

Development of a Systematic Framework for Cultural Adaptation and Contextualization of Evidence-Based Psychological Interventions

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Abstract

Background

Innovative interventions to address mental health needs in low- and middle-income countries (LMICs) have increased. Before implementation, it is important to culturally adapt these interventions. There is a pressing need for a systematic approach that is feasible in settings with resource constraints, to guide not only content modification but also implementation elements to inform scalability and quality assurance. We harmonized existing guidance in cultural adaptation to develop a transparent framework for rapid and systematic cultural adaptations. We piloted this approach in Nepal for Group Problem Management Plus (PM+), a trans-diagnostic, task sharing intervention, for adults with psychological distress in humanitarian settings.

Methods

Building upon the ecological validity model, a 10-step process was used to adapt the Group PM + intervention in preparation for a feasibility trial in Nepal. A process evaluation was conducted after the trial to gather feedback on the adaptations. Detailed documentation tools were used to ensure rigor during the adaptation process.

Findings

The complete adaptation included a 10-step process; 1) Identify mechanisms of action, 2) Conduct a literature desk review for the culture and context, 3) Conduct a Training of Trainers (ToT), 4) Translate intervention materials, 5) Conduct an expert read-through of the materials, 6) Qualitative assessment of intervention population and site, 7) Conduct practice rounds, 8) Conduct an adaptation workshop with experts and implementers, 9) Pilot test the training, supervision, and implementation, and 10) Review through process evaluation. An iterative process with rapid modification of content and procedures was necessary. For Group PM+, key adaptations were harmonizing the mechanisms of action with cultural models of distress; modification of recruitment procedures to assure fit between cultural models of distress and population; and development of a skills checklist to monitor facilitator engagement with mechanisms of action.

Conclusion

A 10-step cultural adaptation process could feasibly be implemented in a humanitarian setting to rapidly prepare a psychological intervention for widespread implementation. Having a standard systematic approach will help develop a body of literature and lessons to facilitate the process for greater cultural appropriateness and effectiveness of psychological interventions worldwide.

Contributions To The Literature

- Though many adaptation frameworks exist, there are very few studies that operationalize the adaptation process. This research study builds on existing frameworks and includes a step-by-step rigorous guideline for adaptation, contextualization, and implementation of interventions.
- Though this study was conducted with Group Problem Management Plus (PM+), a psychological intervention, this adaptation framework and guideline can be applied in different contexts to adapt psychological or other

interventions. Detailed documentation guidelines are also included for use in different sites and contexts.

- This systematic adaptation approach uses minimal resources and is therefore fitting for humanitarian settings and low- and middle- income countries (LMICs).

Background

Prevalence of psychological distress is high amongst populations in low and middle-income countries (LMICs) that are affected by conflict, poverty, and violence (1, 2). LMICs are often unable to cope with such high rates of distress, due to fragmented health systems and limited number of mental health professionals (3). In such contexts, innovative interventions are especially important. Innovative interventions are defined as interventions that can be scaled-up to reach larger populations, can be delivered through routine health care, and utilize concepts of task-sharing (4). Along with expanding the reach of innovative interventions, cultural compatibility must also be addressed. Literature has shown that translating interventions directly from one culture to another without any other changes may reduce the effectiveness of the intervention and could even cause harm (5, 6). Therefore, a rigorous cultural adaptation process to fit the cultural context is essential prior to intervention implementation.

Effective cultural adaptation methods maintain the core principles of the treatment and should be based on culturally-grounded evidence and a clear, thoughtful process. Adapting evidence-based psychological treatments (EBTs), to incorporate cultural concepts of distress, is an important step in increasing the acceptability and relevance of the treatment and the overall effectiveness of the program (7, 8). It is promising that even with small adaptations, psychological interventions, such as problem-solving and behavioral activation for depression as defined by Western criteria, have been successfully implemented with symptom reduction in diverse populations (9). This evidence highlights the importance of selecting a cultural adaptation framework that utilizes tried-and-tested approaches while clearly guiding change on the delivery and contextualization of the intervention material.

For an EBT to be considered effective in a cultural context, it is also necessary to modify the presentation of intervention content, delivery framework of the treatment and its scalability to increase the acceptability and uptake for the desired population (10). Adaptation is an iterative process and often occurs alongside trial and error during implementation. There is a need to develop a framework that both maintains the fidelity and the core mechanisms of action of the treatment but acknowledges that a certain amount of *program drift* is natural (10).

Overview of Cultural Adaptation Frameworks

Existing cultural adaptation frameworks are varied in their theoretical underpinnings and their implementation process for adaptation. Though they may differ in design, the main intention for all cultural adaptation frameworks is to increase the effectiveness of the EBT by making changes that align with the culture of the beneficiary population, while maintaining the components of the evidence-based research that supports the treatment. There have been many attempts to organize the theories and elements suggested by the existing frameworks (11–14). Findings were summarized from numerous studies and condensed to three main distinctions that need to be balanced when adapting EBTs.

The first distinction is *surface* vs. *deep* adaptations. *Surface structure* adaptations refer to modifying superficial characteristics to better fit preferences of the beneficiary population (15). An example is translating treatment materials to match the native language (16). *Deep structure* adaptations target cultural values, norms, traditions, beliefs, and the beneficiary population's perceptions of the illness's treatment and etiology. Examples include integrating traditional healing practices in the interventions and deriving intervention activities from local conceptual

models of illness. Some cultural adaptations of interventions have used this dichotomy as an explicit framework, while others have used *surface vs. deep* as an approach and adapted it further (17). Data shows that even surface level adaptations, such as pictorial material depicting participants ethnically similar to beneficiary populations, resulted in discernable improvements in participant retention (18, 19) highlighting the importance of even “simple” cultural adaptations.

The second distinction is between the adaptation of *core vs. peripheral* aspects of the intervention. *Core* components are the main evidence-based ingredients of an intervention that are integral to the treatment (20). *Peripheral* components are related to the acceptability and feasibility of the intervention and exist to support the core components and the goals of the treatment. Examples include changes to language and methods of engagement and delivery. While promoting adaptations that are responsive to the needs of the beneficiary population, it is also important to follow the intervention as intended. This *fidelity vs. fit* distinction must be balanced to promote cultural appeal to the intervention while also following tried and tested methods to increase effectiveness (21). Despite the clarity brought about by identifying three key distinctions in the literature, these aspects of cultural adaptations are not straightforward. For example, common factors in psychotherapy such as therapeutic alliance, changing expectations of personal effectiveness, and encouragement (22, 23) could be classified as *peripheral*, or supportive components, but in fact may be *core* and integral to the success of the treatment.

