolescents live in low-and-middle income countries (LMICs), where poverty, political instability, lack of health infrastructure, diverse beliefs about mental health, and/or lack of a well-prepared mental health workforce create barriers to obtaining high quality, or sometimes any, mental health care. The global consequences of failing to address this burden in adolescence has significant implications, including a continuing and expanding cycle of educational failure, violence, abuse, exploitation, poverty, and poor

adult mental health outcomes.

One in five of the world's adolescents lives in India (United Nations Children's Fund, 2011), making it the world's largest population of adolescents, exceeding 200 million. Access to mental health care in India is extremely limited, with 1.93 mental health workers per 100,000 population (WHO, 2018a), compared with 71.7 per 100,000 in high-income countries (WHO, 2018b). Of this already limited workforce, only a small fraction of workers are specifically oriented towards adolescent mental health needs. This context thus represents one of the most significant global mental health challenges: developing and scaling a mental health service solution for tens of millions of adolescents with diverse mental health problems, while contending with an insufficient workforce and extremely limited infrastructure for both mental health care training and service delivery.

1.2. Strategies to address this challenge

To date, multiple efforts to address the challenges of mental health

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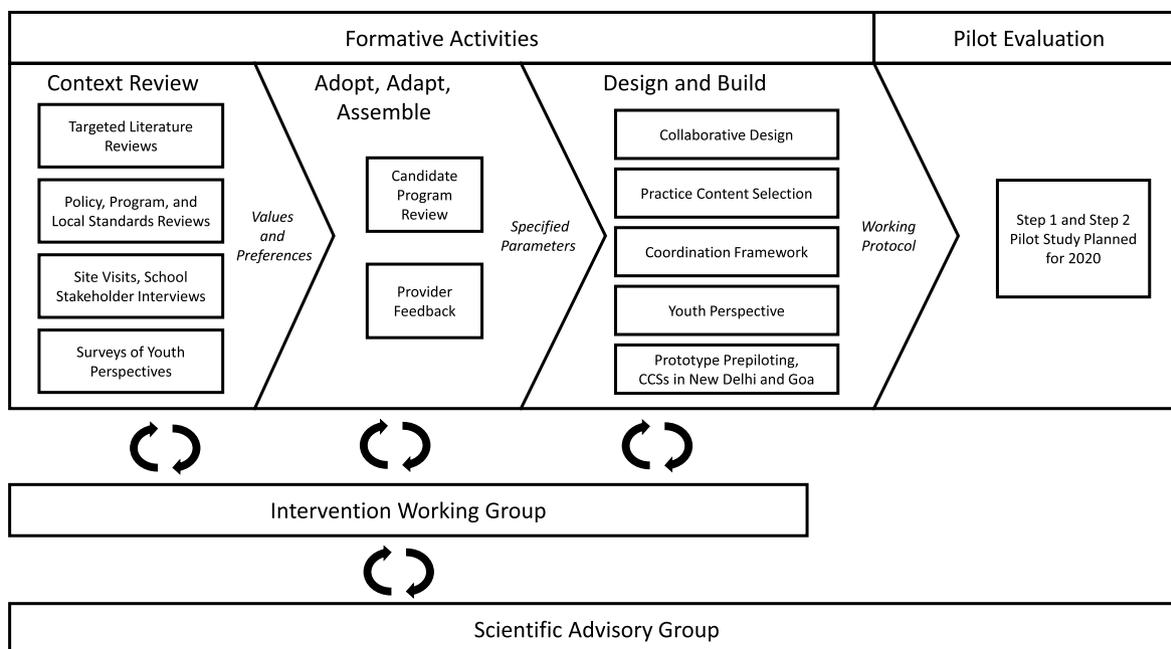


Fig. 1. Formative activities preceding the pilot evaluation of the PRIDE Step 2 protocol.

service delivery in LMIC contexts have involved the selection and adaptation of established evidence-based treatments (EBTs) (Bass & Hamdani, 2019). For example, Trauma-Focused Cognitive Behavior Therapy (TF-CBT) has been effective in reducing traumatic stress symptoms among 5-18-year-old youths in Zambia, using contextual adjustments for youth as well as the locally available workforce (Murray et al., 2015). This implementation strategy has at least two important benefits. First, the resulting research demonstrates that existing EBTs can be robust to new and challenging contexts and helps to articulate promising contextual adaptations. Second, there is a direct clinical impact when such services are scaled for high-priority clinical targets such as traumatic stress in youth.

At the same time, research has shown that the strategy of serving a given population with a proliferation of multiple EBTs, even if appropriately adapted to context, has diminishing returns as one attempts to serve the great diversity of mental health presentations typical of adolescence (Chorpita, Bernstein, Daleiden, 2011). Thus, calls have continued for complementary approaches to extend the reach of EBTs, both locally and globally (e.g., Kazdin, 2019; Murray & Jordans, 2016; Rotheram-Borus, Swendeman, & Chorpita, 2012), some of which argue for building new treatment systems *directly in context* (e.g., Chorpita, 2002; Israel, Schulz, Parker, & Becker, 1998). In India, this approach has been successfully demonstrated with adult mental health concerns, as part of the Program for Effective Mental Health Interventions in Under-resourced settings (PREMIUM; Vellakkal & Patel, 2015). PREMIUM involved the development of two scalable and low-cost psychological treatments for the high-priority targets of adult depression (Healthy Activity Programme; HAP; Patel et al., 2017) and alcohol use disorders (Counselling for Alcohol Problems; CAP; Nadkarni, 2017). The design of HAP and CAP involved extensive formative research and pilot studies (spanning three years), ensuring that context-specific evidence on risk and protective factors, help-seeking, and resource constraints could be integrated with relevant international empirical and theoretical literature. Both resulting treatments demonstrated significant clinical outcomes comparable to the outcomes of psychological treatments delivered by mental health professionals in high-resource settings.

1.3. The PRIDE program

Returning to the challenge of adolescent mental health noted above, we sought a scalable and strategically targeted mental health solution that could serve the needs of a large portion of the adolescent population. Thus, PRIDE (PREmium for aDoLEscents) is a program which proposed a stepped care architecture for mental health care to address a diversity of common mental health challenges in India's secondary schools. In its current design, PRIDE's stepped care model begins with a universal informational component that uses school-wide and classroom-level activities to create awareness about mental health issues and increase demand for mental health care (Parikh, Michelson, Malik, et al., 2019). This information is supplemented by a first-line, low-intensity transdiagnostic problem-focused intervention ('Step 1') for school-going adolescents with elevated mental health symptoms who demonstrate a need for services above and beyond information resources (Michelson et al., 2019). Two recently completed trials of this Step 1 component demonstrated that 50.0% and 44.8% of adolescents did not show remission of their symptoms after 6 weeks, indicating the need for a more intensive intervention for these adolescents (Michelson et al., 1999). The two central aims of the current paper are (1) to outline the phases of formative activities for the PRIDE Step 2 treatment in the context of our goal of building a scalable mental health solution in a limited-resource stepped-care context, and (2) to provide a definitive description of the PRIDE Step 2 working protocol to be tested in future trials.

2. Development process

The process of developing the PRIDE stepped care model proceeded in phases over a period of approximately three and a half years, and Fig. 1 refers specifically to the formative activities and planned pilot evaluation for the Step 2 protocol within the model. Step 1 was developed more or less concurrently and is described elsewhere (see Michelson et al., 2019; Parikh, Michelson, Malik, et al., 2019). Step 2 was therefore intended to serve as the most intensive resource in the stepped care model, representing a targeted intervention for the most common addressable mental health concerns encountered in public schools in India. Thus, the formative activities began with an intensive review of the local context, following methods used in the PREMIUM

Table 1
Statement of values and preferences.

DIMENSION	VALUES/PREFERENCES
Resources	
Funding	No cost to students, minimal or no cost to schools, grant-funded service and administrative personnel for project with eventual transition to publicly funded service personnel
Time	Scheduling to be youth- and parent-centric and expert-guided, while respecting that academic success and school functioning is a priority; sessions fit within school period, and treatment episodes fit around school calendar, holidays, and exams
Space	Safe, confidential, private space in school setting; no services in a hospital, clinic, or outside school
People	10-19-year-olds, adolescents with non-specialist providers, but guardian/specialist involvement in case of serious issues; family and peer support desirable but aim to minimize collateral encounters other than information sharing with guardian; entire school involved to reduce stigma and enhance acceptance; referrals accepted from all sources; peer supervision for providers
Materials	Illustration rich, character-based client- and provider-facing material in Hindi, and English; step-by-step with explicit decision guidance of minimal difficulty and complexity; workbook plus one-on-one interaction; possible digital adjunct to support youth interest in video/chat with peer and provider but with the constraint of severely limited digital technology access, knowledge, and support
Activity	
Assessment	Assessment individualized to youth goals balanced with standardized, validated, multisource measurement prioritizing clinical targets and outcomes likely to influence life functioning
Planning	Requiring minimal provider expertise, prioritizing data-based algorithms for key decisions (e.g., eligibility, target selection, treatment selection); Target selection among high prevalence options based on screening with preference for maximizing coverage of all emotional and behavioral targets excluding high risk; Treatment selection among practices derived from the evidence base
Treatment	Treatment using evidence-based procedures; prioritizing concrete behavioral over abstract techniques that address problem-solving, engagement, and skill development (coping, social, and self-management); guardian psychoeducation and parent management skill option desirable but not required; session management with step-by-step guide of limited difficulty; episode management and problem-solving not initially specified; adaptation minimized but guided by provider knowledge; relationship and change management with provider-driven contact that treats youth as equal, prioritizes collaborative guidance, and ongoing support to maintain the relationship through step up to more intensive services
Monitoring	Youth and provider report of emotional, behavioral, and risk status across sessions; frequent enough to inform some modest individualization in “run time”
Quality Assurance and Improvement	Service support and supervision routinely provided by peers with limited expert guidance; evidentiary framework minimally specified preference of trained independent provider model with peer supervision; reasoning and review minimized except for peer supervision; implementation management by project team
Coordination	
Participants	Self-help, guided self-help, or individual therapy with a preference for efficiency
Targets	Support multiple treatment targets in a single protocol with modular approach; unified or transdiagnostic approach possible, especially at lower steps (e.g., general cognitive-behavioral skills, mindfulness)
Providers	Single Step 2 provider with hand-off referral for management of serious issues
Treatment Episodes	Stepped care model with (a) universal self-help or supported self-help, (b) intensive face-to-face, and possibly (c) specialist service (for suicidality, depression, temperament/personality disorders, other severe problems); step promotion based on impairment in addition to diagnosis with option to skip a step if needed
Theory	Risk and protective factors conceptualized within broad ecological-transactional framework with mechanism of change based on enhanced problem- and emotion-focused coping
Privacy	Pervasive support for privacy and confidentiality with clear coordination and boundaries for information sharing
Complexity	Procedures and decision framework streamlined to increase feasibility and scalability, but the framework should support extensibility (e.g., “add on” features that could be introduced in mature versions post-implementation) and utility (e.g., the ability to handle a diversity of common cases or challenges)
Outcomes	
Status: Client	Symptoms related to presentation preferred over diagnosis; functioning (especially academic and social); screening domains as required by local standards
Status: Context	Recruitment and enrollment status as outcome of school-wide contextual sensitization activities; Qualitative cooperative inquiry group topic
Engagement	Therapeutic alliance, client satisfaction; qualitative cooperative inquiry group topic (Heron, 1996)
Utilization	Workflow status routinely managed by project team
Integrity	Clinical case records, Qualitative cooperative inquiry group topics

