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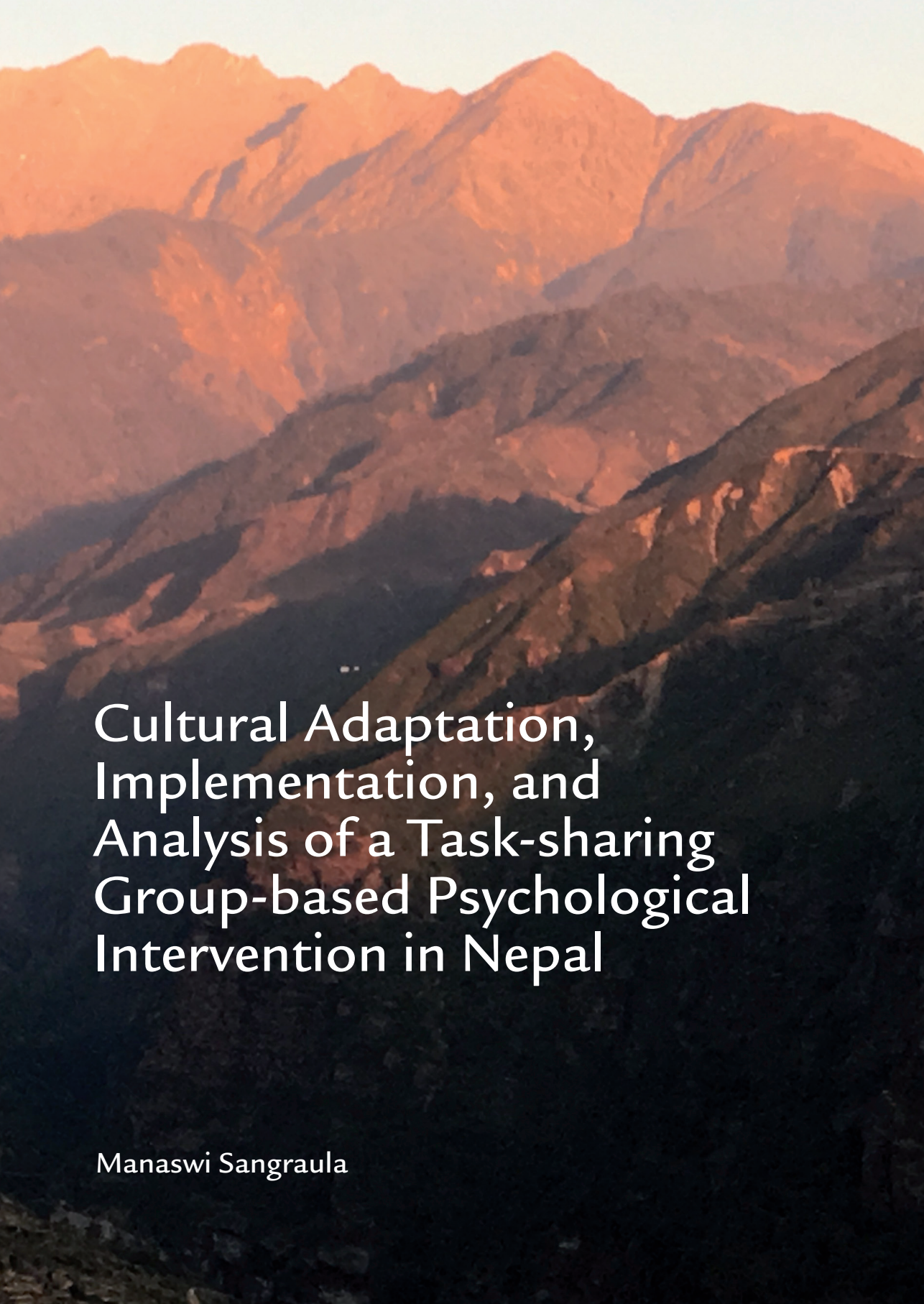

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Manaswi Sangraula

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Promotor:

prof. dr. M.J.D. Jordans	Universiteit van Amsterdam

Copromotor:

dr. B.A. Kohrt	George Washington University

Overige leden:

prof. dr. J.T.V.M. de Jong	Universiteit van Amsterdam
prof. dr. R. Reis	Universiteit van Amsterdam
prof. dr. J.M. Richters	Universiteit van Amsterdam
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TABLE OF CONTENTS

ACRONYMS

AE	Adverse Events
AHW	Auxiliary Health Worker
AUD	Alcohol Use Disorder
AUDIT	Alcohol Use Disorder Identification Test
CBO	Community Based Organization
CBT	Cognitive Behavioral Therapy
CHW	Community Health Workers
CIDT	Community Informant Detection Tool
CMD	Common Mental Disorders
CPSW	Community Psychosocial Worker
c-RCT	cluster Randomized Controlled Trial
DPHO	District Public Health Officer
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, fourth edition
DSMC	Data Safety Monitoring Committee
GBD	Global Burden of Disease
GHQ	General Health Questionnaire
GMH	Global Mental Health
GroupACT	Group Facilitation Assessments of Competencies Tool
GCS-R	Group Cohesion Scale Revised
Group PM+	Group Problem Management Plus
EBT	Evidence Based Treatment
ENACT	Enhancing Assessment of Common Therapeutic factors
EUC	Enhanced Usual Care
EVM	Ecological Validity Model
FC	Fidelity Checklist
FCHV	Female Community Health Volunteer
FGD	Focus Group Discussion
HA	Health Assistant
HIC	High Income Country
INGO	International Non-Governmental Organization
IPV	Intimate Partner Violence
IRR	Inter-rater Reliability
ICC	Intra-class Correlation Coefficient
KII	Key Informant Interview
LMIC	Low- and Middle- Income Country
MHPSS	Mental Health and Psychosocial Support
mhCACI	mental health Cultural Adaptation and Contextualization for Implementation
mhGAP	mental health Gap Programme
MSPSS	Multidimensional Scale of Perceived Social Support

NGO	Non-Governmental Organization
PHQ	Patient Health Questionnaire
PHCCs	Primary Health Care Centers
PRIME	Programme for Improvement of Mental health care
PI	Principal Investigators
PSYCHLOPS	Psychological Outcomes Profile
PMHP	Psychosocial and Mental Health Problems
RA	Research Assistant
RCT	Randomized Controlled Trial
REP	Replicating Effective Programs
RTC	Reducing Tension Checklist
SAE	Serious Adverse Events
SUDS	Subjective Units of Distress Scale
TEI	Traumatic Events Inventory
ToT	Training of Trainers
TPO	Transcultural Psychosocial Organization
VDC	Village Development Committee
WHO	World Health Organization
WHODAS	WHO Disability Assessment Scale

INTRODUCTION

CHAPTER 1

Background and Dissertation Structure

GLOBAL MENTAL HEALTH: AN OVERVIEW

Global mental health (GMH) is defined as an area of study, research, and practice within the larger field of global health, focused specifically on mental ill-health and the wellbeing of populations. The term 'global' implies that all people deserve access to mental health care regardless of their income, race, gender, religion, and other societal structures (Kirmayer & Pedersen, 2014). Therefore, this lens focuses not only on developing but also developed countries. GMH also focuses on the inequities in treatment that may exist *within* a country (Vikram Patel & Prince, 2010). The term 'mental health' is used instead of 'psychiatry' to acknowledge the field's inclusivity of anthropology, social sciences, and other disciplines that play just as large of a role as 'medicine' in GMH.

Mental health has been a neglected field for many years. Formal health care, of any kind, was unequally and unjustly distributed throughout the colonial era and attention turned to infectious disease epidemics, war, famine, and natural disasters after nations gained independence from colonialism (Whitley, 2015). After the establishment of modern psychiatry, its application was mostly concentrated in the West as it was believed that persons in non-western countries were not 'modern' enough to experience internal conflict (Henry, 1956, p. 2). Public health efforts continued to focus on reducing infectious diseases into the 21st century. As the discipline of 'tropical medicine' transformed into 'international health,' the framework was still based on delivering western medical practices to underdeveloped nations (Brown et al., 2006). At the start of the new century, international health was redefined as 'global health' to highlight the interdependence of health in high, low and middle income countries (LMICs) and to incorporate health problems that are impacted by politics, social structures, and global patterns of injustice (Kirmayer & Pedersen, 2014). As the result of progress in global health, many countries have recently experienced the epidemiological transition and the reduction of communicable diseases, leading to greater disability and burden from non-communicable diseases such as mental illnesses. Therefore, research, policies and practices in mental health have been receiving greater attention.

Global mental health is defined not only as a field of study but a movement that aims to treat those with mental illnesses with dignity and to right 'historic wrongs' (Horton, 2007; Kleinman, 2009). This movement to improve services for people living with mental health problems is distinguished from medical anthropology and cultural psychiatry, which focus on understanding local concepts of mental illness rather than implementing treatment (Kirmayer & Pedersen, 2014). In 2007, The Lancet Commission on Global Mental Health called upon the global health community to scale up services for those affected by mental health problems all over the world ("Scale up Services for Mental Disorders," 2007). Mental health as a fundamental human right and the commission has played a key role in the inclusion of mental health on the Sustainable Development Goals (SGDs).

However, like other movements, many have challenged the core assumptions of GMH. A main critique is that GMH employs a top-down approach that impo-

ses western ideas of mental health and illness on non-western countries (Whitley, 2015). Practices and evidence-based treatments developed in western countries may not be culturally applicable or socially acceptable in non-western countries that have different concepts of suffering (Kleinman, 2009). For example, what appears to be 'depression' may be a 'normal reaction to a difficult circumstance' (Summerfield, 2008). This argument also claims that GMH often does not validate and include local traditional healing approaches that may be acceptable, normalized, and have a history of reducing the suffering of local people (Fernando, 2012; Sax, 2014). Furthermore, social inequalities, chronic poverty, structural violence, and conflict are the roots of mental health problems 'and are important determinants of mental health outcomes rather than what is recognized in current studies'(Wilkinson & Pickett, 2006).

Despite these criticisms, the GMH movement continues its attempt to address the unjust distribution of mental health services worldwide as a moral priority, through research, interventions, and policies. However, there are important lessons to be learned from critiques and their practical applications. These critiques can be counteracted by using a cultural lens and setting specific intentions when conducting GMH research. These include 1) understanding the influences of social determinants of health and cultural concepts of suffering and incorporating these models into an intervention before attempting treatment implementation in a given context, 2) testing if an intervention is feasible and acceptable in the setting before investing time and effort into testing the intervention for effectiveness. This dissertation follows this approach and aims to highlight the complexities and best practices in conducting a GMH randomized controlled trial (RCT) in an LMIC setting. It is necessary to clarify this process for application to future implementation research.

BACKGROUND: MENTAL HEALTH PROBLEMS IN LOW AND MIDDLE-INCOME COUNTRIES

Mental health and substance use disorders are a leading cause of disability worldwide and account for 7.4% of the total disability burden according to global burden of disease (GBD) studies (Whiteford et al., 2013). Specifically, common mental disorders (CMDs), including depressive, anxiety, post-traumatic, and general distress symptoms, account for a large portion of this burden. Depressive disorders were the third leading cause of this burden, after lower respiratory infections and diarrheal diseases, with a higher rate of disability for women compared to men (Ferrari et al., 2013). Mental health stressors affect all ages and it is estimated that 29.2% of adults will experience a CMD at some point in their life (Steel et al., 2014). Depressive disorders have a global prevalence rate of 4.7% (Ferrari et al., 2013) and 7.3% for anxiety disorders (Baxter et al., 2013). Prevalence rates for CMDs are even higher in LMIC settings. The rates of depression and posttraumatic stress average

at 30.6% and 30.8%, respectively, amongst populations impacted by humanitarian crises (Steel et al., 2009).

In order to effectively address mental health problems in LMICs and humanitarian settings, it is crucial to understand the social, economic and demographic-based factors that negatively impact mental health. Though many problems are context specific and cannot be generalized to all LMICs, studies provide substantial evidence on potential overall risk factors for poor mental health (Roberts & Browne, 2011). Exposure to traumatic events are endemic in humanitarian settings and LMICs and were reported by 21% of participants in 84 studies (Steel et al., 2009). Similarly, prevalence of mental disorders was 22.1%, or one in five people, at any given time in conflict-affected populations (Charlson et al., 2019). The point prevalence was highest for mild forms of these disorders (13%), followed by moderate forms (4%) and severe disorders such as schizophrenia and bipolar disorder (5.1%) (Charlson et al., 2019). Traumatic events experienced by conflict-affected populations include but are not limited to sexual abuse, disability due to violence, displacement, and murder of a loved one. These events are associated with a sense of worse security (de Jong et al., 2008). Unsurprisingly, stressful and traumatic events have shown to negatively impact mental health (de Jong et al., 2008; Roberts & Browne, 2011).

Aside from humanitarian disasters, LMICs also often face structural and social inequities, such as discrimination and social marginalization, which are also sources of poor mental health (Brandon A Kohrt et al., 2009). For example, as a result of gender inequities, women in many countries have a greater prevalence of anxiety disorders when compared to men (Kohrt & Worthman, 2009) and in general have worse overall psychological health (Roberts & Browne, 2011). These social conditions in unjust societies are often further exacerbated by infrastructural issues and limited supplies for the population. Low income, assets, and decreased access to food and water have been shown to negatively impact mental health (de Jong et al., 2008). Unemployment status and living in rural communities, when compared to urban, were also associated with worse psychological health (Pevalin & Robson, 2007).

The consequences of untreated mental health problems are dire and lead to poverty, disability and even premature death (Lund et al., 2010; Teferra et al., 2011; Whiteford et al., 2013). Growing evidence from epidemiological studies shows that mental illness and social inequalities, such as poverty, function in a cycle (Lund et al., 2011). This cycle can be explained by two causal pathways. The Social Causation Hypothesis states that conditions of poverty increase mental health problems through increased daily stress, social exclusion, malnutrition, structural and physical violence, and trauma. The Social Drift Hypothesis states that those with mental illnesses are more likely to become more impoverished or remain in poverty because of decreased productivity, societal stigma, loss of employment, and increased health expenditures for treatment (Lund et al., 2011). Programs such as individual or group psychotherapy, drug treatment, and family psychoeducation

all address the Social Drift Hypothesis and could potentially impact an individual's poverty outcomes (Lund et al., 2011). Mental health problems significantly impact a person's quality of life and social functioning but the consequences of a lack of treatment surpass the individual and affect societies as a whole. An estimated $1.15 trillion of global cost is attributable to CMDs (Chisholm et al., 2016). Therefore, research on the under-treatment of mental health conditions and testing of psychological interventions is more than just an academic concern. It has the potential to make a significant positive impact on global development as well.

THE PROBLEM: THE TREATMENT GAP

The prevalence of mental health problems is further exacerbated by a lack of access to effective treatments, a gap difficult to address due to systemic challenges in LMICs (Jordans et al., 2013). Furthermore, mental health is often of low priority in countries that routinely suffer from humanitarian crises and conflict (Chisholm et al., 2007). Evidence-based psychological treatments are recommended as the first line of care because of their effectiveness in treating CMDs but are inaccessible for most populations (Vikram Patel et al., 2016). Based on a systematic review of studies published until 2015, only 7% to 28% of those who needed treatment, in low- and high-income countries, received adequate support (Chisholm et al., 2016). This creates a 'treatment gap' between the people who need treatment and those who receive it. Even with efforts to increase access to tested interventions in recent years, it is estimated that there is a treatment gap of up to 93% in LMICs (Chisholm et al., 2016).

Low availability of treatment corresponds with low utilization and demand for services in LMICs (Jordans et al., 2015). Mental health problems are likely to go undetected or under-detected due to lack of awareness and ineffective community case identification methods (Jordans et al., 2015; Kohrt et al., 2018). A lack of education on mental health leads to low recognition of CMDs in oneself and community members and to the under-utilization of services (Saraceno et al., 2007). Stigma is another major barrier to accessing care and people with mental health problems have noted that the stigma can be more burdensome than the condition itself (Semrau *et al.*, 2015). Stigma may also exist around receiving the treatment and further discouraging individuals from seeking care (Saraceno et al., 2007).

Once need for treatment is recognized, shortage of mental health trained personnel and a lack of psychological treatments in health facilities pose barriers to care (Hanlon et al., 2014). The number of psychiatrists and psychologists are often limited in LMICs, making it difficult to provide direct care or even conduct quality supervision for non-specialists trained in delivering mental health care (Brandon A. Kohrt et al., 2015). Approximately 52.6% of those experiencing mental health disorders in LMICs make at least one visit to a service provider (Thornicroft et al., 2017). Of these, many are misdiagnosed with only physiological rather than psychological

problems. Quality of mental health services differs between countries with different income levels. Whereas one of five people in HICs receive adequate care for depression, this figure is only one out of 27 in LMICs (Thornicroft et al., 2017).

POTENTIAL SOLUTIONS: TASK-SHARING PSYCHOLOGICAL INTERVENTIONS

In the past 20 years, there have been several calls to action for innovations to effectively address this treatment gap in LMICs (Fairburn & Patel, 2014). Task-sharing is a strategy to close this gap by training non-specialists to deliver mental health interventions. Highly qualified mental health workers train community health workers (CHWs) or lay people to deliver mental health interventions designed to be led by non-specialists (Patel, 2012). This strategy makes efficient use of the available human resources. It also expects mental health delivery agents to have less training and qualifications when compared to traditional mental health personnel, making this strategy particularly helpful in LMIC and humanitarian settings.

In 2010, the World Health Organization (WHO) launched the Mental Health Gap Programme (mhGap), a guide that promotes the integration of mental health into primary care using task-sharing concepts (World Health Organization et al., 2008). mhGap provides guidance on treatment of depression, psychosis, anxiety and alcohol and substance use disorders, by suggesting psychosocial and pharmacological interventions to be delivered by non-specialists. It has been applied to many settings. In mhGap and other task-sharing interventions, the role of the mental health personnel preparing the non-specialists goes beyond the training phase. Supervision, quality assurance, and support to non-specialists throughout program implementation is crucial in successfully administering a task-sharing intervention (Patel & Kirkwood, 2008). The term 'task-sharing' is increasingly used to describe this approach instead of 'task-shifting' because of the focus on providing supervision, assuring adequate referral services, and embedding the method into the current health system.

Along with reducing the treatment gap, task-sharing programs are sustainable because of their utilization of local resources including local lay people to coordinate and deliver interventions (Fairburn & Patel, 2014). Approximately 33% of task-sharing interventions in LMICs employ CHWs. Since CHWs are often employed by government-run community health centers, their inclusion may increase the sustainability of programs (Singla et al., 2017). Local nurses and midwives are also cadres of health workers who are perceived as dependable sources of information in most communities. Other task-sharing approaches train lay people with no previous health experience to work as non-specialists. These community members then have the tools to tackle the needs of their own communities. Non-specialists provide mental health literacy skills to their communities to address social suffering even after completion of the intervention trial (McInnis & Merajver, 2011). By

training local community members, task-sharing interventions take into account the importance of peer support and the value of training non-specialists who have frequent contact with the target population (Singla et al., 2017). Non-specialists are also more likely to share social and cultural backgrounds with those they are providing care for. Thus, it has been noted that they may provide even better care than highly trained professionals, especially in resource constrained settings where those who live in the communities themselves may have the most knowledge of its needs (Rahman et al., 2012).

Within the family of task-sharing psychological approaches, trans-diagnostic interventions are increasingly gaining popularity. Trans-diagnostic approaches are those that can be used to treat many mental health problems, as opposed to single-disorder focused interventions that only target individuals with a certain diagnosis or symptomology. In order to treat a wide range of mental health problems, trans-diagnostic interventions use treatment components from multiple evidence-based treatments (EBTs) (e.g., cognitive behavioral therapy (CBT), psychoeducation, behavioral education) and condense and combine them for the intervention (Bolton et al., 2014). This approach moves beyond single-disorder focused interventions and instead emphasizes symptom presentation, such as low mood and poor daily functioning, rather than a specific diagnosis. Screening for general poor psychological health catches those with depression, anxiety and stress, which often have overlapping symptoms and co-morbidities. These interventions also contribute to a broader understanding of mental health as overall health and well-being rather than the absence of specific mental illnesses (Roberts & Browne, 2011). This lens may especially be helpful and appropriate in non-western countries and LMICs where specific disorders may be misdiagnosed due to differences in culture. Thus, trans-diagnostic interventions address the ongoing debate about the relevance of DSM-IV categories in LMICs (Murray et al., 2014).

Trans-diagnostic interventions also have pragmatic implications on implementation and dissemination processes in LMICs. Mental health services in LMICs are under-resourced and under-funded. It is therefore difficult to train non-specialists on multiple single-disorder focused EBTs to address many disorders. Because of the narrow focus of single-disorder EBTs, a significant portion of the beneficiary population, who are experiencing distress but do not fit the screening criteria for the single-disorder, will be unable to take part in treatment. This is a missed opportunity in LMICs and humanitarian settings to decrease suffering amongst a larger group of people (Murray et al., 2014). Though single-focus EBTs often decrease symptoms beyond the target focus, the manuals do not provide guidance for non-specialists on how to tackle comorbidities and additional symptoms participants may encounter. Because of the simplified and prescriptive trainings necessary for task-sharing approaches, non-specialists lack the skills to add and remove therapeutic elements to address different mental health problems. Thus, trans-diagnostic approaches may reduce time, cost, and other resources by teaching non-specialists a single framework that can treat a variety of mental health problems

present in their communities (Murray et al., 2014). Trans-diagnostic interventions also further the goals of task-sharing by increasing population reach while minimizing costs.

Along with trans-diagnostic interventions, group-based interventions are increasingly utilized in addressing the treatment gap and 50% of task-sharing approaches use at least some form of this method (Singla et al., 2017). Group-based therapies can reach a greater number of people at once, while training fewer non-specialists for service delivery (Chiumento et al., 2017). This increased reach has major implications especially in humanitarian and LMIC settings where there are constraints on human resources and coordination of health services distribution. The cost of group therapy is considerably lower than the cost of individual therapy (Vos et al., 2005). Humanitarian settings often lack financial resources and only 0.3% of all development funding for health is allocated to mental health (Liese et al., 2019). Therefore, cost-effectiveness is important to consider for the sustainability and acceptability of psychosocial interventions in LMICs and humanitarian settings. From a clinical standpoint, group and individual therapies have shown similar effectiveness outcomes (Cuijpers et al., 2008). Cost-effectiveness, positive outcomes, and population reach make group-based psychosocial interventions a potential solution to the treatment gap.

Because a majority of individual, group, and trans-diagnostic psychological interventions are developed in western countries, it is important to test their efficacy and effectiveness in LMIC and humanitarian settings. RCTs testing scalable psychotherapies outside of western countries have increased in number in recent years. These interventions often target specific populations including primary care recipients, torture survivors, individuals with HIV and refugees (Singla et al., 2017). Psychotherapies for depression developed in western countries are found to be just as or more effective in non-western countries (Cuijpers et al., 2013). A meta-analysis found that psychological treatments delivered by non-specialists in primary care or community settings had a medium to strong effect in improving treatment outcomes for a number of CMDs, with a pooled effect size of 0.49 (Singla et al., 2017). The effect of these treatments also depended on factors such as the therapeutic elements used in the intervention. The effects of these therapies have been found to be comparable to those of medications in LMICs (Cuijpers et al., 2013).

CHALLENGES AND PRIORITY AREAS FOR RESEARCH

Cultural Adaptation of Psychological Interventions

Although many studies have demonstrated the effectiveness of scalable psychological treatments, the majority of EBTs are developed in western countries, which may impact treatment acceptability when implemented in other contexts (Chowdhary et al., 2014). Psychotherapy incorporates an understanding of human behaviors, thoughts, and emotions, all of which are strongly interrelated with culture (Frank

& Frank, 1993). Culture influences symptomology, shapes coping strategies, and determines clinical presentations and help-seeking behavior (Kirmayer & Swartz, 2013). The process of cultural adaptation tackles these issues of acceptability and is defined as "the systematic modification of an evidence-based treatment...to consider language, culture and context in such a way that it is compatible with the client's cultural patterns, meanings, and values" (Bernal et al., 2009). This definition points to the interconnectedness of culture, social determinants of health, and psychotherapy. Cultural viewpoints must be respected, and approaches may even cause harm or increase problems if they contradict or ignore core cultural values. Therefore, from an ethical perspective, cultural adaptation is an integral step in the implementation process (Bernal et al., 2009).

Adapting EBTs to fit the culture of the targeted population can increase their applicability, patient satisfaction, and overall effectiveness (Benish et al., 2011; Bernal et al., 2009). Cultural adaptations can also help address practical barriers to care, such as the lack of trained mental health professionals and limited literacy in the targeted population (Chowdhary et al., 2014). At the same time, it is important for the EBT to retain its tried-and-tested methods that have gathered supporting evidence in other cultural contexts. Because of the lack of mental health resources globally, it is impractical to create a new treatment for each specific population. The process of cultural adaption is recognized as a 'middle ground' between the two viewpoints that EBTs can be delivered without any changes made for the cultural group and a cultural-specific approach for each intervention site (Chowdhary et al., 2014). Therefore, cultural adaptation requires a careful balance of population-fit and maintaining fidelity to the original evidence-based intervention.

Practitioners utilize a range of methods and frameworks for the adaptation process. Regardless of the framework used, documenting and reporting each step of the cultural adaptation process is important for evaluation and replication (Domenech Rodríguez & Bernal, 2012). Methods of cultural adaptation often include literature reviews, consultations with stakeholders and local experts, a formative research phase including in-depth interviews with target groups, piloting of the trial and an evaluation phase (Chowdhary et al., 2014). Incorporating the voices of the target population in the adaptation process helps to reduce personal or organizational biases and assures that that adaptations are grounded in the belief systems of program participants (Hwang, 2009).

An important step of the adaptation process is to identify the aspects of the EBT that do not require adaptation and function as the "core" of the psychological treatment (Bernal & Sáez-Santiago, 2006). Core components include specific elements of the EBT, such as problem-solving techniques for problem-solving therapy. They may also include some non-specific therapeutic aspects of the treatment, such as empathy towards the intervention participants. Adaptations to the method of delivery and activities supporting these techniques may increase acceptability. Language adaptations must also go beyond literal translations and integrate idioms of distress and colloquial phrasing (Bernal et al., 2009). Relationships between par-

ticipants and delivery agents and their therapeutic boundaries must also be considered in terms of what is appropriate for the cultural context (Chowdhary et al., 2014). Overall findings from systematic reviews have found that interventions that utilize a cultural adaptation process are more effective than those without (Benish et al., 2011).

Implementation of Task-sharing Approaches

Despite growing evidence for the effectiveness of task-sharing approaches, there are many challenges in implementation and dissemination of these interventions in LMICs. Conceptual models aim to better understand the factors that affect the successful implementation of these interventions. Most models highlight the importance of addressing three 'layers' to be considered during implementation and dissemination of an intervention (Murray et al., 2014). These layers include: 1) Local government legislature and policies, 2) Organizational culture, climate, and leadership, and 3) Culture and behavior of the delivery agents and target population (Proctor et al., 2009). Implementation science research also recognizes the importance of measuring indicators of success over time and that challenges throughout different phases of implementation may vary (Murray et al., 2014). Systemic, structural and human resources related challenges are all cited in the literature as major barriers to successful implementation.

Studies have found that task-sharing interventions are perceived as acceptable and feasible by service providers, supervisors, and stakeholders (Padmanathan & De Silva, 2013). However, systemic and human resource related challenges must be addressed and accounted for during implementation. The education and training of non-specialists can pose as a challenge to the feasibility and quality of an intervention. Approximately a quarter of task-sharing approaches utilize non-specialists with only a primary education (Singla et al., 2017). 30.8% of approaches utilize non-specialists with post-graduate education (Singla et al., 2017). The education level of non-specialists may be contingent upon the availability of human resources and the target population of the intervention. The wide range of education levels among non-specialists highlights the importance of providing sufficient mental health training to ensure quality of care (Mendenhall et al., 2014).

However, the majority of task-sharing interventions do not test the competency of non-specialists before service delivery (Singla et al., 2017). Competency tests for non-specialists should be further considered to prioritize quality of care rather than just population reach (Kohrt et al., 2015). Delivery agents and supervisors have also expressed a strong need for a framework that structures supportive ongoing supervision after initial trainings (Jordans et al., 2007; Padmanathan & De Silva, 2013). Findings have shown that workers who did not feel competent in service delivery were able to overcome this barrier when they received further training and supervision (Padmanathan & De Silva, 2013). Accountability of supervisors and their adequate training to provide quality supervision are also ongoing challenges that must be addressed in future studies (Mendenhall et al., 2014).

Stigma against mental health problems and use of mental health services has been well-documented as a common implementation barrier across LMIC settings (Semrau et al., 2015). A few strategies exist to combat this stigma and ease implementation. These include understanding local terms used to further stigmatize mental health, avoiding this terminology, and replacing it with suitable non-stigmatizing language (Kohrt & Hruschka, 2010). Some psychological interventions also prioritize community events to reduce levels of stigma amongst the local population. This strategy can increase the level of community support throughout the implementation process (Murray et al., 2014). These efforts can also be conducted with mental health providers to reduce the stigma that they may hold against beneficiary populations (Rai et al., 2017). Despite known strategies to reduce community stigma against mental health in LMICs, further effort is necessary to adequately address this large structural barrier during intervention implementation.

Need for Measuring Mechanisms of Action

Non-specific factors, or common factors, are elements that are present to all therapies. Four factors common to all therapies include: a relationship between patient and therapist, a rationale for why the treatment is being delivered, procedures provided to the patient and a healing setting (Frank & Frank, 1993). Many models of common factors have been developed and can be conceptualized in multiple ways. For example, common factors can be grouped into three categories of support (e.g. identification with therapist, therapeutic alliance, trust), learning (e.g. feedback, changing expectations, cognitive learning), and action (e.g. behavioral regulation, cognitive mastery, working through something) (Cuijpers et al., 2019). In contrast, specific factors or specific elements are those with foundations from particular psychological mechanisms and include problem-solving, self-talk, emotional regulation, exposure and others. These factors can be grouped into four domains including interpersonal, emotional, cognitive, and behavioral (Singla et al., 2017). Most scalable psychological interventions use both specific and non-specific factors as part of the treatment.