Other challenges have also been reported in the adaptation literature. Adaptation frameworks are noted to be difficult to implement in real-world settings (20). Most original studies have not described their tools and process, which makes it difficult to replicate their adaptation methods (24). Therefore, a theoretically-grounded and explicit adaptation guide is necessary, especially one that can be applied to various populations. Many adaptation studies have been conducted with ethnic minorities in the United States (25). Though this is an overlooked and often marginalized population, these minorities are based in a high-income country (HIC) where resources such as time and personnel may not be as constrained as in LMICs. These constraints create unique needs, especially in humanitarian settings, where a transparent, thorough, and prescriptive framework is necessary to guide rapid and systematic adaptations.

There is a growing body of psychological interventions being adapted and developed for LMICs and humanitarian settings (26). Problem Management Plus (PM+) is a trans-diagnostic intervention employing empirically supported strategies that can be delivered by non-specialists to adults impaired by distress (27). Two recent randomized controlled trials in Pakistan and Kenya demonstrated the efficacy of individually delivered PM+ (28, 29). To make PM+ more scalable, cost-effective, and acceptable in different contexts, it is important to test a group version as well (30, 31). Group PM+ includes several evidence-based strategies that target common mental health disorders, such as depression and anxiety, over five in-person group sessions.

Aim

Considering the mechanisms of action, delivery, scalability, and quality assurance, we will describe an explicit guide to adapting and contextualizing EBTs. We will then highlight the key adaptations made through this process in the context of Group PM+ in Nepal and gather data on how the adapted and contextualized intervention was perceived by participants, community members, and families. By tracking the progress of cultural adaptation from the methodology, implementation, to feedback from the community, we aim to meet the following objectives:

1. Create explicit guidance for cultural adaptation and contextualization that can be applied to various populations with a focus on implementation, scalability, and quality monitoring.
2. Report on the cultural adaptation process of Group PM+.

3. Gather feedback from program stakeholders after implementation to analyze the effectiveness of specific adaptations.
4. Suggest the most valuable steps in adapting an EBT under time and resource constraints.

Methods

Setting

Nepal is a low-income country with a history of internal conflict, political instability, and natural disasters. In 2015, an earthquake resulted in injuries, deaths and displacement. 34.3% and 33.8% of participants in an earthquake affected district scored above the validated cut-off scores for depression and anxiety respectively (32). The country reports that there are 0.52 psychologists and 0.36 psychiatrists for every 100,000 people, mostly working in larger cities and are not easily accessible to those in rural areas (33). The lack of trained specialists and their limited reach to populations around the country makes an intervention with non-specialists a practical and important solution to consider. To date, there have been minimal efforts to adapt EBTs in the Nepal (34). Group PM+ was considered an appropriate intervention to test in this setting due to its scalability and task-sharing approach.

The Group PM+ intervention's adaptation process and feasibility trial was conducted in Sindhuli district, which was heavily impacted by the 2015 earthquake (35,36). Two Village Development Committees (VDCs) were selected for the adaptation process and the feasibility trial to follow. There were no specialized mental health treatment facilities in the district and the closest psychiatric services were approximately six-hours away from the study site. For this reason, local health posts were the first portal of care and the referral sites for program participants. The adaptation process and implementation of the trial was conducted by the staff of Transcultural Psychosocial Organization (TPO) Nepal based in Kathmandu, Nepal. TPO Nepal was established in 2005 and is a leading mental health service delivery, training, and research organization (37).

Study Methodology

A study was conducted to demonstrate the feasibility and acceptability of Group PM+ in Nepal (36). The pilot feasibility study was registered on ClinicalTrials.gov (NCT03359486). A ten-step adaptation model was followed in preparation for a feasibility and acceptability trial. After the feasibility trial, qualitative interviews were conducted with program stakeholders to gather data on the acceptability and scalability of the adaptations (35). After making improvements to the adaptations, a definitive Group PM+ trial will be conducted in a flood-affected area of Nepal to test the effectiveness of the program and the adaptations made to support it (38).

Ecological Validity Model (EVM)

We used the Ecological Validity Model (EVM) to guide our adaptation of the Group PM+ intervention (39,40). The EVM framework was selected because it allows the treatment to keep its core principles and directs focus to the periphery, but equally important, aspects of the intervention (40). This framework is based on the view that individuals must be understood within their cultural, social, and political environment. Their personal motivations, attitudes, beliefs, and goals must also align with the intervention. The EVM framework serves to "culturally center" an intervention through eight dimensions that must be incorporated for an intervention to have ecological validity and be embedded within the cultural context (41). These dimensions include language, persons, metaphors, content, concepts, goals, methods, and context (see **Table 1**).

[TABLE 1]

Overview of Cultural Adaptation and Contextualization Methodology

The adaptation process was an ongoing, iterative process and some of the steps overlapped with one another. Questions addressed in each step were based on what was or was not answered in the prior steps and the iterative process of this methodology more easily allowed for finding a balance between *fidelity* versus *fit*. The format of this methodology was participatory and involved a high level of engagement with the communities where the intervention was delivered. For this reason, the methodology was helpful in ensuring that adaptations were made not only to the clinical treatment material but also the scalability and implementation of the intervention.

A detailed data collection process and documentation system allowed us to ensure that each adaptation made was based on evidence. We created a matrix before the start of the adaptation process based on the FRAME approach for documentation (42): 1) the eight broad dimensions from EVM, 2) implementation strategy (what exactly should be changed in the intervention material), 3) rationale for change (description of why it should be changed and what it would accomplish for the intervention), and 4) evidence for change (which adaptation step(s) the change was a result of). All changes and adaptations were listed in the EVM matrix during the length of the process (see **supplemental online material**).

The following approach charts the cultural adaptation process from the preparation phase before the feasibility trial, through the trial, and any changes after the trial (see **Table 2**).

[TABLE 2]

1. Identify the key mechanisms of action

The mechanisms of action are theorized process by which a psychological intervention alleviates distress and supports behavioral change (43). Cognitive-behavioral therapies are built upon a theoretical framework that changes in cognition will precede emotional and behavioral changes. Four types of interpersonal distress are theorized as the cause of depression in interpersonal psychotherapy. Behavioral reinforcement cycles of avoidance and distress are targeted in behavioral activation therapy. The specific mechanisms of action for Group PM+ were identified by reading literature of the same intervention conducted in different contexts and discussing with experts that have developed and implemented the intervention (27,28,31), (see **Table 3**).

[TABLE 3]

2. In-depth Literature Review (and consulting with experts)

A systematic review of existing literature on mental health interventions in Nepal was conducted to extract data on: mechanisms of action, delivery agents, trainings, supervision methods, process measures, outcome measures, psychoeducation method, integration into health systems, and cultural/ethno-psychology elements. Databases such as PubMed, PsychInfo and PsychiatryOnline were searched as well as grey literature from policy briefs and annual reports of local NGOs. Though not a formal part of the literature review, interviews were also conducted with staff from leading mental health organizations in Nepal to identify issues for community engagement and implementation related to mental health research and service delivery in Nepal. Data were summarized for key findings, gaps in research and methodology, and recommendations for Group PM+ adaptation in Nepal.