research that was the intellectual predecessor of the PRIDE program (e.g., Patil et al., 2014). The product of this first phase was intended to be a general set of values and preferences to describe a contextually appropriate set of offerings for the Step 2 service (see Fig. 1). These values and preferences guided the second phase of formative activities, adopt-adapt-assemble, which involved selection or design of the protocol(s) fitting those preferences. The product of the adopt-adapt-assemble phase would be a set of parameters to inform the third phase, and these could include: (1) a list of suitable EBT candidate programs to choose (i.e., adopt) and organize into an array, (2) a set of specific adaptations to selected EBTs that would be needed for them to work in the planned context (i.e., adapt), or (3) a list of functional requirements and blueprints for an original protocol to be built from components in the evidence base (i.e., assemble). The third phase was intended to yield a working protocol, array, or intervention system with strong a likelihood for both effectiveness and sustainability in the planned contexts of India's schools.

To pursue a goal of maximizing integrity throughout the design process, we employed a formal model of treatment integrity. Regan, Daleiden, and Chorpita (2013) defined integrity analysis as “the structured comparison of observed values (i.e., what is happening) with expected values (i.e., what should be happening) within strategically selected domains ..., for the purposes of managing uncertainty” (p. 80). Specifically, Regan et al. (2013) referred to four key domains, namely, integrity of resources, activities, coordination, and outcomes. *Resources* refer to assets and capital (e.g., materials, people, knowledge, funding, space, time), *activities* refer to the occurrence of behaviors and events (e.g., specific practices, service encounters), *coordination* refers to relations among resources and activities (e.g., sharing, fit, flow), and *outcomes* refer to the status of goals and objectives (e.g., youth symptom reduction, functional improvement). Thus, the design would involve establishing expected values in these four domains (e.g., who is the preferred or ideal workforce, as an example of resource integrity; how should Step 1 connect to Step 2 ideally, as an example of coordination

integrity) and comparing these with observed values (e.g., who is available to deliver services; what obstacles are there to a Step 1 – Step 2 transition?), and attempting to reconcile those differences.

The formative activities were guided distally by a Scientific Advisory Group (SAG), comprising an international group of clinicians and researchers with backgrounds in global mental health, dissemination, treatment design, and evidence-based practice, who met approximately once per year. The work was guided more proximally by an Intervention Working Group (IWG), comprising intervention development teams at UCLA working closely with research coordinators and clinical experts based in the UK and at Sangath, India. The IWG communicated as often as weekly throughout much of the design phase. All three phases are described in detail below, with their activities analogous to a study “method,” and their set of products or outputs analogous to study “results.”

3. Context review

3.1. Activities

The rationale for a deep review of the context was that the intervention approach would need to be sustainable in that context and need to fit the values, concerns, and priorities of the local population, the characteristics and competencies of the planned workforce, and the regulations and standards of the school settings. The review included site visits and tours at local schools by members of the IWG and SAG to provide a sensitivity to the practice context (e.g., the size and layout of a typical school, student/teacher ratio, resources, access to private meeting space, extent of internet access). The typical environment afforded minimal privacy, had limited internet access, and had rather large student populations with very few teachers and administrators (e.g., one school in New Delhi had more than 9000 students served by approximately 45 teachers). As indicated in the Context Review phase of Fig. 1, the SAG also performed or oversaw multiple formal investigations of the local context, including locally-relevant literature reviews (e.g., Boustani et al., 2020 in press), review of documentation on local regulations and standards and stakeholder perspectives and policies regarding adolescent mental health in India (Roy et al., 2019), assessment of school preferences and priorities through stakeholder interviews (Parikh, Michelson, Sapru, et al., 2019), and surveys of adolescents in India to obtain their perspectives about mental health, stress, and coping (Gonsalves et al., 2019; Parikh, Sapru, et al., 2019). The findings from these meeting notes, field notes, and peer-reviewed studies were consolidated by members of the IWG through summary documentation reviewed iteratively until consensus was achieved. This activity ultimately yielded a *Statement of Values and Preferences*, organized according to the categories outlined in the Regan et al. (2013) integrity framework.

3.2. Values and preferences

This *Statement of Values and Preferences* (see Table 1) was a primary output of the *Context Review* phase that served to drive the team's subsequent design decisions. According to our integrity framework, the *Statement of Values and Preferences* set expected values for subsequent decision-making (i.e., what should things look like ideally, given what is known about the context?). Consistent with the assertion that integrity analysis “is an iterative process in which values selected at one time may need to be replaced and new values may need to be introduced,” (Regan et al., 2013, p. 82) our *Statement of Values and Preferences* served as a decision guide for desired properties, not as a fixed set of necessary requirements.

The reviews of consumer perspectives suggested a high degree of stress, burden, and hopelessness that included anxiety, depression, anger, poor concentration, and rumination. In addition, adolescents generally demonstrated low mental health literacy, concerns about

stigma, and minimal use of active coping strategies. These findings were translated into preferences for youth-centric services that built coping skills to address multiple problems and that were free to students through the school setting yet also minimized resource demands on schools. Scheduling of treatment sessions and episodes was expected to be flexible and to fit within an externally constrained calendar punctuated by many potential service interruptions due to school events, such as exams and holidays. Also preferred was a single, coherent, yet extensible framework of minimal complexity that stepped multiple episodes of care to include (a) school-wide sensitization to address stigma, (b) low intensity services, and (c) more intensive services that could primarily be delivered by non-specialist providers. A preference was specified for richly illustrated, character-based materials in the youth's preferred language. The key outcomes included reduced symptomatology, improved academic and social functioning, and scalability of services. In addition to producing a *Statement of Values and Preferences*, the Context Review phase also identified several intervention programs that were potential candidates for satisfying these values, to be examined more fully in the next phase.

4. Adopt adapt assemble

4.1. Activities

Broadly speaking, implementation of quality mental health services in a new context forces a choice about whether to pursue one of three strategies. First, one can **adopt** an existing evidence-based program or set of programs that is best suited to the population, workforce, setting, and service context, an initial step represented in several traditional implementation frameworks (e.g., Damschroder et al., 2009; Proctor et al., 2011). The key benefit of such an approach is the reduced uncertainty that results from taking a known resource and implementing it with a high degree of integrity. The principal drawback, however, involves the requirement that the population, workforce, setting, and service context are similar enough to the research context in which the treatment was developed and tested. In other words, if there is an existing evidence-based program that has been successful in a research context highly similar to the planned service context, one can minimize uncertainty about achieving similar success by choosing that program and following it with integrity (cf. “Rollout concept;” Real & Poole, 2005, p. 69).

Unfortunately, the wholesale generalization of a specific evidence-based program to a service context is not always possible (e.g., Chorpita et al., 2011; Southam-Gerow, Chorpita, Miller, & Gleacher, 2008), which thus calls for a second strategy: to **adapt** a candidate program (cf. “Modification concept;” Real & Poole, 2005, p. 70). This approach involves changing a subset of features to fit a known treatment program or set of programs to fit the intended service context, or “effective adaptation of the innovation to the user group” (Real & Poole, p. 70). When such adaptations are minimal, such as translating the client-facing materials into a new language, shortening the duration of sessions slightly, or simplifying a procedure that is not central to the theorized mechanisms, one can maintain some of the benefits of the **adopt** approach: relatively low uncertainty about desired outcomes, given the similarity to the research context, while solving otherwise potentially significant barriers to implementation. As the number or degree of adaptations becomes larger, however, uncertainty about implementation success increases.

Finally, the strategy to **assemble** a treatment is appropriate for situations in which the first two options do not produce a suitable choice. Although the resulting program or programs are essentially “new,” this path can nevertheless manage uncertainty by building on existing theories, components, and/or structures of existing treatment programs, rather than “building completely from scratch.” Models for implementation development are relevant here, such as the Medical Research Council Complex Intervention Framework (CIF; Medical

Table 2
Parameter specification.