Psychological treatments utilizing a combination of specific and non-specific factors effectively treat mental disorders. An RCT may demonstrate that when compared to a control group, the treatment leads to clinical outcomes. For example, behavioral therapies can change maladaptive behaviors (Cuijpers et al., 2019). But how does this change come about and why did the intervention lead to change? The *how* and *why* of this question are addressed by *mechanisms of action*. Mechanisms of action are the events that are responsible for the change and the reasons why change occurred (Kazdin, 2007). Mechanisms of action are different from specific/non-specific factors because they are changes that happen *in* the patient, while specific/non-specific factors are *part of* the therapy (Cuijpers et al., 2019). Self-understanding, improvements in views of the self, and acquisition of skills are examples of mechanisms of action (Gibbons et al., 2009).

There are several reasons why it is important to evaluate mechanisms of action and measure them in effectiveness studies. 1) Operationalizing mechanisms of action

can support in understanding mediators. Mediators are variables that may partially explain the relationship between the treatment and outcome but do not explain the process of how change came about (Kazdin, 2007). 2) Psychological treatments can have many outcome effects aside from decreasing emotional and social problems. For example, psychological treatments have also been found to mitigate physical conditions such as physical pain and high blood pressure (Kazdin, 2007). Elaborating on mechanisms of action will explain how these effects came about. 3) Once mechanisms of action for a treatment are further operationalized, we can understand what processes beyond the specific/non-specific elements are critical to a treatment. We then know that these crucial aspects of the treatment that create change must stay unaltered during cultural adaptation of the psychological intervention. 4) By moving beyond the specific/non-specific elements and understanding what else is critical to the treatment, we can strengthen and improve the pathways towards positive treatment outcomes. Valid and reliable tools to measure mechanisms of action are greatly needed. We must include these tools in effectiveness studies.

Research Design of Randomized Controlled Trials (RCTs)

Positive results of randomized controlled trials (RCTs) are usually necessary before recommending a therapy for wide-spread implementation and uptake by policymakers (Cuijpers & Cristea, 2016). Because of the significant impact of these trials, high-quality RCTs must be designed to evaluate effectiveness. Firstly, it is important to account for the risk of bias when conducting RCTs. Possible sources of bias include improper allocation of treatment and control, inadequate blinding of allocation to the participants, inadequate blinding of the assessors, working with incomplete datasets and lack of inclusion of intent-to-treat analysis (Cuijpers et al., 2018). Though studies with a lower risk of bias often have smaller effect sizes between the treatment and control groups, they may more accurately represent the impact of a treatment.

The type of control group needs to be accounted for when conducting effectiveness studies and is significantly associated with the effect size. Control groups of different designs yield varying effect sizes (Cuijpers et al., 2013). Effect sizes in western countries were lower than those in developing countries (Cuijpers et al., 2019). There was a significant difference in the effect sizes in different world regions with the lowest effect sizes in North America and highest in South Asia, East Asia, the Middle East, and North Africa. These results could be because most studies in non-western countries use care-as-usual as their control groups (Cuijpers et al., 2019). Because of the lack of access to mental health services in these countries, care-as-usual could mean getting no treatment at all. In comparison, populations in western countries generally have more access to primary and mental health care which implies that their care-as-usual control groups have greater access to treatments than what is available in non-western countries (Cuijpers et al., 2013).

Two-thirds of scalable psychological interventions in LMICs focus exclusively on women and the remaining one-third also had predominantly female par-

ticipants (Singla et al., 2017). Though females experience high rates of CMDs in LMICs, men also suffer from mental health problems, especially those concerning behavior, such as substance abuse and intimate partner violence (IPV). Because gender equity plays a large role in women's health in LMICs, men's mental health is also inextricably linked with women's outcomes. For example, men's alcohol problems increase the risk of depression in their female partners (Nayak et al., 2010). Perceived spousal support may also be an element of the mediating pathway to psychological well-being (Singla et al., 2017). The lack of male inclusion in RCTs point to GMH's need to increase understanding of impacts of societal factors and the interrelationships between these factors on mental health outcomes.

NEPAL

Background: Nepal and Sources of Mental Health Problems

The dissertation describes research conducted in Nepal, a low-income country in South Asia with a history of political instability, structural violence, and natural disasters. Though Nepal has made gradual progress on development over the last few decades, it is behind other countries in South Asia and ranks 147th out of 177 countries in the world in the UN's Human Develop Index (UNDP, 2019). The population of the country has increased to 29.3 million in recent years, with 80% living in rural areas. Nepal is home to over 125 ethnic and caste groups spread amongst the three main geographic regions of the country; the mountains, hills, and *terai* plains (Central Bureau of Statistics (CBS), 2014). Difficult terrain and the remoteness of many regions in the country contribute to a lack of access to education and healthcare, leading some areas of the country to be more developed than others (Do & Iyer, 2010). Nepal is prone to humanitarian crises and struggles with chronic stressors such as poverty, inequality in gender, caste, and ethnicity, and a broken healthcare system. These stressors contribute to high rates of mental health problems and a lack of services to treat those who need it the most (Kohrt et al., 2012; Kohrt & Worthman, 2009).

In 2006, Nepal emerged from a decade-long internal conflict fought between the Communist Party of Nepal (Maoist) and government security forces (Thapa & Sijapati, 2004). Poverty, caste discrimination, regional inequality, wealth inequality and dissatisfaction with governance are all cited as the roots of the insurgency (Tol et al., 2010). The main objective of the Maoist insurgents was to replace the century old monarchy with a people's republic guided by a new constitution addressing inequality experienced throughout the country (Do & Iyer, 2010). It is estimated that the conflict killed over 14,000 people and displaced over 200,000 (Kohrt et al., 2012; Singh et al., 2007). Those already vulnerable prior to the conflict were the most affected by it, including women, children, and those living in poverty, and the already fractured health system became even more difficult to manage (Luitel et al., 2015). It was often the case that medicine, general health services, and mental health ser-

vices, did not reach rural regions of the mountainous country. However, Nepal has made significant progress in health indicators since the end of the conflict.

Nepal is also prone to natural disasters. The *terai* experiences yearly flooding. In 2015, the Gorkha earthquake displaced 450,000 people and killed 8,900 (Kane et al., 2018). Country prevalence estimates of mental health disorders prior to the earthquake are lacking. However, a study conducted three months post-earthquake, in earthquake affected districts, found that one in three adults were experiencing depression and anxiety symptoms. One in five adults engaged in harmful alcohol use, and one in ten adults had current suicidality (Kane et al., 2018). This indicates a need for post-humanitarian psychosocial care.

Besides natural disasters and internal conflict, long-standing social risk factors correlate to mental health problems in Nepal (Kohrt et al., 2012). Growing evidence demonstrates that social inequalities can lead to a range of physical and mental health outcomes, not just for those who are marginalized but for others as well in unjust societies (Marmot, 2005). In Nepal, inequalities in gender, the hierarchical Hindu caste system and the intersectionality of these social structures have negatively impacted mental health (Jack et al., 2010; Kohrt & Worthman, 2009; Kohrt et al., 2009).

Nepal also lags behind in gender indicators. Compared to other countries in South Asia, Nepal has a higher workload for women. Women have lower literacy rates, higher mortality rates and laws that discriminate against them rather than protect (Gautam et al., 2011). While gender discrimination is a country-wide problem, it may be even more evident in conservative upper caste groups compared to other social sectors (Kohrt & Worthman, 2009). Nepal has a complex caste system, which has historically marginalized some groups while giving privilege to others. Caste discrimination has been institutionalized and can be seen by the lack of diversity and representation in government and leadership positions (Tol et al., 2010). Regardless of caste, Nepali women report greater mental health problems compared to men (Kohrt et al., 2009).

Though mental health problems are prevalent in Nepal, there are many societal barriers to seeking treatment including not knowing where to go for treatment, belief that the problem will resolve itself, doubt regarding effectiveness of treatment, and stigma (Luitel et al., 2017). The stigmatization of mental health is common amongst men and women of different caste and ethnic groups throughout the country. The functions of the mind and body are regarded as two different entities in Nepali culture (Kohrt & Harper, 2008). Mental health problems, such as CMDs, are often associated with the mind and are thus stigmatized. Those with severe mental illnesses who exhibit deviation from socially accepted behavior are highly stigmatized (Brenman et al., 2014). However, those with physical illnesses are spared from stigmatization and are thought of as experiencing "real" pain (Kohrt & Harper, 2008). Because of this, physiological presentations of mental health symptoms, such as headaches or being unable to sleep, are presented more often in healthcare settings compared to emotional symptoms, such as feelings of sadness or anxiety. Physiological symptoms are easier to identify compared to emo-

tional or "mind" related symptoms and are more easily accepted by Nepali society.

Ultimately, the stigma surrounding mental health problems decreases health-seeking behavior. Some of the most common concerns for mental health care recipients in Nepal include: concern that they may be seen as "crazy" for receiving treatment, concern that they may be seen as weak for having a mental health problem, and concern that others may not take them seriously because they received mental health care (Luitel et al., 2017). Health professionals may themselves stigmatize treatment recipients (Brenman et al., 2014).

Mental Health Services in Nepal: History, Policies, and Progress

Despite its high prevalence of mental health problems caused by humanitarian and chronic stressors, Nepal continues to lack proper access to treatment for its population. Since the late 1990s, Nepal's government has attempted to increase access to mental health care and integrate services within the current health system. However, lack of commitment by the unstable government and failure to operationalize and implement stated activities are major challenges (Luitel et al., 2015). Mental health personnel and scope of practice for these personnel are severely lacking. In 2017, a total of 103 psychiatrists, 18 psychiatric nurses, and 24 clinical psychologists were available for a country of approximately 30 million (WHO mental health summary, unpublished). Nepali psychiatrists within the country were concentrated in urban areas and occasionally visited rural areas to provide care (Luitel et al., 2015). Only 10 government hospitals provided psychiatric services with approximately 700 hospital beds, and only one government hospital focused solely on providing psychiatric services. Due partially to the scarcity of mental health services in Nepal, less than 5% of people with alcohol-use disorder and less than 10% of those with depression seek formal treatment (Luitel et al., 2017).

The Nepali government developed a mental health policy in 1997 that committed to integrating mental health services into the current health care system. The policy also aimed to prepare human resources for mental health treatment and protect human rights of those with mental disorders, though it has not been implemented as originally intended. These objectives were further reinstated in 2014 through the National Health Policy which noted that the government has previously been unable to prioritize the health and mental health needs of vulnerable populations. However, limited tangible progress has been made since.

In order to trace updates in the Nepali government's policies and efforts on providing mental health services, my colleague Krishna Karki and I conduced a literature review and interviews in 2017 to identify the history of mental health services in Nepal, key government policies, and programs related to mental health in Nepal. It is important to note that though mental health has often been listed as a priority in the history of health policy in Nepal, the government has rarely taken committed action on mental health objectives. Therefore, it was difficult to note the exact changes and impact in the health care system brought about by each policy. Key findings of this review are highlighted in the table below.

TABLE 1. Overview of Nepal's National Mental Health Policies and Program Activities

	Year	Policy/Activity	Details
Policies related to mental health and patient rights	1975	Release of a WHO report prioritizing mental health	· WHO released a report stating that the detection and management of mental health disorders should be integrated with the regular tasks of primary health workers. · WHO began to provide ongoing funding for mental health work in Nepal starting in 1980.
	1982	Disabled Welfare and Protection Act	· The Disabled Welfare and Protection Act of 1982 created the provision to provide treatment to mentally disabled people in hospitals and rehabilitation centers. · Persons with mental illness cannot be kept in jail if they have not committed a criminal offense.
	1991	Nepal Medical Association (NMA) requested Institute of Medicine (IOM) to develop a National Mental Health Policy	· Nepal Medical Association (NMA) requested Institute of Medicine (IOM) to develop a National Mental Health Policy. · This marked the first start to draft a national Mental Health Policy.
	1996	National Mental Health Policy (NMHP)	· The final plan of the National Mental Health Policy (NMHP), Strategy and Plan of Action, as drafted by IOM, was accepted and endorsed by the national government. · This policy intended to ensure the availability and accessibility of minimum services for all by year 2000. · The policy has four main objectives: 1) to ensure the availability and accessibility of minimum mental health services for all of Nepal's population, 2) to prepare human resources in the field of mental health, 3) to protect the fundamental human rights of the mentally ill, 4) to increase mental health awareness.
	2006	Mental Health Treatment and Protection Act	· Legislation to protect human rights of people with mental illness against abuse by health workers and the general population is drafted but is not endorsed by the government.
	2010	Convention on the Rights of Persons with Disabilities (CRPD)	· The CRPD is an international human rights treaty of the United Nations intended to protect the rights and dignity of persons with disabilities. · Nepal became the 86th country to ratify the Convention on the Rights of Persons with Disabilities (CRPD) and the 53rd country to ratify the Optional Protocol in 2010. · The CRPD states that persons with different disabilities, including mental health conditions, should be able to participate equally and fully in all aspects of their lives, including access to treatment.

	2010	Addition of mental health as "essential health care" in the National Health Sector Program (NHSP-II)	· Mental Health Services were included in the essential health care service (EHCS) package by NHSSP II as recommended by the World Health Organization (WHO). · NHSSP II stated that "the Ministry will integrate mental health within existing and future health and social programs; develop a low-cost and sustainable district system to provide mental health promotion, prevention and treatment; improve the quality of mental health data from the Health Management Information System (HMIS) and census data; and appoint a focal person for mental health within the Ministry". · It emphasized piloting and scaling up community based mental health care and the promotion of non-communicable disease control through partnerships with local governments and community-based organizations (CBOs).
	2014	Multi-sector Action Plan for Prevention of Non-Communicable Diseases	· The Multi Sector Action Plan for Prevention of Non-Communicable Diseases (NCDs) 2014 - 2020 is created. · Mental health is listed as a priority area and calls for leadership, health promotion, health systems strengthening and increased research in the field of mental health and other NCDs.
	2014	National Health Policy	· The vision of National Health Policy 2014 is that "All citizens of Nepal should be physically, mentally, socially and emotionally healthy and should be able to lead a productive and a high-quality life". · The policy stated that mental health illness is non-communicable and treatment services should be effectively implemented based on existing mental health policy. · Treatment should be provided through community level services as well as tertiary care. · Mental health services should and will be incorporated and implemented with a periodical plan in the future. · The policy also noted that the government has not been able to give priority to the health and mental health needs of children, adolescents, seniors, and those with genetic diseases or occupational health hazards.

	2016	Standard Treatment Protocol (STP)	· The Ministry of Health endorsed a Standard Treatment Protocol in 2016 for recognizing symptoms, diagnosis, treatment and management of depression, epilepsy/seizure, psychosis, anxiety disorder and alcohol use disorder (AUD). · The Primary Health Care revitalization division and non-government organizations took initiation in developing this protocol. · The protocol provides general information on mental health, a treatment protocol for mental illness, and basic information on medication and adverse drug reactions. Based on this protocol, mental health trainings should also be provided to all health workers.
	2017	Revision of Mental Health Policy	· The 1996 Mental Health Policy is currently being revised to ensure access to quality mental health and psychosocial services as fundamental rights to citizens and to integrate mental health services with primary health care provided by the government.
Establishment of government-based services and treatment	1961	First out-patient mental health care	· The first out-patient department (OPD) for mental health services opened in Bir Hospital, Kathmandu. · There were 5 in-patient hospital bed in 1965 and this was extended to 12 beds in 1971. · Psychiatry was established as a separate department in Bir Hospital, one of the most visited hospitals in Nepal, in 1985.
	1986	Psychiatric OPD services began in Tribhuvan University Teaching Hospital (TUTH) in Kathmandu	· Psychiatric OPD services began in Tribhuvan University Teaching Hospital (TUTH) in Maharajgunj, Kathmandu with 12 psychiatric in-patient beds.
Establishment of leading mental health NGOs	1985	First integrated community mental health program in Nepal	· United Mission to Nepal (UMN) began the first integrated community mental health program in Nepal in Lalitpur District outside of Kathmandu · In 1989, this program was pilot tested in Morang district with necessary funding and an agreement with the government.
	1990	Establishment of Centre for Victims of Torture (CVICT)	· Centre of Victims of Torture (CVICT) was established in Kathmandu, Nepal initially to support survivors of torture and conflict. · The organization has since served over 43,000 survivors.
	2001	Establishment of Kopila Nepal	· Kopila Nepal was established in Pokhara, Kaski District with the aim of promoting life standards of vulnerable children. · Since their establishment, their integrated community mental health services program, with a focus on women and children, has reached five districts (Gorkha, Lamjung, Syangja, Tanahu, and Kaski district).

	2003	Establishment of Center for Mental Health Counseling (CMC)	· Center for Mental Health Counseling (CMC) was founded and began working on the project that UMN and TUTH had established using their framework. · Since the start of their work, CMC has provided community mental health services in 33 districts.
	2005	Establishment of Transcultural Psychosocial Organization (TPO) Nepal	· TPO Nepal, one of the country's leading mental health organizations, was founded with the aim of conducting psychosocial research, delivering evidence-based programs and increasing mental health capacity throughout the country. · The organization started by focusing efforts on conflict-affected populations and refugees and has since worked to integrate mental health services into the primary health system.
	2009	Establishment of KOSHISH	· KOSHISH began their community based mental health program that covered Dhading district (2009 - 2011), Bhakthapur district and Tanahu district (2009 - present), as well as Kavre and Lalitpur district (2016 - present).
	2009	Establishment of Livelihoods Education and Development Society (LEADS)	· Livelihoods Education and Development Society (LEADS) began their Basic Needs community mental health model and covered 39 VDCs in Baglung and Myagdi district from 2009 - 2013. · Their model included a livelihood component for their beneficiaries.

Because of challenges in implementing integrated mental health care, implementation of community mental health services in Nepal is directed by NGOs and INGOs. As part of the literature review, we identified seven key organizations that focused on a range of mental health symptoms/disorders and delivered mental health services by coordinating with the existing health system. Collectively, these organizations implemented programs in less than half of Nepal's districts at the time of data collection, which reveals how limited access to mental health treatment still is, even with efforts from the non-governmental sector. A few of the organizations trained counselors through a three or six-month curriculum. Counselors usually focused their efforts on specific populations such as refugees, survivors of domestic violence, and those affected by human trafficking. Most frameworks implemented by the mental health organizations focused on addressing the needs of vulnerable populations. Some frameworks also emphasized the importance of supporting livelihoods and economic development in parallel with mental health. Integration of mental health services with the current health system also emerged as a key theme in the organizations' strategies. Several organizations aimed to increase access to care by providing mental health trainings to health workers, such as health assistants (HAs), auxiliary health workers (AHWs), and female community health volunteers (FCHVs).

Transcultural Psychosocial Organization (TPO) Nepal, a leading mental health organization in Nepal, has focused their efforts on the integration of mental health services within primary healthcare. TPO Nepal was established in 2005, as the internal conflict was ending but left the country with thousands of people in need of post-trauma mental health care. The foundation of the organization lies in the humanitarian context. Initial efforts focused on understanding the mental health effects of the conflict, conducting research and developing interventions for vulnerable populations, including children and child-soldiers (Jordans et al., 2010; Kohrt et al., 2010; Luitel et al., 2013; Tol et al., 2010). Since then, TPO Nepal has also conducted significant research in validating and culturally adapting extensively used mental health questionnaires to be used in the Nepal context (Burkey et al., 2018; Kohrt et al., 2011, 2016).

Tools such as the Community Informant Detection Tool (CIDT) have been developed to address underlying barriers in accessing mental health care, such as stigma and lack of community mental health awareness (Jordans et al., 2015; Subba et al., 2017). The organization has also focused efforts on increasing the quality of care provided by paraprofessionals (Kohrt et al., 2015). With the increase of task-sharing interventions worldwide, TPO Nepal has implemented the Programme for Improvement of Mental health care (PRIME), a research consortium working in five countries to evaluate the impact of a multi-faceted mental health care approach (Jordans et al., 2013). The organization has also taken lead in Nepal's efforts to implement the WHO mental health Gap Action Programme (mhGAP) Intervention Guide, an approach to train health workers on mental health, which has been implemented in various parts of the country (Keynejad et al., 2018). TPO Nepal's strengths lie in its experience working in humanitarian contexts and delivering quality care through task-sharing approaches.

RESEARCH THEMES

Innovative approaches are especially necessary in settings such as Nepal that have many interconnected barriers to accessing quality mental health care. The dissertation follows a randomized controlled trial (RCT) of a psychological intervention through all of its phases: cultural adaptation before introducing the intervention to the communities, implementation of the feasibility and acceptability trial, outcomes of the feasibility and acceptability trial, implementation of the effectiveness trial, outcomes of the effectiveness trial, and an exploratory analysis of differences within therapeutic groups. This research aims to highlight the importance of following a phased approach when conducting a large effectiveness trial. This dissertation examines the following research questions:

- → What methodology should be followed to conduct a thoughtful cultural adaptation process that aligns with and respects the culture, views, and

needs of the beneficiary community while retaining fidelity to the tried-and-tested psychological treatment? How can this be conducted in an LMIC setting with limited time and resources without sacrificing quality and depth of adaptations?

- → How feasible and acceptable is the culturally adapted intervention in Nepal? What were the main challenges in implementing a task-sharing intervention and what components of the intervention need to be further adapted before conducting the final trial?
- → How effective is the intervention in Nepal? What are key lessons to be learned in implementing an RCT in an LMIC setting with a task-sharing approach?
- → What are the added psychosocial benefits of conducting group-based interventions in LMIC settings? How do the characteristics of a therapeutic group impact participants' treatment outcomes?
- → How do these findings contribute to the current literature and discussions around the implications of trans-diagnostic interventions, mechanisms of action, and cultural adaptation?

GROUP PROBLEM MANAGEMENT PLUS (PM+)

This dissertation focuses on mapping the implementation of Group Problem Management Plus (PM+). Group PM+ is a low-intensity, trans-diagnostic, brief psychological intervention that was developed by the WHO. This intervention is designed for adults with symptoms of CMDs (e.g. depression, anxiety, stress, grief). The mechanisms of action learned in each session can also be useful for those with co-morbid mental health symptoms. The term "problem management" highlights the foundational concept of the intervention that problems encountered by those living in adverse settings, such as humanitarian and LMIC settings, cannot necessarily be "solved" but can be "managed" if tools are provided (Dawson et al., 2015). The "plus" refers to strategies that can increase an individual's capacity to manage problems. The intervention is composed of five sessions, delivered once a week for five consecutive weeks. In these sessions, participants learn evidence-based psychological strategies including stress reduction, behavioral activation, problem-solving and strengthening social support (Dawson et al., 2015). Independent practice outside of the sessions is encouraged.

Individual PM+, where participants meet one-on-one with non-specialists, was implemented in Pakistan (Rahman et al., 2016). It has since been adapted to be delivered in a group setting to enhance cost-effectiveness and accessibility. This adaptation retains the core components of individual PM+ but lasts three hours and is delivered by one non-specialist for eight or more participants (Dawson et al., 2015). The group format has since been implemented in Pakistan with women in a conflict-affected setting and in Kenya with women who experienced based violence (Bryant et al., 2017; Rahman et al., 2019). These group trials were conducted with

only female participants and Nepal is the first country where Group PM+ will be implemented with both women and men. The feasibility and acceptability trial determined if this intervention is suited for men and the effectiveness trial tested the intervention's impact.

STRUCTURE OF DISSERTATION

The chapters of this dissertation follow the phases of the RCT chronologically. They map the progression from cultural adaptation of the intervention, to implementation and analysis of the feasibility trial before the larger effectiveness study, and finally to a secondary analysis of group level effects.

Chapter two outlines the cultural adaptation of a psychosocial task-sharing intervention for adults in Nepal and forms the foundation for the subsequent chapters. While there are many models for cultural adaptation, there is a strong need for a prescriptive cultural adaptation process that is easy to follow and implement, especially in low-resource settings. Chapter two develops a specific guideline and describes the implementation process of this cultural adaptation framework in Nepal. This process occurred before introducing the intervention to communities in Nepal. Chapters three and four outlines the implementation and analysis of the intervention in a feasibility and acceptability trial. Before investing time and resources in a large trial to test the effectiveness of an intervention, it is necessary to conduct a smaller pilot trial. A pilot trial provides and opportunity to diagnose implementation challenges, address them, and learn important lessons before ultimately testing the intervention for effectiveness on a larger scale.

Chapters five and six present the effectiveness trial. A cluster randomized controlled trial (c-RCT) methodology was used to test the effectiveness of the intervention. This c-RCT was conducted in a different location from the pilot trial with a significantly larger sample size. Therefore, this phase presents a more complex implementation process and analysis and is the culmination of all efforts and lessons learned from previous phases. Chapter seven is an exploratory analysis of the between and within group level effects for the intervention. This includes an exploration of the concept of "group cohesion", the bonding and feelings of oneness amongst group members, similar to therapeutic alliance in individual psychotherapy. This chapter aims to highlight the mechanisms that contribute to differences in outcomes between groups in group-based interventions.

As the conclusion of this dissertation, chapter eight discusses the contributions from this research to the field of global mental health. I aim to use a public health perspective in this chapter to contribute to future methods in implementation science.

PERSONAL TRAJECTORY

I was born in Kathmandu but was raised in the United States. I always felt drawn to moving back and working in Nepal. After completing my bachelor's degree, I worked on research and public health programming for various populations in the US, including adolescents and the homeless. While I mainly focused on access to healthcare and reproductive health issues, I began to see mental health and suffering as a common thread that is often left unaddressed in public health. I pursued a Master's in Public Health (MPH) to further understand how social and health disparities impact psychological well-being. I moved to Nepal in 2016 to gain further insight and experience on this by working with TPO Nepal.

When I first began working on Group PM+, I was focused on the cultural adaptation of the intervention. Though many frameworks for adaptation were available, a detailed process was lacking, especially one that focused not only on the content but how the intervention would be implemented. Our team spent months documenting the outcomes of interviews with community members, ideas for scalability and changes we made to the manual. Our efforts culminated in a detailed 10-step process for adaptation, which is the second chapter of this dissertation. The contextualization process continued as we implemented a feasibility trial in Sindhuli district and an effectiveness trial in Morang district. Though my interest in adaptation remained, I began to broaden my focus to overall best practices for successfully implementing psychological interventions in low-resource settings.

From living in both districts where we implemented Group PM+, I observed how deeply society and culture influence people's personal mental health experiences. I realized that as researchers, this understanding should be the backbone of every intervention, analysis, and trial. Therefore, our implementation methods must be reconsidered in each setting and should be informed by the needs of communities, rather than the other way around. Throughout the course of my work on these trials, I became interested not just in whether a particular intervention reduces distress but *how* interventions lead to psychological change. After hearing the experiences participants shared about attending Group PM+, I became especially interested in how group therapy uniquely impacts mental health outcomes and what factors facilitate this process. This dissertation follows the expansion and addition of my interests, from adaptation and contextualization, to implementation science, and eventually to critically assessing the many mechanisms that ultimately impact the psychological outcomes to an intervention. This personal and professional trajectory has been extremely fulfilling, especially because it has brought me closer to Nepal. I hope that my research has contributed to further solidifying rigorous implementation methods for psychological trials in low-resource settings that are truly informed by culture and context.

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CULTURAL ADAPTATION AND CONTEXTUALIZATION

CHAPTER 2

Development of a cultural adaptation framework for mental health interventions in low-resource settings

This chapters is based on: Sangraula, M., Kohrt, B.A., Ghimire, R., Shrestha, P., Luitel, N.P., van't Hof, E., Dawson, K., & Jordans, M.J.D. (Under Review) Development of the Mental Health Cultural Adaptation and Contextualization for Implementation (mhCACI) Procedure: A Systematic Framework to Prepare Evidence-Based Psychological Interventions for Scaling

ABSTRACT

Background

Because of the high burden of untreated mental illness in humanitarian and low- and middle-income country settings, scaling-up effective psychological interventions requires a cultural adaptation process that is feasible and acceptable. We propose a method of adaptation that focus on the intersection of culture and treatment mechanisms of action, that goes beyond surface level cultural attributes.

Methods

Building upon the Ecological Validity Model, we developed a 10-step process, the mental health Cultural Adaptation and Contextualization for Implementation (mhCACI) procedure, and piloted this approach in Nepal for Group Problem Management Plus (PM+), a task-sharing intervention, proven effective for adults with psychological distress in low-resource settings. Detailed documentation tools were used to ensure rigor and transparency during the adaptation process.

Results

The mhCACI is 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, 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. For Group PM+, key adaptations were harmonizing the mechanisms of action with cultural models of 'tension'; modification of recruitment procedures to assure fit; and development of a skills checklist.

Conclusion

A 10-step mhCACI process could feasibly be implemented in a humanitarian setting to rapidly prepare a psychological intervention for widespread implementation.

BACKGROUND

Prevalence of psychological distress is high amongst populations in low and middle-income countries (LMICs) that are affected by conflict, poverty, and violence (Charlson et al., 2019; Thornicroft et al., 2017). LMICs are often unable to cope with high rates of distress, due to fragmented health systems and limited number of mental health professionals (Jordans & Tol, 2013). In such contexts, interventions are needed that can be scaled-up to reach larger populations, can be delivered through routine health care, and utilize concepts of task-sharing, i.e., use of non-specialists to deliver intervention components (Patel et al., 2018). Intertwined with expanding the reach of interventions is the need to assure that programs are culturally appropriate or culturally compelling (Panter-Brick et al., 2006). Global mental health efforts have also previously been criticized for cultural insensitivity and lack of alignment with local norms, family structures and practices, and cultural conceptualizations of distress (Summerfield, 2013). Moreover, only changing the content of a manualized psychological treatment, without modifying the implementation strategies, may lead to limited delivery or uptake of the new services. Therefore, both cultural adaptation and contextualization of content and implementation strategies are needed for effective scale-up (Chambers & Norton, 2016).

Overview of Cultural Adaptation Methods

Though they may differ in design, the main intention for all cultural adaptation frameworks is to increase the effectiveness of the evidence-based treatments (EBTs) 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 (Bernal & Scharró-del-Río, 2001; Sue, 2003). There have been many attempts to organize the theories suggested by the existing frameworks and are therefore condensed into three main distinctions that need to be balanced when adapting EBTs (Bernal & Domenech Rodriguez, 2012; Griner & Smith, 2006; Hall et al., 2016; Huey et al., 2014).