3. Training of Trainers (ToT)

Clinical Supervisors and supporting counselors were given a 10-day training by a Group PM+ trainer from a previous study site. This training focused on how to train facilitators in delivering Group PM+. The participants of this ToT identified overlap of approach with preexisting practices in the program site and suggested culturally fit adaptations to intervention content. The Group PM+ Clinical Supervisors gathered the adaptations suggested by the trainees and reviewed them before finalization. Suggestions that modified the mechanisms of action were rejected. Other suggestions that adapted peripheral aspects of the intervention, such as the language or metaphors, were documented, accepted and finalized into the manual by the Clinical Supervisors.

4. Translation of Manual

Clinical supervisors incorporated initial changes into the English manual which was then translated to Nepali by a professional translator. During the translation process, clinical supervisors regularly reviewed the translator's progress to ensure that the manual would be translated into lay Nepali and could be understood by non-specialist delivery agents. After completing the translation of the manual, the Clinical Supervisors reviewed it fully for any additional changes in language. This was an ongoing process and focused on language rather than the content of the manual. Study staff without a clinical background also reviewed the manual to ensure its comprehensibility for lay persons.

5. Expert read-through

Experienced bilingual Nepali psychosocial counselors read through the Nepali language intervention manual and suggested changes in language and content to fit into the cultural context during a one-day workshop. The main objective of this step was to gain additional perspective from persons experienced in the program's mental health context on the intervention's content, language, and applicability.

6. Formative qualitative study

Based on gaps identified in prior steps, a formative qualitative study was conducted at the proposed study site to gather data on implementation, such as the community's awareness of mental health, identification of pre-existing community resources and identification of practical problems faced by community members. Local stakeholders such as female community health volunteers (FCHVs), key leaders, health workers, and community members were identified for Key Informant Interviews (KIIs) (n=18) and Focus Group Discussions (FGDs) (n=2). Interviews were then coded by two coders (MS and RG) using deductive analysis and key findings related to program implementation and cultural ethno-psychological elements were summarized to be applied to the manual and program implementation strategy, which included community sensitization programs, recruitment, family meetings, referral pathways, and follow-up with participants.

7. Practice rounds

Clinical supervisors conducted Group PM+ practice rounds to gain experience delivering the 5-session intervention, gather feedback from the participants on their comprehension and relatability of the intervention, and apply any further changes to the manual and implementation strategy. Practice rounds were conducted with one female group from a nearby community organization and one male group. During these practice rounds, the facilitators (clinical supervisors) noted if adaptations already made in the manual were feasible and acceptable among participants and if further adaptations were necessary to improve the participants' engagement and understanding of the material. After each session, the participants were encouraged to give feedback to the facilitators on content, language, materials and methods used, and facilitation skills. This information was collected through informal interviews with the participants and noted down by the Clinical Supervisors.

8. Team adaptation workshop

A team workshop with the study Principal Investigators, Program and Research Coordinators, and Clinical Supervisors was conducted to summarize all intervention adaptations listed to date on the EVM matrix. Certain adaptations were accepted or rejected based on if and to what degree they brought changes to the core mechanisms of action. Once all adaptations were thoroughly discussed, Clinical Supervisors made final changes to the manual before the start of the trial. Program staff also modified competency and quality monitoring procedures. Because of the iterative nature of this methodology, most large-scale changes, such as the delivery agents, delivery location, and target population, had been discussed with the team and integrated into the manual and into the delivery of the intervention prior to the workshop.

9. Implementation and Supervision

Lay Nepali community members were recruited to deliver Group PM+ to their communities as part of the feasibility trial (35,36). Regarding the trial procedures, Enhanced Usual Care (EUC) was compared to Group PM+ intervention. We employed a randomized control trial (RCT) design where the two chosen VDCs in Sindhuli district were randomly assigned to EUC or PM+. Approximately 60 participants, that were similar in population size, ethnic demographics, and access to health facilities, were recruited for each arm. During the Group PM+ training, the facilitators (n=4) were encouraged to suggest changes in the manual's language and feasibility and acceptability of the proposed implementation strategy. These changes were further incorporated into the manual and other program documentation. Cultural adaptation was an iterative process throughout the feasibility trial. All staff recorded notes about first-hand experiences working on program recruitment, delivery, and engagement with the community, and shared these experiences with their supervisors. Some changes were made in real-time while others required further discussion at the end of the trial.

10. Review through Process Evaluation

After completing the intervention, qualitative interviews were conducted with field staff, intervention participants, participants' families, and other key community stakeholders to gain perspective on the successes and challenges of varying adaptation and implementation strategies. Questions for these stakeholders were related to feasibility and acceptability of various cultural adaptations, feedback on the implementation strategies, program fidelity, and overall challenges. A total of 31 Key Informant Interviews (KIIs) and 6 Focus Group Discussions (FGDs) were conducted with stakeholders and then analyzed by the Program Coordinator and Clinical Supervisor. A deductive data analysis process was used; key themes were identified prior to analysis and a codebook with themes related to feasibility and acceptability of the manual content and implementation was developed (35). Interviews were coded using NVivo software and the two coders (MS and RG) established an acceptable inter-reliability rate (IRR) (IRR = 0.8) during the coding process. Once analyzed, key changes and their rationale were discussed within the core team and implemented further to the intervention before the definitive trial.

Results

Conceptualization of Stress and Tension

As part of the adaptation process, we aimed to create a conceptual model that linked each mechanism of action to how distress was viewed in this context. This model needed to be relatable enough for the lay-facilitators to use during their training in order to promote a comprehensive and culturally appropriate view of how the Group PM+ intervention could reduce distress. The literature review and qualitative study before the trial found that the word *tension* was used

commonly in lay-Nepali language by community members of all ages, gender, and socioeconomic status as a non-stigmatizing term to refer to stress (44). *Tension* was used as an idiom of distress, as a proxy to depression complaints which is targeted by the intervention. The *tension* ethnopsychology model was conceptualized during the workshop as the team was finalizing the adaptations before the trial (see **Figure 1**).

[FIGURE 1]

According to the ethnopsychology model, adversity or practical problems lead to *tension*. This *tension* can have a physical manifestation and lead to somatic problems and/or emotional problems. *Tension* can also lead to a lack of energy, feeling unmotivated, and isolation from friends and family. Each Group PM+ session addresses managing the roots of *tension* or its effects, which are also integrally linked with one another. Because of the contextual fit of the model, elements of the *tension* model were also used during the recruitment process to explain the effects of adversity on our lives to local community members.

Key Adaptations

Adaptations made before the feasibility trial were systematically documented in the EVM matrix (see **Supplementary online material**). Key adaptations are summarized in **Table 4**.