DIMENSION	DETERMINED AT DESIGN TIME	DETERMINED DURING RUN TIME
Resources		
<i>Funding</i>	Public, pre-funded, no service dependent billing or contingency, runtime eligibility determination	Youth eligibility for services
<i>Time</i>	1-3 sessions per module for 4 primary plus 2 optional modules, Runtime scheduling of 6–10 semiweekly to weekly sessions within 6 weeks duration	Duration of each session, number of sessions per module, number of modules, spacing of sessions, and duration of episode
<i>Space</i>	Semi-private space in school for services, Support facilities provided by institutions participating in research	Maximize privacy within semi-private space (e.g., curtain, positioning of seating); School determines specific spaces available
<i>People</i>	9th – 12th grade youth for sensitization; Eligible youth for consent, measurement, and treatment; Eligible guardian for consent and measurement; Provider with at least Master's degree for treatment; Psychologists for expert consultation; Youth, guardian, and school staff for referral	Decisions about youth and guardian inclusion, consent, and continuation; Decisions about provider case participation, consultation seeking, project participation, and treatment continuation
<i>Materials</i>	Consent forms and specific measures for youth and guardian, youth-facing handouts, Youth Top Problems dashboard, and flipbook, Provider-facing flipbook, clinical record form, manual, appendices; illustration rich, culturally representative, and character-based analogue material in Hindi, and English with no digital adjunct, Video for universal sensitization and recruitment	Frequency of referencing material beyond minimum specifications; integration of youth preferences for terminology; seeking outside instructional support regarding specific material
Activity		
<i>Assessment</i>	Initial assessment battery	–
<i>Planning</i>	Target and treatment selection options constrained by consensus informed through development process with run-time target selection and episode management guided by decision algorithms; Run-time target selection determines treatment plan	Initial treatment pathway decision
<i>Treatment</i>	Psychoeducation & Engagement, Relaxation, Behavioral Activation, Exposure, Assertiveness & Communication, Cognitive, Problem-Solving, Maintenance & Termination; session management with step-by-step instructions in modules developed using a common session guide; episode management by a common treatment pathway with conditional branching; Relationship and change management with general recommendation to adopt a collaborative style with some representation of provider as an “expert” due to cultural role expectations.	Election to use optional practices; response to emergent life events; use of modules, rate, and depth of coverage in session; use of algorithms, flow, persist, supplement, and step-up in episode; relational style decisions
<i>Monitoring</i>	Youth Top Problems; Mood Ratings (ideographic); SDQ Session by Session version	Relative weighting of client data, protocol, and knowledge in decision-making
<i>Quality Assurance and Improvement</i>	Evidentiary framework of evidence-based knowledge represented as protocol, client data informing runtime decision-making with problem-solving, reasoning, and adaptation guided by provider knowledge supported through peer and expert consultation	Seeking peer or expert consultation
Coordination		
<i>Participants</i>	Individual format, youth and provider share language, runtime case allocation decisions	Caseload decision (Number of clients per provider)
<i>Targets</i>	Modular approach for three targets of mood, anxiety, and conduct that builds upon generic problem-solving approach in Step 1 with a coherent framework for extensibility for non-specified targets	Target priority decision (i.e., which to focus on in the middle phase of treatment)
<i>Providers</i>	Modular protocol with integrated data features supports provision by single or multiple providers; Single provider is prioritized to maximize relationship and change management and intangibles, such as shared knowledge	Client-provider matching decision (e.g., using same provider from Step 1)
<i>Episodes</i>	Universal sensitization and recruitment with two steps for eligible youth using single framework that supports extensibility; Step 1 is a generic problem-solving episode, Step 2 is more intensive targeted service episode; Client data and algorithm used to guide step-up decisions	Program eligibility determination; Step transition decision
<i>Theory</i>	Enhanced coping through problem-solving skills at Step 1 with problem-solving serving as the guiding metaphor for the mechanism of change to continue growth of coping competency in the youth's natural ecology or via Step 2 development of additional problem- and emotion-focused skills	Shared understanding with youth guided by protocol content and provider knowledge
<i>Privacy</i>	Privacy and confidentiality safeguards defined and conveyed in sensitization, consent, and treatment activities	Proactive safeguarding, actual response to enquiries about youth, decision that conditions met to break confidentiality
<i>Complexity</i>	Prioritize strong design-time defaults with limited runtime decision-making; Provide explicit guidance for runtime decision-making; Use single framework with common design elements; Limit number of modules; Balance initial burden with appetite for complexity as expertise develops; Support expertise through peer and expert consultation	Use of materials; Exercise of learned skills; Seek consultation
Outcomes		
<i>Status: Client</i>	Strengths and Difficulties Questionnaire with Impact Supplement, Mood rating, Youth Top Problem rating, Personalized benchmarks for Youth Top Problems	Identification of top problem(s) and Identification of goal(s) guided by treatment protocol
<i>Status: Context</i>	Recruitment and enrollment during sensitization, No case-specific measurement	–

(continued on next page)

Table 2 (continued)

DIMENSION	DETERMINED AT DESIGN TIME	DETERMINED DURING RUN TIME
<i>Engagement</i>	Relationship: Session Feedback Questionnaire (initial version only), Expectancy: SDQ SxS Thinking about Future item, Attendance: Encounter Frequency, Clarity: No case-specific measurement, Homework: Workbook completion; Satisfaction: Client Satisfaction Questionnaire-8	Content of homework assignment guided by treatment protocol
<i>Utilization</i>	CONSORT style workflow status report	–
<i>Integrity</i>	Clinical case records, Cooperative inquiry with peers and experts	–

Research Council, 2019) and the RE-AIM framework (Glasgow, Vogt, & Boles, 1999). The CIF emphasizes the importance of attending rigorously to developing and piloting a new intervention, prior to its downstream evaluation, such that more a pragmatic intervention is likely to emerge. Although our efforts corresponded primarily to the development (first) phase of the CIF, we concurrently attended heavily to considerations relevant to the implementation (fourth) phase as well. Our thinking was also guided by the RE-AIM framework, which emphasizes the importance of intervention *impact*, described as a product of five factors: Reach (who it might serve), Efficacy (how well it might work), Adoption (whether it might be chosen), Implementation, and Maintenance (how feasible and sustainable it is). With these considerations in mind, the IWG proceeded deliberately through each of the adopt, adapt, and assemble activities in order, which are detailed next.

Adopt. The IWG with guidance from the SAG used the outputs of the Context Review phase to identify promising candidates for adoption, which principally included MATCH-ADTC (Chorpita & Weisz, 2009) and a youth version of the Common Elements Treatment Approach (CETA; Murray et al., 2018). Both programs were judged to have many desirable properties for the PRIDE endeavor but fell short of satisfying a sufficiently large volume of the desired values and preferences. In particular, MATCH was not regarded as an ideal fit for the eventual non-specialist workforce, and CETA was judged as being a useful paradigm but was designed as a single step treatment (already including the problem-solving component which was the core of the PRIDE step 1 treatment) and requiring considerable supervision, particularly for the decision making step by front-line providers. Neither program was available with appropriate language resources for this context.

Adapt. In this logical progression, both MATCH and CETA were then considered for structural adaptations to address fit. In addition, some consideration was given to whether the Unified Treatment for Adolescents (Ehrenreich-May et al., 2017) could be adapted for fit to this local context. Challenges remained regarding degree of structure (which needed to afford flexibility but with minimal complexity), scope (e.g., the desire to manage anger and peer problems as well as anxiety and depression related concerns), and training burden for a non-specialist workforce. Ultimately, the re-design, implementation burden, and ultimate fit of targeted adaptations of these candidate programs were felt to introduce a considerable level of uncertainty, and thus none of these candidates was chosen for adaptation.

Assemble. The distinct features of the context thus demanded a highly specific set of affordances not readily available in the evidence base, despite our review of hundreds of possible candidates (PracticeWise, 2017) and therefore it was felt that assembling a protocol for this context was the most appropriate strategy. To minimize uncertainty about program performance, we sought to capitalize on as much of the relevant evidence base as possible, aggregating across many relevant clinical trials to outline treatment content, basic process architectures (e.g., sequence and flow), and a unifying theoretical approach. As noted above, we were guided in principle by conceptual frameworks such as RE-AIM (Glasgow et al., 1999), for instance, seeking to maximize impact according to the framework's five dimensions. However, we sought a framework that also offered not only a

guiding conceptual model, but also robust strategies and tools for the design process. We therefore explicitly chose the Managing and Adapting Practice (MAP) system for this purpose (Chorpita & Daleiden, 2014), given its formal structures and resources for designing and building context- or client-specific interventions based on aggregate consideration of both conceptual and architectural features of all relevant evidence-based practices. As noted by Chorpita and Daleiden (2014), the MAP system is not a treatment itself; instead, it features “a treatment selection, design, implementation, and evaluation kit” (p. 336) and thus can serve as a treatment “builder.”

4.2. Specified parameters

The output of the “Adopt, Adapt, Assemble” phase was the *Parameter Specification* that provided expected values for the Design and Build phase (see phases 2 and 3 in Fig. 1). The *Parameter Specification* values are shown in Table 2, in which rows refer to the resource, activity, coordination, and outcome integrity domains, and columns refer to the tier of control, namely design-time or run-time. Chorpita and Daleiden (2014) defined design-time control as “engineering an object or entity to have certain attributes and features in advance, before it is free to behave in a given environment” whereas run-time control is defined as “the manner in which an object or entity is further configured or affected by interacting with its environment” (p. 325). The specific design-time parameters were configured by the IWG as part of the protocol and were thus fixed affordances for the therapist and adolescent during treatment. For example, the “Treatment” row and “Determined During Design Time” column of Table 2 shows, among other things, which clinical procedures should be in the working protocol, named in advance by the investigation team. When a parameter was specified for run-time control by the IWG, the decision-making about the actual value of the parameter was delegated to the therapeutic context, such that the therapist and adolescent would collaborate on the decision-making during treatment. For example, whether any of those procedures could be repeated in a subsequent session before advancing to the next procedure was determined by the therapist and youth together, based on how things were going at that time (i.e., an affordance described in the “Treatment” row and “Determined During Run Time” column of Table 2).