The first distinction is *surface* vs. *deep* adaptations. *Surface structure* adaptations refer to modifying superficial characteristics, such as translating treatment materials, to better fit preferences of the beneficiary population (Ahluwalia et al., 1999; Burge et al., 1997). *Deep structure* adaptations target cultural values, norms, traditions, beliefs, and the beneficiary population's perceptions of the illness's treatment and etiology. Surface level adaptations, such as pictorial material depicting participants ethnically similar to beneficiary populations, resulted in discernable improvements in participant retention (Harachi et al., 1997; Kumpfer et al., 2002) highlighting the importance of even "simple" cultural adaptations.

The second distinction is between the adaptations 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 (Chu & Leino, 2017). *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. 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 (Castro et al., 2004; Kilbourne et al., 2007). 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 (Cuijpers et al., 2019; Heim & Kohrt, 2019) could be classified as *peripheral,* or supportive components, but in fact may be *core* and integral to the success of the treatment.

Despite a range of theoretical lenses to view cultural adaptation, the adaptation procedures have been criticized as difficult to replicate in real-world settings and lacking in transparency (Chu & Leino, 2017; Escoffery et al., 2018). Additionally, most adaptation studies of psychological treatments have been conducted with ethnic minorities in high-income countries (HICs) (Bernal et al., 2009). Though this is an overlooked and often marginalized population, these minorities are based in settings where resources such as time and personnel may not be as constrained as in low-resource and humanitarian settings that require rapid implementation. These constraints create unique needs, especially in LMICs and humanitarian settings, where a transparent, thorough, and prescriptive framework is necessary to guide rapid and systematic adaptions.

Though an existing cultural adaptation methodology has been presented to adapt individual PM+ with refugee populations (Perera et al., 2020), our approach has several advantages including a central focus on the mechanisms of action, attention to implementation parameters beyond content modification (e.g., how do participants become engaged in the intervention, how is it explained to the public and families), rigorous documentation, and creation of a cultural distress model that goes beyond simply translating mental health terminology.

Aim

Our aim was to harmonize existing approaches to cultural adaptation and contextualization, as well as address gaps in current approaches. We piloted our adaptation approach to document the process and identify key adaptations in the context of Group Problem Management (PM+) in Nepal (Sangraula et al., 2020), including gathering data on how the adapted and contextualized intervention was perceived by participants, community members, and families. 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 mechanisms of action, implementation, scalability, and quality monitoring.
2. Report on the cultural adaptation process of Group PM+.

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

The resulting methodology is the mental health Cultural Adaptation and Contextualization for Implementation (mhCACI) procedure.

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 (Kane et al., 2018). To date, there have been minimal efforts to adapt EBTs in Nepal (Ramaiya et al., 2017). 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 (Sangraula et al., 2020; Sangraula et al., 2018). Two Village Development Committees (VDCs) were selected for the adaptation process. The adaptation process and implementation of the trial was conducted by the staff of Transcultural Psychosocial Organization (TPO) Nepal based in Kathmandu, Nepal (Upadhaya et al., 2014).

Ecological Validity Model (EVM) and Replicating Effective Programs (REP) Framework

We built the mhCACI procedure upon the Ecological Validity Model (EVM) to guide our adaptation of the Group PM+ intervention content (Bernal et al., 1995; Bernal & Sáez-Santiago, 2006). The EVM 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 (Bernal & Sáez-Santiago, 2006). This model is based on the view that individuals must be understood within their cultural, social, and political environment. 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 (Bernal, 2003). These dimensions include language, persons, metaphors, content, concepts, goals, methods, and context.

TABLE 1. Ecological Validity Model (EVM) Domains

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.

We also structured the adaptation and contextualization methodology within the Replicating Effective Programs (REP) framework, which considers intervention training, supervision, and fidelity assessments as crucial components to the implementation of effective interventions while allowing for local flexibility (Kilbourne et al., 2007). REP includes four phases: (1) pre-conditions (e.g. identifying need and target population), (2) pre-implementation (e.g. community input and training), (3) implementation (e.g. program delivery and evaluation), (4) maintenance and evolution (e.g. re-customization and preparing intervention for implementation in another context or dissemination) (Cabassa & Baumann, 2013).

Study Methodology

This study was registered in ClinicalTrials.gov (NCT03359486). As part of the ten-step cultural adaptation model, qualitative interviews were conducted with program stakeholders to gather feedback on the acceptability, scalability, and implementation of the adaptations (Sangraula et al., 2020). Integrated within the maintenance and evolution phase, a subsequent Group PM+ evaluation will be conducted in Nepal with the integrated changes in implementation methods (van't Hof et al., 2020).

Overview of mental health Cultural Adaptation and Contextualization for Implementation (mhCACI) Methodology

The adaptation process was an ongoing, iterative process and some overlapping steps. 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.

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 (Stirman et al., 2019): 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.

TABLE 2. Ecological Validity Model (EVM) Matrix for Adaptations

Adaptation Dimension	**Pages**	**Implementation Strategy**	**Rationale for Change**	**Evidence for Change**	**Description of evidence base**	**Status of change**
Language People Metaphors Content Concepts Goals Methods Context	Note where in the intervention manual this change should occur	Description of what exactly should be changed in the manual, or other intervention material	Description of why it should be changed and what this change would accomplish for the intervention	Note what steps in the adaptation process provided evidence for this change (ex. 1 - Identifying mechanisms of action, 2 - literature review, 3 - ToT etc.)	Describe the evidence that suggested this change	Note the status of creating this change in the manual or other intervention material (ex. In-process, completed etc.)

The following approach charts the cultural adaptation process from preparation through implementation (see **Table 3**). We present the steps as they would fit into the first three phases of the REP Framework (pre-conditions, pre-implementation, and implementation).

TABLE 3. Overview of Adaptation steps: Activities, Participants, and Methods of Analysis

Adaptation Step	Objectives	Activities	Participants	Data collection and Methods of Analysis	Duration
Phase I: Pre-Condition *Identify need for intervention, Identify intervention for local setting, Package intervention for Training and Assessment*					
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 the 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

Phase II: Pre-Implementation *Orientation to core elements, Customize delivery, Identification of Barriers, Staff Training needs, Technical assistance needs*					
3.Training of Trainers (ToT)	To incorporate pre-existing practices in program site To identify how existing training transmits mechanisms of action To identify overlap of approach with preexisting practices in program site	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 supervisors (2) Additional counselors for intervention support (6)	Participants of ToT write suggested adaptations directly in the manual. Clinical Supervisors review suggested adaptations after the ToT before finalizing into the manual.	10 days
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 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.	1.5 months

Phase III: Implementation *Ongoing community partnership, Booster trainings and supervision, Process Evaluation, and Feedback and Refinement of Intervention Package and Training*					
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). Finalize adaptations thus far by adding all small or large changes in EVM matrix	1 day

9. Implementation and Supervision	To gather feedback from the implementation and supervision process to further adapt intervention To summarize experiences using intervention manual and proposed intervention implementation strategies and scalability	Conduct intervention facilitator training Gather any suggestions for changes from the facilitator training Conduct intervention, supervision and implement all program activities Record detailed notes about firsthand experiences on implementing intervention	Clinical Supervisors (2) Delivery Agents (8) Research Supervisor (1) Program Coordinator (1) Program Participants (60)	Trainers (Clinical Supervisors) record suggested adaptations, during training of delivery agents, directly into the manual and review before finalizing for implementation within the program. 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.	6 months

10. Review through Process Evaluation	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 To gather information from field staff on adaptation suggestions and improvements to increase the feasibility, acceptability, and fidelity of the program	Conduct KIIs and FGDs with community members, key stakeholders and local staff in program site Focus questions for trial participants, family members, local health workers, and community leaders on feasibility, acceptability and implementation of intervention. Focus questions for staff on intervention and program fidelity, and challenges in feasibility and acceptability.	Intervention facilitators (8) Research Assistants (8) Intervention participants (8) Intervention Participants' familles (3)	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. Conduct Key Informant Interviews (KIIs) and Focus Group Discussions (FGDs) with a variety of local stakeholders to 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) Code interviews using deductive analysis and summarize key findings related to main dimensions **[Table 5]**. Apply findings from process evaluation to the manual and program implementation strategy for the future program implementation **[Table 5]**.	2 months

Phase I: Pre-Conditions

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 (Kazdin, 2007). 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 (Bryant et al., 2017; Dawson et al., 2015; Rahman et al., 2019).

TABLE 4. Mechanisms of Action of intervention

Intervention Mechanisms of Action	Description of Mechanism	Implementation of Mechanism
Stress Management	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
Managing Problems	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
Behavioral Activation	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
Strengthening Social Support	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.

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

A systematic review of existing literature on mental health interventions in Nepal was conducted. 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.

Phase II: Pre-Implementation

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. The participants of this ToT identified overlap of approach with preexisting practices in the program site and sug-

gested 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. Clinical supervisors regularly reviewed the translator's progress to ensure that the manual could be understood by non-specialist delivery agents. 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 regarding community's awareness of mental health, collaboration with pre-existing community resources and identification of practical problems faced by community members. Key Informant Interviews (KIIs) (n=18) and Focus Group Discussions (FGDs) (n=2) were conducted with female community health volunteers (FCHVs), leaders, health workers, and community members. Interviews were coded by two coders (MS and RG) using deductive analysis. Key findings related to program implementation and cultural ethno-psychological elements were applied to the manual and program implementation strategy, including community sensitization, recruitment, family meetings, referral pathways, and participant follow-up.

Phase III: Implementation

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. 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 all core program and research staff was conducted to summarize all intervention adaptations listed to date on the EVM matrix. Program staff also modified competency and quality monitoring procedures. Once all adaptations were thoroughly discussed, Clinical Supervisors made final changes to the manual before the start of the trial.

9. Program Implementation, Supervision, and Process Evaluation

Lay Nepali community members were recruited to deliver Group PM+ to their communities (Sangraula et al., 2020; Sangraula et al., 2018). During the Group PM+ training, the facilitators were encouraged to suggest changes in the manual's language and feasibility and acceptability of the proposed implementation strategy. We employed a randomized control trial (RCT) design where the two chosen VDCs in Sindhuli district 120 participants were randomly assigned to enhanced usual care (EUC) or PM+. As part of supervision, 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.

After completing the intervention, 31 KIIs and 6 FGDs 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. A deductive data analysis process was used; key themes were identified prior to analysis and a codebook was developed (Sangraula et al., 2020). 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. Key implementation challenges, successes, and further suggestions for the program were extracted and summarized from the interviews.

10. Re-customization of Intervention

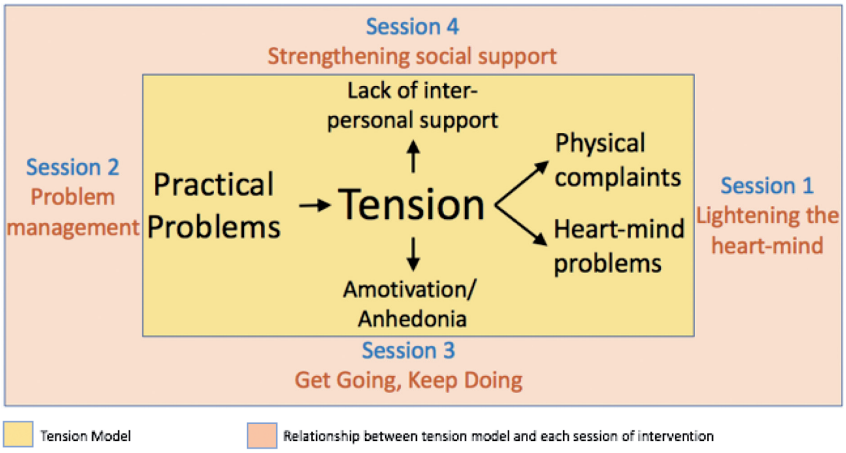
Field notes from program implementation and supervision, along with results of the process evaluation were gathered and synthesized into the EVM matrix **(above)** to highlight suggested key changes for re-customization of the intervention. The program staff then discussed appropriate changes related to program content, recruitment methods, quality assurance, and strengthening the mechanisms of action. Program materials were further revised to reflect the outcomes of implementation assessment before implementation in a new context.

RESULTS

Conceptualization of Stress and Tension

As a central focus of the adaptation process, we aimed to create a conceptual model by linking the mechanism of action to how distress was experienced in this context. *Tension* was used as a non-stigmatizing idiom of distress, as a proxy to depression complaints which is targeted by the intervention, and was commonly used in lay-Nepali language by community members of all ages, gender, and socio-economic status (Rai et al., 2017). The *tension* ethnopsychology model was conceptualized during the workshop as the team was finalizing the adaptations before the trial.

FIGURE 1: Tension Conceptual Model



According to the ethnopsychology model, adversity or practical problems lead to *tension,* which 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 facilitator training and the recruitment process to explain the effects of adversity on our lives to local community members.

Key Adaptations

Adaptations were systematically documented in the EVM matrix. Key adaptations are summarized in **Table 5**.

TABLE 5. Key Adaptations from each step

Adaptation Steps	Key Adaptations
Phase I: Pre-Conditions	
1. Identify Mechanisms of Action	Four key mechanisms of action were identified; stress management, managing problems, behavioral activation, and strengthening social support[4,6]. 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.
2. In-depth Literature Review	The literature review suggested that mental illness is deeply stigmatized in Nepal and idioms of distress such as *man ko samasya* or tension 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]. 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].
Phase II: Pre-Implementation	
3. Training of Trainers (ToT)	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 me-mapping (an activity where participants identify their close relationships in pictorial form)[4,5,7]. As part of the training, trainers read the manual and reviewed other implementation material thoroughly and suggested further language, such as man ko samasya, to decrease self-stigma. This aligned with the results of the literature review[1,5,7,8]. 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].
4. Translation of manual	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]. 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 manual[7].
5. Expert read-through	Experts with experience counseling in Nepal stressed the importance of gender matching facilitators and participants for the intervention[2,7,8]. 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].

6.Formative qualitative study	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]. 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].
Phase III: Implementation	
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 sessions4,7,8. 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 material[2]. 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 and Supervision	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-stigmatizing program name[3,4,8]. 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 *man* (heart-mind) and the causes and symptoms of *man ko samasya*. This method of engagement was found to be especially helpful with recruitment and de-stigmatizing mental health issues[3,4,5,7,8].
10. Review through Process Evaluation	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 trial[3]. 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].

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

Pre-conditions

Identification of distress and relatability of clinical content

Understanding sources of distress was key to identifying need for intervention in the local community. Identified daily stressors, such as financial burden, grief, and migration, were incorporated into the stories used during sessions. Participants in the trial found these problems, the case story, and pictorial representations on posters to be highly relatable (Sangraula et al., 2020). Clinical supervisors and facilitators noted that physical health was a source of stress for the majority of program participants. The feedback received demonstrated that more content was necessary to address physical problems and train facilitators on how to work with participants who did not discuss their emotional 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.

Pre-Implementation

Use of local idioms to increase acceptability and reduce stigma

Community sensitization events were a vital component of recruitment to address the stigma and lack of awareness of mental health issues at the program site (Sangraula et al., 2020). Facilitators invited community members to discuss 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 stigmatization by the community for participating in the intervention and self-stigmatization by the participants themselves, key adaptations were made to the metaphors, the concepts, and the intervention packaging. 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 program implementation was successful in supporting the facilitators' understanding of how each session aimed to reduce stress.

Implementation

Recruitment, training, and supervision of intervention facilitators

Recruiting, training, and hiring local lay workers was a critical adaptation to increase scalability of the Group PM+ intervention. 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. 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.

Engagement with potential beneficiaries

The Community Informant Detection Tool (CIDT) helped easily identify members of the community experiencing mental health symptoms through using vignettes and pictures (Jordans et al., 2015). 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 severe symptoms are more noticeable than those with general distress. For future scalability and dissemination, it is recommended to train local community members on using the general distress version only and with regular on-site supervision.

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 (Kohrt et al., 2015). Clinical supervisors attended at least two of the five sessions per PM+ group and used the fidelity checklist to measure facilitators' competency in delivering the intervention. Facilitators also used the checklist while conducting sessions to ensure that the mechanisms of action were addressed thoroughly. 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 (Sangraula et al., 2020).

The participants noted that of the different techniques they learned, the deep breathing technique was the most memorable and used the most outside of the sessions (Sangraula et al., 2020). This technique was noted as the most tangible, accessible, and lead to the most immediate results. However, facilitators found it difficult to track how often participants were practicing at home.

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 by the facilitators to be one of the most difficult sessions to deliver and for real-life application outside the sessions. Therefore, the definitive trial incorporated an image of a hand with a step for problem solving written on each finger. A 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 incorporated 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 practice skills.

DISCUSSION

Outputs and Applications

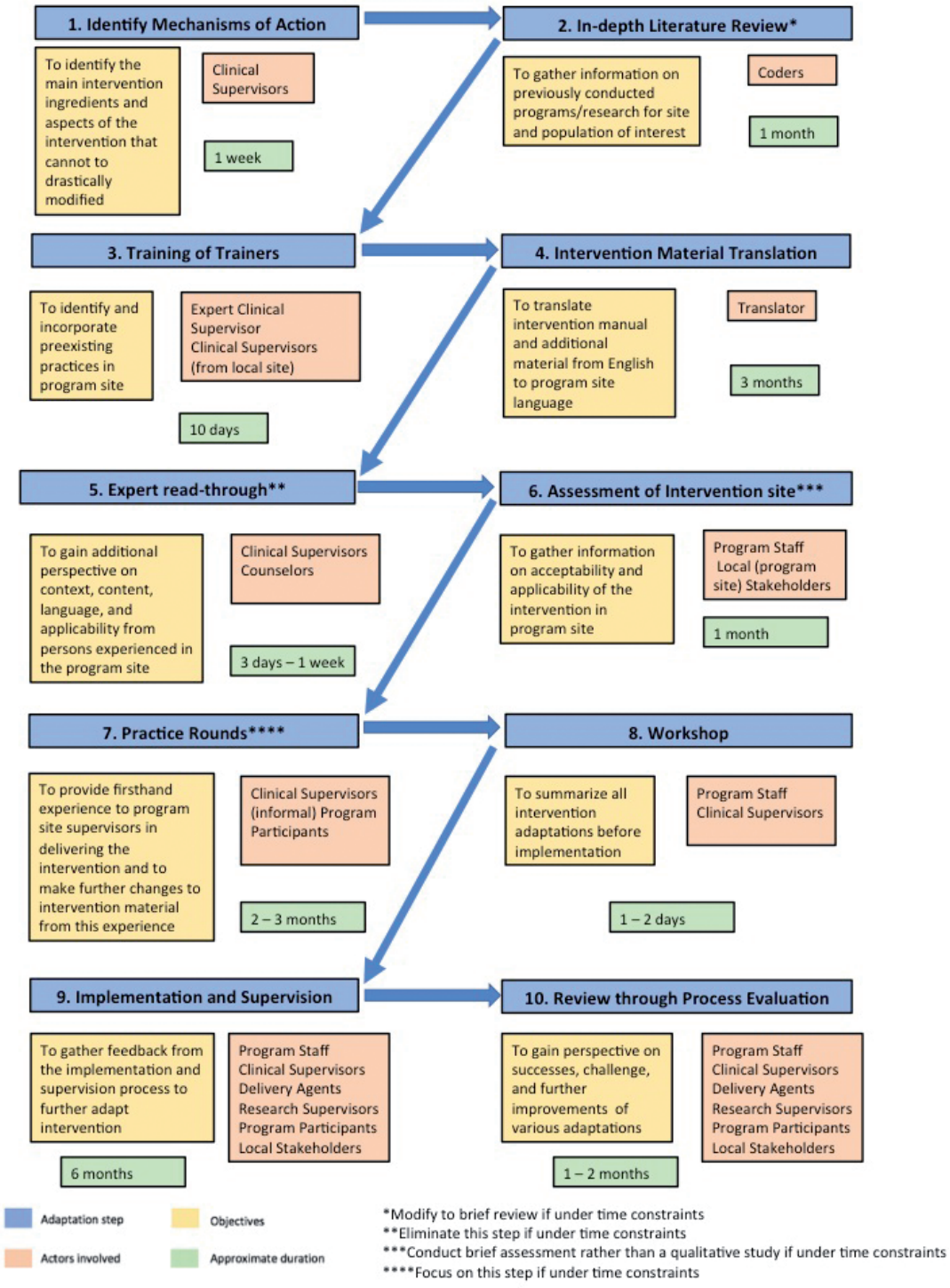
This study provides a methodology for the mhCACI that incorporates cultural adaptations to clinical content, scalability and implementation. Because this cultural adaptation methodology has been integrated into the REP framework, this study further bridges the gap between cultural adaptation and implementation science research (Cabassa & Baumann, 2013; Mutamba et al., 2018). The scalability and implementation aspects were shown to be just as important as the clinical content when adapting an intervention. 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.

The specific adaptations made to the intervention as well as the contextualization of the implementation process were demonstrated to be feasible and acceptable. The intervention had a high retention rate with 75% of the participants completed 4 – 5 sessions (Sangraula et al., 2020). All facilitators (n=4) scored above a 75% on the fidelity checklist developed to measure the competency and overall fidelity to the intervention. The intervention group showed an improvement in outcomes, especially in general psychological distress. Qualitative interviews with the Group PM+ facilitators, supervisors, and beneficiaries suggest that benefits can be attributed to the cultural adaptations and contextualization process.

In reality, adaptation processes are often conducted constrained by staff and time in low-resource settings. Therefore, we have created one mhCACI procedure with two versions: the first model to be used in contexts with at least modest time and resources, and the second in contexts with high-level constraints.

FIGURE 2: **Cultural Adaptation Step-by-step Guide**



For the shorter mhCACI procedure, 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 clinical staff who developed in-depth knowledge of the intervention when conducting prior adaptation steps were best fit to suggest the most meaningful changes. 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. The practice rounds step resulted in the greatest number of adaptations and were important step in addressing the logistical aspects of the intervention, such as time management, venue location and to gather feedback from participants within the targeted population. Therefore, we recommend shortening other steps and focusing 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 (Bernal & Domenech Rodriguez, 2012), 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. As a result, we found it best to focus less on which category an adaptation would be labeled, 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. 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. The results are also limited to qualitative work and the participants', staff, and stakeholders' perceptions of effectiveness. Regardless of compressing the adaptation process to fit resource limited contexts, the nature of the cultural adaptation itself is iterative and requires depth and heavy documentation.

Conclusion

This study proposes the mhCACI procedure as a clear and systematic adaptation process that can be conducted within implementation science methodologies, such as the REP framework. We provide documentation tools to guide the mhCACI procedure for future interventions. The combination of the REP framework and the 10-step methodology allows for a focus on intervention content, scalability, quality monitoring, and flexibility while maintaining fidelity. Though this process was

used to adapt a mental health intervention in an LMIC setting, it can be used to adapt interventions for various populations, such as ethnic minorities in high-income countries or humanitarian settings. With the increase in interventions that employ the concept of task-sharing (Patel, 2012), this process also serves as an example for future interventions in LMIC 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.

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TESTING PSYCHOLOGICAL INTERVENTIONS FOR FEASIBILITY AND ACCEPTABILITY

CHAPTER 3

Protocol for a feasibility study of Group Problem Management Plus (PM+) in earthquake-affected communities in Nepal

This chapter is based on: Sangraula, M., van't Hof, E., Luitel, N. P., Turner, E. L., Marahatta, K., Nakao, J. H., van Ommeren, M., Jordans, M.J.D., & Kohrt, B. A. (2018). Protocol for a feasibility study of group-based focused psychosocial support to improve the psychosocial well-being and functioning of adults affected by humanitarian crises in Nepal: Group Problem Management Plus (PM+). *Pilot and feasibility studies*, *4*(1), 126.

ABSTRACT

Background

The prevalence of common mental disorders increases in humanitarian emergencies while access to services to address them decreases. Problem Management Plus (PM+) is a brief 5-session trans-diagnostic psychological WHO intervention employing empirically supported strategies that can be delivered by non-specialist lay-providers under specialist supervision to adults impaired by distress. Two recent randomized controlled trials in Pakistan and Kenya demonstrated the efficacy of *individually* delivered PM+. To make PM+ more scalable and acceptable in different contexts it is important to develop a *group version* as well, with 6 – 8 participants in session. A study is needed to demonstrate the feasibility and acceptability of both the intervention in a new cultural context and the procedures to evaluate Group PM+ in a cluster randomized controlled trial.

Methods

This protocol describes a feasibility trial to Group PM+ in Sindhuli, Nepal. This study will evaluate procedures for a cluster randomized controlled trial (c-RCT) with Village Development Committees (VDCs), which are the second smallest unit of government administration, as the unit of randomization. Adults with high levels of psychological distress and functional impairment will receive either Group PM+ (n=60) or enhanced usual care (EUC; n=60). Psychological distress, functional impairment, depression symptoms, posttraumatic stress disorder (PTSD) symptoms and perceived problems will be measured during screening, pre-treatment baseline, and 7-10 days after the intervention. The primary objective of this trial is to evaluate the acceptability and feasibility of the intervention, to identify issues around implementation of local adaptation methods, training, supervision, and outcomes measures, and to assure procedures are adequate for a subsequent effectiveness c-RCT.

Conclusion

Outcomes from this trial will contribute to optimizing feasibility and acceptability through cultural adaptation and contextualization of the intervention as well as refining the design for a c-RCT, which will evaluate the effectiveness of Group PM+ in Nepal.

BACKGROUND

Humanitarian crises, such as the earthquake in Nepal in April 2015, cause significant psychological and social suffering. Nepal's fragmented and under-resourced mental health and social services are not able to cope with such a high level of need (Luitel et al., 2015). The country has 0.22 psychiatrists and 0.06 psychologists per 100,000 people, mainly working in large cities (Luitel et al., 2015). Nepal has basic health care units with primary care staff and midwives, and in most districts, there are other community care providers, often working for NGOs. The availability of this system makes a model of care provision through non-specialists a particularly important implementation strategy.

In low-resource settings, mental health interventions may need to be short of duration and carried out by non-specialists in the communities to make them sustainable and feasible to implement on a broader scale. A simplified psychological intervention, *Problem Management Plus (PM+),* has been developed by the World Health Organization (WHO) to address this. It has four core features that make the intervention suitable for low resource settings exposed to adversities: 1) a brief intervention (5-sessions), delivered individually or in groups, 2) delivered by non-specialists (high school graduates with no mental health experience), using the principle of task shifting, 3) designed as a trans-diagnostic intervention, addressing a range of client-identified emotional (e.g., depression, anxiety, stress) and practical problems, and 4) designed for people in communities in low- and middle-income countries (LMIC) affected by any kind of adversity (e.g., violence, disasters) (Dawson et al., 2015).

Recent randomized controlled trials (RCTs) in Peshawar (Pakistan) and Nairobi (Kenya) have indicated individually delivered PM+ to be effective in diminishing depression and anxiety symptoms, managing self-selected practical or psychological problems, and improving daily functioning (Bryant et al., 2017; Chiumento et al., 2017). The first evaluation of a Group PM+ is underway in Pakistan (Chiumento et al., 2017). This paper describes the study protocol of a feasibility trial with Group PM+ in Nepal before evaluating effectiveness in a fully powered cluster RCT (c-RCT). Feasibility studies are valuable to address issues related to process, resources, management, or scientific approaches (Thabane et al., 2010; Van Teijlingen & Hundley, 2001) in so the issues can be addressed before conducting definitive randomized trials.

Objectives

For Group PM+ in Nepal, we will implement trial procedures to gather information about feasibility, acceptability, safety, and delivery of the intervention in a Nepali community setting; and to assess training, supervision, and outcomes measures. The Group PM+ manual has been adapted for post-earthquake rural Nepal through qualitative formative research. The feasibility trial will further identify whether the clinical and content adaptations are appropriate for the setting. Possible problems

of acceptability, compliance, delivery of the intervention, randomization, blinding, recruitment and retention will be assessed before the effectiveness c-RCT is conducted (Thabane et al., 2010). The feasibility study will include two trial arms: enhanced usual care (EUC) and Group PM+. We will assess the acceptability and feasibility of the Group PM+ intervention compared to EUC and will collect data for design of a full-scale effectiveness c-RCT of Group PM+ compared to EUC. We will use a mixed-methods design with qualitative and quantitative approaches to determine feasibility. The objectives include the following:

1. Establish the feasibility and acceptability of the Group PM+ intervention in a rural Nepal community [Primary Objective];
2. Establish the feasibility and acceptability of intervention delivery by Group PM+ trained non-specialists;
3. Determine recruitment and retention rates for Group PM+ sessions;
4. Establish feasibility and acceptability of outcome measures;
5. Demonstrate feasibility of cluster randomization procedure to limit biases and risk of contamination;
6. Demonstrate ethics and safety of trial procedures using the adverse event protocol.

METHODS

Setting

Nepal is a low-income country in South Asia with a population of approximately 27 million with the majority (83%) of the population living in rural areas (Central Bureau of Statistics, 2014). The country suffered a decade-long civil war from 1996-2006 with a range of psychiatric sequelae among adults and children (Kohrt et al., 2012; Kohrt et al., 2008; Luitel et al., 2013). In 2015, there were two major earthquakes in 2015, killing approximately 10,000 people and injuring 20,000. A mental health epidemiological study in Sindhupalchowk, Gorkha, and Kathmandu conducted 3-months post-earthquake found that one in three adults were experiencing depression and anxiety, one in five adults engaged in harmful alcohol use, and one in ten adults had current suicidality (Kane et al., 2010). The compromised infrastructure and limited availability of specialized mental health services is an impediment to addressing this burden of mental health problems.

The study will take place in Sindhuli district, a region southeast of Kathmandu, which was heavily impacted by the earthquakes. In Sindhuli, 250 people were injured and 15 were killed. Over 22,000 households were fully damaged and 10,000 partially damaged. In response to the earthquake's effects on Sindhuli, Transcultural Psychosocial Organization (TPO) Nepal in collaboration with International Medical Corps (IMC) conducted mental health and psychosocial support (MHPSS) activities in over half of the district's VDCs from 2015 - 2017. TPO Nepal is a Nepali

non-governmental mental health research and training organization, with specific expertise in humanitarian settings (Upadhaya et al., 2014). For the Group PM+ feasibility study, two Village Development Committees (VDCs) that had not previously received services were selected for randomization to either EUC or the intervention. Approximately 5,000 people live in each VDC.