[TABLE 4]

Relatability of clinical content

Changes were made to the stories used during sessions based on the formative qualitative interviews, practice runs, and expert read-throughs. In these stories, the female character presented problems such as having too much work at home, relationship issues with her husband and mother-in-law and her own mother's death. The male character presented problems such as the stress of returning from a manual labor job abroad, financial burden of raising a family, and relationship issues with his wife. Participants in the trial found these problems, the case story, and its pictorial representations on posters to be highly relatable and sympathized with the characters in the story (35).

Clinical supervisors and facilitators noted that physical health was a source of stress for the majority of program participants. This may be because most participants were of older age and lacked easy access to proper treatment. Though the intervention focused heavily on managing emotional and practical problems, the feedback received demonstrated that we needed to add more content on physical problems and train facilitators on how to work with participants who only discussed these types of problems. Some suggestions included adding characters in the case story that faced more physical ailments, and posters representing these problems to validate participants' distress. Facilitators should also be trained further in how somatic problems are connected to mental well-being, using the *tension* model as a guide, so that they can further address the participants' concerns.

Reinforcement of mechanisms of action

A combined competency and fidelity checklist was created based on both Group PM+ elements and common factors in psychological treatments, drawn from the ENhancing Assessment of Common Therapeutic factors (ENACT) tool (45). The fidelity checklist was used to measure the whether key activities were implemented and the competency with which they were completed in each session. Facilitators also used this checklist while conducting sessions to ensure that the mechanisms of action were addressed thoroughly during the session. Clinical supervisors attended at least two of the five sessions per PM+ group and used the fidelity checklist as a tool to rate the skills of the four facilitators. Each session had 9–10 items and rated the facilitator's level of competency to the intervention manual on a scale of

1–3. The Reducing Tension Checklist (RTC) tool was also developed to assess whether participants applied the mechanisms of action learned in the sessions to their daily lives. This tool was used pre- and post-intervention (35).

The participants noted that of the different techniques they learned, the deep breathing technique was the most memorable and was used the most outside of the sessions (35). This technique was noted as the most tangible, accessible, and lead to the most immediate results. Facilitators found it difficult to track or gauge how often participants were practicing at home. For the next trial, participants and facilitators recommended making all mechanisms of action more memorable and easier to practice at home by creating a method to track time that participants spent practicing outside of sessions.

As a result of the process evaluations, the team decided to incorporate more imagery and memorable metaphors to each of the sessions. For example, the second session focused on effective problem solving, was considered to be one of the most difficult sessions for the facilitators to deliver and for the participants to practice outside the sessions. As a result of these findings, we decided for the definitive trial to incorporate an image of a hand with a step for problem solving written on each finger. A similar card was created for each of the five sessions with visual imagery of each mechanism of action on one side and a space to plan when to practice on the other side. This set of cards was called the *tension* toolkit. We also decided to incorporate several concrete tools to support each of the sessions, such as a small pouch (*thaili*) after the third session for participants to store a rock, or kernel of corn each time they do a pleasurable activity at home. The objective of these tools is to provide physical items to help participants remember the content of the sessions and skills learned throughout the intervention.

Use of local idioms to increase acceptability and reduce stigma

Community sensitization events were a vital component of recruitment because stigma and lack of awareness of mental health issues in the program site (35). These events were led by the facilitators who invited community members to attend and discuss the causes, signs, and symptoms of *tension*. Facilitators prompted community members with questions about causes of *tension* and *man ko samasya* (heart-mind problems), and impact of adversity on personal behaviors and emotions. The participatory format of engaging with the community during sensitization activities while using de-stigmatizing terms was successful in encouraging community members to volunteer for study screening.

In further efforts to reduce stigma against the intervention, key adaptations were made to the metaphors, the concepts, and the “branding”. To reduce stigmatization by the community for participating in the intervention and self-stigmatization by the participants themselves, a context appropriate name was voted on by the local staff that chose *Khulla Man*, meaning open-hearted. Some participants described their own heart-mind as being *Khulla* (open) or having a *Khulla Man* after the sessions. Similarly, the tension model conceptualized before the trial was successful in that it supported the facilitators’ understanding of how each session supported in reducing stress.

Importance of staff, training, and acceptable recruitment methods

One of the key adaptations made for the feasibility was to recruit, train, and hire local lay workers, as a method of task shifting and to increase the capacity of local community members. A 20-day Community Psychosocial Worker (CPSW) Training, as is standard to certify this cadre of workers in Nepal, was delivered before 10 days of Group PM+ training. Because the four CPSWs who delivered the intervention were from different locations in the study catchment area, they conducted groups in areas that were close to their homes but not necessarily in their own neighborhood. As indicated by the qualitative interviews, participants found comfort in having their groups led by a facilitator who was from a familiar location but who the participants did not know very well. Similarly, helpers were hired to assist the

facilitators during the sessions. Because concepts of time and punctuality were flexible in this context, it was noted that having a helper remind participants to arrive on time helped increase attendance and reduce drop-out rates.

The Community Informant Detection Tool (CIDT) helped easily identify members of the community experiencing mental health symptoms through using vignettes and pictures. It has been previously successful in Nepal (46), and a general distress, *man ko samasya*, version was developed for this trial. Female Community Health Volunteers (FCHVs), mothers' group members, and other local community leaders received a one-day training on how to use this tool to refer those with general distress to the study. They were also trained on the severe mental health CIDT version to identify who not to recruit. However, this led to confusion amongst some trainees who referred those with severe mental illness to the study, since their signs and symptoms are clearer than those with general distress. For the next trial, it is recommended to train local community members on using the general distress version only and with regular on-site supervision.

Discussion

Outputs and Applications

This study provides a model that incorporates changes to the clinical content, scalability and implementation in a cultural adaptation method. Ultimately, this study further integrates cultural adaptation into implementation science research (47). The scalability and implementation aspects were shown to be just as important as the clinical content when adapting an intervention. As a result, a *tension* ethnopsychology model was developed as a conceptual foundation to key adaptations. Adaptations were made to case stories, visuals, and materials to reflect the context. Using a context appropriate intervention name, utilizing the CIDT for recruitment, and conducting community sensitization events supported in reducing the stigma. We also adapted the facilitator trainings, and created the fidelity checklist, RTC, and tension toolkit to reinforce the mechanisms of action and ensure quality of care. As part of this study, we have also designed a clear and detailed documentation process that will assist in conducting evidence-based adaptations to future interventions. This work builds on prior research in LMICs and can be integrated for use into approaches such as the Replicating Effective Programs (REP) framework (48).

The outcomes of the pilot Group PM+ trial demonstrates that the specific adaptations made to the intervention as well as the contextualization of the implementation process was feasible and acceptable. The intervention had a high retention rate with 75% of the participants completed 4 – 5 sessions (35). All facilitators (n=4) scored above a 75% on the fidelity checklist developed to measure the competency and overall fidelity to the intervention. Though the study was not powered, the intervention group showed a greater change in outcomes, especially in general psychological distress. We hypothesize that the positive quantitative and qualitative results of the pilot trial can in part be attributed to the cultural adaptations and contextualization that supported the overall implementation of the Group PM+ intervention.