Generally, the design-time parameters focused on setting boundaries around basic operating procedures, such as defining the eligible population (9–12th grade youth with non-response to Step 1 treatment), setting (school-based), format (individual therapy), relational style (expert-guided collaboration), primary treatment targets (anxiety, mood, and conduct), assessment model (specific measures, administration schedule), theory of change (enhance coping through problem-solving and behavioral skills), evidentiary framework (research informed in protocol, client data informed decision-making, provider expertise supported through consultation), treatment architecture (single, coherent, modular framework with integrated data features extensible for non-specified targets), treatment practices (specific cognitive-behavioral practice elements), and decision-making expectations (strong default prioritization, data-informed, algorithmically-guided). The types of decisions delegated to the treatment run-time environment include determining treatment eligibility and participation,

safeguarding privacy, some aspects of relational style, treatment target prioritization, scheduling and dosing of treatment, response to emergent life events, relative weighting of case data, protocol, and knowledge in decision-making. Providers and consultants also made several project run-time decisions including project participation and continuation, caseload mix and capacity, seeking instructional support and consultation from peers or experts.

5. Design and Build

5.1. Activities

Collaborative design. This third phase of the formative activities required the IWG to articulate a “blueprint” based on the requirements and parameters specified in the previous phase, and in turn building a working version of the protocol from these blueprints. This phase involved several activities, guided by a collaborative design process among IWG members, which included regular phone calls, meetings, and document exchange between the intervention design laboratory at UCLA and the implementation team at Sangath. To facilitate as well as document this collaboration, one member of the UCLA design team (RG) spent a year in residence in India, which included participating in local meetings and international conference calls, as well as trialing successive iterations of the protocol with adolescents in Goa and Delhi, along with the Sangath implementation team. This collaborative design process (see Fig. 1) was documented using qualitative sources including meeting notes, emails, supervision recordings, field notes, and semi-structured interviews. Given the potential for this process to inform methods for future collaborative design-in-context (i.e., the “Assemble” strategy), these sources will be coded and analyzed using the qualitative analytic approach of coding consensus, co-occurrence, and comparison for themes such as design characteristics and cultural salience.

Practice content selection. Assembly of an appropriate protocol requires the selection of procedures to fit the intended population, target problems, workforce, and context. The MAP system uses a specific methodology, called relevance mapping (Chorpita et al., 2011), whereby features of the population and context are matched to protocols in the literature that meet a given standard of evidence. The content of these protocols can be abstracted in a variety of ways, but for the purposes of assembling a protocol for PRIDE, we chose to examine coded practice elements from the literature (i.e., discrete clinical procedures within protocols, such as relaxation or problem-solving training; Chorpita & Daleiden, 2009). Boustani et al. 2020 (in press) reported on this set of analyses, which involved an epidemiological dataset from a community sample and a second, smaller dataset of self-reported problems among youth seeking services in the PRIDE locations of Goa and New Delhi, India. Boustani et al. 2020 (in press) found that practices common to the intended age group and problem types included: behavioral activation, cognitive coping, communication skills, exposure, goal setting, maintenance, problem solving, psychoeducation, and rapport building. It should be noted that this type of practice elements analysis can identify candidate practices for inclusion, but it does not in and of itself yield a treatment (see Chorpita & Daleiden, 2014). Thus, the IWG used this list as a starting point for discussion of elements to be organized ultimately into an intervention prototype. This discussion involves simultaneous consideration of not only the youth, workforce, and context, but must consider how the practices will work together in an organized sequence or logic model, which we describe next.

Coordination framework. The MAP system for assembling an intervention organizes practices into three phases of treatment, referred to as Connect, Cultivate, and Consolidate. These phases serve the respective functions of (1) orienting and engaging, (2) building and rehearsing skills and competencies to address the focus of treatment, and (3) mastering and generalizing the skills to new situations and contexts as formal supports are faded. Based on the practice content analyses of

Table 3
Overview of modules in the working protocol.

Phase	Module	Practice Element
Let's Get Started	1. Getting to Know You	Psychoeducation and Engagement
	2. Relaxation	Relaxation
Pick Your Adventure	3. Behavioral Skills	One or More of
	• Being Active	• Behavioral Activation
	• Facing Our Fears	• Exposure
You Made It	• Being Assertive	• Assertiveness & Communication
	4. How We Think	Cognitive (optional)
	5. Solving Problems	Problem Solving (optional)
	6. Looking Ahead	Maintenance & Termination

Boustani et al. 2020 (in press), the practices were selected and arranged as follows. For the Connect phase (“Let's Get Started” in the Step 2 protocol; see Table 3), we chose to include psychoeducation for youth, a rapport-building procedure identified in the relevance mapping analyses, and relaxation (to create an engaging context using a culturally familiar procedure). For the Cultivate phase (“Pick Your Adventure”), we chose one procedure for each of three expected possible treatment targets: exposure for anxiety, behavioral activation for depression, and an assertiveness and communication skills procedure that included some aspects of social skills for conduct and anger problems. Cognitive coping was a common procedure in the analyses by Boustani et al. 2020 (in press) but given concerns among some members of the IWG about complexity for a non-specialist workforce as well as for the targeted adolescent population, it was included only as an optional procedure to be added in the final Consolidate phase of treatment (“You Made It”). Similarly, problem solving was included only as an optional practice for review, elaboration, and synthesis, given that Step 2 was intended to follow Step 1 non-responders who would have already had some training in problem solving (see Table 2, episode coordination). Finally, the protocol concluded with a maintenance procedure for putting all the skills together and supporting their continued use.

One particular tradeoff in the protocol coordination involved the competing values of needing to be comprehensive in scope (i.e., transdiagnostic), while needing to have limited complexity to facilitate scaling with a non-specialist workforce. The IWG considered two possible solutions. The first had been to build the protocol around a single transdiagnostic procedure, such as relaxation, that could potentially have generalized effects across diverse student presentations (e.g., reducing anxiety, depression, or peer-directed anger). This approach has as an exemplar the Unified Treatment (Barlow, Allen, & Choate, 2004), which is designed for adult anxiety and depression. In consultation with the SAG, however, it was decided that the expected presentations in the adolescent sample were too diverse and the evidence base was comparatively limited to choose this approach. This in turn dictated our ultimate strategy, reflected above, which was to have each primary presentation receive one matching procedure in the Cultivate phase of treatment (hence, “Pick Your Adventure”).

This approach of selecting matching procedures from a larger set of modules satisfied our scope criterion, and it has growing support in the evidence base (Chorpita et al., 2017; Weisz et al., 2012). However, it requires a provider (or supervisor) to select the primary treatment target; in this case, which “adventure” to pick. It is known more generally that as protocol flexibility increases, more complex decisions are needed (e.g., which practices to implement and when), which can in turn threaten successful implementation (cf. Glasgow et al., 1999). School mental health workforces in LMICs (if even available) face significant implementation challenges, including minimal training in delivering EBTs and even less access to run-time evidence to help them make decisions within complex protocols and contexts (Kieling et al., 2011).

We proceeded with a modular design that called for one decision

about the focus of treatment at the middle phase (which of the three procedures to use). One more decision was part of the coordination model as well: whether to perform either of the optional modules. Early trialing of the protocol by the implementation team reaffirmed that the first middle-phase treatment focus decision could be a concern or limitation for scaling with non-specialists. The latter decisions about the optional modules were considered less of a threat to the design integrity, in part because the procedures were by definition not considered essential and so any decision errors would be less consequential.

Given the remaining concerns about the initial treatment focus decision, we then decided to develop a one-page guide, specifically designed to facilitate the decision about treatment focus. Knudsen et al. 2020 (in preparation) reported on an open trial evaluation of this resource and its associated training with mental health providers in India. In that investigation, a team of direct service providers corroborated the IWG-reported concerns by showing poor convergence with expert decision makers at pre-training, using case vignettes that represented a mix of single-disorder and comorbid presenting problems drawn from local high school students in India and that were reviewed/edited by community providers for cultural relevance. Post-training results showed considerable improvement in terms of agreement with experts on decisions made for treatment focus using a second set of vignettes. Following the inclusion of this specific decision support and the brief training into the PRIDE Step 2 model, the IWG felt that the resulting protocol successfully balanced scope of focus with a manageable level of complexity.

Youth perspective. Another aspect of the Design and Build phase of the formative activities (see Fig. 1) was to gather information about youth perspectives on the treatment program as it was developed. In particular, we wanted to focus on whether the youth experience was satisfying and that it would foster a high level of engagement in the service model. Poor engagement in children's mental health services has long been a public health concern (Becker, Boustani, Gellatly, & Chorpita, 2018), and less is known about treatment engagement in LMICs. Thus, as various iterations were tested with youth, members of the IWG sought to identify the types of engagement challenges that could arise. One member of the design team performed semi-structured interviews with providers and students about their perceived acceptability of the intervention. Providers also reported on in-session engagement challenges using a session record form that included a quantitative engagement challenge scale. These findings were fed back regularly to the full IWG as development proceeded and led to multiple design improvements along the way, which included adding provider scripts for introducing student-facing materials, such as the illustrated flipbook, and simplifying the goal setting procedure to be more relevant to the student's reported problem.