The selected VDCs have a diverse population with over 15 ethnicities, including Brahman/Chhetri, Magar, Tamang, and Dunwar. The national language Nepali is spoken by the majority of inhabitants. A formative qualitative study in these VDCs demonstrated that residents of these VDCs have minimal access to and awareness of mental health issues and its treatment. Each VDC has one government health post, which represents the first and most accessible portal of care, though often not the well-resourced. Primary healthcare workers in these facilities include health assistants, community medical assistants, auxiliary nurse midwives, and female community health volunteers (FCHVs).

Design

Two VDCs in Sindhuli will be randomly assigned to EUC or PM+. Though not identical, the two VDCs are similar in population size, ethnic demographics, and access to health facilities. The two VDCs will be randomized in a public drawing by the District Public Health Officer (additional details provided below in the *Randomization* procedure). The two VDCs are separated by an adjoining VDC in attempt to limit intervention contamination among the beneficiary populations.

Intervention: Enhanced Usual Care (EUC) versus Group PM+ intervention

Until recently, treatment-as-usual in rural Nepal for individuals with common mental disorders (CMD) in Nepal usually consists of no psychological/psychiatric treatment in local health facilities. Whereas experiencing a CMD rarely leads to treatment initiation, persons with severe mental illnesses are typically brought by family members to tertiary psychiatric services in the Kathmandu valley, and this is often after a long delay between onset of symptoms (Luitel et al., 2015). Beginning in 2012, the WHO mental health Gap Action Programme (mhGAP) Intervention Guide was adapted for use in Nepal and piloted in Chitwan district through the Programme for Improving Mental Health Care (PRIME) (Jordans et al., 2016). After the 2015 earthquakes, the mhGAP Humanitarian Intervention Guide (World Health Organization et al., 2008) was adapted and contextualized for Nepal and Nepali psychiatrists were taught to train primary care workers using mhGAP. This approach was used in Sindhuli. Therefore, the EUC arm in Nepal will receive a referral to primary care-based depression treatment.

Participants in the Group PM+ arm will receive 5 three-hour sessions of Group PM+. Each session focuses on teaching participants techniques to manage their stressors and problems. These sessions include 1) Managing Stress, 2) Behavioral Activation, 3) Managing Problems, 4) Strengthening Social Support, and 5) Review of Techniques (Dawson et al., 2015). See Table 1 for more details on each session.

TABLE 1. Mechanisms of Action of PM+ intervention

Intervention Mechanisms of Action	**Description of Mechanism**	**Implementation of Mechanism**
Stress Management	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
Managing Problems	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
Behavioral Activation	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
Strengthening Social Support	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.

In the intervention arm, there will be approximately 7 - 10 groups with six to eight participants per group, separated by gender and with gender-matched facilitators. Facilitators will be supported by volunteer helpers in organizing the logistics of the group sessions, reminding participants about the sessions and meeting non-attenders (participants who do not show up for Group PM+ sessions). Participants will be provided with calendars and reminder calls by the facilitators' helpers, if necessary, to decrease drop-out rates.

To conduct awareness raising activities and facilitate recruitment, five non-specialists will be recruited in the EUC arm and another five in the Group PM+ arm. The requirement for the non-specialists will be at least ten years of education, over 25 years of age, and living in either the EUC or Group PM+ VDC. The non-specialists will be trained by TPO Nepal for 20 days on basic psychological skills to become community psychosocial workers (CPSWs). Twenty days is the standard length for CPSW training through TPO Nepal, based on the expectation that brie-

fer training would not equip facilitators to provide quality care to intervention participants. CPSWs from the intervention arm will then be given a 10-day Group PM+ training using the adapted manual and other clinical materials. Intervention training includes education on adversity and its impact upon mental health, basic counselling skills, delivering Group PM+, skills in group facilitation, and facilitator self-care. Group "Helpers" will receive a basic 2-day training on assisting facilitators during Group PM+ sessions and participating alongside CPSWs in practice PM+ groups. The main role of helpers will be logistics and childcare. Competency and fidelity will be assessed with modified version of the Enhancing Assessment of Common Therapeutic Factors (ENACT) tool tailored for Group PM+ (Kohrt et al., 2015).

Feasibility criteria

The primary objective is to evaluate feasibility and acceptability of both the intervention and the trial procedures for the subsequent c-RCT (see **Table 2**). The following indicators will clarify what procedures to carry on to the full trial and where modifications should be made to study design or content. Overall feasibility and acceptability will be evaluated by the following indicators to determine progression to the full trial:

TABLE 2. Objectives

Domains	Participants	Research Questions
1. Acceptability of Group PM+	Participants, family, CPSWs, community, TPO psychosocial team	Is PM+ stigmatizing? Is it acceptable for CPSW to deliver PM+? What were parts of the program that could have been changed to make the program more acceptable for the community?
2. Implementation logistics – PM+ sites, local leadership	CPSWs, community, RAs and TPO research staff, TPO psychosocial team	How would we make this program better with implementation (in terms of venue, coordination with local leadership, etc.)?
3. Feasibility of PM+ and burden (time, frequency, distance – providers and participants) (PSYCLOPS), training	Participants, family, CPSWs, community, TPO psychosocial team	How would you make this program more sustainable? How would we make this program more effective? Should the program be longer? /Should we have longer sessions? What helped the most? What is a good amount of training? (Is 20 days enough? Or, do they need more?)
4. Fidelity and supervision (areas of deviation and cause, competency, amount and form of supervision	CPSWs, TPO psychosocial team	How did the CPSWs deviate from the material in the PM+ manual? Why did they deviate from the material? (ex. Lack of understanding, lack of supervision, found that some material was not as understood by the participants, etc.)? Was there a need for more or less supervision? What were the challenges to supervision?
5. Utility (perceived) of PM+/interpretation "reducing tension", perceived benefit	Participants, family, CPSWs, community, TPO psychosocial team	What do CPSWs think about participant experience? Does reducing tension help participants? What type of problems is this helpful for? What is this not helpful for? Who is this useful for?
6. Contagion (knowledge of PM+ techniques among controls and how learned)	Participants (controls), family, CPSWs, RAs and TPO research staff, TPO psychosocial team	Did anyone involved in PM+ teach friends, family, and community members about PM+? Did the mechanisms of action for PM+ reach the control VDC? If so, how did those in the control group learn?
7. Blinding/randomization – sources and timing of unbinding	CPSWs, mhGAP, community, RAs and TPO research staff, TPO psychosocial team	What were the types of treatment that participants got and why did they get that treatment? When did RAs and CPSWs know that different groups received different treatment? How did they know about the different groups?

8. Recruitment and retention (participants and providers), family	Participants, family, CPSWs, community, RAs and TPO research staff, TPO psychosocial team	What were challenges to recruitment? What were challenges to retention of participants in the program? What are possible solutions to recruitment and retention?
9. Adverse events, ethics, safety – number, type and frequency of adverse events adequacy of reporting and referral of adverse events	Participants, family, CPSWs, mhGAP, RAs and TPO research staff, TPO psychosocial team	Were staff equipped to handle any adverse events? What was the type and frequency of adverse events referred?
10. Referral and control condition	Participants, family, CPSWs, mhGAP, community, TPO psychosocial team	Were mhGAP services available? Was medication available in local health posts? Was the TPO counselor used by the community? Was transportation available to those who needed it?
11. Assessment feasibility, acceptability, interpretation	Participants, RAs and TPO research staff, CPSW	Were the assessments feasible to conduct? Did the participants understand the assessments? What were the challenges to conducting assessments?

a) **identification of qualitative themes** reporting that both CPSWs and beneficiaries perceive group PM+ as being acceptable, feasible, and useful; the qualitative data will be coded for themes that participation reduces psychological distress, that participation does not damage familial or community relations, that participation is perceived as safe, and that participation is not perceived as stressful resulting in worsening mental health;
b) **fidelity to Group PM+ elements at the level of 75% or greater** according to the mean fidelity checklist for Group PM+ elements across all sessions;
c) **lack of significant socio-demographic group differences**; tabulation of descriptive summaries for baseline characteristics comparing Group PM+ participants and EUC participants without significant group differences in education, economic status, age, gender, and medical comorbidities;
d) **retention of at least 67% of participants** through completion of 5 Group PM+ sessions;
e) **fewer than 15% missing items** on outcome measures across all assessments;
f) **presence of adverse events among fewer than 10%** of participants and any serious adverse events;

In domains where criteria are met, we will retain the procedure for the full trial. In domains where criteria are not met, we will modify procedures for the full trial. The presence of any adverse events and serious adverse events will be addressed by the trial team to identify alternative strategies for the full trial and Data Safety Monitoring Committee, which is described in detail below. The number of feasibility and acceptability criteria that are not met will determine the extent of intervention and trial design modification.

Measures/outcomes

Outcomes among participants will be measured through baseline (t0) and follow-up (t1) assessment. The baseline (t0) assessment will be conducted after the family meeting. The follow-up assessment (t1) will be scheduled 1-1.5 weeks after the 5th Group PM+ session (i.e., 8-8.5 weeks after the pre-intervention assessment). All instruments will be administered by trained research staff blind to the allocation status of the participants. The main analysis metric will be differences in primary and secondary outcomes between t0 and t1.

The primary outcome measure will be the Patient Health Questionnaire (PHQ-9), a well-known 10-item instrument measuring symptoms of depression (Kroenke & Spitzer, 2002), (See **Table 3**). The measure has been clinically validated in Nepal (Kohrt et al., 2016). There are eight secondary outcome measures. To diminish the burden of time and questionnaires administered to the participants, many short form versions of the assessments will be used. The WHO Disability Assessment Scale (WHODAS) has been used previously in Nepal (Thapa & Hauff, 2012; Tol et al., 2007, 2009), with excellent internal consistency between items (=0.90) and validity with multiple mental health measures for depression ($r=0.70$, $p<0.001$); anxiety ($r=0.64$, $p<0.001$); and PTSD ($r=0.37$, $p<.001$). The GHQ-12 measures general psychological distress and has been clinically validated in Nepal (Koirala et al., 1999). The Psychosocial Mental Health Problems (PMHP) scale is a locally developed 5-item assessment of common psychosocial problems (Luitel et al., 2013). The heart-mind screener is also locally developed and will be used to determine the acceptability of local idioms of distress and impairment due to these problems (Kohrt et al., 2016). The PCL-5 (8 items) was shown in a recent study to have comparable diagnostic utility to the 20 items PCL-5 (Price et al., 2016).

TABLE 3. Quantitative outcome measures

Construct	Instrument	Description	Assessment Time Periods		
			Enrollment t(-t_1)	Baseline (t_0)	Follow-up (t_1)
Primary Outcome (Participants)					
Depression symptoms	*Patient Health Questionnaire (PHQ-9)*	Participants rate depression symptoms over past two weeks		X	X
Secondary Outcomes (Participants)					
General Psychological Distress	*General Health Questionnaire (GHQ-12)*	Participants measure their general psychological distress	X		X

Daily Functioning	*WHODAS*	Participants rate their ability to engage in daily activities	X		X
General Psychological Distress	*Somatic symptoms of Nepali Psychosocial and Mental Health Problems (PMHP)*	Participants rate their somatic symptoms related to psychosocial health		X	X
General Psychological Distress	*Heart-mind*	Participants note if they have had any "man ko samasya" or heart-mind problems recently	X	X	X
General Psychological Distress	*Tension Checklist*	Participants note if they have had any tension recently		X	X
Alcohol use disorder	*Alcohol Use Disorders Identification Test (AUDIT)*	Participants rate alcohol use and associated behavior, as well as daily ethanol consumption	X		
Post-traumatic stress symptoms	*PTSD Checklist for DSM5 (PCL-5)*	Participants rate their post-traumatic stress symptoms on a scale		X	X
Personalized Outcome	*Psychological Outcome Profiles (PSYCLOPS)*	Participants list their emotional and practical problems and rate how much each problem affects them		X	X
Ways of Coping	*Reducing Tension Checklist (RTC)*	Participants assess their own behavioral and psychosocial skills related to coping		X	X
Traumatic Events	*Traumatic Events Inventory (TEI)*	Participants rate if they have been exposed to certain traumatic events throughout their lifetime		X	X
Perceived Social Support	*Multidimensional Scale of Perceived Social Support (MSPSS)*	Participants assess their own connectedness with close family, friends and other forms of support		X	X
Suicidality	*Suicidality*	Participants rate if they have recently had suicidal thoughts, ideation, and plans	X		

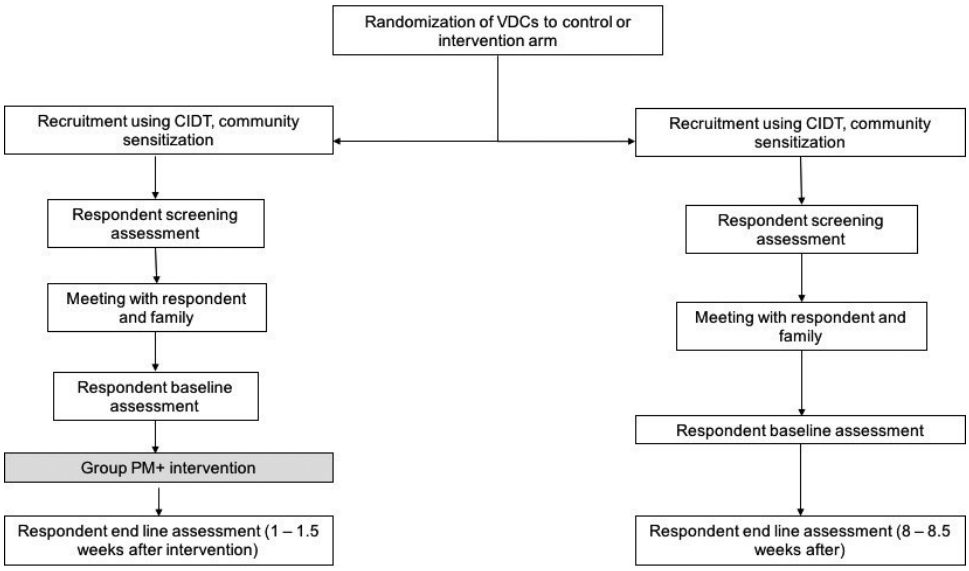
The Multidimensional Scale of Perceived Social Support (MSPSS) has been locally adapted in Nepal during a study amongst widows (Hendrickson et al., 2018) and has been modified to for this trial. In the assessment, participants will assess their own connectedness with close family, friends, and other forms of support. The Reduced

Tension Checklist (RTC) has been locally developed based on a coping checklist (Neacsiu et al., 2010) to assess skill acquisition of PM+ skills. The Psychological Outcomes Profiles instrument (Ashworth et al., 2004) will be administered pre-and post-intervention as well as from sessions two to five for the PM+ intervention arm. The PSCYHLOPS will not be administered during session one of PM+ because of the proximity in time between pre-intervention and start of the sessions.

Randomization

Two VDCs will be selected within Sindhuli district for the control and intervention arms (**See Figure 1**). A meeting will be organized with the District Public Health Officer (DPHO) where VDCs will be randomly drawn for either of the trial arms. We chose to involve the DPHO in the randomization process to increase community engagement and governmental support for the research trial. The DPHO will conduct a drawing open to government staff and the research team. He will draw one of the two names out of a hat. There are several sources of potential contamination. CPSWs from both VDCs will be trained together for the initial 20-day community psychosocial training. Because of the proximity between the two VDCs, communities may be in contact with one another. CPSWs and RAs will be given a strict code of conduct to keep patient treatment confidential during the trial to reduce unblinding. Regardless, sources of potential contagions will be monitored closely and addressed in the full-scale trial after completion of the feasibility trial.

FIGURE 1. Flow chart for Group PM+ cluster randomized controlled trial.



Flow diagram from recruitment to end line assessment for participants/respondents in control and intervention VDCs. Grey box represents intervention. Abbreviations: CIDT, Community Informant Detection Tool (see below in Recruitment). VDC, Village Development Committee.

Participants

Residents of the two VDCs 18 years of age and older are eligible for enrollment. There is no maximum age for the enrollment. However, assessors will use their discretion to discontinue screening for those that are unable to properly comprehend the questions due to age or are unable to physically reach session locations within the VDC.

Inclusion Criteria

Adults potentially with a common mental disorder are eligible to participate when they are over 18 years old and speak and understand Nepali. The General Health Questionnaire (GHQ; see below) and the WHO Disability Assessment Schedule 2.0 will be used for the screening criteria. *Screening positive* is defined as positive on all the following: score >2 on a screening questionnaire for common mental disorders (Goldberg, 1988; Minhas & Mubbashar, 1996), score >16 on a screening questionnaire for functional impairments (Üstün et al., 2010). Because of the lack of other services and potential benefit from participation in Group PM+, individuals with suicidality are not excluded. However, persons with current suicidal plans will be referred to the TPO counselor in addition to the invitation to participate in Group PM+.

Exclusion criteria

Alcohol dependency will be assessed by the alcohol use disorders identification test (AUDIT). Persons with a score 16 and higher will be excluded from participation. WHO's guidelines for use in primary care report that people that score below 16 can benefit from simple advice (Babor et al., 2001) also stated that people who score 16 and higher would benefit most from simple advice plus brief counselling and continued monitoring. For this reason, potential participants who score 16 and above on the AUDIT will be excluded from the study and referred to a mhGAP trained health professional in the area. In case of any suspected severe psychiatric disorders (e.g., psychosis) or problems (e.g., active suicidality), the individual will be referred to the health facility where health workers have been trained in mental health treatment (following mhGAP) and/or the TPO counselor in the area. For urgent treatment (e.g. active suicidality), participants will be immediately referred to the local TPO counselor and/or the nearest psychiatric services, which are available in a hospital seven hours drive from the study site. A TPO Nepal counselor and clinical supervisor for the trial will also be available to facilitate the referral process and provide follow-up psychosocial care, if and when needed. Symptoms of psychosis and severe cognitive impairment are based on clinical judgment of the assessor. The assessor (research assistant) will be given training on a community case finding tool for detection of psychosis (Jordans et al., 2015) so they can better understand clinical symptoms for exclusion (see more details below on the community case detection tool in the *Recruitment* section). If the respondent is not able to comprehend or answer the consent and/or demographic questions coherently, the questionnaire will be terminated at that point.

In addition to collecting trial outcomes, we will conduct a qualitative component. We will conduct key informant interviews (KII) and focus group discussion (FGD) and collect process notes. For the qualitative component, we will select a subsample of intervention and control arm participants for KIIs and focus group discussions. In addition, we will conduct KIIs with CPSWs, family members of participants, research staff, community officials, and primary health care staff.

Recruitment

In the study VDCs, CPSWs will conduct awareness raising activities to educate the public about availability of treatment for CMDs. In addition, female community health volunteers (FCHVs) and members of local community organizations (such as mothers' groups, youth groups, etc.) will be trained on the Community Informant Detection Tool (CIDT) to identify people in the community with potential common mental disorders. The CIDT is a vignette-based tool for pro-active case detection by lay people, which has been developed and tested in Nepal (Subba et al., 2017). The CIDT has a positive predictive value of .68 for adults (Jordans et al., 2015). The adapted version of CIDT for this study will include both inclusion vignettes (e.g., general distress, developed for the trial) and exclusion vignettes (e.g., psychosis, which have already been developed and validated). When community members and FCHVs identify a person in the community with symptoms of common mental disorders as described in the vignettes, they will ask them if they would like support for their stress related problems. If people indicate they would like to receive support, then they will be told that a research assistant (RA) will visit them to conduct further screening. Individuals who meet CIDT criteria for exclusion conditions will be referred to local mhGAP trained health workers. RAs will conduct additional recruitment by screening patients attending primary health care centers.

After screening by the RAs, CPSWs will hold a family meeting with the potential participant and a family member if they choose to have a family member participate. The family meeting will consist of: (a) information about the results of the screening, (b) brief psychoeducation about the psychological consequences of adversity and (c) information on seeking services from local health facilities with health care providers trained in basic mental health and psychosocial support. Those in the Group PM+ arm will also receive information about the intervention. Based on the family meeting, individuals can choose whether they want to enroll in their respective treatment arms and continue in the study.

Blinding and concealment

CPSWs, RAs, trial participants, and local mhGAP trained health workers will be blinded to the conditions of the two arms. Facilitators in the intervention arm and CPSWs in EUC will be instructed not to disclose the treatment that any participants are receiving except with their clinical supervisors. Assessors will be asked at baseline to indicate what treatment they think each participant will receive. Assessors will be asked the same question at end line for each participant. This will provide some

data on the amount of unblinding that might occur in the RCT. Study statisticians will be blinded to treatment arm during analysis.

Sample size

Approximately 60 participants will be enrolled in each treatment arm through proactive case-finding methods. Because power calculations will not be carried out for this trial, 60 participants, or 7 -10 groups, per arm will provide enough relevant information to inform feasibility and acceptability for the definitive effectiveness RCT following the trial. In addition, approximately 12 trial participants will be recruited for the qualitative interviews, as well as 10-15 additional key informants. We anticipate conducting 4 focus groups at the conclusion of the trial.

Financial incentives

Participants will receive compensation in the form of household goods (e.g., soap, toothpaste) equivalent to 100-200 Nepali Rupees per assessment, to compensate for time invested in the research. Assessments will take a maximum of one hour and thirty minutes and participants will be informed of this time frame as part of the consent process. Participants will not be compensated monetarily for the time they spend in the sessions. For those in the treatment arm, snacks and tea will be offered to the participants at every session. Travel costs to sessions and to assessments will be compensated for as well. Actual cost basis is not currently feasible because of the unavailability of local transport receipts but a fixed amount for compensation will be calculated based on the area that they come from.

Data management and monitoring

All Principal Investigators (PI) on the study will have access to primary data. The site PI will conduct quality assurance checks on data collected by the research assistants who will use a password protected tablet to collect data. The data on the tablet will be synchronized and uploaded in the Open Data Kit (ODK) daily, saved on a private server, and transferred to a data-analytic computer program (e.g., SPSS) without the identifying key. Results will be published regardless of being negative or positive results and submitted to peer- reviewed scientific journals. A Data Safety Monitoring Committee (DSMC) will be established specifically for oversight of the trial and review of serious adverse events and adverse events. The DSMC will include psychiatrists, non-governmental organization experts in psychosocial programs, and researchers and will determine any appropriate action in respect of ongoing trial conduct (e.g., referral to specialized care). The DSMC has the right to unblind at the individual level at any time.

Planned analyses

Qualitative analyses

Focus group discussions (FGDs), key informant interviews, and process evaluation notes will be coded in NVIVO (Ltd, 2012) and analyzed using content analysis

(Hsieh & Shannon, 2005) for themes of cultural acceptability, experience of CPSWs delivering Group PM+, adequacy of training duration, structure of training, content of training, and follow-up engagement, following approaches used in similar global mental health studies (Singla et al., 2017). Coding will be done by multiple independent raters, and inter-rater reliability will be calculated using Kappa scores. Data analysis will be conducted throughout each step to facilitate iterative revision then finalization of the manual. Following the Consolidated Criteria for Reporting Qualitative Studies (COREQ) we will document the process according to the 32-item checklist (Tong et al., 2007). Broadly, for Domain 1 "research team and reflexivity", the qualitative research team will include the PIs, TPO staff; the degrees will range from MD, PhD, to MA and Bachelors; the occupations will include academic medical faculty, NGO staff, and members of WHO; there will be both male and female qualitative staff; and staff experience in qualitative research will range from 1 month to greater than 10 years; the relationship with participants will not precede the study; participants will know that research staff are employed by or associated with TPO Nepal; and interviewer characteristics (age, education, region of origin, etc.) will be reported. For study design, content analysis will be used; selection will be reported as described above; setting features including location and presence of non-participants will be reported; an interview guide will be used; there will be repeat interviews at different times in the training and supervision timelines; audio will be recorded; duration will be documented; data saturation or lack thereof will be reported; and transcripts will not be returned to participants for analysis. There will be approximately 4 coders; the coding tree will be published; themes will be identified in advance with the option to generate additional themes; participants will not provide feedback on the coding; quotations will be presented; data and findings will be consistent; and major and minor themes will be clearly presented.

Statistical analyses

We will employ statistical analyses comparable those used in another pilot c-RCT being conducted in Nepal (Kohrt et al., 2018). The quantitative outcomes of interest will be summarized descriptively using appropriate summary statistics (mean and standard deviation for continuous outcomes and numbers and proportions for categorical outcomes) and graphically over time for both study arms. Trends for each score will be plotted to examine between- and within-person differences and to determine the plausible pattern (e.g., linearity) of those trends. As noted by Eldridge et al., there are concerns that sample size estimates based on this trial's data could be too small, therefore, we will also draw upon other studies in Nepal to inform the subsequent effectiveness study sample size (Eldridge et al., 2016). We plan to power the full trial based on conservative estimates of the parameters of interest rather than exclusively those obtained from this c-RCT by using the upper bound of the 95% CI for the intra-class correlation coefficient (ICC) and by comparing our estimates to those from other studies of similar outcomes to be sure we will

increase our estimates if we find them to be considerably smaller than those from other studies. By using such a 'triangulation' approach and by obtaining context-specific data, we are confident that we will be able to better design the full-scale c-RCT than in the absence of the feasibility c-RCT data. The data will also be used to inform the choice of effect estimate (e.g., difference in slopes or in means at a specific follow-up time point) in the future c-RCT that will build on the current study. Preliminary indicative estimates of differences in primary and secondary outcomes by arm will be obtained. In practice, we will power the future c-RCT predominantly based on magnitudes of effect that are of public health relevance rather than using magnitudes of effects obtained from the study, which will not necessarily be indicative of what could be attained in an appropriately powered larger c-RCT.

Mixed methods framework

This feasibility study will follow the Good Reporting of a Mixed Methods Study (GRAMMS) guidelines: First, mixed methods are being used to evaluate feasibility and acceptability qualitatively while quantitative information will be used for the design of the full trial. Second, qualitative and quantitative will be assessed generally during the same intervals of the study after delivery of Group PM+. Both methods will be clearly documented in publications regarding sampling, data collection, and analysis. Integration will occur in regard to qualitative descriptions of and quantitative scores on key variables. Because this is a feasibility study, inference testing on the quantitative data are limited; therefore, we cannot compare qualitative and quantitative data with regard to effectiveness of the Group PM+. Sixth, insights resulting specifically from integration of qualitative and quantitative will be highlighted.

Ethics and research governance

Consent

The informed consent process will consist of two steps: informed consent for screening and informed consent for taking part in the Group PM+ trial. A research assistant will conduct informed consent for screening. When a possible participant screens positive, the CPSW will conduct a family session in which potential participants will decide if they would like to take part in Group PM+. The research assistant will ask the potential participant what family member they would like present for the consent procedure. Potential participants also have the option of not including a family member in the consent process. With this model, the participant can gain support from their family in deciding if they would like to participate in the trial. In either phase of the consent process, it will be made clear that refusal to participate will not have an impact on any type of support they receive and that they will still be referred to local mhGAP trained health workers and a counselor if needed.

Harms

The main risk is potential psychological distress amongst participants of the intervention arm depending on the type of interactions with other group members and group facilitator. Participants can stop their involvement in the trial at any point. All patients referred to mhGAP trained health workers and TPO counselors are expected to be receiving quality clinical care and management of adverse events. Primary healthcare workers are supervised by a psychiatrist in Kathmandu who can provide information on medications and receive referrals for patients with worsening symptoms or other clinical concerns. All changes in treatment resulting from Adverse Events or Serious Adverse Events will be reported to the DSMC in Nepal. TPO Nepal is responsible for data collection and storage and making data available to the DSMC, funders, and IRBs for audits when appropriate.

Post-trial care

Group PM+ facilitator training will be provided to those that attended CPSW basic training in the control arm after the trial. Though they will not be compensated through TPO, facilitators in the control arm could deliver Group PM+ sessions post-trial to their community with support from the local government. Primary healthcare workers will remain in the VDC and continue to provide mental health care for members of the community and Group PM+ trial participants.

Dissemination

Findings from the feasibility study will be published in academic journals, disseminated through the Mental Health Innovation Network (www.mhinnovation.net), and reported to research funder (Office of U.S. Disaster Foreign Assistance/USAID). Findings will also be disseminated in Nepali and English to key stakeholders including district, provincial, and national government through reports and presentations. Authorship eligibility will comply with guidelines of the International Committee of Medical Journal Editors, with additional attention to recommendations for equitable representation of researchers from LMIC for academic authorship (Kohrt et al., 2014). In keeping with transparency recommendations, data will be made publicly available after publication of primary analyses.

Timescale

Participants for the Group PM+ trial will be recruited starting approximately three months after the initial CPSW training (See **Table 4** for SPIRIT enrollment and assessment schedule). Group PM+ sessions will begin for those in the intervention arm within a maximum of two weeks after consent. Within these two weeks, baseline will be conducted for both arms. End line will be collected a week to a week and a half after the intervention is complete in the intervention arm and eight weeks to eight and a half weeks after initial screening in the control arm. We anticipate that the trial will conclude by Spring 2018.

TABLE 4. Schedule of enrollment, interventions, and assessments for Group PM+.

STUDY PERIOD			
PARTICIPANTS *(direct beneficiaries)* – participants of Group PM+ or Control Arm			
	Enrollment	**Baseline**	**Follow-up**
TIMEPOINT	$-t_1$	t_0	t_1
ENROLLMENT:			
Allocation	X		
Eligibility screen	X		
Informed consent	X	X	
INTERVENTIONS:			
PM+	X	X	X
Control	X	X	X
ASSESSMENTS:			X
GHQ-12	X		X
WHODAS	X		
AUDIT	X		X
Suicidality	X		X
PMPH		X	
PHQ-9		X	
PCL-5		X	X
PSYCLOPS		X	X
RTC		X	X
TEI		X	X
Heart-mind	X	X	X
MSPSS		X	X
Tension Checklist		X	X

DISCUSSION

The results of the feasibility trial will be used to determine whether we can move forward with the same procedures for the full trial in another region of Nepal. If there are qualitative or quantitative indicators of problems with feasibility and acceptability impacting recruitment, retention, randomization, fidelity, or safety, those relevant procedures will be modified. This is an external feasibility study and therefore data will not be carried forward from this study to the full trial. If significant modifications are needed, we will consider the need for an internal pilot in the context of the full trial (Avery et al., 2017).