We have created one cultural adaptation guides with two applications; the first model to be used in contexts without time or resource constraints and the second in contexts such as LMICs with various constraints (see **Figure 2**).

[FIGURE 2]

The longer process includes a thorough literature review and a read-through by experts. Though we

conducted a formative qualitative study as part of the adaptation process, we found that an assessment of the intervention site could have sufficed for the purpose of adaptation. This assessment should be tailored to the needs of

the intervention and should be approached as a method to gather information from and to engage the local community, which was proven to play a large role in the success of the intervention. This could include, amongst other activities, meeting with local stakeholders, potential service users, their families, and other services being offered in the area.

In reality, adaptation processes are often conducted under staff and time constraints in low-resource settings. Throughout the adaptation process, we took note of which steps are absolutely necessary versus those that could be combined or eliminated altogether, while not compromising quality in favor of time. Using this “time constraints” method, it is still possible to create *deep* rather than *surface* structure changes. The literature review step has been modified from in-depth to an overall review. The expert read-through has been eliminated since we found that the training of trainers and other steps that involved study clinical staff who developed in-depth knowledge of the intervention when conducting the other adaptation steps were best fit to suggest the most meaningful changes. The practice rounds were found to be the most helpful and the greatest number of adaptations were made from this step as compared to the others. The practice rounds were an important step in addressing the logistical aspects of the intervention, such as time management, venue location and also to gather feedback from participants within the targeted population. Therefore, we recommend shortening other steps and focus mainly on conducting several practice rounds or sessions as part of the adaptation process, if under extreme time constraints.

The eight dimensions of cultural adaptation, as presented by Bernal and colleagues (11), were helpful in conceptualizing the types of changes that could be made, while preserving the treatment’s core mechanisms of actions. However, we found that a few of the dimensions, such as content and context, are similar in their definitions and overlapped with one another. These dimensions also seemed to apply to the majority of the adaptations compared to a dimension such as *persons* that applied to very few adaptations. As a result, we found it best to focus less on which dimension an adaptation would be categorized as and instead allow the eight dimensions to serve as a framework to better understand that the treatment and implementation needs to be adapted within the cultural context.

Limitations

Limitations to the study must be accounted for before using this adaptation model for other interventions. This paper documents the adaptation process till the end of the feasibility trial. It does not incorporate findings from the definitive trial to understand if all the adaptations made after the feasibility trial were successful. It is difficult to identify which adaptations were the most important and which had the highest impact on the intervention because there are many potential factors contributing to its success. Though manual content and implementation complement one another, it is also difficult to isolate which aspects were most successful and to specifically recommend it for future interventions. The current results are also limited to qualitative work and the participants’, staff, and stakeholders’ perceptions of what were and were not effective. Regardless of compressing the adaptation process to fit resource limited contexts, the nature of the cultural adaptation itself is lengthy, iterative and requires depth and heavy documentation. However, these are compromises that must be made for a successful adaptation process.

Conclusion

This study proposes not only a clear adaptation process but also documentation tools to guide adaptations of future interventions. Through this process, adaptations have been made to not only the intervention but the EVM framework itself, with a focus on scalability, and quality monitoring. Though this process was used to adapt a mental health intervention in a developing country, it can be used to adapt interventions for various populations, such as ethnic

minorities in high-income countries or in other LMICs. With the increase in interventions that employ the concept of task-sharing (49), this process also serves as an example for other interventions in humanitarian or developing country settings. Though this process was used to adapt a group intervention, it is flexible enough to be used to adapt an individual intervention or even a treatment beyond mental health.

Abbreviations

CIDT – Community Informant Detection Tool

CPSW – Community Psychosocial Worker

EBT – Evidence-based Treatment

ENACT – ENhancing Assessment of Common Therapeutic factors

EUC – Enhanced Usual Care

EVM – Ecological Validity Model

FCHV – Female Community Health Volunteer

FGD – Focus Group Discussion

HIC – High Income Country

KII – Key Informant Interview

LMIC – Low and middle-income Country

PM+ – Problem Management Plus

RCT – Randomized Controlled Trial

RTC – Reducing Tension Checklist

TPO – Transcultural Psychosocial Organization

Declarations

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Availability of data and materials

Please contact the authors for data requests.

Authors' contributions

The study was designed by BAK, MJDJ, NPL, EvO, and MS. The manuscript was drafted by MS, with support from BAK and MJDJ. MS, RG, and PG conducted the implementation of the adaptation process. MS and RG conducted qualitative interviews, coding, and analysis. All authors read and approved the manuscript.

Competing interests

The authors declare that they have no competing interests.

Ethics approval and consent to participate

Ethical approval has been received from the Nepal Health Research Council (NHRC) and the World Health Organization.

Consent for Publication

All participants provided written informed consent before participating in the study, which included consent to publish anonymous quotes from individual participants.

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Tables

TABLE 1. Ecological Validity Model (EVM) Framework Dimensions

Dimensions	Definition
Concepts	Concepts refer to how the treatment material is thought of and communicated to the facilitators, intervention participants, community members, and other stakeholders. The program’s and the facilitator’s credibility may be reduced if the communication of concepts and the concepts themselves do not match the local culture.
Methods	Methods are the procedures followed to achieve treatment goals. These methods and procedures should be congruent with the participants’ culture and use of language.
Goals	Goals are the agreement between participants and facilitator in what participants would like to achieve during the course of the treatment. These goals must be realistic and fit with the participants’ values and personal motivations.
Context	Context refers to the participants’ economic, social, political and cultural environment. This should look beyond just the participant as an individual and focus on outside factors, such as socialization, discrimination and family history, that could influence the treatment.
Content	The knowledge, values, customs, and traditions shared by the participants should be integrated into all elements of the treatment. This can be seen as a starting point for culturally adapting the recruitment process, assessments, and the treatment itself.
Metaphors	Culturally appropriate symbols or concepts should be embedded within the intervention that support participants in absorbing the treatment’s core mechanisms of action. Metaphors used may be pictorial, idioms, commonly used phrases or item and symbols.
Persons	A culturally appropriate intervention must consider the role of ethnicity, race, gender, class and other relevant social constructs in the relationship between the participants and facilitators. This relationship should respect expectations and limitations that are reflective of the local culture.
Language	Language is inherently attached to culture and is related to the expression of emotional experiences. The intervention should be in the language most comfortable and accessible to the participants and should also use appropriate terminology based on the education levels of the facilitators and participants.