Pre-piloting and clinical case series. Concurrent with these investigations and developments, IWG members based in Sangath led a clinical case series (CCS) to pilot successive iterations of the protocol, gathering data on outcomes, and gathering impressions about feasibility, complexity, generalizability, suitability of materials, and overall delivery experience. This CCS was conducted over a period of 10 months (July 2018–April 2019) in six secondary schools aided by Archdiocese Board of Education (ABE), Goa, India. The participants were students in 8th through 10th grade who were not fully responsive to the first line of intervention (Step 1) or who relapsed within a year of receiving Step 1 and sought treatment again. For the CCS, non-response to Step 1 was defined as scoring at or above the locally validated borderline cutoff (19 for boys and 20 for girls; Bhola, Sathyanarayanan, Rekha, Daniel, & Thomas, 2016) on the Total Difficulties Scale of the Strengths and Difficulties Questionnaire's (SDQ) and/or at or above the clinical cutoff (2 or more) on the SDQ Impact scale during post-Step 1 assessment.

Eligible participants were offered the Step 2 intervention by three school-based providers who were employed by the project (one

doctoral student, one postgraduate psychologist and one non-specialist mental health worker). Written informed assent and corresponding parental consent were obtained from all adolescents younger than 18 years of age, and informed consent was obtained from adolescents aged 18 years or older.

A pre-post design was used to examine the acceptability and feasibility of the Step 2 intervention. Post assessments were carried out between 12 and 18 weeks from baseline (Mean = 113.8 days; SD = 34.3), depending on the duration of the Step 2 intervention. From a total of 23 eligible adolescents, seven opted out from participation in the Step 2 intervention. Adolescents' self-reported reasons were as follows: improvement in problems (n = 3), lack of parent consent (n = 2), competing time demands (n = 1), and lack of interest (n = 1). Thus, a total of 30.4% cases were lost in the transition from Step 1 to Step 2, and 16 adolescents (69.6%) participated in the intervention. The parent of one of these 16 students did not consent for research participation on treatment outcome; thus, this student received the intervention, but her outcome data were not included in the analysis. There was no difference on any demographic variables of those who participated and those who opted out.

The majority of the 16 adolescents received a full course of Step 2 intervention (n = 13, 81.3%), defined as completion of modules on a minimum of three components across the treatment phases (relaxation, one of the problem-specific skills, and maintenance & termination). During the initial phase of the intervention, two of the 16 adolescents dropped out, one due to extended absence from school and the other due to a self-reported resolution of the problem.

On average, the 13 treatment completers received 9.3 sessions (SD = 2.1) over a period of 3 months (Mean = 89.1 days; SD = 38.0; school holidays and examinations contributed to treatment duration). The average duration of the individual session was 33 min (SD = 5.7), which fit well into the standard 30–35 min class period. Outcome scores were obtained for all 15 consenting participants (completers and non-completers) except one, due to extended school absence. The majority of participants assessed at post were fully remitted (n = 9, 64.3%), with SDQ Total Difficulties and Impact scores (Goodman, Ford, Simmons, Gatward, & Meltzer, 2000) both dropping below clinical thresholds, Table 4 shows that pre-post changes were significant on the SDQ Total Difficulties and Impact Scales, as well as the Youth Top Problems instrument (YTP), an ideographic measure of youth functioning (Weisz et al., 2011). Scores on a measure of satisfaction (i.e., Client Satisfaction Questionnaire; Larsen, Attkisson, Hargreaves, & Nguyen, 1979) were in the good to excellent range (M = 3.4; SD = 0.25). All 14 of those participants reported that the counselling service had helped them deal more effectively with their problems and that they liked the quality of service.

Although the overall cases series demonstrated that the protocol was feasible and acceptable, multiple improvements were nevertheless introduced along the way aiming to improve the ease of use and utility for students and providers. Examples included (a) revising the provider-facing materials make them simpler but with more detail where needed, (b) shifting from design-time to run-time authority for some pragmatic decisions, such as which type of relaxation method to pursue (e.g., providers had a preference for choosing the method collaboratively with the student up front, rather than trying each of three different

Table 4
Pre and post scores from the Goa clinical case series.

Measure	Pre		Post		t	p
	M	SD	M	SD		
SDQ Total Difficulties	22.1	3.9	13.1	5.6	19.22	.001
SDQ Impact	3.4	1.9	1.1	1.8	3.31	.006
Youth Top Problems	6.7	1.9	3.0	2.0	4.23	.002

Note. SDQ = Strength and Difficulties Questionnaire.

methods, which was more time consuming), (c) adding opportunities to rehearse previously learned skills, and (d) increasing description of the cognitive aspects of some skills.

5.2. Working protocol

This third phase of formative activities yielded a *Working Protocol* that met the specified parameters from the prior phase and was sufficiently compatible with the Step 1 protocol (see Fig. 1). Within our integrity framework, the working protocol was intended to provide expected values to guide youth and provider interactions during the Combined Step 1 and Step 2 Pilot Evaluation (planned for late 2019 and early 2020). The Step 2 *Working Protocol* built upon the Step 1 protocol's introduction of a three-step problem-solving framework, using the POD acronym for Problem, Options, Do It. The Step 2 *Working Protocol* used a visual metaphor of a personal journey through a series of skills in which the youth chose the path of the journey.

Technically, the *Working Protocol* was a cognitive-behavioral treatment primarily targeted to mood, anxiety, and conduct problems and organized into six modules that progressed through three phases, as noted above (see Table 3). Although the protocol library consisted of six modules, the core treatment pathway was designed for each individual youth to complete four modules with optional branches to strengthen additional skills. As previously noted, the library of cognitive-behavioral skills developed through the treatment included problem-solving, relaxation, behavioral activation, exposure, assertiveness & communication, cognitive restructuring, and maintenance & termination. Again, due to elective branching within the treatment pathway, by the end of a treatment episode, each individual youth would have completed a minimum of three primary skills (relaxation, maintenance & termination, plus behavioral activation, exposure, or assertiveness & communication) in addition to the problem-solving skill previously encountered in Step 1.

In terms of structure, each module was designed with two interfaces: (1) youth-facing materials, which served as a direct technical interface (e.g., handouts), and (2) provider-facing materials, which served to guide the social interactional interface (i.e., what the therapist might say and do). Youth-facing materials included an illustrated flipbook and handouts incorporating character-rich depictions with minimal but strategic use of text. Provider-facing materials included a manual with outline and appendices (e.g., step-by-step practice instructions, decision algorithms to guide coordination, etc.), an event sheet for characterizing the nature of encounters (e.g., type, mode, participants, and topic of contacts), and a clinical record form for capturing treatment session details (e.g., duration & scheduling, engagement & participation, materials & module steps used, risk & progress assessment, etc.). In addition, shared progress monitoring tools included a bar graph for tracking status on YTP (Weisz et al., 2011), a mood rating, and the Session by Session (SxS) version of the Strengths and Difficulties Questionnaire.

The protocol was designed to be delivered in an individual format on a flexible schedule with 1–3 sessions per module by non-specialist providers with protocol-specific training. The actual duration of sessions, number of sessions per module, the spacing of sessions, and the overall duration of the treatment episode were determined during implementation by the youth and provider based on monitoring data, youth preferences, and contextual constraints. The implementation guidelines for the pilot evaluation suggested 6–10 semi-weekly to weekly sessions within a 6-week period. Structured supports for developing provider expertise in the working protocol consisted of self-directed learning, workshop training, direct service experience, ongoing peer consultation, and expert consultation upon request.

Provider facing materials example. For the purposes of illustration, we present an example of the *Working Protocol* provider module for Relaxation in Fig. 2. The PRIDE Step 2 provider interface is a written manual to guide the performance of treatment delivery, setting

expected values for activities to occur in collaboration with the student. The interface design had three main functions: (1) accommodate diversity of the providers and the students they treat (e.g., can novice and experienced providers each interact with the materials in ways best suited to their evolving expertise?); (2) balance ‘design-time’ and ‘run-time’ control in treatment delivery (e.g., signifying which activities are constrained and which can be personalized); and (3) eliminate the need for intensive, instructive training by guiding and motivating provider self-learning through the manual itself.

As can be seen in Fig. 2, the provider interface includes structured steps at varying levels of detail designed in advance to support baseline differences in the provider's and student's current status and to guide appropriate, adaptive action at run-time (e.g., choosing a harder or easier activity in the session). For example, the “Presentation 1 2 +” section in the upper left of the module signifies that repetition of the procedure across sessions is possible (but optional) and which presentation is represented (e.g., the step and script content differ for presentation 2 and above). Different components of the module also support providers at various points in their stages of learning the protocol. For example, as beginner providers gather more experience, they may progress from reading much of the module script verbatim within the full-version of the module interface (“script” column in Fig. 2) to guiding the activity with the corresponding provider-facing flipbook page (not shown), to merely referencing icons or brief descriptions once steps can be produced smoothly from memory (“steps” column in Fig. 2).

To map out pathways to learning the Step 2 treatment protocol, the module interface provides intuitive design elements (Norman, 2002), which are described in Table 5. Altogether, these features build a codified conceptual model for providers to easily translate to their own mental model of the treatment protocol. Finally, in addition to handling the complex nature of treatment delivery, the interface was designed with an eye towards its look and feel. A clean layout coupled with light, calming colors and simple text aim to make the process of delivering and learning the treatment enjoyable, which can reinforce skill learning and mastery (cf. Lyon & Koerner, 2016; Norman, 2009).