There is growing evidence that interventions carried out by lay people from the communities are sustainable and feasible to implement on a broader scale, espe-

cially in low-resourced settings. As a brief trans-diagnostic intervention, PM+ has shown to be effective in reducing depression symptoms and improving people's functioning in Pakistan and Kenya. If Group PM+ in Nepal is shown to be feasible and effective, this would provide evidence to scale-up within the country and would have implications for other low-resourced settings.

TRIAL STATUS

The trial is open and recruiting as of December 17, 2017. The protocol was last verified 22 January 2018. Subsequent protocol modifications will be reported to funders, IRBs, and registered with ClinicalTrials.gov.

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TESTING PSYCHOLOGICAL INTERVENTIONS FOR FEASIBILITY AND ACCEPTABILITY

CHAPTER 4

Feasibility and acceptability of Group PM+

This chapter is based on: Sangraula, M., Turner, E. L., Luitel, N. P., van't Hof, E., Shrestha, P., Ghimire, R., Bryant, R., Marahatta, K., van Ommeren, M., Kohrt, B. A., & Jordans, M. J. D. (2020). Feasibility of Group Problem Management Plus (PM+) to improve mental health and functioning of adults in earthquake-affected communities in Nepal. *Epidemiology and psychiatric sciences, 29*.

ABSTRACT

Background

Psychological interventions that are brief, acceptable, effective and can be delivered by non-specialists are especially necessary in low- and middle- income countries, where mental health systems are unable to address the high level of psychosocial needs. Problem Management Plus (PM+) is a 5-session intervention designed for those impaired by psychological distress while living in communities affected by adversity. Individual PM+ has demonstrated effectiveness in reducing distress in Kenya and Pakistan, and a group version of PM+ (Group PM+) was effective for conflict-affected women in Pakistan. This paper describes a feasibility and acceptability trial of locally adapted Group PM+ for women and men in an earthquake affected region of rural Nepal.

Methods

In this feasibility cluster randomized controlled trial, participants in the experimental arm were offered five sessions of Group PM+ and participants in the control arm received enhanced usual care (EUC), which entailed brief psycho-education and providing referral options to primary care services with health workers trained in the mental health Gap Action Programme Intervention Guide (mhGAP-IG). A mixed-methods design was used to assess the feasibility and acceptability of Group PM+. Feasibility was assessed with criteria including fidelity and retention of participants. Acceptability was assessed through in-depth interviews with participants, family members, program staff, and other stakeholders. The primary clinical outcome was depression symptoms assessed using the Patient Health Questionnaire (PHQ-9) administered at baseline and 8 – 8.5 weeks post-baseline (i.e., after completion of Group PM+ or EUC).

Results

We recruited 121 participants (83% women and 17% men), with equal allocation to the Group PM+ and EUC arms (1:1). Group PM+ was delivered over five 2.5 to 3-hour sessions by trained and supervised gender-matched local non-specialists, with an average attendance of 4 out of 5 sessions. The quantitative and qualitative results demonstrated feasibility and acceptability for non-specialists to deliver Group PM+. Though the study was not powered to assess for effectiveness, for all 5 key outcome measures, including the primary clinical outcome, the estimated mean improvement was larger in the Group PM+ arm than the EUC arm.

Conclusion

The intervention and trial procedures were acceptable to participants, family members, program staff and the communities and participants found the intervention to be beneficial. Because feasibility and acceptability were established in this feasibility trial, a fully powered randomized controlled trial will be conducted for larger scale implementation to determine the effectiveness of the intervention in Nepal.

INTRODUCTION

Low- and middle-income countries (LMICs) have fragmented mental health systems which cannot cope with the high level of mental health needs (Jordans & Tol, 2013). LMICs have limited availability to provide adequate mental health treatment (Luitel et al., 2015; Thornicroft et al., 2017). Innovative psychological treatments that utilize task-sharing are necessary to increase the availability of quality care in LMICs (Patel et al., 2018). Problem Management Plus (PM+) is a 5-session intervention developed by the World Health Organization (WHO) suitable for low-resource settings for clients impaired by psychological distress (Dawson et al., 2015). Randomized controlled trials (RCTs) in Pakistan and Kenya have found that PM+ delivered individually is effective for managing practical or psychological problems (Bryant et al., 2017; Dawson et al., 2016; Khan et al., 2019).

A group version of PM+ has been developed (Group PM+) with the potential to reach a higher number of people and therefore is more cost effective for low-resource settings. Group PM+ was shown to be effective in reducing anxiety and depression symptoms in women in a conflict-affected region of Pakistan (Rahman et al., 2019). To date, Group PM+ has not been evaluated for feasibility and acceptability when delivered in both males and females, nor has it been evaluated following a natural disaster. The aim of this paper is to evaluate the feasibility and acceptability of the Group PM+ intervention in Nepal (Sangraula et al., 2018), in order to subsequently conduct a fully powered effectiveness trial of Group PM+.

METHODS

Setting

Nepal is a low-income country with a history of humanitarian crises due to conflict, political instability, and natural disasters. In April 2015, Nepal was hit with two earthquakes resulting in 8,000 deaths, 20,000 people injured, damaged homes and livelihood, and substantial internal displacement (Kane et al., 2018). Various studies suggest high rates of disabling distress after the earthquakes (Kohrt et al., 2012; Luitel et al., 2013). An epidemiological study in three districts affected by the earthquake found that one in three adults were experiencing high levels of depression and anxiety symptoms, one in five adults engaged in harmful alcohol use, and one in ten adults had current suicidality (Kane et al., 2018).

This Group PM+ feasibility study took place in Sindhuli district, which was impacted by the earthquakes (Sangraula et al., 2018). Within Sindhuli district, we selected two Village Development Committees (VDCs) for the intervention and control arms. The two VDCs have a diverse population with over 15 ethnicities. There are no specialized mental health treatment facilities in Sindhuli district, and the closest psychiatric referral services are approximately 6-hours away

from the study sites. A functioning, though often not well-resourced, government health post in each VDC is the first portal of care and was used in the study as a point of referral.

Design

The feasibility study design and *a priori* aims are outlined in a separate pilot and feasibility protocol publication (Sangraula et al., 2018), and this study was registered on ClinicalTrials.gov (NCT03359486). The study was designed as a two-arm cluster randomized controlled trial (cRCT), comparing Group PM+ versus enhanced usual care (EUC).

Randomization

A randomization procedure was used, in which names of the two VDCs were written on cards and placed into a hat. The District Public Health Officer (DPHO) was to draw one card from the hat which would be allocated as the intervention arm VDC and the VDC in the remaining card would be allocated to the control arm. Program staff, including community psychosocial workers (CPSWs) and research assistants (RAs) were only assigned to either VDC after the random drawing to reduce risk of unblinding.

Intervention: Group PM+

Participants in the Group PM+ arm received 5 sessions of Group PM+, with each session lasting 2.5-3 hours. These sessions included: 1) Managing Stress, 2) Behavioral Activation, 3) Managing Problems, 4) Strengthening Social Support, and 5) Review of Techniques (Dawson et al., 2015). Please see supplementary material for further detail on techniques used in Group PM+.

There were 10 groups in the Group PM+ arm. Participants were allocated to groups based on their location of residence across the intervention arm study site. The group consisted of six to eight people and were separated by gender and with gender-matched facilitators. Facilitators were supported by volunteer local helpers in organizing logistics and reminding participants about the sessions. Community Based Psychosocial Workers (CPSW) were the service providers for the groups and are a cadre of psychosocial workers in Nepal that are trained through and work for NGOs, such as Transcultural Psychosocial Organization (TPO) Nepal.

Control: Enhanced Usual Care (EUC)

Both the EUC and intervention arm received a family meeting, delivered by CPSWs. The family meeting consisted of; (a) psychoeducation on adversity, (b) benefits from support, (c) information on the availability of mental health services by an mhGAP-trained health worker in the nearby clinic. After the 2015 earthquakes, the mhGAP Humanitarian Intervention Guide was adapted and contextualized for Nepal (mhgap HIG). Nepali psychiatrists were taught to train primary care workers using mhGAP (Jordans et al., 2016). One health worker

from each of the selected study VDCs received a 10-day mhGAP training to identify, assess and treat common mental disorders (CMDs). Consent was obtained to take part in the study and the follow-up questionnaires during the start of the family meeting.

Main outcomes

The main objective of this feasibility trial was to determine the acceptability and feasibility of the group intervention in the Nepal setting, through collecting both quantitative and qualitative data. These results will inform changes to the methodology and study processes for the fully powered RCT. The quantitative indicators in Table 1 determined progression to the main trial.

TABLE 1: Feasibility and acceptability criteria and outcomes

Feasibility and Acceptability criteria	**Definition and Measures**	**Outcomes**
Fidelity to Group PM+ elements at the level of 75% or greater	This was operationalized as the mean fidelity checklist for Group PM+ elements across all sessions. A combined competency and fidelity checklist was created based on both Group PM+ elements and common factors in psychological treatments, with the latter items drawn from the ENhancing Assessment of Common Therapeutic factors (ENACT) tool (Kohrt, Jordans, et al., 2015). The tool was used to measure whether or not key activities were implemented and the competency with which they were completed in each 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 to 3.	All Group PM+ facilitators (n=4) scored ≥75% in all 5 sessions

Lack of significant socio-demographic group differences	Tabulation of descriptive summaries for baseline characteristics comparing Group PM+ participants and EUC participants without significant group differences in education, economic status, age, gender, and medical comorbidities	Participants in both the arms were similar in - age categories (with the mean age around 45 - 46 years old), gender (16 -17% male), occupation (half the participants worked as housewives followed by farming), marital status (around 80% were married followed by 11 - 15% were widowed), and religion (87- 90% practiced Hinduism). Participants in the arms differed slightly by their caste group; the intervention arm had a high percentage of Danuwar caste and control arm had a high percentage of Brahman/Chhetri caste. There were also differences in a few other descriptors including most-used language, self-perceived socioeconomic status (SES), and education status.
Retention of at least 67% of participants	Through completion of 5 Group PM+ sessions; 100% retention is defined as attending all five sessions	Of the total participants (n = 61), 32 (52.5%) attended all 5 sessions, 14 (23%) attended 4 sessions, 10 (16%) completed 2 - 3 sessions, 3 (5%) completed 1 session and 2 (3%) did not attend any sessions. 46 (75%) completed 4 - 5 sessions.
Fewer than 15% missing items	Operationalized as 15% of missing individual items across five- key outcome measures (PHQ-9, WHODAS, GHQ, PCL-5 and RTC).	There were no missing outcomes across the five key measurements
Presence of adverse events among fewer than 10% of participants and any serious adverse events	Adverse events included marked increased in suicidal thoughts of trial participants, increased emotional distress, and increased family conflict from the start of the trial. Serious adverse events include death of trial participants, suicide attempt, serious violence. This was operationalized as fewer than 10% of participants experiencing any serious adverse events.	A total of seven adverse events (5%) were reported amongst the 121 participants. The majority of these adverse events followed-up by a counselor included suicidality and included one death due to a health problem unrelated to the study.

Community detection and case identification

The Research Assistants (RAs) were briefed on the Community Informant Detection Tool (CIDT), a tool that incorporates vignettes, illustrations, and local idioms of distress for the use of lay workers to identify, but not diagnose, those with common mental health disorders, such as alcohol use problems, psychosis, and depression (PPV = 0.68 and NPV= 0.91 for adults) (Jordans et al., 2015; Subba et al., 2017).

While a general distress version was designed to recruit participants for the study, the RAs were trained on the psychosis CIDT so they could identify those that would not qualify for the study. Program staff used the CIDT to train local stakeholders, such as Female Community Health Volunteers (FCHVs), social mobilizers and other local leaders, to identify potential participants for screening. RAs were informed of such potential participants, who were subsequently screened.

Recruitment and Training of Non-specialist Providers and Research Assistants

Five non-specialists, CPSWs as described above, in each arm were hired to facilitate recruitment through community sensitization, conduct family meetings (both arms), and facilitate Group PM+ sessions (treatment arm). Local community members were recruited as non-specialists, as a strategy to increase mental health capacity building in rural areas. Selected CPSWs had at least ten years of education, over 25 years of age, and were living in either of the study VDCs.

CPSWs, in both the control and intervention arms, were first trained for 20 days on basic psychological skills to become CPSWs, which is the standard length of training provided by TPO Nepal throughout the country (Jordans et al., 2003; Kohrt et al., 2015). This was also based on the expectation, as gathered through the contextualization process, that a briefer training would not equip facilitators to provide quality care to intervention participants. Competency in common factors, a set of therapeutic skills and competencies that are common to different psychological treatments, was assessed with the ENACT (Kohrt et al., 2015) before and after the core foundational training prior to Group PM+. After the foundational training, competency in at least 70% of the items was needed to be included in the subsequent care provision in Group PM+ and EUC arms. This minimum competency was determined based on prior studies using the ENACT in Nepal (Kohrt et al., 2018).

Subsequently, CPSWs from the intervention arm received an additional 10-day training on Group PM+ using the adapted manual and other clinical materials (such as posters and case stories used in the sessions) to become Group PM+ facilitators. Group "helpers" received a basic 2-day training on assisting facilitators during Group PM+ sessions and participating alongside facilitators in practice PM+ groups. The helper's role was to encourage participants to attend sessions, support facilitator with group logistics such as arranging materials, setting up the venue and distributing snacks. Eight Research Assistants (RAs) were also locally recruited from the two sites.

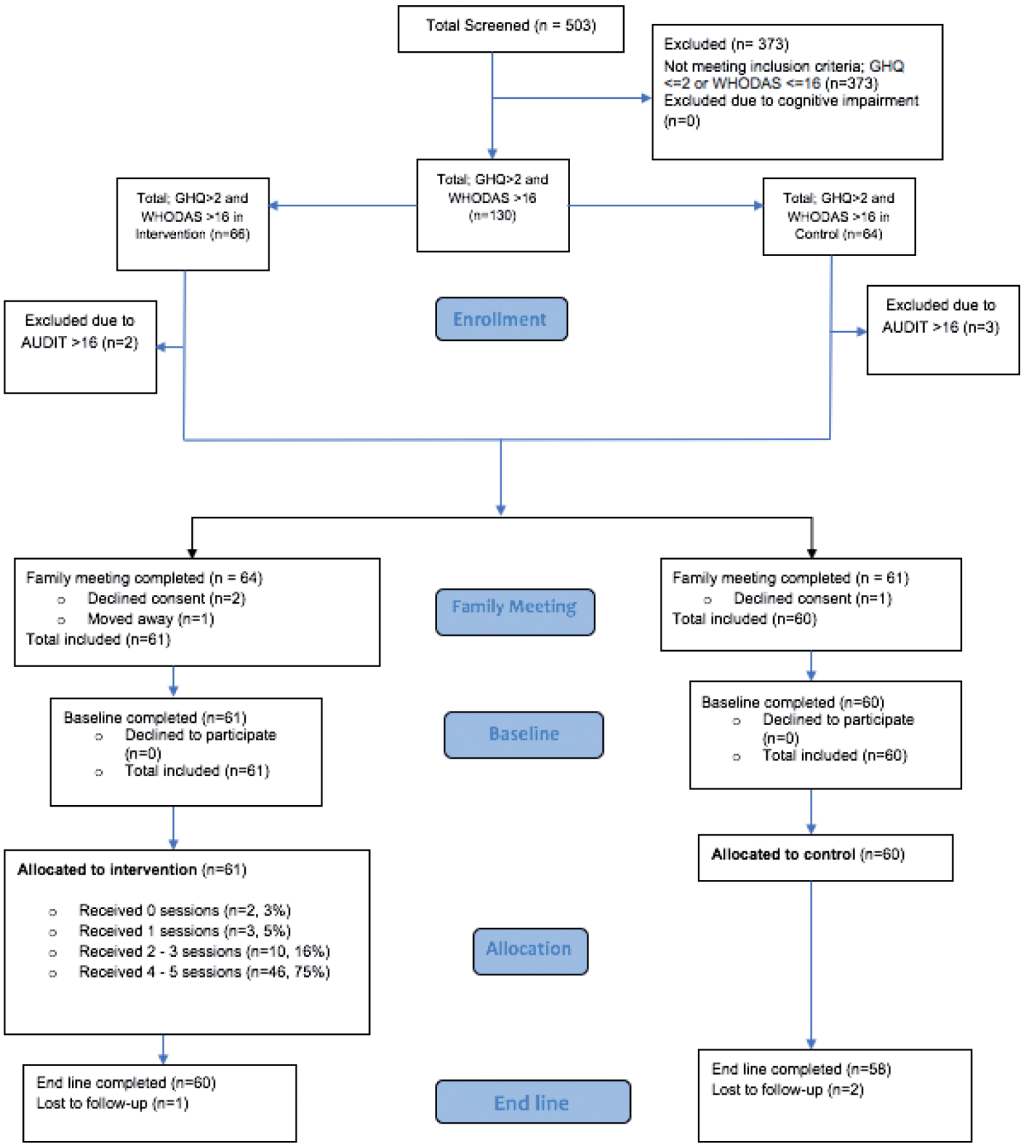
Blinding

CPSWs, RAs, trial participants, and local mhGAP trained health workers were blinded to the allocation of the study conditions. The VDCs of the two arms were separated by another VDC which worked as a buffer and physical barrier against contamination between the two arms. CPSWs in both arms were instructed not to disclose the treatment that any participants received except with their clinical supervisors. The trial statistician was blinded to treatment arm during analysis.

Measures

Assessments were conducted with participants during baseline (two weeks after screening and before the intervention), and the follow-up assessments were conducted at approximately 8-8.5 weeks after the baseline assessment so that, in the Group PM+ arm, it would be 1 – 1.5 weeks after the last session.

FIGURE 1. **Group PM+ Study Flow Chart**



Screening

Residents of the study VDCs 18 years of age and older were eligible for enrollment. There was no maximum age for enrollment, but assessors used their discretion to discontinue screening for those that were unable to properly comprehend the questions due to age or hearing and speaking ability. Inclusion criteria for the study participants were: score of >2 on the General Health Questionnaire (GHQ) (Minhas & Mubbashar, 1996), and a score of >16 on the WHO Disability Assessment Schedule 2.0 (WHODAS), a questionnaire for functional impairment. The WHODAS has been previously used in Nepal (Thapa & Hauff, 2012; Tol et al., 2010; Tol et al., 2009), with high internal consistency between items ($\alpha = 0.90$) and validity with multiple mental health measures for PTSD ($r = 0.37$, $p < 0.001$), depression ($r = 0.70$, $p < 0.001$), and anxiety ($r = 0.64$, $p < 0.001$). The GHQ-12 has been clinically validated in Nepal (Koirala et al., 1999).

Participants presenting symptoms of psychosis and severe cognitive impairment were excluded from the study. Assessment of this exclusion criteria was based on judgment of the assessors (RAs), who were given training on the exclusion criteria using the CIDT for psychosis (Jordans et al., 2015). If during the screening process, the respondent was not able to comprehend or answer the consent and/or demographic questions coherently, the questionnaire was terminated at that point and the participant was excluded.

The WHO's guidelines report for the Alcohol Use Disorders Identification Test (AUDIT) that people who score 16 or higher on it are recommended to receive advice plus counseling and continued monitoring (Babor et al., 2001). Therefore, persons with a score >16 on the AUDIT, which assesses alcohol dependency, were excluded from participation and were referred to the mhGAP trained health professional in their VDC, for further continuous support and monitoring.

Imminent risk of suicide was determined through a short screening questionnaire and persons with current suicidal plans and/or current suicidal ideation and prior attempts were referred to a psychosocial counselor but were not excluded from participating in the study.

Details on Outcomes of Quantitative Indicators

All Group PM+ facilitators adhered to over 75% of the intervention elements. The two study areas were similar in how affected they were by the earthquake and almost all demographic measures including occupation of participants, religious affiliation, and marital status. Still, there were some differences in the caste composition, primary language of recruited participants, and self-perceived socioeconomic status. This pilot trial was conducted in a small catchment area and differences in socio-demographics will likely not pose as a barrier in a fully powered trial. Though 32 participants (52.5%) attended all 5 sessions, 75% of the participants attended 4 – 5 sessions. This relatively high retention rate can be attributed to; (i) helpers reminding participants, and (ii) facilitators having been recruited from the local area that were able to relate well to their participants.

There were no missing items across the five key outcomes. Fewer than 10% (6 adverse events, and 1 serious adverse event) of adverse events were reported amongst the participants in either the control or intervention arm and there was one death - unrelated to the study, indicating that study procedures and PM+ did not cause harm or exacerbate distress.

Quantitative Assessments

The primary clinical outcome measure was the Patient Health questionnaire (PHQ-9), which measures symptoms of depression. It has been clinically validated in Nepal with a cut-off score of ≥10 (sensitivity=0.94, specificity=0.80, PPV=0.42, and NPV=0.99) (Kohrt et al., 2016).

The WHODAS (>16) and the GHQ-12 (>2) were included in the screening as part of the inclusion criteria and were also included as secondary outcome measures (Minhas & Mubbashar, 1996; Thapa & Hauff, 2012; Tol et al., 2010; Tol et al., 2009). The heart-mind screener, another locally developed tool, was used to determine if participants identified with a local idiom of distress and if they experienced impairment due to these problems (sensitivity=0.94, specificity=0.27, PPV=0.17, NPV=0.97) (Kohrt et al., 2016).

There were two other secondary clinical outcomes that include; Post-traumatic Stress Disorder Checklist DSM-5 (PCL-5), and the Psychosocial Mental Health Problems (PMHP). The Post-traumatic Stress Disorder Checklist for DSM-5 (PCL-5), an eight item scale, was shown to have comparable diagnostic utility to the 20-item PCL-5 in a recent study (Price et al., 2016), and was used to reduce burden on participants from using the full Nepali version of the PCL (Kohrt et al., 2012; Luitel et al., 2013). The Psychosocial Mental Health Problems (PMHP) scale is a locally developed five-item assessment of common psychosocial problems in Nepal (Luitel et al., 2013).

Additionally, The Multidimensional Scale of Perceived Social Support (MSPSS) self-assesses participants' connectedness with family, friends and significant others (Zimet et al., 1990) and has been locally adapted (Hendrickson et al., 2018) and validated to use with Nepali populations (Tonsing et al., 2012). The three subscales within the MSPSS were found to be significantly correlated (Family with Friends, $r = .530$; $p < .01$; Family with Significant Others, $r = .540$, $p < .01$; and Significant Others with Friends, $r = .575$, $p < .01$) (Tonsing et al., 2012).

The Reducing Tension Checklist (RTC) was developed for this study to evaluate use of coping strategies of Group PM+ and was developed based on a coping checklist (Neacsiu et al., 2010). The items are worded such that participants in the control arm could also endorse these strategies (e.g. questions on helping family and friends, practicing slow breathing, and tackling everyday problems).

Demographic characteristics of participants were recorded at baseline and traumatic events were also assessed using the Traumatic Events Inventory (TEI) (Schwartz et al., 2005), which has been previously used in Nepal (Kohrt, Worthman, et al., 2015). An earthquake questionnaire was also developed for this trial to de-

termine the severity in which participants were affected by the earthquake. The Psychological Outcomes Profiles (PSYCHLOPS) (Ashworth et al., 2004) was administered pre- and post- intervention and from sessions two to five for the intervention arm to assess the main problems that participants faced and if it changed over time. Though the PSYCHLOPS was intended for analysis as a secondary outcome, it was used in the study as a clinical tool for facilitators and clinical supervisors to track the weekly progress of participants. Please see supplementary material for further detail on timeline of quantitative outcome measures.

Qualitative Evaluation

Qualitative interviews followed a semi-structured interview guide developed for each category of key informants, which included Group PM+ participants (n=7), family members of participants (n=8), Group PM+ facilitators (n=4), CPSWs in the control arm (n=4), control arm participants (n=5) and mhGAP trained health workers (n=2). Both males and females with different rates of retention in the PM+ sessions were interviewed and Focus Group Discussions (FGDs) with groups of PM+ participants, program staff including CPSWs and RAs at different time points within the trial. The qualitative interviews explored questions on the acceptability of the trial procedures, utility of the intervention, challenges faced, and suggestions for trial procedures, as included below in the analysis.

Data analyses

Quantitative analyses were predominantly descriptive. The main outcomes of interest for this pilot trial were generated using data collected on fidelity, outcome data availability and drop-out. Baseline participant characteristics were summarized by arm. Likewise, continuous clinical outcome measures and changes in these measures were summarized by arm at baseline and at endline as means and standard deviations. Because of the pilot nature of the trial, we did not generate estimates of intervention effect but instead descriptively compare between arms the mean change within arm of each continuous outcome measure to obtain an indication of the potential for an intervention effect. To help inform a future fully powered cRCT, we generated preliminary estimates of clustering measured by intracluster correlation coefficients (ICC) of 5 key outcomes (PHQ-9, WHODAS, GHQ, PCL-5 and RTC). Although in a future trial we expect that randomization will occur at the VDC level, it is not possible to obtain ICC estimates for clustering by VDC as only two VDCs are enrolled in this pilot. Instead, we sought to generate estimates of clustering at a smaller unit, namely that of the ward (at baseline) and of the group at endline for participants in the Group PM+ VDC. Such ICC estimates were generated using an intercept-only linear mixed model estimated using restricted maximum likelihood estimation with random intercepts for ward (for baseline data) or for group (for endline data).

The qualitative data was analyzed using a thematic content analysis approach. Interviews were first recorded, transcribed verbatim, and translated for subsequent

analysis. Researchers first familiarized themselves with the transcripts, coded interviews based on previously identified themes and subthemes, added further themes if necessary, and finalized coding. Data were then reviewed by code to further draw out key information and quotes were identified that illustrate significant themes.

Ethics

Ethical approval was obtained from the National Health Research Council (NHRC, reg #371/2016) and the WHO Ethical Review Committee (ERC.0002817). Participants were enrolled only after voluntary written (verbal consent only if participant was illiterate). Participants with suicidal planning were reported immediately to the counselor for follow-up and all changes in treatment resulting from adverse events or serious adverse events were reported to the Data Safety Management Committee (DSMC). TPO Nepal was responsible for the data collection, storage, and making data available to the DSMC, funders, and IRBs for audit when necessary.

RESULTS

Study population and baseline descriptives

A total of 130 (25.8%) of the 503 screen individuals were screened positive, of which 66 and 64 were in the Group PM+ VDC and EUC VDC, respectively (Figure 1). Of these 130 individuals, 5 were excluded due to an AUDIT score of 16 or more. Of the remaining 125 eligible individuals, all initially consented but there were 4 further exclusions before baseline. Three participants declined consent to conduct the family meeting and one participant moved away before the family meeting could be conducted. As a result, 121 (24.1%) individuals were eligible and did not withdraw before baseline, of which all (100%) completed the baseline survey. There were 10 males in each arm.

TABLE 2: Demographic characteristics of 121 enrolled participants by study arm

Characteristic – n (%)*	**Group PM+ (n=61)**	**EUC (n=60)**
Male	10 (17%)	10 (16%)
Age (years) – mean (SD)	46.7 (14.0)	49.3 (13.6)
Age categories (years)		
< 30	3 (5%)	6 (9.8%)
30 - < 40	13 (21.7%)	11 (18.0%)
40 - < 50	18 (30.0%)	19 (31.2%)
50 - < 60	10 (16.7%)	14 (23.0%)
60- <70	11 (18.3%)	7 (11.5%)
70+	5 (8.3%)	4 (6.6%)
Education level		
Illiterate	36 (59%)	48 (80%)
Informal education	11 (18%)	7 (12%)
Primary	6 (10%)	3 (5%)
Secondary	4 (7%)	2 (3%)
Higher secondary	4 (7%)	0 (0%)
University	0 (0%)	0 (0%)
Occupation		
Farmer	20 (33%)	21 (35%)
Office Job	2 (3%)	0 (0%)
Business	4 (7%)	0 (0%)
Daily wage laborer	3 (5%)	4 (7%)
Unemployed	1 (2%)	1 (2%)
Housewife	29 (48%)	33 (55%)
Other	2 (4%)	1 (2%)
Marital status		
Unmarried	2 (3%)	2 (3%)
Married	50 (82%)	48 (80%)
Widowed	7 (11%)	9 (15%)
Divorced	1 (2%)	0 (0%)
Separated	1 (2%)	1 (2%)

Family type		
Singular family	26 (43%)	42 (70%)
Nuclear family	35 (57%)	18 (30%)
Lives with		
Extended family with spouse	12 (20%)	16 (27%)
Extended family without spouse	7 (11%)	12 (20%)
With parents	6 (10%)	1 (2%)
Spouse only	6 (10%)	5 (8%)
Spouse and children only	25 (41%)	22 (37%)
Other	5 (8%)	4 (7%)
Number of members in household		
Median (25th, 75th percentile)	5 (3, 6)	5 (3, 6)
Caste		
Brahman/Chhetri	13 (21%)	27 (45%)
Dalit	9 (15%)	14 (23%)
Danuwar	23 (38%)	3 (5%)
Other	16 (26%)	16 (26%)
Religion		
Hindu	55 (90%)	52 (87%)
Other	6 (10%)	8 (13%)
Most-used language		
Nepali	37 (61%)	58 (97%)
Danuwar	22 (36%)	2 (3%)
Other	2 (3%)	0 (0%)
Self-perceived socioeconomic status		
Very bad	0 (0%)	11 (18%)
Bad	8 (13%)	17 (28%)
Normal	38 (62%)	27 (45%)
Good	14 (23%)	5 (8%)
Very good	1 (2%)	0 (0%)
Chronic disease		
Reported a chronic disease	18 (30%)	20 (33%)

Of those with chronic disease, primary** type of disease		
Hypertension	5 (28%)	6 (30%)
Asthma	3 (17%)	6 (30%)
Other	10 (55%)	8 (40%)
Earthquake exposure		
Experienced aftershocks	60 (98%)	57 (95%)
Home badly damaged or destroyed	26 (43%)	34 (57%)
Trapped under rubble	8 (13%)	1 (2%)
Injury from the earthquake	4 (7%)	6 (10%)
Close friends or family injured	7 (11%)	5 (8%)
Close friends or family killed	1 (2%)	2 (3%)
* Unless otherwise stated; ** If more than one was reported, the primary type was selected and the secondary reported in "Other". In these data, each person reported at most one.		