TABLE 2. Overview of Adaptation steps: Activities, Participants, and Methods of Analysis

Adaptation Step	Objectives	Activities	Participants	Data collection and Methods of Analysis	Duration
1. Identifying mechanisms of action	To identify the main ingredients of the intervention that lead to outcomes and cannot be drastically modified	Collaborate with researchers/personnel that developed the intervention Conduct background reading and research on the core techniques and activities of the intervention	Researchers (4) Clinical Supervisors (2)	Summarize each mechanism of action and solidify the team's understanding of these core concepts	1 week
2. In-depth Literature Review	To identify issues for engagement/ implementation related to mental health research and services in program site To gather information on previously conducted programs/research for site and population of interest	Conduct a systematic review of existing literature Identify experts in the field of service delivery and interview	Coders (2) Articles (43) Interviewers (2) Experts interviewed (7)	Screen articles for those that address relevant interventions in program site Extract data from selected articles on delivery agents, trainings, supervision, process and outcome measures, psychoeducation methods, integration into health system, and cultural/ethno-psychology elements. Summarize data for key findings, recommendations for intervention and gaps in research and methodology.	2 months
3. Training of Trainers (ToT)	To incorporate pre-existing practices in program site To identify how existing training transmits mechanisms of action	Training of counselors and clinical supervisors on delivering intervention trainings to delivery agents (CPSWs)	Expert Clinical supervisor (from a previously conducted intervention site) (1) Local Clinical	Participants of ToT write suggested adaptations directly in the manual. Clinical Supervisors review suggested adaptations after the ToT before	10 days

	To identify overlap of approach with preexisting practices in program site		supervisors (2)	finalizing into the manual.	
			Additional counselors for intervention support (6)		
4. Translation of the manual	To translate the intervention manual (and additional intervention material) from English to program site language	Translate manual (and additional intervention material) from English to program site language	Translator (1) Clinical supervisors (2)	Clinical Supervisors conduct frequent meetings with the translator to verify that the language is easy to understand for delivery agents	3 months
5. Expert read through	To gain additional perspective on context, content, language, and applicability from persons experienced in the program site	Expert counselors read through manual and program material and suggest changes	Counselors (3) Clinical Supervisors (2)	During a one-day workshop, counselors read through the manual together and note necessary changes based on the eight dimensions of the Bernal Framework.	1 day
6. Formative qualitative study	To gather information on acceptability and applicability of the intervention in program site To identify existing resources in the community as sources of referral	Conduct key informant interviews and focus group discussions with community members and key stakeholders in study site Focus questions on understanding community's awareness of mental health, identification of pre-existing mental health and other resources in the community, identify practical problems to adapt in the manual	Local stakeholders, female community health volunteers (FCHVs), local health workers (18+) Interviewers (3)	Create interview guide to address remaining questions on resources in the community, level of awareness on topic of interest, and program implementation details. Conduct Key Informant Interviews (KIIs) and Focus Group Discussions (FGDs) with a variety of local stakeholders to gather varying perspectives (ex. For Group PM+, 18 KIIs and 2 FGDs were conducted with local community members, mother's group members, Female	1.5 months

				Community Health Volunteers, and other key informants).	
				Code interviews using deductive analysis and summarize key findings related to program implementation and cultural elements for the manual.	
				Apply findings from qualitative analysis to the manual, other program material, and program implementation strategy.	
7. Practice Rounds	To provide firsthand experience to program site supervisors in delivering the intervention and to make further changes to intervention material from this experience	Clinical Supervisors conduct all sessions of the intervention with target populations (ex. For Group PM+, all 5 sessions were conducted with one female and one male group)	Clinical Supervisors (2) Female participants (6) Male participants (6)	Facilitators (Clinical Supervisors) of intervention noted if adaptations already in the manual were feasible and acceptable among practice round informal participants.	2 – 3 months
8. Team Adaptation Workshop	To summarize all intervention adaptations before implementation	Discuss all suggested adaptations Finalize adaptations thus far and document accepted adaptations in an Ecological Validity Model (EVM) overview	Program Staff (Principal Investigators, Program Coordinator, Clinical Supervisors) (6)	Prepare the EVM matrix (see supplementary material) to summarize adaptation principles, page needed to be changed within manual, implementation (what should be changed), rationale (why it should be changed), and evidence (which adaptation method informed suggested change).	1 day

				Finalize adaptations thus far by adding all small or large changes in EVM matrix (supplementary material)	
9. Implementation and Supervision	<p>To gather feedback from the implementation and supervision process to further adapt intervention</p> <p>To summarize experiences using intervention manual and proposed intervention implementation strategies and scalability</p>	<p>Conduct intervention facilitator training</p> <p>Gather any suggestions for changes from the facilitator training</p> <p>Conduct intervention, supervision and implement all program activities</p> <p>Record detailed notes about firsthand experiences on implementing intervention</p>	<p>Clinical Supervisors (2)</p> <p>Delivery Agents (8)</p> <p>Research Supervisor (1)</p> <p>Program Coordinator (1)</p> <p>Program Participants (60)</p>	<p>Trainers (Clinical Supervisors) record suggested adaptations, during training of delivery agents, directly into the manual and review before finalizing for implementation within the program.</p> <p>Field and program staff record process notes reflecting daily on experiences using the manual, feasibility of the intervention, community perceptions, supervision, challenges, and suggestions for change.</p>	6 months
10. Review through Process Evaluation	<p>To gain perspective on the successes and challenges of varying adaptations and implementation strategies, as experienced by community stakeholders and program participants, to address during the definitive trial</p> <p>To gather information from field staff on adaptation</p>	<p>Conduct KIIs and FGDs with community members, key stakeholders and local staff in program site</p> <p>Focus questions for trial participants, family members, local health workers, and community leaders on feasibility, acceptability and implementation of intervention.</p>	<p>Intervention facilitators (8)</p> <p>Research Assistants (8)</p> <p>Intervention participants (8)</p> <p>Intervention Participants' familles (3)</p>	<p>Synthesize data through Focus Group Discussions (FGDs) with field staff and in a workshop with program team to discuss changes necessary for the definitive trial.</p> <p>Conduct Key Informant Interviews (KIIs) and Focus Group Discussions (FGDs) with a variety of local stakeholders to</p>	2 months

<p>suggestions and improvements to increase the feasibility, acceptability, and fidelity of the program</p>	<p>Focus questions for staff on intervention and program fidelity, and challenges in feasibility and acceptability.</p>	<p>gather varying perspectives (ex. For Group PM+, 31 KIIs and 6 FGDs were conducted with local community members, FCHVs, mother's group and other key informants)</p> <p>Code interviews using deductive analysis and summarize key findings related to main dimensions [Table 5].</p> <p>Apply findings from process evaluation to the manual and program implementation strategy for the future program implementation [Table 5].</p>
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Table 3. Mechanisms of Action of intervention