Coordination module. We also provide an illustration of one of the protocol features for managing coordination, or flow of treatment (see Fig. 3). Modeled after the MAP Connect-Cultivate-Consolidate process, the Step 2 treatment planner is an interface for strategic, responsive application of Step 2 procedures. It offers a coordinated flow that articulates the possible, impossible, and preferred sequences of content based on the goals of PRIDE Step 2. It keeps essential protocol features intact (i.e., psychoeducation, engagement, relaxation) and allows evidence-informed selection of other preferred practices (i.e., behavioral activation, exposure, or assertiveness training) and optional practices (i.e., cognitive, problem solving) in response to run-time demands, using the decision support guide described above. The three apples that surround each module icon are designed to serve as checklists, which help to convey to the provider and student which practice has been done and allows collaborative tracking of what has been covered so far. Checklists are powerful tools proven to increase the accuracy of behavior and to reduce error – particularly slips and memory lapses – and are especially important within the context of the complexity in treatment delivery. This version of treatment planner was designed as a tree to represent certain therapeutic practices as roots (e.g., psychoeducation) and foundations (e.g., engagement) of treatment. As students progress through treatment, they metaphorically climb up the tree to reach the sky. This provides a cohesive, recurrent message connecting the other protocol materials students receive (e.g., handouts) with the final goals of treatment, as well as with any Step 1 materials.

5.3. Summary and next steps

This paper summarizes a process of reviewing context and literature to produce and test a suitable candidate protocol system to address the



MODULE 2 RELAXATION

MATERIALS

QUICK TIPS

Presentation

1 2 +



Progress Monitoring Tools: YTP, SxS, Mood Rating



Handout 4: Relaxation



Appendix 4 or 5: Progressive Muscle Relaxation or Happy Place

- Ensure that the student is seated in a comfortable position throughout.
- Tell the student to imagine they are blowing bubbles to help improve deep breathing.
- Minimize noise and distractions, if possible.
- Benefits may not be immediate. Keep practicing!
- Don't forget to administer weekly progress monitoring and assess for risk!**

STEPS

SCRIPT

 Set Agenda	<ul style="list-style-type: none"> Tell the student about what you will cover in today's session: <ul style="list-style-type: none"> "Today we will be talking about relaxation. There are several strategies you can use to relax. Today I will introduce them and we will practice together." Ask the student if he/she agrees and if there are any additional items that he/she would like to talk about.
 Progress Monitoring	<ul style="list-style-type: none"> Administer the YTP, SxS, and mood monitoring rating scale.
 Introduce Relaxation	<ul style="list-style-type: none"> Assess for prior knowledge or use of relaxation strategies (e.g., yoga, meditation). If the student has experience, ask them about what they like about using those strategies and how relaxing helps their mood. Explain how feeling tense can affect the student's body, emotions, and behavior: <ul style="list-style-type: none"> "Sometimes, when people feel [student's problem: angry, sad, worried, tension] they may notice that feeling not only in their minds but also somewhere in their bodies. Have you ever noticed a physical sensation in your body related to how you feel? For example, when some people are [student's problem: angry, sad, worried, tense], they may notice their heart is beating fast, or their head hurts, or their stomach clenches [use Flipbook illustration 15 and point to the corresponding parts of the body]. Does any of that sound familiar to you? For example, when I feel stressed, I notice my shoulders hurting. Relaxation helps our minds and bodies feel better when we have these difficult emotions and problems." Introduce various relaxation techniques: <ul style="list-style-type: none"> "There are several strategies you can try to help you relax. Different things work for different people. Today we will be learning two of three relaxation skills. We will start with deep breathing, and then you can choose either happy place or deep muscle relaxation [describe each briefly]. Which of these would you like to learn today? We will learn the other one next time we meet." Use Flipbook 3: Relaxing to point out the illustrations for each technique. If the student expresses excitement about one of the two remaining techniques, teach that technique first to engage them.
 Deep Breathing	<ul style="list-style-type: none"> Explain pre and post-mood ratings: <ul style="list-style-type: none"> "We are going to do an experiment and see whether your mood changes after learning and practicing deep breathing together. It might change or it might not – let's try it out and see." Take the student's mood rating from the beginning of the session and note it down on the pre-relaxation mood scale on Handout 4: Relaxation. Next, ask the student to sit in a comfortable position with hands on their lower abdomen. Ask the student to breathe in slowly for 5 seconds through their nose, pause at the top of the breath, and then release slowly, feeling the air flow out. Take three more deep, full breaths. Take a brief pause, then repeat the cycle if required. Take a post-mood rating on Handout 4: Relaxation. Ask the student what they liked/did not like about the practice.
 Second Technique	<ul style="list-style-type: none"> Ask the student whether they would like to learn happy place or deep muscle relaxation next. Depending on their response, follow the Happy Place or Deep Muscle Relaxation scripts. Take a mood rating on Handout 4: Relaxation before and after completing the exercise. Ask the student which of the two techniques they liked best and connect it to their problem: <ul style="list-style-type: none"> "You said you liked [happy place, deep breathing, or deep muscle relaxation] best of the relaxation skills we learned today. That's great, because relaxation may help with your [student's problem]. When you practice relaxation this week, try to do it when you feel [problem] and notice whether it helps you feel better."
 Home Practice	<ul style="list-style-type: none"> Ask the student to practice their preferred technique(s) at home. Discuss potential barriers to practicing. Remind the student to take a mood rating on Handout 4: Relaxation before and after the relaxation exercises.

Note: The term "practice" on youth and provider facing materials denotes rehearsal, whereas in the context of the larger context of our design work, "practice" refers to a specific clinical procedure.

Fig. 2. Example provider-facing module illustrating a relaxation procedure. Note: The term "practice" on youth and provider facing materials denotes rehearsal, whereas in the context of the larger context of our design work, "practice" refers to a specific clinical procedure.

Table 5
Example design elements of the working protocol.

Element	Purpose	Examples
<i>Internal consistency</i>	Help providers connect meaning across modules; once a provider learns one module, it is much easier to learn another module	Signifiers are styled the same and placed in the same locations; content for each session fits within one page
<i>External consistency</i>	Make it intuitive	Module interface layout consistent with common design conventions (e.g., just as logos are commonly presented at the top left corner of webpages, so are our icon signifiers for module type)
<i>Signifiers</i>	Indicate important actions for treatment delivery	Step icons mark transitions from one type of therapeutic activity to another (i.e., set agenda, instruct with or without flipbook, discuss, review/reflect, practice in or out of session)
<i>Constraints</i>	Reduce cognitive load and consolidate learning	Wide variety of therapeutic activities represented by only seven different step icons (e.g., “practicing deep muscle relaxation” and “practicing going to a happy place” all correspond to the same icon representing “in session practice”); Step icons are further grouped with like-colors (e.g., two icons for in- and out-of-session practice both colored orange; handout material icon uses the same image – a paper and a pencil – as outside-of-session practice icon)
<i>Mapping</i>	Make it intuitive	Naturalistic signifiers represent therapeutic content (e.g., thought bubble icon indicates reflection, juggler icon indicates in-session practice)
<i>Discoverability</i>	Help guide the provider’s attention to areas most helpful to their stage of mastery and set the stage for new affordances	Full model interface step icons less prominent, to highlight the visible relationship between the size of each script box and the approximate amount of time to spend on each module step; in contrast, flipbook step icons designed for more visibility to highlight their use as checklists

mental health needs of adolescents in India. The purposes of this paper were (1) to describe the structured collaboration that occurred, illustrating in some detail how an intervention system can be assembled for a unique LMIC context, and (2) to describe and illustrate the protocol that will be tested in subsequent evaluations within the PRIDE research portfolio. This extensive collaboration yielded several insights that we feel are likely to generalize to similar intervention selection or development efforts.

One observation is that the process of choosing or developing an intervention model with wide reach for a low-resource context can be time-consuming and can involve extensive investigation, planning, prototyping, and refinement. We found that as one comes to understand

the planned implementation context in more detail, initial estimates of generalizability of candidate EBTs can begin to seem overly optimistic. Indeed, even small changes in context could potentially impact quality and outcomes, such as organizational climate differences among service clinics in the same region, serving nearly the same populations (Glisson & Hemmelgarn, 1998). Thus, in contexts such as India, we favored deliberate and thorough activity in the first two phases to avoid common risks (e.g., picking a treatment with minimal context review; assembling a new treatment without having reviewed suitable candidates to adapt or adopt first, or without a detailed initial blueprint).

In the service of that activity, we see value in organizing a development team characterized by diverse points of view, expertise, and

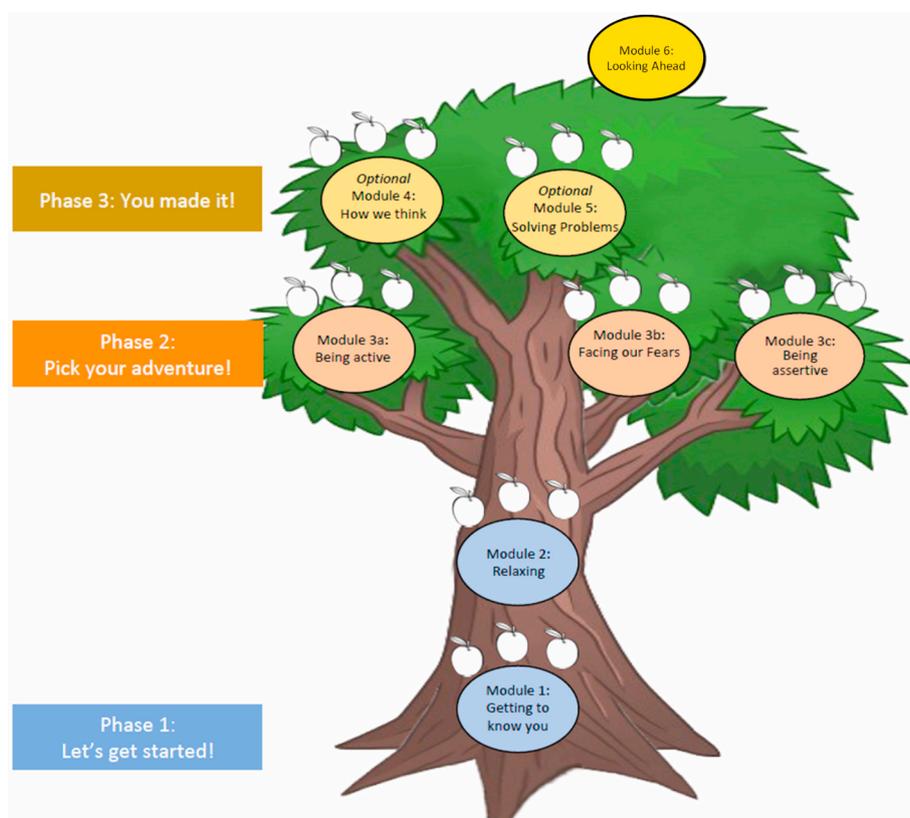


Fig. 3. A handout illustrating coordination flow for the Step 2 Protocol.