Feasibility and acceptability

This study showed good feasibility with high retention (97.5%) of the 121 participants from baseline to endline. There were no missing items among the 5 multi-item variables, for the 5 quantitative outcome measures, for all the 121 participants at baseline. The 118 participants at endline, all of whom had all 5 key multi-item variables available, had no missing items. Moreover, a majority of (52.5%) participants attended all 5 group sessions with only 5 participants (8%) attending fewer than 3 of the 5 group sessions.

TABLE 3: Quantitative acceptability and feasibility measures

Variable – n (%)[a]	**Group PM+**	**EUC**
Acceptability of intervention	n=4	n=4
Competency in common factors (%, IQR)		
Pre-training in psychosocial foundations	23% (11-44%)	27% (11-61%)
Post-training in psychosocial foundations	76% (61-89%)	84% (72-94%)
Fidelity of PM+ facilitators		
To 75% or more items in each of 5 group sessions	4 (100%)	-
To 75% or more items in more than 3 group sessions	4 (100%)	-
Group PM+ Participation	**n=61**	**n=60**
Number of sessions attended		-
0	2 (3%)	-
1	3 (5%)	-

2	0 (0%)	-
3	10 (16.4%)	-
4	14 (23.0%)	-
5	32 (52.5%)	-
		-
Outcome measurements	**n=61**	**n=60**
All items of outcome measured at baseline[b]		
PHQ-9	61 (100%)	60 (100%)
WHODAS	61 (100%)	60 (100%)
GHQ	61 (100%)	60 (100%)
PCL-5	61 (100%)	60 (100%)
RTC	61 (100%)	60 (100%)
All items of outcome measured at endline[b,c]		
PHQ-9	58 (100%)	60 (100%)
WHODAS	58 (100%)	60 (100%)
GHQ	58 (100%)	60 (100%)
PCL-5	58 (100%)	60 (100%)
RTC	58 (100%)	60 (100%)
All key outcomes measured[b]		
Baseline	61 (100%)	60 (100%)
Endlinec	58 (100%)	60 (100%)
Time (days) between: [median (25th, 75th percentile)]		
Screening and Baseline interview	10 (5, 32)	9 (6, 14)
Baseline interview and Endline interview[c]	42 (36, 47)	48 (43, 52)
Adverse events		
Any adverse event[d]	4	2
Serious adverse event	0	1[e]

a Unless otherwise noted;
b Of 5 key measures: PHQ-9, WHODAS, GHQ, PCL-5 and RTC. Note, at baseline, WHODAS and GHQ were measured at screening and the remaining three measures at the baseline interview. Additionally, there were no missing items for any of the 5 measures at either time point;
c Of those who were not lost to follow-up (n= 58 in intervention and n=60 in control);
d All 6 were suicidal thoughts;
e Death unrelated to the study.

Ten of the 61 participants of Group PM+ were male, and 6 of the 10 male participants attended all 5 sessions. Likewise, fidelity of PM+ facilitators was adequate with all four group PM+ facilitators adhering to 75% or more items in each of the group sessions they conducted. Regarding competency in common therapeutic factors, ENACT scores for Group PM+ and EUC groups were above 70%; two CPSWs who scored below 70% were dropped after the initial 20-day psychosocial skills training (as described above).

Clinical outcomes

At baseline, outcomes were broadly comparable between the participants of the Group PM+ and EUC arms with mean (SD) PHQ-9 scores of 9.8 (4.9) and 10.7 (4.4) in the Group PM+ and EUC arms, respectively (Table 4). Across the 121 participants, the PHQ-9 had a mean (SD) of 10.3 (4.6). The WHODAS had a mean (SD) of 21.3 (4.8), the GHQ-12 had a mean (SD) of 22.8 (5.0), the PMHP had a mean (SD) of 10.7 (3.0), and the PCL-5 had a mean (SD) of 19.5 (6.8). Baseline outcomes for the 118 participants who also had data at endline were comparable to those of the overall study population of 121 participants. For the 118 participants with endline data, nearly all outcomes improved on average over time in both arms decreases in PHQ-9, GHQ-10, WHODAS, PMPH and PCL in both study arms and an increase in MSPSS in both study arms. For all 5 key outcomes, the estimated mean improvement was larger in the Group PM+ arm than the EUC arm, with larger mean decreases in scores observed for all 5 outcomes. No formal between-group comparisons were made given that the pilot trial was not powered to detect meaningful differences. For the other outcomes of RTC and MSPSS, as hypothesized, both increased on average in the Group PM+ arm, whereas very small decreases were observed in the EUC group; of 5.0 (SD=5.8) in Group PM+ compared to an average decrease in EUC of -0.7 (4.6). Estimates of clustering by ward at baseline were large ranging from 0.10 (95% CI: 0.03,0.41) for WHODAS to 0.21 (0.08,0.45) for PCL-5 when clustering was by ward at enrollment.

TABLE 4: Outcomes at baseline and endline of n= 121 enrolled participants by study arm – mean (SD) reported

		For all n=121 enrolled		For n=118 not lost to follow-up at endline						ICC (95% CI)	
		Baseline		Baseline		Endline		Change		Baseline	Endline
Construct	**Instrument (range)**	**Group PM+ (n= 61)**	**EUC (n= 60)**	**Group PM+ (n= 60)**	**EUC (n= 58)**	**Group PM+ (n= 60)**	**EUC (n= 58)**	**Group PM+ (n= 60)**	**EUC (n= 58)**	**(n=121)[b]**	**(n= 60)c**
Primary outcome											
Depressive symptoms	PHQ-9 (0-27)	9.8 (4.9)	10.7 (4.4)	9.7 (4.8)	10.9 (4.3)	6.2 (3.7)	9.3 (4.3)	-3.5 (4.8)	-1.6 (3.4)	0.12 (0.03, 0.41)	-
Secondary outcomes											
Daily functioning	WHODAS (12-60)	21.8 (5.3)	20.8 (4.1)	21.5 (4.9)	20.9 (4.2)	12.1 (8.0)	15.7 (6.4)	-9.4 (8.4)	-5.2 (6.7)	0.10 (0.01, 0.59)	0.09 (0.01, 0.62)
General psycho-logical distress	GHQ-12 (0-36)	24.3 (4.8)	21.3 (4.7)	24.2 (4.8)	21.4 (4.8)	11.9 (6.6)	17.6 (6.0)	-12.3 (7.5)	-3.7 (7.0)	0.16 (0.02, 0.62)	0.06 (0.00, 0.75)
Psychosocial MH Problems	PMHP (5-20)	10.2 (3.3)	11.1 (2.7)	10.1 (3.3)	11.2 (2.7)	9.1 (3.0)	11.2 (2.9)	-1.0 (2.8)	-0.1 (2.7)	0.16 (0.05,0.41)	0.03 (0.00,0.97)
PTSD	PCL-5 (8-40)	17.6 (7.2)	21.5 (5.9)	17.5 (7.2)	21.8 (5.7)	14.8 (8.1)	20.5 (5.6)	-2.7 (7.0)	-1.3 (5.6)	0.21 (0.08,0.45)	-
Other outcomes											
Reducing tension skills	RTC (0-40)	15.6 (4.7)	10.1 (5.0)	15.6 (4.8)	10.2 (5.1)	20.6 (5.8)	9.4 (4.2)	5.0 (5.8)	-0.7 (4.6)	0.24 (0.09, 0.50)	0.21 (0.05, 0.59)
Perceived social support	MSPSS (12-60)	33.4 (7.9)	29.9 (8.7)	33.3 (8.0)	29.6 (8.7)	34.2 (7.0)	29.4 (8.7)	0.9 (7.5)	-0.1 (7.9)	-	0.04 (0.00,0.87)

Estimates of clustering by group at endline were smaller ranging from 0.03 (95% CI: 0,0.97) to 0.09 (0.01,0.62), though were not estimable for PHQ-9 and PCL-5. As expected, confidence intervals were wide in all cases due to the small sample size.

Qualitative Outcomes

As captured by responses from CPSWs and RAs, the study was initially met with some hesitancy from community members due to prior notions that only those with severe mental illnesses need support. Referring to mental health issues as *man ko samasya* (heart-mind problems) (Kohrt & Harper, 2008) or *tension* (an English term used commonly in Nepal for distress) (Clarke, Saville, et al., 2014; Rai et al., 2017), non-stigmatizing local idioms of distress, made the study more acceptable to community members. CPSWs reported that community sensitization events helped clarify to the community that this program was for people with general distress rather than severe mental illness. Group PM+ participants found the Nepali program name, *Khulla Man* meaning "an open and light heart-mind" as a cultural concept of catharsis, to be acceptable. Both male and female participants also referred to their own heart-mind as being lighter after completion of the program.

Both male and female Group PM+ participants responded positively to the program. Participants reported enjoying the group format of the program and spending time outside the home with others. Both male and female participants reported that the group format also helped them realize that others in their community experience similar problems and that they should be shared with friends and family. They noted improvements in their somatic symptoms, such as restlessness and feelings of weakness, and social functioning. Though session materials such as calendars for reminders seemed to be effective as reported by the facilitators, some participants noted that they were too busy to practice techniques at home but enjoyed the sessions and requested additional weeks. Participants' expectations of monetary incentives, rather than the content of the program, seemed to have attributed to drop-outs. Facilitators noted that after several rounds of conducting PM+ group sessions, other community members also showed interest in participating in Group PM+.

This was the first Group PM+ study that included males and demonstrated a high retention rate amongst their groups. Similar to female participants, male participants also reported enjoying the session activities and case stories, and practiced techniques taught in the sessions at home. Program staff reported that barriers to recruiting men included their initial hesitance in discussing personal problems and emotions with others, busy work schedule, and lack of men in the villages due to labor migration.

Participants in the EUC and intervention group preferred to conduct assessments with gender-matched research assistants rather than those of a different gender for fear of perceptions from their family and others in the community. Some EUC participants thought of the assessments as the treatment and noted that answering the questionnaires helped them feel lighter, whereas a few others

were disappointed by the lack of treatment especially because accessing referral services was a noted challenge. Participants in both arms reported that they visited the health post for treatment, though not at a high rate, and were dissuaded when the health post was closed or did not have the medications as listed in the free drug list provided. Health workers trained in mhGAP suggested additional refresher trainings to better support those that were referred to the health posts.

TABLE 5: **Qualitative Interview Results**

Domain	Theme	Quote
Acceptability	Idiom usage (usage of *"khulla man"*, use of tension)	*"We learned that we shouldn't hide our tension and that we need to share it with our friends. We shouldn't let our stress affect us. When we share our feelings with our friends then it will help us a lot. I learned this from 'khulla mann' program. We learned that we should give suggestions to our neighbors too so I liked it."* – Female Participant, Group PM+ *"I have good thoughts these days, I am satisfied…So this has given me new strength, motivation. I have learned that we should open up about our problems and only then other people will be willing to help us…I received help from my sisters-in-law. If I hadn't opened up (Khulla) about my problem and had stayed by myself then who would know about my problem? If we open up about the problem, we are facing then they will help in what they can. So, I am really happy to be able to learn all these things."* – Female Participant, Group PM+
	Acceptability of assessments and intervention	*"I feared that people in the community will say anything bad about it [RA]…because he was a man…my husband isn't here and my mother in-law was also here so I was really stressed about it but I took time to talk to him."* – Female Participant, Enhanced Usual Care *"My child is very small. So, I used to be late [to sessions]…when I asked my sisters-in-law to look after my child, they used to take it in a negative way…I had a small store so I had to manage time to go to the program. But it was manageable."* – Female Participant, Group PM+ *"In this last session that I am conducting, the participants said that they wouldn't be getting anything except lunch so because of this reason, some didn't come."* – Facilitator, Group PM+
	Benefits of a group format	*"It felt like everyone has problems and not just me. I used to think that only I went through things but I asked the others if they also had problems."* – Female Participant, Group PM+ *"I have made friends too. We [participants] live nearby so we meet with each other. We share that the program was good and that we will join such programs again. All of us live nearby so we gather and talk about our problems."* – Female Participant, Group PM+ Participant

	Hesitancy because of prior notions of MH	*"Yes, people have said negative things about this program too because they haven't understood it. Those who have understood about this program have realized that it is good."* – Research Assistant, Group PM+ Arm *"After learning the skills, it's something you do for yourself. If I share with others, they may say, "this program isn't good." They might make fun of me…If they say things like that, then it won't feel good for me…It is best for me to learn and just do it myself."* – Female Participant, Group PM+ *"In the beginning, they didn't open up well. When we went for community sensitization in the beginning, no one shared with us that they have mental health problems…And they opened up later about the kind of problems that they were experiencing…they feared to open up at first because…people in the community might say negative things to them."* – Community Psychosocial Worker, Enhanced Usual Care
Perceived utility	Improvements in somatic symptoms Session materials/practicing outside of sessions	*"…when I feel weak, I do those activities. Now I have forgotten all [all of tension]. I used to have so much tension. I didn't want to eat. Couldn't sleep. I didn't want to walk anywhere. My legs used to be so sore and tired after I walked…Now I have forgotten all these things."* – Female Participant, Group PM+ *"Whenever I feel bored or bad, I look at the calendar [from the program] and I would remember what was taught in the training and I would do it. Before, I didn't want to sit with friends or attend any kind of wedding or pooja (prayer) programs. I just wanted to stay alone and I used to think a lot and weep. But after attending the Khulla Man program, I don't feel that way."* – Female Participant, Group PM+
	Males in Group PM+	*"Before when we used to have conflict in our family, we used to have lots of stress and we didn't know what to do. But after this training, even though we have conflict in family, we now have realization that we shouldn't hide these things in ourselves but we should rather share it with our close friends…You have to tell it to someone you trust; be it your wife or friends."* – Male Participant, Group PM+ *"I liked everything about this program. The story of Ram Bahadur was shared from the beginning…he felt the same way as us. I learned what might happen to our heart…So we learned how to calm our heart…by reading the story. I realized that I had these kind of problems but there might be other people who might have faced such problems before too."* – Male Participant, Group PM+

DISCUSSION

The feasibility RCT met all the pre-defined feasibility and acceptability criteria (Table 1). The high rates of participation in the sessions seems to indicate that the participants found the intervention to be acceptable, which was supported by the qualitative findings. Additionally, only three participants were lost to follow-up which indicates feasibility of trial procedures. The feasibility of assessments, procedures, and the intervention indicates that a fully powered Group PM+ trial is achievable in the Nepal context.

The descriptive study results, if also supported by the fully-powered trial, suggest better improvements in the Group PM+ arm and indicate that Group PM+ delivered by non-specialists has the potential to reduce psychological distress relative to EUC, in line with current evidence that effective psychological interventions can be delivered by non-specialized workers (Singla et al., 2017). Though not powered, the quantitative evaluation indicated more improvements in those who received Group PM+ compared to EUC, especially in daily functioning and general distress. This was supported by the qualitative analysis in which Group PM+ participants mentioned overall changes in somatic symptoms and an increased understanding of how to manage their problems.

The study was initially met with hesitancy amongst community members due to their understanding that only those with severe mental illness need support. This highlights the importance of using de-stigmatizing local idioms and language during the initial planning phase with local stakeholders, the recruitment process, assessments, and the intervention itself (Kohrt & Hruschka, 2010; Kohrt & Harper, 2008). As experienced by the CPSWs in both arms, sensitization events worked to normalize experiencing adversity and distress, and to differentiate to the community that this program was for those with general distress rather than severe mental illness.

The group format of this intervention also had some inherent benefits, based on the qualitative evaluations, such as reducing self-stigma amongst participants, as they felt that there were many others in their community seeking support. Perhaps because most of the Group PM+ participants were housewives, they noted enjoying the company of a group and taking time away from daily household chores. Furthermore, the pervasiveness of community groups (mother's groups, youth groups etc.) in rural Nepal and other LMICs adds to the acceptability of a group intervention in the Nepal context (Clarke, Azad, et al., 2014).

A strength of this study is the addition of the combined competency and fidelity checklist based on ENACT, to measure facilitator competency in common factors and adherence to the manual during intervention delivery. Another strength was the use of the RTC, to measure the participant's use of skills learned in Group PM+ sessions. The outcomes evaluation indicates an increase in RTC scores at follow-up in the intervention arm as compared to the control arm, suggesting that the delivery and uptake of intervention strategies appears feasible. Participants, howe-

ver, indicated practicing some techniques more than other techniques and a recommendation for the definitive trial is to develop and strengthen tools that reinforce techniques learned, to increase the likelihood that participants will implement and practice them outside of the sessions.

As the limited number of trained mental health workers remains a larger barrier in receiving proper care in LMICs (Kakuma et al., 2011), the referral system was a noted challenge in the intervention and EUC arms. Though health posts with mhGAP trained health workers were near-by and an improvement from the standard of care in rural Nepal, participants referred for mental health care faced barriers such as absence of trained health workers, lack of medication, and closed facilities when they should be open. Though we did not succeed due to the rural nature of the study area, more efforts should be made, in a next trial, to refer EUC and intervention arm participants to better-resourced health facilities to ensure follow through, especially for the EUC arm.

This was the first Group PM+ study that included males and demonstrated a high retention rate amongst male groups. However, barriers identified included recruiting men because of an increase in labor migration, their work outside of the home, and hesitancy in discussing personal problems and feelings with others. The overall feasibility and acceptability of conducting the intervention and EUC procedures amongst men, as demonstrated through this study, indicates that it is possible to include both genders in a larger trial in the Nepal context, with some potential barriers in recruitment.

Limitations of the study design include of the risk of contamination and the inability to maintain complete blinding. The CPSWs and RAs from the two arms were initially trained together. The two areas for each arm were near one other, which may have increased the likelihood of participants, CPSWs, or research staff communicating with each other. However, it should be noted that all local staff were assigned to work in their VDC only, which decreased the likelihood of un-blinding during the study, it is recommended for the fully powered trial to be stricter on blinding procedures.

In conclusion, the study shows encouraging results regarding the feasibility and acceptability of the Group PM+ intervention delivered by non-specialists in rural Nepal. The initial planning phase with stakeholders, recruitment process, assessments, and the intervention itself showed feasibility and acceptability among both male and female participants. For all key outcome measures, the estimated mean improvement was larger in the Group PM+ arm than the EUC arm. A larger fully powered trial will seek to establish intervention effectiveness in the Nepal context.

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TESTING PSYCHOLOGICAL INTERVENTIONS FOR EFFECTIVENESS

CHAPTER 5

Protocol for an effectiveness study of Group PM+ for adults affected by humanitarian crises Nepal

This chapter is based on: van't Hof, E., Sangraula, M., Luitel, N. P., Turner, E. L., Marahatta, K., van Ommeren, M., Shrestha, P., Bryant, R., Kohrt, B. A., & Jordans, M. J. (2020). Effectiveness of Group Problem Management Plus (Group-PM+) for adults affected by humanitarian crises in Nepal: study protocol for a cluster randomized controlled trial. *Trials, 21*, 1-16.

ABSTRACT

Background

Globally, the lack of availability of psychological services for people exposed to adversities has led to the development of a range of scalable psychological interventions with features that enable better scale-up. Problem Management Plus (PM+) is a brief intervention of 5 sessions that can be delivered by non-specialists. It is designed for people in communities in low- and middle-income countries (LMIC) affected by any kind of adversity. Two recent randomized controlled trials in Pakistan and Kenya demonstrated the effectiveness of individually delivered PM+. A group version of PM+ has been developed to make the intervention more scalable and acceptable. This paper describes the protocol for a cluster randomized controlled trial (c-RCT) on locally adapted Group PM+ in Nepal.

Methods

This c-RCT will compare Group PM+ to enhanced usual care (EUC) in participants with high levels of psychological distress recruited from the community. The study is designed as a two-arm, single-blind c-RCT that will be conducted in a community-based setting in Morang, a flood affected district in Eastern Nepal. Randomization will occur at ward level, the smallest administrative level in Nepal, with 72 enrolled wards allocated to Group PM+ or to EUC (ratio 1:1). Group PM+ consists of five approximately 2.5-hour sessions, in which participants are taught techniques to manage their stressors and problems and is delivered by trained and supervised community psychosocial workers (CPSWs). EUC consists of a family meeting with (a) basic information on adversity and mental health, (b) benefits of getting support, (c) information on seeking services from local health facilities with mhGAP-trained staff. The primary outcome measure is levels of individual psychological distress at endline (equivalent to 20±1 weeks after baseline), measured by the General Health Questionnaire (GHQ-12). Secondary outcome measures include levels of functioning, depressive symptoms, post-traumatic stress disorder symptoms, levels of social support, somatic symptoms and ways of coping. We hypothesize that skills acquired will mediate any impact of the intervention.

Conclusion

This c-RCT will contribute to the growing evidence-base for transdiagnostic psychological interventions delivered by non-specialists for people in communities affected by adversity. If Group PM+ is proven effective the intervention manual will be released for use giving the opportunity to further adaptation and implementation of the intervention in diverse settings with communities that require better access to psychological interventions.

BACKGROUND

Globally, the lack of availability of psychological services for people exposed to adversities has led to the development, by the World Health Organization (WHO), of a range of scalable psychological interventions with features that enable better scale-up. The interventions are short of duration and carried out by non-professionals from the communities to make them sustainable and feasible to implement on a broader scale. One of these interventions is Problem Management Plus (PM+) (Dawson et al., 2015; World Health Organization, 2010). It has several core features that make the intervention suitable for low-resource settings exposed to adversities. It is a brief intervention of 5 sessions that can be delivered by non-specialists and is designed for people in communities in low- and middle-income countries (LMIC) affected by any kind of adversity as a transdiagnostic intervention, addressing a range of emotional (e.g., depression, anxiety, stress) problems.

Nepal is a low-income country with a history of humanitarian crises due to conflict, political instability and natural disasters in the form of earthquakes and monsoon related floods and landslides. Over 1.6 million people are affected by flooding in Nepal every year. The 2015 earthquake resulted in serious internal displacement, cost the lives of over 8,000 people, and injured almost 20,000 people (OCHA, 2015). A large proportion of the population in Nepal is affected by either floods or earthquakes through the loss of livelihood or homes and property. Humanitarian crises and natural disasters cause significant psychological and social suffering to affected populations. Nationwide population-based prevalence data on mental health problems is not available, but various studies suggest high rates of disabling distress (Kane et al., 2018; Kohrt et al., 2012; Kohrt et al., 2008; Luitel et al., 2013; Tol et al., 2007).

There are large unmet needs for mental health care in Nepal, which is especially pronounced given recent and frequent humanitarian crises. There are 0.52 psychologists and 0.36 psychiatrists per 100,000 people (World Health Organization, 2018), mostly working in large cities and inaccessible to those in rural areas. Midwives and community care providers, often working for NGOs, provide primary care in most of Nepal and this system allows for a model of care through non-specialized services as an possible solution to consider (Manaswi Sangraula et al., 2018).

This paper describes the protocol for a cluster randomized controlled trial (c-RCT) of locally adapted Group PM+ in Nepal. Two randomized controlled trials in Pakistan and Kenya demonstrated the effectiveness of individually delivered PM+ (Bryant et al., 2017; Rahman et al., 2016). A group version of the intervention was developed to make PM+ more scalable and acceptable in different contexts. The first trial with Group PM+ in Pakistan showed promising results for women (Chiumento et al., 2017; Rahman et al., 2019) and positive findings from the study described in the current protocol is expected to lead to WHO releasing Group PM+ for global use. This study follows on a feasibility c-RCT conducted in a rural flood-affected region of Nepal (Sangraula et al., 2018).

METHODS

Objectives

This study aims to evaluate the effectiveness of the locally adapted Group PM+ intervention in communities affected by adversity in Morang, Nepal. The cluster randomized controlled trial (c-RCT) will compare Group PM+ to enhanced usual care (EUC) in participants with high levels of psychological distress recruited from the community. The primary hypothesis is that at endline (20±1 weeks after baseline for the control arm participants, and 12+1 – 2 weeks after the time of the final group session for the Group PM+ arm participants), people receiving Group PM+ will have lower psychological distress scores, as measured by the GHQ-12, compared to people in the EUC control. The secondary hypotheses is that people receiving Group PM+ will also report less severity of depression symptoms, posttraumatic stress disorder (PSTD) symptoms, personalized measures of distress, culture-specific symptoms of psychological distress, somatic symptoms, higher levels of functioning, and social support at the post-treatment assessments. We also hypothesize higher levels of skill use related to the Group PM+ intervention content.

A qualitative component is added to the project with the objective to explore the effectiveness of the intervention and barriers to scale-up of Group PM+ with relevant stakeholders including participants, families and Group PM+ facilitators.

Design and setting

The study is designed as a two-arm, single-blind c-RCT that will be conducted in a community-based setting in Morang, a flood-affected district in Eastern Nepal. Outcomes will be measured on participants' level at baseline and at two additional time points midline and end line. Midline is seven weeks after baseline (for the Group PM+ participants, this will be approximately one week after concluding the intervention). End line is 20±1 weeks after baseline for the control arm participants, which is approximately 12+1 – 2 weeks after the time of the final group session for the Group PM+ arm participants. End line is the primary endpoint for the study.

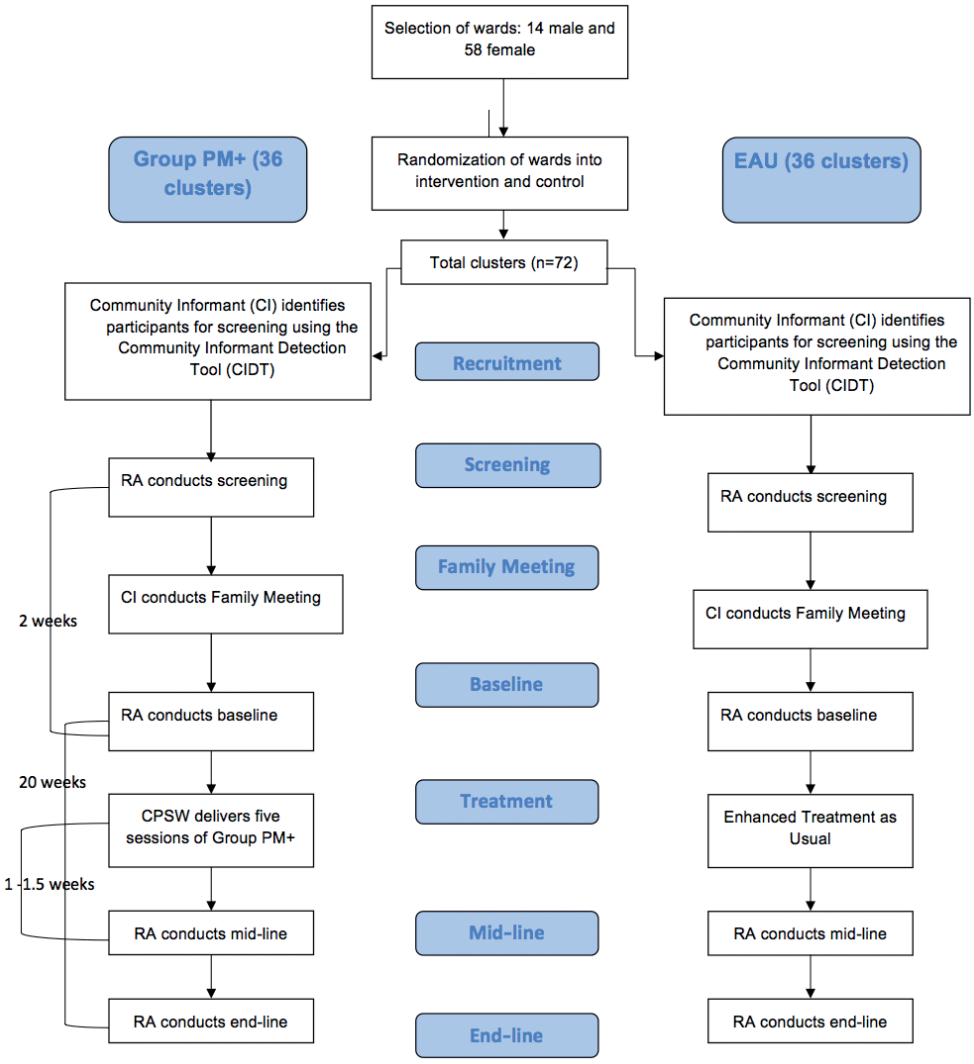
Administrative levels in Nepal are: (1) provinces; (2) districts; (3) *nagarpalikas or gaupalikas* (municipalities or rural municipalities); and (4) wards. Randomization will occur at the ward level, the smallest administrative level in Nepal, with half of 72 enrolled wards receiving Group PM+ and the other half receiving EUC. Importantly, given that the groups of the Group PM+ intervention will be of a single gender (see details below in *Group PM+ intervention*) and that we do not have resources to enroll more than one group per ward, we will select a sub-set of 14 of the 72 wards to be those which we enroll male participants and the remaining 58 wards will enroll female participants. This fraction (14/72), close to 20% of all wards, was selected to reflect the anticipated uptake of services which was expected to be lower in this region than in studies conducted by our team in other regions (Luitel et al., 2017; Luitel et al., 2018). Further, we note that the selection of 14 wards will not be random but instead those 14 wards will be selected to be 14 wards that are

close together and that are, nevertheless, representative of the types of wards in the study region. More specifically, we selected these 14 "male" wards close together so that we can best use resources of the male personnel trained to deliver to the Group PM+ intervention. Because of the sub-selection of "male" and "female" wards, randomization will be stratified by gender and will account for several other baseline cluster-level covariates using restricted randomization (see details below in *Randomization and sample size*).