Intervention Mechanisms of Action	Description of Mechanism	Implementation of Mechanism
<i>Stress Management</i>	Participants learn deep breathing. They are encouraged to incorporate this mechanism into daily life (e.g. when doing housework, walking, etc.). Grounding techniques are incorporated to bring participants back to the present.	Session 1-5
<i>Managing Problems</i>	Participants learn which of their problems are solvable and which are unsolvable. One solvable problem is chosen and participants brainstorm solutions, then identify manageable steps to implement their solutions and accomplish their goals.	Session 2-5
<i>Behavioral Activation</i>	Participants review the inactivity cycle. They choose a small activity that they enjoy doing (e.g. making and drinking tea, meeting a friend etc.) or a task they need to complete and create a detailed plan about when and how to conduct this activity as a first step in breaking the inactivity cycle.	Session 3-5
<i>Strengthening Social Support</i>	Participants learn to recognize who amongst their family and friends are existing and potential sources of support and how best to strengthen connections with them. Participants could also identify broader community and organizational forms of support. Social network mapping activities are incorporated in this mechanism.	Session 4-5

Note: The first four sessions of PM+ each address a specific mechanism of action. The fifth and last session is a review of the mechanisms of actions learned in the intervention.

TABLE 4. Key Adaptations from each step

Adaptation Steps	Key Adaptations
1. Identify Mechanisms of Action	<p>Four key mechanisms of action were identified; stress management, managing problems, behavioral activation, and strengthening social support^{4,6}.</p> <p>Because these mechanisms of action cannot be changed, adaptations in the next steps will be made to support the beneficiary population's comprehension of these techniques.</p>
2. In-depth Literature Review	<p>The literature review suggested that mental illness is deeply stigmatized in Nepal and idioms of distress such as <i>man ko samasya</i> or <i>tension</i> can be used in rural communities to refer more openly to general distress. This suggests a need for developing a non-stigmatizing conceptual framework for this intervention to be used in the Nepal context^{1,3,4,5,8}.</p> <p>Task-sharing trainings are common in Nepal, due to the lack of trained mental health professionals. Trainings are followed by frequent on-site and off-site supervision for the non-specialists. We decided that for Group PM+, Clinical Supervisors will conduct weekly office supervision and will observe two sessions per group^{2,7}.</p>
3. Training of Trainers (ToT)	<p>Trainers suggested adding pre-existing counseling techniques to the Group PM+ intervention in order to strengthen the mechanisms of action. These techniques were previously proven to be effective in the Nepal context. Examples include grounding techniques (where participants are brought to the present moment by using senses to identify what is around them) and mapping (an activity where participants identify their close relationships in pictorial form)^{4,5,7}.</p> <p>As part of the training, trainers read the manual and reviewed other implementation material thoroughly and suggested further language, such as <i>man ko samasya</i>, to decrease self-stigma. This aligned with the results of the literature review^{1,5,7,8}.</p> <p>Trainers suggested adding multiple culturally appropriate ice breakers and energizers throughout the group sessions. This was to ensure that participants would stay on task throughout each session^{4,5,7}.</p>
4. Translation of manual	<p>Translation of the manual was an iterative process where the translator met often with study staff to review translations and to ensure that the language was simple and accessible for lay facilitators^{1,4}.</p> <p>While the translator was making progress on the manual, the Clinical Supervisors felt the need to create a fidelity checklist for the facilitators to follow during sessions and to use alongside the manual⁷.</p>
5. Expert read-through	<p>Experts with experience counseling in Nepal stressed the importance of gender matching facilitators and participants for the intervention^{2,7,8}.</p> <p>Family engagement was identified as a key component in prior mental health interventions in Nepal. A family meeting, to involve participants' families in the clinical process, was added as a component to Group PM+^{2,4,5,6,7,8}.</p>
6. Formative qualitative study	<p>Local community members identified that it is deemed acceptable for facilitators of lower caste to work with participants of higher caste in the local area. Therefore, facilitators from all castes can be hired to deliver the intervention^{2,8}.</p>

Nearby resources such as health posts, mothers' groups, domestic violence NGOs, and safe homes were identified as referral services for intervention participants if needed^{7,8}.

Gender issues and social discrimination were identified as sources of stress for community members. It was suggested to add these issues in the manual and other clinical material^{4,8}.

7. Practice rounds

Participants in the practice rounds suggested adding more posters and visuals to the clinical content. They also suggested personal problems that characters may have for these materials. Examples included an unemployed man returning home from working a labor job abroad, a daughter-in-law having an argument with her mother-in-law, and a woman unable to concentrate on her work in the farm due to stress^{3,4,8}.

Clinical supervisors found that when running the practice sessions, participants would often arrive late and some would forget the day of the week the sessions were held on. This highlighted the importance of having a helper who could call the participants a day before the session as a reminder or gather them from their homes before the start of each session. Participants also suggested the distribution of a calendar during the first session as a reminder of when to attend the following sessions^{4,7,8}.

Clinical supervisors noted that some participants were dominant while others were quieter. It was suggested to increase training in group facilitation skills and managing dominant and quiet participants. Facilitators must also take special note of gender, socioeconomic status, ethnicity/caste and other social factors and their possible effects on group participation^{2,4,7}.

Some participants in the practice rounds expected monetary benefits from the intervention. Therefore, clinical supervisors found it necessary to clarify that the program is not for those who need support with their economic situation but is for those with *man ko samasya* and *tension*^{4,8}.

8. Team Adaptation Workshop

The role of the helper was further defined during the workshop. From experience gathered from each of the steps, the team agreed that the helper would also be responsible for administrative tasks, such as hanging posters and writing on the board, that would allow the facilitators to place all of their focus on the participants and session material².

Study staff found that it would be necessary to include a method to evaluate participants' progress and suicidal tendencies at the start of each session and to conduct referrals as necessary. It was decided during the workshop that the Psychological Outcomes Profile (PSYCHLOPS) would be administered during snack time at the start of each session^{6,7}.

A general distress version of the Community Informant Detection Tool (CIDT) will be created and used for recruitment of participants^{4,5,6,7,8}.

The *tension* conceptual model was created during the workshop as program staff brought together various conceptual adaptations informed by the adaptation process. The conceptual model relates each session to an aspect of general distress^{4,5}.