professional backgrounds, in which collaborative disagreement is normative. We frequently encountered disagreements among IWG team members, and our common strategy for resolving these disagreements was to adopt an evidence-gathering approach. For instance, when there were conflicting opinions about the most suitable format for the therapist-facing guide, rather than negotiating among ourselves, we instead trialed a variety of different formats and elements and gathered feedback for team review. Similarly, as described above, when there was disagreement over the capacity of therapists to make the treatment target decision (picking the treatment focus), we designed an experiment to assess the extent of the problem and test a candidate solution. This frequent experimentation during design often disconfirmed our initial expectations, and thus enhanced team learning and even led to multiple productive side investigations (see Fig. 1, in which each rectangle refers to one or more completed or planned peer-reviewed study, each of which produced new generalizable knowledge about aspects and process of intervention design).

A particularly common theme, which we expect to be part of many similar design activities, involved the tension of balancing complexity with utility. Attempts to increase the impact of the intervention (e.g., breadth of targets, effectiveness), often involved adding features, decisions, or other components that led to an increase in overall complexity. The local implementation team members frequently raised concerns about scalability and sustainability, whereas the US-based team members prioritized features to manage common challenges or exceptions and strategies to individualize care across a diverse adolescent population. Although we believe this balance was sufficiently achieved to proceed to the piloting phase, this tension highlights the value of “discoverability” within protocol designs (see Table 5), which involves hiding, constraining, or de-emphasizing complex features for early users, but allowing those features to unfold as users’ skill levels become smooth and routine, and as users begin to seek features to handle case complexity.

A related point is that in these deliberations it is easy to overly narrow one’s focus on the low- or under-resourced aspects of the environment, a focus that characterizes much of the literature on implementation in LMIC contexts. However, our integrity model analysis makes clear that although there were indeed resource limitations in this context, there was also a much broader set of contextual issues in the activity, coordination, and outcome domains that were just as important to consider in the design process as specific “resource” limitations. A strong design process can help address a much wider set of contextual constraints and can extend a team’s thinking beyond mere resource limitations when considering various design options. Without that explicit elaboration of ideas, we expect that there would be a general bias toward simplicity rather than toward best fit with the unique context.

More generally, this consideration speaks to the broader issue of ensuring that the design process attends to the expressed preferences/needs of the target population and is not unduly influenced by designers’ or providers’ assumptions about the population’s preferences/needs—even in cases where the providers are familiar with the local context. This sensitivity is especially important in contexts where significant social and class disparities or other power imbalances may exist between local providers and intended intervention recipients—and when those recipients are young people whose voices may traditionally be under-represented in decision-making.

Another key insight during this process involved the value of modularity when prototyping. Since we first wrote about modular design roughly 15 years ago (Chorpita, Daleiden, & Weisz, 2005), the field has seen a proliferation of modular interventions, which primarily herald the value of flexibility that can be afforded (Ng & Weisz, 2015), even though modularity is quite distinct from flexibility. In the PRIDE context, in fact, treatment flexibility was not considered an especially desirable property, given the constraint to minimize run-time decision making. Nevertheless, the modular design enabled a rapid development

and revision cycle, because of its information hiding principle (Parnas, 1972), which meant that changes to one component or level of the protocol could often happen independently, without dictating revisions to other parts of the protocol. Also referred to as “encapsulation,” this property allowed a far greater number of low-effort revisions to be configured and examined than might otherwise have been possible, because it minimized dependencies among the protocol components. For example, changing the flowchart of practice sequences required no re-writing of the practice modules themselves. Likewise, as we added or removed practices (and even added back ones we had removed), the intact nature of each module minimized the narrative revisions required. Our records show that we proceeded rapidly through many dozens of versions of the protocol over the later phases of the design period, and we expect that some of these variants would not have been pursued due to the effort required had we used a traditional integral design (e.g., a manual in book form).

Finally, we return to the notion of reducing uncertainty through treatment selection and design. New contexts (i.e., those in which few existing research trials have been conducted) increase uncertainty about generalizability and about achieving desired outcomes, particularly contexts for which the volume of design constraints dictates assembling an intervention rather than adopting or adapting. We sought to manage this threat explicitly by building integrity into the protocol throughout the design process, incorporating data features and algorithms into the run-time monitoring. As uncertainty increases, so too does the need to monitor quality and outcomes as the protocol is in use. We mentioned but did not dive deeply into such operational run-time supports (e.g., supervision, QA/QI, selection/training), but our design framework directly facilitates and extends such implementation support operations, which are likely to be critical to the success of the intervention. Nevertheless, the best way to reduce uncertainty at the program level is through empirical testing in a research trial, and thus, our next steps are to perform a pilot randomized trial of the full stepped care model in 2020 in Goa and New Delhi schools to evaluate more formally the performance of PRIDE Step 2 in these contexts.

CRediT authorship contribution statement

Bruce F. Chorpita: Conceptualization, Writing - review & editing. **Eric L. Daleiden:** Conceptualization, Writing - review & editing. **Kanika Malik:** Conceptualization, Writing - review & editing. **Resham Gellatly:** Conceptualization, Writing - review & editing. **Maya M. Boustani:** Conceptualization, Writing - review & editing. **Daniel Michelson:** Conceptualization, Writing - review & editing. **Kendra Knudsen:** Conceptualization, Writing - review & editing. **Sonal Mathur:** Conceptualization, Writing - review & editing. **Vikram H. Patel:** Conceptualization, Writing - review & editing.

Declaration of competing interest

Drs. Chorpita and Daleiden are partner/owners of PracticeWise, LLC, which provided consultation and analytic support to the project.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.brat.2020.103698>.

References

- Barlow, D. H., Allen, L. B., & Choate, M. L. (2004). Toward a unified treatment for emotional disorders. *Behavior Therapy*, 35, 205–230.
- Bass, J. K., & Hamdani, S. U. (2019). Scaling up and implementing psychotherapies in low-resource settings. In D. J. Stein, J. K. Bass, & S. G. Hofmann (Eds.). *Global mental health in psychotherapy* (pp. 67–84). Cambridge, MA: Academic Press.
- Becker, K. D., Boustani, M., Gellatly, R., & Chorpita, B. (2018). Forty years of engagement research in children’s mental health services: Multidimensional measurement and