The c-RCT is the design of choice when an intervention is group-based and when the population is expected to receive clinical and community services according to their location (i.e. ward) of residence. An alternative design is an individually-randomized group treatment trial (IRGT) in which individuals, rather than clusters are randomized (Pals et al., 2008; Roberts & Roberts, 2005). An IRGT design is typically expected to have greater power than a c-RCT for the same number of enrolled individuals and same degree of outcome clustering. However, such a design would not be suitable given concerns about contamination of the intervention within wards had there been both Group PM+ and EUC participants in each ward.

Additional enrolment strategies will be employed to minimize the risk of contamination. Specifically, given that some wards will be contiguous with each other, before participant recruitment begins, we will map the area and specify a localized area within each ward from which we will seek to recruit participants. The locations within the wards will be selected so that recruited participants from each ward are geographically far from those recruited in neighboring wards to minimize the chance that participants from different wards (i.e. from different clusters) interact with each other. Such a strategy will be used to conserve independence of clusters and to avoid contamination of EUC clusters with information from the Group PM+ intervention. Figure 1 gives an overview of the design.

Figure 1. Flow Chart



This community-based study is being conducted in 5 municipalities and 3 rural municipalities that together encompass 72 wards within Morang, a densely populated district in the Eastern *terai* (lowland) region of Nepal. The selected areas have a diverse population with over 20 castes and ethnicities, including Tharu, Brahman/Chhetri, Yadav, and Rai. The national language of Nepali is spoken by the majority of inhabitants. Morang is flood-affected annually and in 2017, it was estimated that over 19,000 people were displaced and over 12,000 homes were partially damaged due to the natural disaster (Sangraula et al., 2018). There are three Primary Health Care Centers (PHCCs) within the selected areas that provide basic health-

care and have an attending health worker trained in WHO mental health Gap Action Program (mhGAP) and will be used for EUC referral.

Study arms

Group PM+ intervention

Problem Management Plus (PM+) is a WHO trans-diagnostic psychological intervention that is delivered by trained non-specialist lay-providers in 5 sessions to adults impaired by distress (Dawson et al., 2015; World Health Organization, 2010). The manual comprises of the following evidence-based techniques: (a) problem solving, (b) stress management, (c) behavioral activation, and (d) accessing social support.

The Group PM+ intervention consists of five 2.5 to 3-hour sessions in which participants are taught techniques to manage their stressors and problems. Table 1 gives an overview of the content of the 5 sessions. The aim is to have six to eight participants per group, with separate groups for men and women and with gender-matched facilitators. Information on seeking services from local health facilities with mhGAP-trained health care staff trained in providing mental health care and/or psychosocial support is provided to the Group PM+ participants as well as to the EUC participants.

Community psychosocial workers (CPSWs) are trained as Group PM+ facilitators (Sangraula et al., 2018). CPSWs are a cadre of community health workers that have a long track record in providing psychosocial support in Nepal (Kohrt et al., 2015). For this study individuals from the community will be recruited to become new CPSWs. Fifteen local community women and men who have completed higher secondary school (equivalent of 12th grade education) from the study region will be selected based on their basic communication skills as reflected through the interviews., management and organization skills, interest and motivation to serve community people, and commitment to work in the given time. They are then given a 10-day basic CPSW training, with a standard curriculum developed by TPO Nepal. The CPSW training includes an overview of psychosocial concepts, cause and effects of psychosocial issues, basic communication skills, common mental health problems in communities, group facilitation skills and psychoeducation. Competency is evaluated before and after the CPSW training with a standardized role play assessment tool (ENACT) that has been developed in Nepal and used for non-specialists in humanitarian settings (Kohrt et al., 2018).

The CPSW training is followed by a 10-day Group PM+ training using the adapted manual and other intervention materials. Group PM+ is named *Khulla Man* ("open heart-mind" in Nepali), which is consistent with Nepali ethnopsychological models of distress, trauma, and recovery. The Group PM+ training includes learning about the impact of adversity on mental health, basic counselling skills, how to deliver the content of the Group PM+ manual, group management skills and self-care. Competency is assessed with ENACT again at the conclusion of the PM+ training, and fidelity is assessed with a PM+ specific checklist.

After completing PM+ training, three rounds of practice sessions will be completed by each CPSW in an adjoining district that is not a part of the study area. Competency assessments and supervision will be conducted during these practice sessions. Based on ENACT pre and post scores, clinical judgement during the PM+ practice sessions, assessments using the fidelity sheet, and the PM+ competency criteria, twelve CPSWs (ten female and two male) out of fifteen will be selected. In regard to ENACT, the CPSW, who scores the lowest points i.e. 1 (Need improvement) for each item, will be removed from the study.

Three types of supervision will be provided by TPO Nepal supervisors for PM+ providers while running the PM+ groups. Firstly, face-to face group supervision will be provided in the office twice a week for Group PM+ facilitators. Secondly, there is on-site supervision, in which a supervisor will sit in and observe at least 2 sessions per PM+ group. Fidelity and competency assessments will be conducted during these sessions to verify the delivery of Group PM+ to participants. Intervention fidelity is monitored through independent observations of 10-15% of sessions of each facilitator against tailored checklists. Fidelity and competency tools will be used and direct feedback will be given to PM+ facilitators leading the group. These sessions will also be audio recorded and reviewed in the in-office supervision sessions. Lastly, individual supervision sessions between the supervisors and Group PM+ facilitators will be conducted as needed. Supervision sessions will be documented using standard supervision forms and facilitators will discuss any reoccurring or unique challenges and successes during the sessions with the supervisors.

Facilitators are supported by assistants called 'Group PM+ helpers' who receive a basic 1-day training on assisting Group PM+ delivery and participate alongside CPSWs in practice PM+ groups. They help with the logistics and organizational aspects of the group sessions, such as reminding participants when sessions take place, reminding those that do not show up for the sessions, and providing childcare. Additional tools such as calendars, session cards and reminders, all developed specifically for the Nepal implementation of Group PM+, are used to increase retention of the material and attrition by participants.

TABLE 1. Mechanisms of Action of PM+ intervention

PM+ Mechanisms of Action	Description of mechanism	Implementation of mechanism
Stress Management	Participants learn deep breathing. They are encouraged to incorporate this mechanism into daily life (i.e. when doing housework, walking, etc.). Grounding techniques are incorporated to bring participants back to the present.	Session 1
Behavioral Activation	Participants review the inactivity cycle. They choose a small activity that they enjoy doing (i.e. making and drinking tea, meeting a friend etc....) and create a detailed plan about when and how to conduct this activity as a first step in breaking the inactivity cycle.	Session 2
Managing Problems	Participants learn which of their problems are solvable and which are unsolvable. One problem is chosen amongst the solvable problems and participants brainstorm tangible solutions, then creating manageable steps to accomplish their goals.	Session 3
Strengthening Social Support	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. Social network mapping activities are incorporated in this mechanism.	Session 4

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

Enhanced Usual Care (EUC)

In rural regions of Nepal, care-as-usual for most people with mental health problems until recently consisted of no psychological or psychiatric treatment in local health facilities. People with severe mental conditions would often, after a long delay between onset of symptoms, be taken to tertiary psychiatric services in the Kathmandu valley, or other urban settings with psychiatric services, by family members (Luitel et al., 2015). The Programme for Improving Mental Health Care (PRIME) has been implemented in Chitwan district, in southern Nepal, and has implemented and evaluated the WHO mental health Gap Action Programme (mhGAP) Intervention Guide since 2012 (Jordans et al., 2016; Jordans et al., 2019). The mhGAP *Humanitarian* Intervention Guide (World Health Organization et al., 2008) was contextualized for Nepal after the 2015 earthquakes and Nepali primary care workers in many districts, including Morang, have since been trained using mhGAP. Both the EUC and intervention arm will receive a referral to mhGAP trained primary health care worker providing treatment when needed (e.g. severe psychiatric disorder or suicidality).

Participants in the EUC control clusters will receive a time-restricted (between 30 and 45 minutes) family meeting conducted by local Community Informants

(CIs), that will consist of; (a) basic information on adversity and mental health, (b) benefits of getting support, (c) information on seeking services from local health facilities with mhGAP-trained health care staff trained in providing mental health care and/or psychosocial support (Manaswi Sangraula et al., 2018). The mhGAP training that these health care staff received consists of a 6-day training, focusing on a selected number of mental disorders including common mental disorders, including an additional module on anxiety disorders (excluding PTSD). This family meeting will be conducted with family members of the participant or the participant only based on participants' preferences. Both arms will receive the same family meeting format and referral information to primary care-based treatment.

Randomization

The unit of randomization is the ward (i.e. the cluster), as this is the smallest unit of administration in Nepal. This unit was selected to ensure sufficient number of clusters, as there are only 17 municipalities/ villages in the district, which would be the next possible level of randomization. Municipalities with mainly non-Nepali speaking inhabitants will be excluded. A total of 72 wards will be selected for participation with a target sample size of 8 participants enrolled per ward (see rationale below in *Sample size justification*). Then, for the 36 wards randomly allocated to Group PM+, a single group of 8 participants will be formed in each ward. As indicated above, of these 72 wards, 14 will be selected as "male" wards and 58 as "female" wards to reflect differences in uptake of services by males compared to uptake by females, as observed in earlier studies conducted by our team (see above). As such, the overall estimated intervention effect will reflect such a 1:4 ratio of males: females should the intervention be scaled up more broadly. Furthermore, as noted above, we will not take a random sample of 14 wards as "male" since it is important that the selected wards are such that whichever 7 are randomly allocated to Group PM+ are sufficiently close in proximity so that it will be reasonably straightforward for two male CPSWs to lead the 7 male Group PM+ groups (i.e. 1 in each of the "male" Group PM wards).

Restricted randomization will be used. Specifically, we will first use stratification by "ward gender" (i.e. randomization separately within 14 "male" wards and within 58 "female" wards). Then, within each "ward gender", we will use covariate constrained randomization to account for three baseline cluster-level covariates that are expected to be related to participant outcomes and for which it is important for us to achieve balance between the two study arms. Those three covariates, all defined as binary, are: (1) access to mental health services (high or less than 1 hour to reach nearest PHCC vs. low or less than 1 hour to reach nearest PHCC), (2) disaster risk (high or landslides or flooding in the last 3-years vs. low-to-moderate or minimal landslides or flooding in the last three years) and (3) rural/urban status (rural defined as wards that do not touch a major highway, majority of homes made of wood/straw/mud, and no local markets and urban defined as wards close to highways, majority of homes made of concrete and access to local markets).

Covariate constrained randomization is a generalized form of stratification which can be used to simultaneously balance on multiple baseline covariates without the need to formally define strata based on the cross-classification of those covariates (Moulton, 2004). In practice, in order to perform covariate-constrained randomization within the two strata defined by the 14 "male" wards and the 58 "female" wards, we will separately implement covariate constrained randomization in Stata software (version 14 (StataCorp, 2015)) using the *cvcrand* procedure (Gallis et al., 2018). Randomization will be performed in advance of enrolment of participants and will be conducted by the study statistician who does not know the study region. The statistician will use a simple data set with only the ward codes and 3 relevant covariates to ensure that there is no room for bias in the implementation. Moreover, a seed will be set so that the implementation is reproducible in Stata statistical software.

Sample size justification

The c-RCT was designed to have at least 90% power to detect moderate effect sizes of 0.46 for the primary outcome of individual psychological distress, measured by the GHQ-12 questionnaire (see details below in *Outcome Measures*) at the primary time point of follow-up 20±1 weeks after baseline for the control arm participants, and 12+1 – 2 weeks after the time of the final group session for the Group PM+ arm participants (i.e. endline). An effect size of 0.46 would correspond to between-arm differences of 3.2 units in mean GHQ-12 for an overall standard deviation of 7 units, a conservative assumption based on data from our pilot c-RCT (Sangraula et al., 2020). Power was calculated in R software (version 3.4.2) by programming a standard calculation for a comparison of two means in a c-RCT with 72 clusters assuming a two-tailed 5% significance level (Hayes & Moulton, 2017). It was additionally assumed that 8 participants would be enrolled in each ward, and that up to 2 participants per ward would drop-out before outcomes were measured (a conservative assumption for the purposes of the power calculation). Clustering of outcomes by ward was assumed to be relatively large with an interclass correlation coefficient (ICC) of 0.2 based on baseline data from a cohort study in the Chitwan district used in the PRIME study (Jordans et al., 2016). Although clustering in the EUC wards is anticipated to be lower than the assumed 0.2 in the Group PM+ wards because EUC participants will not meet in groups, we conservatively assume the same levels in both arms for the purposes of the power calculation.

Participants

People living in the 72 selected wards in Morang district are eligible to participate when they are over 18 years old and understand and speak Nepali. Inclusion criteria to be eligible for the trial are (1) answering affirmative to the heart-mind screener and for functional impairment (Kohrt et al., 2016) and (2) scoring above 16 on the WHO Disability Assessment Schedule for functional impairment (WHODAS) (Üstün et al., 2010). The heart-mind screener is locally developed (sensitivity of

0.94) and will be used to determine the acceptability of local idioms of distress and impairment due to these problems (Kohrt et al., 2016). The WHODAS is a generic instrument assessing health and disability that can be used with adult populations across cultures. Additionally, only males will be eligible for enrolment in the 14 "male" wards and similarly, only females will be eligible for enrolment in the 58 "female" wards. Exclusion criteria for participation in the trial are (1) presence of a severe mental disorder (e.g., psychosis) or cognitive impairment identified by a score above 2 on an adapted version of the WHO Ten Questions Screen (TQS) for disability detection (Stein et al., 1992) and (2) alcohol use disorder (score =>16 on the alcohol use disorders identification test (AUDIT).

Imminent risk of suicide will be determined through a structured screening questionnaire. Persons with current suicidal ideation and suicide plans or recent attempts will be referred immediately to a psychosocial counsellor but will not be excluded from participating in the study. Observable symptoms of psychosis and severe cognitive impairment will be assessed using an observation checklist. Four items are included to examine the client's ability to comprehend questions and follow basic instructions, and the degree to which the client can communicate with the assessor. A positive response above 2 on any of these behavioral items is an indication for exclusion and is discussed with a supervisory team. Alcohol dependency will be assessed by the alcohol use disorders identification test (AUDIT) (Saunders et al., 1993). According to WHO's guidelines for AUDIT use in primary care, people that score below 16 can benefit from simple advice (Babor et al., 2001). Those with a score of 16 or over would benefit the most from advice plus brief counselling and continued monitoring and therefore, those that score 16 or above on the AUDIT will be excluded from the study and referred to a near-by mhGAP trained health professional (Sangraula et al., 2018).

Procedures

Each ward of participating municipalities in Morang district will have 1 community informant (CI) who will conduct recruitment through the use of the Community Informant Detection Tool (CIDT) and community sensitization activities. CIs are often Female Community Health Volunteers (FCHVs), mother's group members, or social mobilizers within their respective communities. CIs will, as much as possible, also be gender-matched for the "gender" of their wards. CIs from intervention and control wards will be trained separately to maintain blinding. Control ward CIs will not be given any information on Group PM+ or any other information about the existence of an intervention arm. Intervention CIs will additionally be given a 1-day training to become Group PM+ 'helpers' for the sessions.

The community informants (CI) will be trained on the CIDT to identity people with common mental disorders in the community. The CIDT is a pro-active case detection approach aimed to increase help seeking using a vignette-based tool designed for the ease of use by lay people. It has been developed and tested in Nepal (Subba et al., 2017), with positive results on the positive predictive value (0.68) and

increasing the utilization of mental health services (Jordans et al., 2015). A general distress CIDT version had been adapted for this trial (Sangraula et al., 2020), which includes gender-matched vignettes for the "gender" of the wards.

After the community informant identifies a person in the community who matches the symptoms described in the vignettes, they will be asked if they would like support for their problems. If so, the research assistant (RA) will then conduct the consent and screening procedures.

People who are identified as meeting the exclusion criteria initially by the RAs will be referred to health workers trained in mhGAP, hospitals with psychiatric services, or counselors. People that meet the inclusion criteria for the study, in both the intervention and control wards, will receive a visit from the CI for a family meeting. Based on the preference of the participants this can either be with or without their family. After the family meeting, RAs will conduct the baseline assessment with enrolled participants. Once baseline is completed, only those in the intervention group will be contacted by Community Psychosocial Workers (CPSWs) to inform them about Group PM+. After all participants in an intervention ward have been contacted by the CPSW, Group PM+ sessions will start.

Informed consent

The consent procedures consists of two steps, first informed consent for screening and then informed consent for participation in the Group PM+ trial (Sangraula et al., 2020). After identification by the CI, potential eligible people will be approached by the research assistant for informed consent for screening. If a participant screens positive, the CI will give more information about the research project and will conduct the full trial informed consent during the family meeting.

All respondents who decide to participate will provide written consent, if possible. Full information on the study will be provided in local, lay Nepali language before obtaining consent from each participant. Given high rates of illiteracy, the consent form will be read to all participants. After providing verbal consent, literate participants will be asked to acknowledge the process with a signature. For illiterate participants, verbal consent or adding a symbol or sign will be sufficient. We will make sure that potential participants fully understand what participation entails and that they, at any time and without any consequences, can withdraw their consent without having to give an explanation. Participants will be made aware that refusal to participate will not have an impact on any type of support they receive outside the study. For the qualitative interviews, separate written informed consent will be taken at the time of the interview.

Outcome measures

Primary outcomes

The primary outcome is levels of individual psychological distress, measured by the GHQ-12 (Goldberg, 1988; Minhas & Mubbashar, 1996) at endline, 20±1 weeks after baseline for the control arm participants, and 12+1 – 2 weeks after the time of

the final group session for the Group PM+ arm participants. The GHQ-12 consists of 12 questions that are scored on a 4-point Likert scale ranging from 0 to 3, with higher total scores representing higher levels of distress. The GHQ-12 has been translated and clinically validated in Nepal (Cut-Off: 1/2, Sens 85.6%, Spec 75.8%, PPV 86.7%, NPV 84%) (Koirala et al., 1999).

Secondary outcomes

Secondary outcomes include levels of depressive symptoms measured by the Primary Health Questionnaire (PHQ) (Kroenke & Spitzer, 2002); general functioning measured with the WHO Disability Assessment Scale (WHODAS) (Üstün et al., 2010); post-traumatic stress disorder (PTSD) symptoms measured by the Post-traumatic stress disorder Check List (PCL-5) (Weathers et al., 2013); levels of perceived social support measured by the Multi-dimensional Scale of Perceived Social Support (MSPSS) (Zimet et al., 1990); and the Somatic Symptom Scale – 8 (SSS-8) (Gierk et al., 2014). Please see table 2 for an overview of the different measures on different time-points.

TABLE 2. Quantitative outcome measures

Construct	**Instrument**	**Description**	**Assessment Time Periods**			
			Enrollment ($-t_1$)	**Baseline (t_0)**	**Midline (t_1)**	**End line (t_2)**
Screening (Participants)						
Daily Functioning	*WHODAS*	Participants rate their ability to engage in daily activities	X			
General Psychological Distress	*Heart-mind*	Participants note if they have had any *"man ko samasya"* or heart-mind problems recently	X			
Alcohol use disorder	*Alcohol Use Disorders Identification Test (AUDIT)*	Participants rate alcohol use and associated behavior, as well as daily ethanol consumption	X			
Suicidality	*Suicidality*	Participants rate if they have recently had suicidal thoughts, ideation, and plans	X			
Primary Outcome (Participants)						
General Psychological Distress	*General Health Questionnaire (GHQ-12)*	Participants measure their general psychological distress		X	X	X

Secondary Outcomes (Participants)						
Depression symptoms	*Depression symptoms (PHQ)*	Participants rate depression symptoms over past two weeks		X	X	X
Daily Functioning	*WHODAS*	Participants rate their ability to engage in daily activities		X	X	X
Post-traumatic stress symptoms	*PTSD Checklist for DSM5 (PCL-5)*	Participants rate their post-traumatic stress symptoms on a scale		X	X	X
Perceived Social Support	*Multidimensional Scale of Perceived Social Support (MSPSS)*	Participants assess their own connectedness with close family, friends and other forms of support		X	X	X
Somatic Symptoms	*Somatic Symptom Scale-8 (SSS-8)*	Participants rate how much they have been bothered somatic symptoms		X	X	X
General Psychological Distress	*Heart-mind*	Participants note if they have had any *"man ko samasya"* or heart-mind problems recently			X	X
Additional Measures of Mechanisms and Potential Mediators						
Ways of Coping	*Reducing Tension Checklist (RTC)*	Participants assess their own behavioral and psychosocial skills related to coping		X	X	X
Traumatic Events	*Traumatic Events Inventory (TEI)*	Participants rate if they have been exposed to certain traumatic events throughout their lifetime		X		X

The WHO Disability Assessment Scale (WHODAS) is a generic instrument assessing health and disability in adults. It assesses difficulties that people are experiencing during the last 30 days, due to their illness, across six domains of functioning (cognition, mobility, self-care, getting along, life activities, and participation). Difficulties are scored on a 5-point Likert scale of: not at all difficult, a little difficult, sometimes difficult, very difficult, or always difficult. The WHODAS can be used with all diseases and across cultures. The scale has been previously used in Nepal and has an good internal consistency between items ($\alpha = 0.90$) and validity with multiple mental health measures for depression ($r = 0.616$, $p < 0.001$), anxiety ($r = 0.624$, $p < 0.001$), and PTSD ($r = 0.499$, $p < 0.001$) (Thapa & Hauff, 2012; Tol et al., 2007).

The Patient Health Questionnaire (PHQ-9) is a 10-item instrument measuring symptom depression (Weathers et al., 2013). It has been translated and clinically validated in a primary care population in Chitwan, Nepal: the validated cut-off score of ≥10 (sensitivity =0.94, specificity = 0.80, positive predictive value (PPV) = 0.42, negative predictive value (NPV) = 0.99, positive likelihood ratio = 4.62 and negative likelihood ratio = 0.07) (Kohrt et al., 2016).

The original Post-traumatic stress disorder Check List PCL-5 is a 20-item checklist corresponding with the 20 DSM IV PTSD symptoms. To diminish the burden of questionnaires administered by participants in this study the 8 -item version will be used. This was shown in a recent study to have comparable diagnostic utility to the 20-item PCL-5 (Price et al., 2016) and has been used in Nepal and will be used in this study to diminish the burden of questionnaires administered by participants (Thapa & Hauff, 2005).

The Multidimensional Scale of Perceived Social Support (MSPSS) (Zimet et al., 1990) is a self-rating tool of perceived social support from three categories of support: family, friends, and significant other. It has been locally adapted (Hendrickson et al., 2018) and validated to use in Nepal (Tonsing et al., 2012). The MSPSS consists of 12 questions that are rated on a 5-point Likert scale ranging from 1 "very strongly disagree" to 5 "very strongly agree". Higher scores indicate higher perceived levels of social support.

The Somatic Symptom Scale (SSS) is an 8-item patient-reported outcome measure of somatic symptom burden (Gierk et al., 2014) that has been translated and adapted using standard cross-cultural approach (Mishra et al., 2018).

TABLE 3. **Schedule of enrollment, interventions, and assessments for Group PM+.**

STUDY PERIOD					
PARTICIPANTS (*direct beneficiaries*) – participants of Group PM+ or Control Arm					
	Enrollment	Allocation	Baseline	Mid-line	End-line
TIMEPOINT	$-t_1$		t_0	t_1	t_2
ENROLLMENT:					
Allocation		X			
Eligibility screen	X				
Informed consent	X		X		
INTERVENTIONS:					
PM+			←	—	→
Control			←	—	→
ASSESSMENTS:					
WHODAS	X		X	X	X
Heart-mind	X			X	X
AUDIT	X				
Suicidality	X				
GHQ-12			X	X	X
PHQ-9			X	X	X
PCL-5			X	X	X
MSPSS			X	X	X
SSS-8			X	X	X
RCT			X	X	X
TEI			X	X	X

Other measures and further data

Competency and fidelity will be assessed with a modified version of the Enhancing Assessment of Common Therapeutic Factors (ENACT) tool tailored for Group PM+ (Kohrt et al., 2015). The ENACT scale is an 18-item assessment for common factors in psychological treatments that can be used with non-specialist in different settings.

At baseline demographic characteristics of participants will be recorded, including age, years of education, occupation and living situation. Traumatic events will also be assessed with the Traumatic Events Inventory (TEI), an 11-item assessment of traumatic exposure associated with poor mental health outcomes (Schwartz et

al., 2005). The TEI has previously been used in Nepal (Kohrt, Worthman, et al., 2015). A natural disaster questionnaire has also been developed for this trial. This consists of five questions on if participants were affected by floods, earthquakes, landslides, fires or other natural disasters in the last 5 years. Participants will be asked if their property were damaged and if they themselves of any relatives and friends were hurt by such natural disasters. Behavioral and psychosocial skills related to coping with emotional distress will be assessed with the Reducing Tension Checklist, that contains 12-item assessment of behavioral and psychological skills to evaluate skill acquisition of PM+ skills with one free response question based on the PSYCHLOPS (Ashworth et al., 2004; Héðinsson et al., 2013). It has been adapted based on PM+ content and findings in phase 1 of the project (Sangraula et al., 2020).

During PM+ sessions the Subjective Units of Distress Scale (SUDS) will be used. The SUDS, a scale of 0 to 10 for measuring the subjective intensity of disturbance or distress currently experienced by an individual (Wolpe, 1990), will be used for each participant during the second to fifth PM+ sessions. The scale has been previously used in Nepal (Segal-Engelchin & Sarid, 2016).

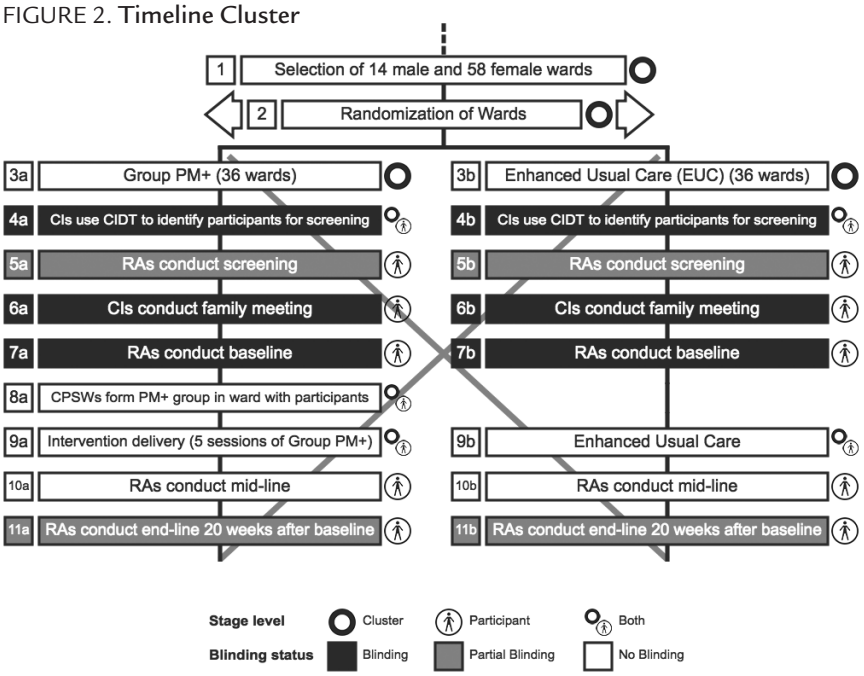
Masking

In this project, research assistants administering all interviews, community informants, research supervisors, and study statisticians will be blinded. The intervention does not allow for the intervention facilitators and participants to be blind to treatment allocation. Blinding of assessors will be ensured by minimizing the chance of contact between assessors and facilitators and having two separate offices for the research and clinical staff. Assessors will also prompt participants not to share any information on the type of treatment that they receive and explain that they are not supposed to know. After each assessment, assessors will be asked to indicate what treatment they think each participant will or has received (e.g. medication, one-on-one counselling, group counselling, referral etc.). This will provide some data on the amount of unblinding that might occur in the RCT. Furthermore, each of the research assistants sign a contract in which they agree to not share any details of the study with others.

Given the challenges of blinding in c-RCTs and the concerns about the potential for selection bias given that participant recruitment occurs after randomization of the wards in which the participants reside (Giraudeau & Ravaud, 2009), we have used the "timeline cluster" to visualize procedures in relation to blinding and participant recruitment (Caille et al., 2016). Specifically, we generated Figure 2 using an online open-access tool developed by the "timeline cluster" authors (Caille et al., 2016). This figure provides additional details to complement the overall study flow chart (Figure 1), including information on whether a specific stage of the process pertains to clusters, to participants or to both. The dark boxes indicate stages in the procedure when both participants, and the study personnel who will interact with those participants, will blinded to which arm the cluster has been allocated to.

We will use a design so that study participants are recruited by trained RA's who do not know which arm the ward (cluster) has been assigned to (see up to stage 7 in each arm, Figure 2). During service delivery (stages 8-9a in Group PM+ and stage 9b in EUC), participants cannot be blinded to study arm. However, as noted above, we have designed the midline and endline data collection procedures such to try to ensure that the RA's conduct the interviews are blinded to study arm (Stages 10-11 in both arms), which is indicated by the light grey shading (i.e. indicating partial blinding because the participants are no longer blinded at this stage). Importantly, when commencing the interview, the RA will emphasize to the participants how important it is that the participants does not reveal details about what kind of services they have received. We recognize that, within a specific ward, if an RA is inadvertently unblinded while conducting the interview with a participant before the final interview in that ward (i.e. before interviewing the 8th of the 8 enrolled participants), that RA would therefore be unblinded for the interviews of remaining participants. We will record data as to whether such unblinding occurred and therefore will be able to report on any threats to data validity. And, even in such a case, the RA's receive rigorous and comprehensive training on procedures to objectively record responses to our instruments and measures and therefore, we expect to be able to mitigate any potential for measurement bias that could arise as a result of unblinding.