9. Implementation

During the recruitment of program participants, the facilitators voted to change the Group PM+ program title to *Khulla Man*, meaning open-hearted, a more culturally appropriate and de-

and Supervision	<p>stigmatizing program name^{3,4,8}.</p> <p>Community sensitization events were led by facilitators and program staff to raise awareness about mental health and recruit participants into the program. Over time, these events went from lecture heavy to discussions about the <i>man</i> (heart-mind) and the causes and symptoms of <i>man ko samasya</i>. This method of engagement was found to be especially helpful with recruitment and de-stigmatizing mental health issues^{3,4,5,7,8}.</p>
10. Review through Process Evaluation	<p>Facilitators mentioned that conducting practice groups supported them in feeling prepared before the start of the trial and recommended that the facilitators conduct more practice groups before the next trial³.</p> <p>Participants noted that though they enjoyed the sessions and practiced what they had learned at home, they sometimes had difficulty in remembering all the techniques learned. As part of the review after the pilot trial, a “tension toolkit” was developed by study staff to help participants remember techniques learned in each session. The toolkit included cards for each session with pictures of the techniques learned, and a space to track how many times participants practiced each technique. A certificate of completion was also included to encourage participants to continue utilizing what they learned after the final session^{3,4,6,7}.</p>

1 Language, 2 Persons, 3 Metaphors, 4 Content, 5 Concepts, 6 Goals, 7 Methods, 8 Context

Figures

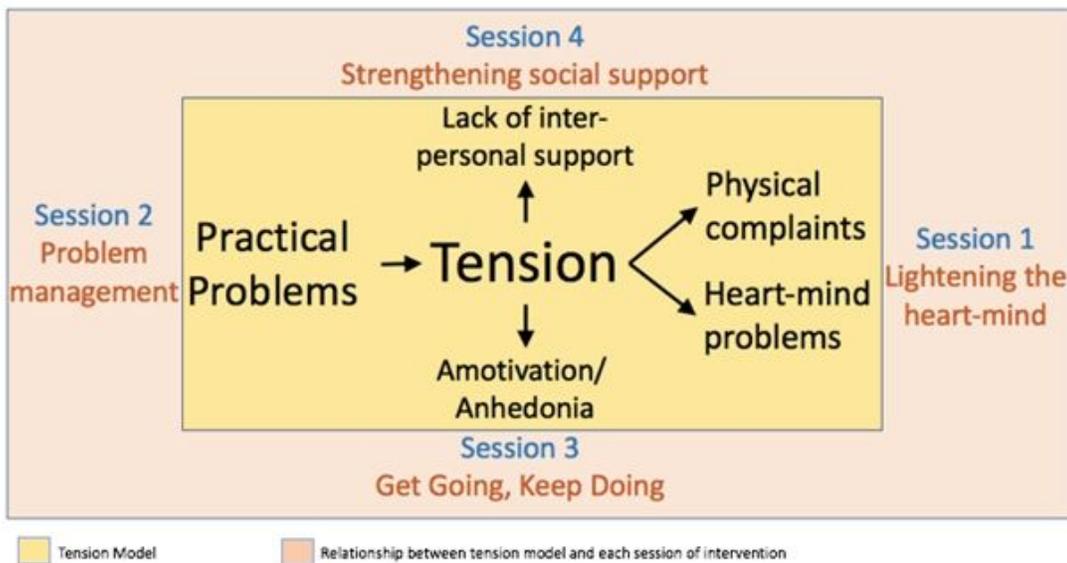


Figure 1

Tension Conceptual Model

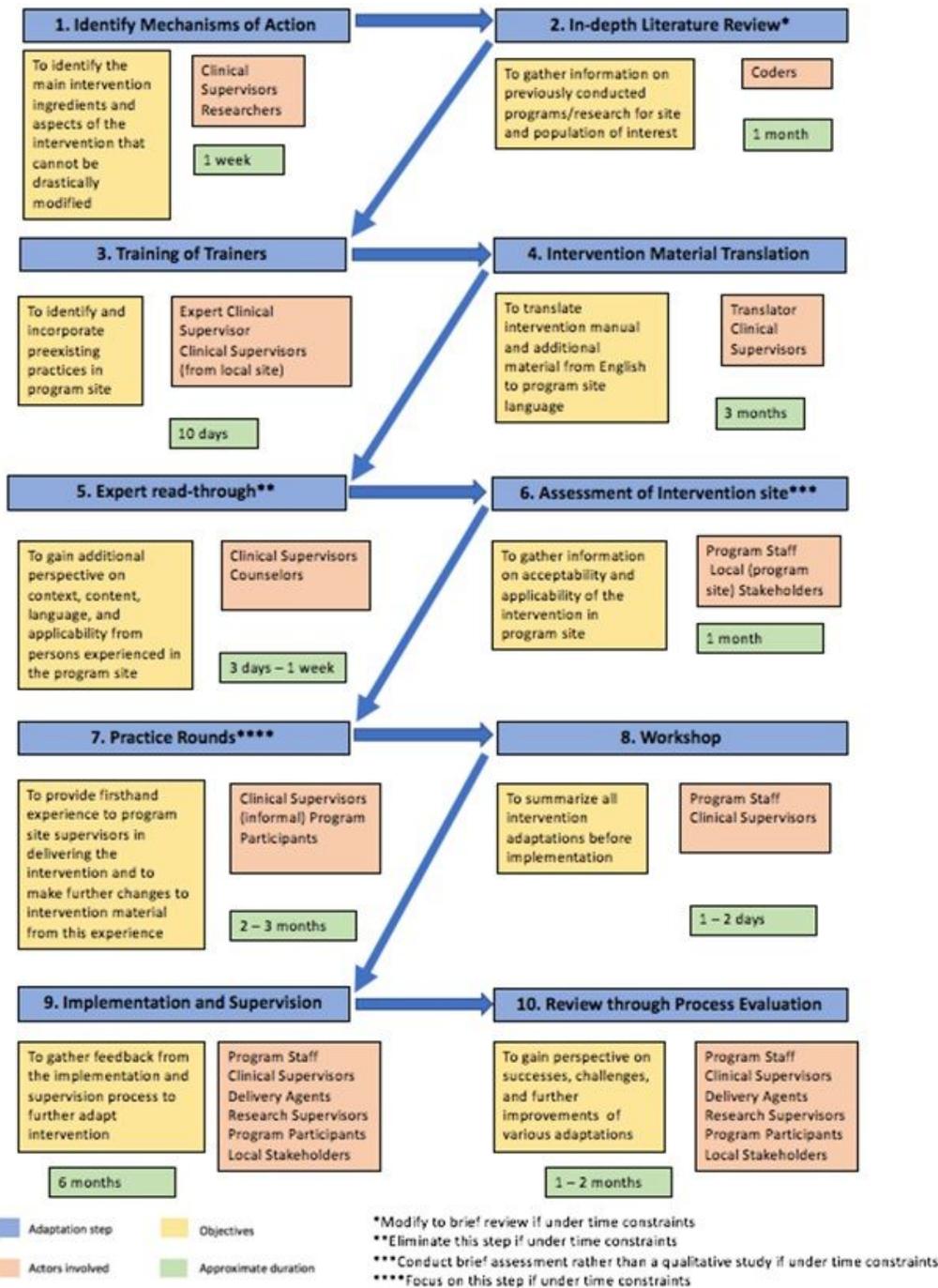


Figure 2

Cultural Adaptation Step-by-step Guide

Supplementary Files

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