- practice elements. *Journal of Clinical Child and Adolescent Psychology*, 47, 1–23.
- Bhola, P., Sathyanarayanan, V., Rekha, D. P., Daniel, S., & Thomas, T. (2016). Assessment of self-reported emotional and behavioral difficulties among pre-university college students in Bangalore, India. *Indian Journal of Community Medicine*, 41, 146. Official Publication of Indian Association of Preventive & Social Medicine.
- Boustani, M. M., Daleiden, E., Bernstein, A., Michelson, D., Gellatly, R., Malik, K., et al. (2020). Using relevance mapping methodology to design an adolescent mental health intervention in India. *Global Health Action*. <https://doi.org/10.1080/16549716.2020.1775062> (in press).
- Chorpita, B., & Weisz, J. (2009). *Modular approach to therapy for children with anxiety, depression, trauma, or conduct problems (MATCH-ADTC)*. Beach, FL: PracticeWise: Satellite.
- Chorpita, B. F. (2002). Treatment manuals for the real world: Where do we build them? *Clinical Psychology: Science and Practice*, 9, 431–433.
- Chorpita, B. F., Daleiden, E., & Weisz, J. R. (2005). Modularity in the design and application of therapeutic interventions. *Applied and Preventive Psychology*, 11, 141–156.
- Chorpita, B. F., Bernstein, A. D., & Daleiden, E. L. (2011). Empirically guided coordination of multiple evidence-based treatments: An illustration of relevance mapping in children's mental health services. *Journal of Consulting and Clinical Psychology*, 79, 470–480.
- Chorpita, B. F., & Daleiden, E. L. (2009). Mapping evidence-based treatments for children and adolescents: Application of the distillation and matching model to 615 treatments from 322 randomized trials. *Journal of Consulting and Clinical Psychology*, 77, 566–579.
- Chorpita, B. F., & Daleiden, E. L. (2014). Structuring the collaboration of science and service in pursuit of a shared vision. *Journal of Clinical Child and Adolescent Psychology*, 43, 323–338.
- Chorpita, B. F., Daleiden, E. L., Park, A. L., Ward, A. M., Levy, M. C., Cromley, T., et al. (2017). Child STEPs in California: A randomized effectiveness trial comparing modular treatment with community implemented treatment for youth with anxiety, depression, conduct problems, or traumatic stress. *Journal of Consulting and Clinical Psychology*, 85, 13–25.
- Ehrenreich-May, J., Rosenfield, D., Queen, A. H., Kennedy, S. M., Remmes, C. S., & Barlow, D. H. (2017). An initial waitlist-controlled trial of the unified protocol for the treatment of emotional disorders in adolescents. *Journal of Anxiety Disorders*, 46, 46–55. <https://doi.org/10.1016/j.janxdis.2016.10.006>.
- Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science*, 4, 50.
- Glasgow, R. E., Vogt, T. M., & Boles, S. M. (1999). Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *American Journal of Public Health*, 89(9), 1322–1327. <https://doi.org/10.2105/AJPH.89.9.1322>.
- Glisson, C., & Hemmelgarn, A. (1998). The effects of organizational climate and inter-organizational coordination on the quality and outcomes of children's service systems. *Child Abuse & Neglect*, 22, 401–421.
- Gonsalves, P. P., Hodgson, E. S., Michelson, D., Pal, S., Naslund, J., Sharma, R., et al. (2019). What are young Indians saying about mental health? A content analysis of blogs on the it's ok to talk website. *BMJ Open*. <https://doi.org/10.1136/bmjopen-2018-028244>.
- Goodman, R., Ford, T., Simmons, H., Gatward, R., & Meltzer, H. (2000). Using the Strengths and Difficulties Questionnaire (SDQ) to screen for child psychiatric disorders in a community sample. *British Journal of Psychiatry*, 177, 534–539.
- Heron, J. (1996). *Co-Operative Inquiry: Research into the Human Condition*. London: Sage.
- Israel, B. A., Schulz, A. J., Parker, E. A., & Becker, A. B. (1998). Review of community-based research: Assessing partnership approaches to improve public health. *Annual Review of Public Health*, 19(1), 173–202. <https://doi.org/10.1146/annurev.pubhealth.19.1.173>.
- Kazdin, A. E. (2019). Annual Research Review: Expanding mental health services through novel models of intervention delivery. *Journal of Child Psychology and Psychiatry*, 60, 455–472.
- Kieling, C., Baker-Henningham, H., Belfer, M., Conti, G., Ertem, I., Omigbodun, O., et al. (2011). Child and adolescent mental health worldwide: Evidence for action. *The Lancet*. [https://doi.org/10.1016/S0140-6736\(11\)60827-1](https://doi.org/10.1016/S0140-6736(11)60827-1).
- Knudsen, K., Becker, K., Guan, K., Gellatly, R., Patel, V., Malik, K., et al. (2020). *Training professionals in India to select case-specific intervention procedures: Implications for a dynamic modular treatment in a low-resource setting*. Manuscript submitted for publication.
- Larsen, D. L., Attkisson, C. C., Hargreaves, W. A., & Nguyen, T. D. (1979). Assessment of client/patient satisfaction: Development of a general scale. *Evaluation and Program Planning*, 2, 197–207.
- Lyon, A. R., & Koerner, K. (2016). User-centered design for psychosocial intervention development and implementation. *Clinical Psychology: Science and Practice*, 23, 180–200. <https://doi.org/10.1111/cpsp.12154>.
- Medical Research Council (2019). *Developing and evaluating complex interventions*. London: Medical Research Council.
- Michelson, D., Malik, K., Krishna, M., Sharma, R., Mathur, S., Bhat, B., et al. (2019). Development of a transdiagnostic, low-intensity, psychological intervention for common adolescent mental health problems in Indian secondary schools. *Behaviour Research and Therapy*, 130. <https://doi.org/10.1016/j.brat.2019.103439>.
- Murray, L., Hall, B., Dorsey, S., Ugueto, A., Puffer, E., Sim, A., et al. (2018). An evaluation of a common elements treatment approach for youth in Somali refugee camps. *Global Mental Health*, 5. <https://doi.org/10.1017/gmh.2018.7>.
- Murray, L. K., & Jordans, M. J. D. (2016). Rethinking the service delivery system of psychological interventions in low and middle income countries. *BMC Psychiatry*, 16(234), 1–6.
- Murray, L., Skavenski, S., Kane, J. C., Mayeya, J., Dorsey, S., Cohen, J. A., et al. (2015). Effectiveness of trauma-focused cognitive behavioral therapy among trauma-affected children in Lusaka, Zambia: A randomized clinical trial. *JAMA Pediatrics*, 169, 761–769. <https://doi.org/10.1001/jamapediatrics.2015.0580>.
- Nadkarni, A., Weobong, B., Weiss, H. A., McCambridge, J., Bhat, B., Katti, B., & Wilson, G. T. (2017). Counselling for alcohol problems (CAP), a lay counsellor-delivered brief psychological treatment for harmful drinking in men, in primary care in India: A randomized controlled trial. *The Lancet*, 389(10065), 186–195.
- Ng, M. Y., & Weisz, J. R. (2015). Annual Research Review: Building a science of personalized intervention for youth mental health. *Journal of Child Psychology and Psychiatry*, 57(3), 216–236.
- Norman, D. A. (2002). The design of everyday things. *Electronic Journal of Communication*. <https://doi.org/10.1002/hfm.20127>.
- Norman, D. A. (2009). *Emotional design*. Ubiquity <https://doi.org/10.1145/985600.966013>.
- Parikh, R., Michelson, D., Malik, K., Shinde, S., Weiss, H. A., Hoogendoorn, A., et al. (2019). The effectiveness of a low-intensity problem-solving intervention for common adolescent mental health problems in New Delhi, India: Protocol for a school-based, individually randomized controlled trial with an embedded stepped-wedge, cluster randomized controlled recruitment trial. *Trials*, 20, 568.
- Parikh, R., Michelson, D., Sapru, M., Sahu, R., Singh, A., Cuijpers, P., et al. (2019). Priorities and preferences for school-based mental health services in India: A multi-stakeholder study with adolescents, parents, school staff and mental health providers. *Global Mental Health*, 6.
- Parikh, R., Sapru, M., Krishna, M., Cuijpers, P., Patel, V., & Michelson, D. (2019). "It is like a mind attack": Stress and coping among urban school-going adolescents in India. *BMC Psychology*, 7, 1–9. <https://doi.org/10.1186/s40359-019-0306-z> 31.
- Parnas, D. L. (1972). On the criteria to be used in decomposing systems into modules. *Communications of the ACM*, 15, 1053–1058.
- Patel, V., Weobong, B., Nadkarni, A., et al. (2014). The effectiveness and cost-effectiveness of lay counsellor-delivered psychological treatments for harmful and dependent drinking and moderate to severe depression in primary care in India: PREMIUM study protocol for randomized controlled trials. *Trials*, 15, 101. <https://doi.org/10.1186/1745-6215-15-101>.
- Patel, V., Weobong, B., Weiss, H. A., Anand, A., Bhat, B., Katti, B., et al. (2017). The healthy activity program (HAP), a lay counsellor-delivered brief psychological treatment for severe depression, in primary care in India: A randomised controlled trial. *The Lancet*, 389(10065), 176–185.
- PracticeWise. *PracticeWise evidence based services database*. PracticeWise: Satellite beach, FL. (2017). Retrieved from www.practicewise.com/ on September 1, 2017.
- Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., Bunker, A., ... Hensley, M. (2011). Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health*, 38, 65–76.
- Real, K., & Poole, M. S. (2005). Innovation implementation: Conceptualization and measurement in organizational research. In R. W. Woodman, & W. A. Pasmore (Eds.). *Research in organizational change and development; research in organizational change and development* (pp. 63–134). Elsevier Science/JAI Press Chapter xii, 327 Pages.
- Regan, J., Daleiden, E. L., & Chorpita, B. F. (2013). Integrity in mental health systems: An expanded framework for managing uncertainty in clinical care. *Clinical Psychology: Science and Practice*, 20, 78–98.
- Rotheram-Borus, M. J., Swendeman, D., & Chorpita, B. F. (2012). Disruptive innovations for designing and diffusing evidence-based interventions. *American Psychologist*, 67, 463–476.
- Roy, K., Shinde, S., Sarkar, B., Malik, K., Parikh, R., & Patel, V. (2019). India's response to adolescent mental health: A policy review and stakeholder analysis. *Social Psychiatry and Psychiatric Epidemiology*, 54, 405–414.
- Southam-Gerow, M. A., Chorpita, B. F., Miller, L. M., & Gleacher, A. A. (2008). Are children with anxiety disorders self-referred to a university clinic like those from the public mental health system? *Administration and Policy in Mental Health and Mental Health Services Research*, 35, 168–180.
- United Nations Children's Fund. (2011). *Adolescence: An age of opportunity*. New York, NY: United Nations Children's Fund.
- Vellakkal, S., & Patel, V. (2015). Designing psychological treatments for scalability: The PREMIUM approach. *PLoS One*, 10(7), Article e0134189.
- Weisz, J. R., Chorpita, B. F., Frye, A., Ng, M. Y., Lau, N., Bearman, S. K., et al. (2011). Youth Top Problems: Using idiographic, consumer-guided assessment to identify treatment needs and track change during psychotherapy. *Journal of Consulting and Clinical Psychology*, 79, 369–380.
- Weisz, J. R., Chorpita, B. F., Palinkas, L. A., Schoenwald, S. K., Miranda, J., Bearman, S. K., et al. the Research Network on Youth Mental Health. (2012). Testing standard and modular designs for psychotherapy with youth depression, anxiety, and conduct problems: A randomized effectiveness trial. *Archives of General Psychiatry*, 69, 274–282.
- World Health Organization (2018a). *Mental health atlas 2017 member state profile*. Geneva: World Health Organization. https://www.who.int/mental_health/evidence/atlas/profiles-2017/IND.pdf?ua=1 Accessed 4 February 2019.
- World Health Organization (2018b). *Mental health atlas 2017*. Geneva: World Health Organization.