FIGURE 2. **Timeline Cluster**



1 **Selection of 14 male and 58 female wards**

2 **Randomization of Wards**

3a **Group PM+ (36 wards)**

4a **Community Informants (CIs) trained in CIDT identify participants for screening in their respective wards**

5a **RAs conduct screening**

6a **CIs conduct family meeting**

7a **RAs conduct baseline**

8a **CPSWs form PM+ group in ward with participants**

9a **Intervention delivery (5 sessions of Group PM+)**

10a **RAs conduct mid-line**

11a **RAs conduct end-line 20 weeks after baseline**

3b **Enhanced Usual Care (EUC) (36 wards)**

4b **Community Informants (CIs) trained in CIDT identify participants for screening in their respective wards**

5b **RAs conduct screening**

6b **CIs conduct family meeting**

7b **RAs conduct baseline**

9b **Enhanced Usual Care**

10b **RAs conduct mid-line**

11b **RAs conduct end-line 20 weeks after baseline**

Data management

The research team will keep the identifying key, linking the name to code numbers, in a secure location and only the study principal investigators (PI) of the study will have access to primary data. Research assistants will not enter any personally identifying details into the data set. Data will be collected using a password-protected tabled, from where data will be synchronized and uploaded in the Open Data Kit (ODK), saved on a private server, and transferred to a data-analytic computer program (STATA) without the identifying key. The site PI will conduct quality assurance checks on data collected by the research assistants on the tablet.

The data collected with other means, like qualitative data and other documentation (e.g. supervision forms and training reports), will be safely stored in locked cabinets at the site office. The qualitative data will be fully anonymized and coded and will not contain any identifying information. Results of this project will be published regardless of being negative or positive results and submitted to peer-reviewed scientific journals.

Data analyses plan

Statistical analyses

Analysis of quantitative outcomes, including the primary outcome of GHQ-12, will adopt the intention-to-treat approach whereby all participants will be analyzed according to the arm to which their ward was randomized. That is, even if intervention arm participants did not attend all Group PM+ sessions, the primary analysis will include them in the Group PM+ arm. The linear mixed effects modeling approach will be used to model participant-level score outcomes. More specifically, the two follow-up time points (midline and endline) will be analyzed within the same model. The following design variables will be included as fixed effects: arm, time (an indicator for the follow-up time-point), the arm-by-time interaction (to allow for different intervention effects at each of the two follow-up time-points), ward gender (to account for the stratified design) and the three covariates used in the constrained randomization procedure (i.e. access to mental health services, disaster risk and rural/urban status). To increase statistical power, each participant's baseline measure of the outcome will be adjusted for as a fixed effect (Hooper et al., 2018). To account for clustering by ward, a random intercept will be included for which the degree of clustering is allowed to differ for intervention and control arm clusters. Due to the repeated follow-up measurements on participants, a random intercept will be included for participant. In the event that baseline outcome data are missing, we will use a constrained longitudinal analysis approach whereby the baseline measure is also modelled as an outcome (rather than a covariate) and the baseline mean level is constrained to be equal between arms (Hooper et al., 2018). In this case, we will allow for changing correlation of outcomes over time by additionally including a random slope for each individual or by using an unstructured residual correlation matrix. For score outcomes for which the assumptions of the linear mixed model are violated, we will transform the outcomes (e.g. log-

transformation) or adopt a bootstrap approach to estimate confidence intervals.

Binary outcomes will be analyzed within the generalized estimating equations framework. Specifically, we will use the modified Poisson approach (Zou & Donner, 2013) assuming a Possion outcome distribution, with an exchangeable working correlation matrix and robust standard errors to account for the outcome model misspecification (i.e. Poisson instead of binomial). Such an approach has been shown to be preferable to a binomial regression model for clustered outcome data (Zou & Donner, 2013). A log link will be used to obtain risk ratios and an identity link to obtain risk differences and the mean model will include the same terms as the models for the continuous outcomes.

Additional supportive analyses will test robustness to missing outcomes, to baseline covariate imbalance and to the combination of both. Specifically, the supportive analyses will include the following three approaches: (1) analyses that account for any baseline covariates that are predictive of missing outcomes, (2) analyses that account for any baseline covariates identified to be imbalanced between treatment arms, and, (3) analyses that combine both approaches (1) and (2), i.e. that account for all baseline covariates identified to be predictive of missing outcomes or to be imbalanced. For approach (1) to assess robustness to missing outcome patterns, if the probability of missingness is only related to the baseline covariates in the model, then these adjusted analyses will provide valid estimates of the intervention effect having accounted for the missing data patterns.

Sub-group analyses will assess whether there are differing intervention effects according to the following variables: gender and baseline depressive symptoms. To do so, the model will include an indicator for the sub-group variable and interactions between that indicator and intervention arm and time-point. Baseline depressive symptoms will be included in the model as a binary variable indicating whether the participant met the cutoff score for depressive disorder, specifically a baseline PHQ-9 score of 10. These analyses are exploratory in nature as the study is not powered to detect such effects. Adherence in the intervention arm will be quantified through the number of sessions attended. Similarly, within the intervention arm, we will examine potential differences in intervention due to different facilitators. To do so, we will analyze outcomes in intervention arm only and see its relationship with facilitator. Likewise, within the intervention arm, we will examine whether estimated outcomes are different for those who completed all five sessions vs. those who completed fewer sessions.

We hypothesize that skills acquired will mediate any impact of the intervention. To this end, we will perform a mediation analysis within the framework outlined by Zhang et al (Zhang et al., 2009) that accounts for the multilevel (i.e. clustered) data structure. We will use the midline measure of the *Reducing Tension Checklist* as the mediating variable and the endline timepoint for outcomes of interest. We note two important features of this analysis: (1) we have selected the midline measure for the hypothesized mediating variable to ensure that it precedes the outcome measure in time in order to be able to make stronger causal claims than we would

were the mediator and outcome measured at the same point in time, and, (2) we will ensure that potential confounders of the mediator-outcome relationship are accounted for in the analysis.

Qualitative evaluation
Semi-structured interviews will be conducted with a subsample of Group PM+ participants (equal number of completers and non-completers); Group PM+ facilitators; control arm participants; research assistants; family members of Group PM+ participants (equal number of intervention completers and non-completers); community informants; and local decision makers. The interviews will be conducted by trained interviewers that are familiar with the key principles of qualitative interviewing. Interviews will follow a semi-structured topic guide that address themes around barriers and facilitators in implementing PM+, satisfaction with the intervention, barriers and facilitators to adherence, and barriers and facilitators to scale up and integrating Group PM+ into other services.

All interviews will follow the same process: Group PM+ participants and other KIs will be selected through convenience sampling. Informed consent will be obtained using a single step procedure where participants are provided oral and written information about the study and its purpose in the local language. The number of KI interviews in each category of respondent will be determined by empirical saturation, with a minimum of 2 - 16 participants per each category. FGDs will also be conducted in relevant categories.

Qualitative data analyses
The qualitative data collected from FGDs, key informant interviews and notes during the process evaluation will be coded in NVIVO (Ltd, 2012) and analyzed using content analysis (Hsieh & Shannon, 2005) on the translated transcripts of the original language. Coding will be conducted by multiple independent raters, and inter-rater reliability will be calculated using Kappa scores.

Ethical considerations
Throughout the different study phases participants in both arms will have access to mhGAP trained health staff in the districts. When necessary they will be referred to a specialist for further assessment or management of severe psychiatric problems. If a participant experiences psychological problem after the project, they will be offered additional support.

All adverse events (AE) and serious adverse events (SAEs) that are reported spontaneously by the participant or observed by either research or intervention staff and will be recorded. All staff will be trained in the TPO Nepal Adverse Events Reporting Mechanism which guides the process of reporting and supporting/referral in case of any adverse events.

All AEs and SAEs will be reported to a local independent Data Safety Management Committee (DSMC). The DSMC includes psychiatrists, non-governmental organiza-

tion experts in psychosocial programs, and researchers and is established specifically for oversight of the trial and review of SEs and SAEs. The chair or a nominated person from the DSMC will review SAEs within 48 hours, deciding if an SAE is likely related or unrelated to the intervention. The DSMC will review all AEs once a month. In both instances the committee will determine necessary appropriate action in respect of ongoing trial conduct (i.e. referral to specialized care). All changes in treatment resulting from Adverse Events or Serious Adverse Events will be reported to the DSMC in Nepal. TPO Nepal is responsible for data collection and storage and making data available to the DSMC, funders, and IRBs for audits when appropriate.

The project has been approved locally by the Nepal Health Research Council, Kathmandu, Nepal and by the WHO Ethical Review Committee (Version 3; Protocol ID: 2817, October 25, 2018).

Dissemination

Findings from the c-RCT will be published through various channels. In Nepal the results will be disseminated to key stakeholders, including district, provincial, and national government, through Nepali and English reports and presentations. Internationally, the findings will be published in academic journals, reports to the research funder (Office of U.S. Disaster Foreign Assistance/USAID) and disseminated through the Mental Health Innovation Network (www.mhinnovation.net) For authorship eligibility we will comply with guidelines of the International Committee of Medical Journal Editors. Also, additional attention will be given to recommendations for equitable representation of researchers from LMIC for academic authorship (Kohrt et al., 2014). After publication of the primary analyses, the data will be made publicly available to keep with transparency recommendations.

DISCUSSION

The described c-RCT on the effectiveness of Group PM+ in Nepal has been informed by a preceding formative work and a feasibility c-RCT with Group PM+ in Nepal (Sangraula et al., 2018). It will contribute to the building evidence-base for transdiagnostic psychological interventions delivered by non-specialists for people in communities affected by adversity. It builds upon the results and shown effectiveness of individual PM+ in Kenya (Bryant et al., 2017) and Pakistan (Rahman et al., 2016) and the first RCT on the effectiveness of Group PM+ has been successfully completed in Swat valley in Pakistan (Rahman et al., 2019).

After individual PM+ has been found to be effective in Kenya and Pakistan, it was released for use by the WHO (World Health Organization, 2010). The intervention manual is now used in different settings all over the world increasing access to an evidence-based intervention for people with mental health problems. If Group PM+ is effective in both Pakistan and Nepal, the Group PM+ manual will also be published and available on WHO's website for free. This will give opportunity for

further adaptation and implementation of the intervention in diverse settings with communities that need better access to psychological interventions. The intervention can be adapted for other LMIC and humanitarian settings, but also in high income settings where brief transdiagnostic group interventions are lacking.

Trial status

The trial is open and recruiting as of November 25, 2018 and will likely be completed by May 31, 2019. The protocol (version 3) was last verified 25 October 2018. Subsequent protocol modifications will be reported to funders, IRBs, and registered with ClinicalTrials.gov.

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TESTING PSYCHOLOGICAL INTERVENTIONS FOR EFFECTIVENESS

CHAPTER 6

Effectiveness of Group PM+: a cluster randomized controlled trial

This chapters is based on: Jordans, M.J.D., Kohrt, B.A., Sangraula, M., Turner, E.L., Wang, X., Shrestha, P., Ghimire, R., van't Hof, E., Bryant, R., Dawson, K., Marahatta, K., Luitel, N., & van Ommeren, M. (Under Review) Effectiveness of a brief psychological intervention for adults affected by humanitarian disasters: a cluster randomized controlled trial of Group Problem Management Plus

ABSTRACT

Background

Globally, 168 million people are impacted by humanitarian emergencies worldwide, presenting increased risk of experiencing a mental disorder. Our objective was to test effectiveness of a brief group psychological treatment delivered by trained facilitators without prior professional mental health training in a disaster-prone setting. We conducted a cluster randomized controlled trial (cRCT) from November 25, 2018 through September 30, 2019. Participants in both arms were assessed at baseline, midline (7-weeks post-baseline; after treatment in the experimental arm) and endline (20-weeks post-baseline). The intervention was Group Problem Management Plus (Group PM+) a psychological treatment of 5 weekly sessions, which was compared with Enhanced Usual Care consisting of a family psycho-education meeting with a referral option to primary care providers trained in mental healthcare.

Methods

The setting was 72 wards (geographic unit of clustering) in eastern Nepal, with one PM+ group per ward in the treatment arm. Participants were adult women and men 18 years of age and older who met screening criteria for psychological distress and functional impairment. Outcomes were measured at the participant level. The primary outcome was psychological distress assessed with the General Health Questionnaire (GHQ-12). Secondary outcomes included depression, post-traumatic stress disorder (PTSD), and functional impairment. The hypothesized mediator was skill use aligned with the treatment's mechanisms of action.

Results

324 participants were enrolled in the control arm (36 wards) and 319 in the Group PM+ arm (36 wards). In the control arm, 302 completed endline, and 303 in the Group PM+ arm. At 3 months post-treatment, mean GHQ-12 total score was 1.4 units (95% CI: 0.3, 2.5) lower in Group PM+ compared to control; standardized mean difference of -0.2 (95% CI: -0.4, 0.0). Group PM+ was associated at endline with a larger proportion attaining more than 50% reduction in depression symptoms (29.9% of Group PM+ arm vs.17.3% of control arm, risk ratio=1.7, 95% CI: 1.2, 2.4).

Conclusion

Group PM+ was not associated with lower PTSD symptoms or functional impairment. Psychosocial skill use at midline explained 31% of the PM+ effect on endline GHQ-12 scores. Therefore, in humanitarian emergencies with a lack of mental health specialists, a 5-session group psychological treatment delivered by non-specialists can be used to modestly reduce psychological distress and depression symptoms, with benefits partly explained by the degree of psychosocial skill use in daily life. To improve the treatment benefit, future implementation should focus on approaches to enhance skill use by PM+ participants.

INTRODUCTION

Globally, 168 million people are impacted by humanitarian emergencies (UN OCHA, 2020). With the COVID-19 pandemic's impacts on healthcare, livelihoods, education, and security, more populations will experience humanitarian emergencies and associated mental health problems (UN, 2020). For most populations in humanitarian emergencies, the burden of mental health problems outweighs the availability of mental health services, and the number of mental health specialists is not sufficient to care for all persons in need. Increasingly, there is evidence that persons without a professional mental health education can effectively deliver psychological interventions (Singla et al., 2017).

Problem Management Plus (PM+) is a 5-session transdiagnostic intervention that incorporates multiple therapeutic techniques and is designed for delivery by non-specialists in humanitarian settings (Dawson et al., 2015). PM+, delivered in an individual format, has shown benefit in Pakistan (Rahman et al., 2016) and Kenya (Bryant et al., 2017), and a group version (Group PM+), also consisting of 5-sessions, has shown benefit among women in Pakistan (Rahman et al., 2019). As PM+ is increasingly used globally, including in the U.S. in response to the COVID-19 pandemic (McBride, 2020) one of the key questions is determining the mechanisms of action by which benefits are achieved so these mechanisms can be emphasized when adapting and implementing in new settings. Therefore, in addition to this being the second trial of Group PM+, it is the first trial of PM+ evaluating mechanisms of action. This is also the first Group PM+ trial including both women's and men's groups.

We conducted a two-arm, single-blind cluster randomized controlled trial (cRCT) that compared Group PM+ and enhanced usual care (EUC) among participants with psychological distress and functional impairment in Nepal, a country prone to humanitarian emergencies. Outcomes were independently assessed at baseline, midline (post-treatment), and endline (3-months follow-up). We hypothesized that at 3 months follow-up, Group PM+ would result in lower psychological distress scores (primary hypothesis), as well as fewer depression symptoms, post-traumatic stress disorder (PTSD) symptoms, and somatic complaints (secondary hypotheses) relative to EUC. We hypothesized that higher levels of psychosocial skill use (the proposed mechanisms of action) will mediate treatment outcomes. The trial protocol contains full design details (van't Hof et al., 2020).

METHODS

Setting

In rural settings in Nepal, mental health care is largely absent (Luitel et al., 2015). The study was conducted in Morang district, in eastern Nepal. Morang's population is mixed by caste and ethnicity, with Nepali language being spoken by the majority. Annual floods affect significant parts of the district (Lutheran World Relief, 2019).

Participants

Participants were at least 18 years of age and could understand and speak Nepali. Eligibility criteria were current psychological distress and impaired functioning. Current psychological distress was assessed with categorical endorsement (yes/no) of a local idiom of distress ("heart-mind problems", Nepali: *man ko samasya*) (Kohrt & Harper, 2008), which has 94% sensitivity for structured clinical depression diagnoses in Nepal (Kohrt et al., 2016). Functional impairment was determined with the World Health Organization Disability Assessment Schedule (WHODAS (Üstün et al., 2010), score >16). Exclusion criteria were presence of a severe mental disorder (e.g., psychosis), cognitive impairment (Stein et al., 1992), or harmful alcohol use (determined by a score >16 on the Alcohol Use Disorders Identification Test) (Saunders et al., 1993).

Intervention

Group PM+ was developed by WHO and is publicly available (Dawson et al., 2015; World Health Organization, 2010) Group PM+ is delivered in 5 weekly sessions lasting approximately 2.5 hours each. Group PM+ comprises the following evidence-based techniques: (a) problem solving, (b) stress management, (c) behavioral activation, and (d) promoting social support. Adults, with at least a high-school diploma equivalent and without prior mental health training, first received a 10-day training on foundational helping skills (Jordans et al., 2003), followed by 10 days of Group PM+ facilitator training with subsequent supervised practice sessions. Face-to-face group supervision was provided weekly.

The EUC control arm and Group PM+ arm participants received a time-restricted (approximately 30 minutes) family psycho-education meeting conducted by briefly trained local community members, consisting of (a) basic information on adversity and mental health, and (b) information about referral options to primary care providers trained in the WHO mental health Gap Action Programme-Intervention Guide (mhGAP-IG) (World Health Organization et al., 2008). The family psychoeducation meeting and referral information were the only additional services provided to EUC participants outside of what was normally available to the general population.

Randomization and masking

The unit of randomization was the ward, the smallest administrative unit in Nepal. Of eligible wards, 20% were allocated for men's groups and 80% for women's groups. This gender ratio was based on service use in a prior district-wide mental health program (Jordans et al., 2019). We followed a restricted randomization procedure. We first stratified by ward gender and then implemented covariate constrained randomization to account for three binary cluster-level covariates: (1) access to existing mental health services ("close" <1 hour to reach services); (2) disaster risk ("high frequency" of landslides or flooding, ≥ once in the past 3 years); and (3) rural/urban status. Wards with mainly non-Nepali speaking inhabitants were excluded.

The researchers (research assistants administering all interviews, research supervisors, and study statisticians) were masked to allocation. We limited risk of unmasking by employing a strict separation between assessors and Group PM+ facilitators (e.g., using two separate offices) and by prompting research participants not to share information with the assessors on the type of intervention that they received. To assess attainment of adequate masking, research assistants were asked to guess the allocation status of study participants after each interview.

Procedures

We recruited and trained one or two community members per ward, who recruited people suspected of having "heart-mind problems", using the Community Informant Detection Tool (CIDT) (Subba et al., 2017). The CIDT is a vignette-based tool for pro-active case detection, developed and evaluated in Nepal, with good positive predictive value for depression when compared to structured clinical interviews (Jordans et al., 2015) After research participants obtained individual consent, participants were screened for eligibility, and all eligible participants received family meetings. Subsequently, research assistants conducted baseline interviews, followed by Group PM+ facilitators delivering 5 sessions for treatment arm participants. Prior to conducting this cRCT, we completed a Group PM+ pilot study to test trial procedures. All pre-defined feasibility and acceptability criteria were met (e.g., recruitment and retention milestones, treatment fidelity, and few adverse events) (Sangraula et al., 2020).

Instruments

The primary outcome is psychological distress, measured using the General Health Questionnaire (GHQ-12) (Goldberg, 1988), which has been validated in Nepal (Koirala et al., 1999). Secondary outcomes include depression symptoms measured using the Primary Health Questionnaire (PHQ-9) (Kroenke & Spitzer, 2002), also validated in Nepal (Kohrt et al., 2016); "heart-mind" problems (Kohrt et al., 2016); general functioning measured with the WHODAS (Jordans et al., 2019); PTSD symptoms using an adapted 8-item Nepali version of the PTSD Checklist (PCL) (Price et al., 2016; Weathers et al., 2013) based on longer versions previously used in Nepal (Kane et al., 2018; Kohrt et al., 2015; Luitel et al., 2013; Thapa & Hauff, 2005); perceived social support using the Multi-dimensional Scale of Perceived Social Support (MSPSS) (Tonsing et al., 2012; Zimet et al., 1990); and the Somatic Symptom Scale 8 (SSS-8) (Gierk et al., 2014). Demographic characteristics of participants, traumatic events (Kohrt et al., 2015; Rothbaum & Davidson, 2005), and exposure to natural disasters were recorded at baseline. We developed a 10-item Reducing Tension Checklist (RTC), our measure of the mechanism of action (see RTC **Supplemental file**). RTC measures the use of behavioural and psychosocial coping skills related to PM+ (e.g., seeking social support, managing problems, stress management) but is worded so that both EUC and PM+ participants can complete the checklist.

Psychological treatment competency of the facilitators was evaluated during training with the ENhancing Assessment of Common Therapeutic factors (ENACT) rating of standardized role plays (Kohrt et al., 2018; Kohrt et al., 2015). During implementation, fidelity to Group PM+ was assessed with a tool adapted from components in the PM+ manual. Fidelity and competency were assessed by supervisors observing two sessions per treatment group using standardized checklists.

Analysis

All analyses reflect the clustered longitudinal nature of the outcome data. Analyses are described in the published protocol (van't Hof et al., 2020) and the statistical analysis plan, which was signed before unmasking the study. Primary analyses used the "intention-to-treat" population. Sub-group analyses excluded intervention arm participants who attended fewer than 4 Group PM+ sessions ("non-completers") whilst using data from all control arm participants. Reporting results is in accordance with the cluster RCT CONSORT extension (Campbell et al., 2012).

This cRCT was designed to have at least 90% power to detect a moderate effect size of 0.46 for the primary outcome (GHQ-12) at the primary timepoint (endline). Assumptions were: intracluster correlation coefficient (ICC) due to clustering by ward of 0.2 within each arm (based on population level data from a community-based sample in Nepal (Jordans et al., 2019)), two-tailed 5% significance level, 72 clusters (36 per arm) with 8 participants per ward and drop-out of up to 2 per ward.

The midline and endline measures of each score outcome were jointly modelled using a linear mixed effects model with ward-level predictors of arm, time, arm-by-time, ward gender, access to mental health services, disaster risk and rural/urban status, as well as the participant-level baseline measure of the outcome. Random intercepts were included for participant and ward, with different ward-level ICC for each treatment arm. Sensitivity analyses additionally adjusted for predictors of missing outcomes. Secondary binary outcomes were analysed using the same predictors within the modified Poisson framework to obtain both risk ratios and risk differences (Zou & Donner, 2013). Using the group-mean centring approach (Zhang et al., 2009), mediation of the intervention effect on the primary outcome at endline was evaluated using a difference-in-coefficients mediation framework for cRCTs to estimate both between- and within-ward effects for the hypothesized participant-level mediator of RTC skill use scores (i.e., number of PM+ strategies used) at midline. Except for the fact that only endline GHQ-12 was modelled, the same model structure was used as for the primary outcome.

Ethics

The trial is registered with ClinicalTrial.gov (NCT03747055). The study has been approved by the Nepal Health Research Council, Kathmandu, Nepal (Ref 481, September 2018) and WHO Ethical Review Committee (version 3, ID 2817, October 2018).

No changes were made to methods or outcomes after trial commencement.

RESULTS

Participant flow and recruitment

Out of 100 wards assessed for eligibility, 72 were eligible wards. 58 were selected for female participants and 14 for male participants (see **Figure 1**). The wards were randomized to the EUC or Group PM+ arms. Participant recruitment occurred from Nov 25, 2018 to May 28, 2019. In the control wards, 1,169 adults were screened and 324 met eligibility criteria. In the Group PM+ wards, out of 885 persons screened, 319 met eligibility criteria.

FIGURE 1. CONSORT Flow Chart

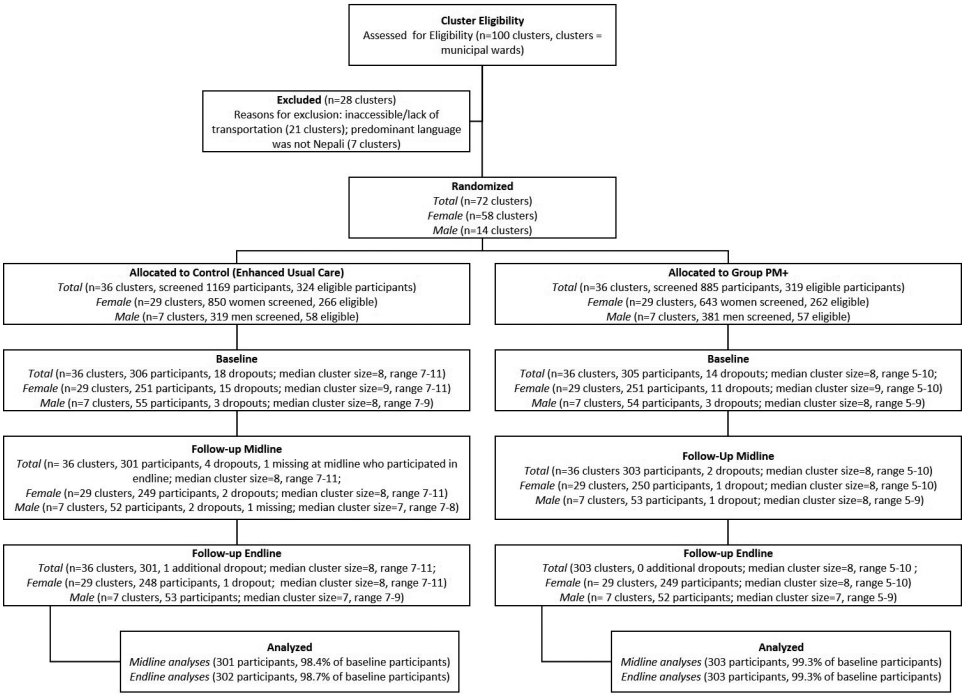

Figure 1: CONSORT flowchart for Group Problem Management Plus (PM+) cluster randomized controlled trial in community settings Morang, Nepal, conducted November 25, 2018 through September 30, 2019. Midline is 7 weeks post-baseline (after completion of the intervention in the Group PM+ arm). Endline is 20 weeks post-baseline (three months after completion of the intervention in the Group PM+ arm). Group PM+ consists of 5-weekly group therapy sessions. Enhanced usual care is a brief (30-minute) family psychoeducation session and passive referrals to primary-care based mental health services. Abbreviations: PM+, Problem Management plus.

See **Table 1** for a description of the sample. Additional baseline demographic variables including exposure to disasters and traumatic events and demographics by gender events are provided in. Reasonable balance between arms was observed for most baseline demographic variables. As per CONSORT recommendations, we did not obtain *p*-values for these comparisons. Likewise, reasonable balance was also observed for the completers population.

TABLE 1. **Baseline characteristics by arm**

Baseline Characteristics	**Control** (N=306)	**Group PM+** (N=305)	**Total** (N=611)
Age (years)			
Mean (SD)	44.1 (14.0)	45.5 (14.8)	44.8 (14.4)
Median (Q1, Q3)	45.0 (33.0, 54.0)	44.0 (35.0, 55.0)	45.0 (34.0, 55.0)
Min, Max	18.0, 83.0	18.0, 91.0	18.0, 91.0
Gender			
Female	251 (82.0%)	251 (82.3%)	502 (82.2%)
Education			
Cannot read or write	88 (28.8%)	88 (28.9%)	176 (28.8%)
Literate or informal education	84 (27.5%)	80 (26.2%)	164 (26.8%)
Primary level	72 (23.5%)	77 (25.2%)	149 (24.4%)
Secondary	47 (15.4%)	45 (14.8%)	92 (15.1%)
Higher secondary	13 (4.2%)	13 (4.3%)	26 (4.3%)
University	2 (0.7%)	2 (0.7%)	4 (0.7%)
Occupation			
Farmer	104 (34.0%)	93 (30.5%)	197 (32.2%)
Business or Job	33 (10.7%)	34 (11.1%)	67 (10.9%)
Daily wage laborer	35 (11.4%)	33 (10.8%)	68 (11.1%)
Unemployed	9 (2.9%)	14 (4.6%)	23 (3.8%)
Student	8 (2.6%)	4 (1.3%)	12 (2.0%)
Housewife	113 (36.9%)	120 (39.3%)	233 (38.1%)
Other	4 (1.3%)	7 (2.3%)	11 (1.8%)
Caste categories			
Upper-caste (Brahman, Chhetri)	110 (36.0%)	110 (36.1%)	220 (36.0%)
Janajati	78 (25.5%)	73 (23.9%)	151 (24.7%)
Madhesi and Local Indigenous	48 (15.6%)	57 (18.6%)	105 (17.1%)
Other	70 (22.8%)	65 (21.3%)	135 (22.0%)
Religion			
Hindu	257 (84.0%)	267 (87.5%)	524 (85.8%)
Buddhist	10 (3.3%)	8 (2.6%)	18 (2.9%)
Muslim	1 (0.3%)	0 (0.0%)	1 (0.2%)
Christian	19 (6.2%)	17 (5.6%)	36 (5.9%)
No religion	1 (0.3%)	1 (0.3%)	2 (0.3%)
Other	18 (5.9%)	12 (3.9%)	30 (4.9%)
Marital status			
Unmarried	16 (5.2%)	17 (5.6%)	33 (5.4%)
Married	249 (81.4%)	242 (79.3%)	491 (80.4%)
Widowed	27 (8.8%)	39 (12.8%)	66 (10.8%)
Divorced	3 (1.0%)	3 (1.0%)	6 (1.0%)
Separated	11 (3.6%)	4 (1.3%)	15 (2.5%)

Primary language			
Nepali	252 (82.4%)	249 (81.6%)	501 (82.0%)
Other	54 (17.6%)	56 (18.4%)	110 (18%)
Household size			
Living alone	11 (3.6%)	9 (3.0%)	20 (3.3%)
With 1 other person	29 (9.5%)	29 (9.5%)	58 (9.5%)
With 2 to 3 other people	125 (40.8%)	122 (40.0%)	247 (40.4%)
With 4 or more other people	141 (46.1%)	145 (47.5%)	286 (46.8%)
Chronic diseases			
Yes	94 (30.7%)	96 (31.5%)	190 (31.1%)
If yes to chronic disease			
Cancer	2 (2.1%)	3 (3.1%)	5 (2.6%)
Diabetes	17 (18.1%)	18 (18.8%)	35 (18.4%)
Hypertension	36 (38.3%)	36 (37.5%)	72 (37.9%)
Asthma	14 (14.9%)	21 (21.9%)	35 (18.4%)
Other	25 (26.6%)	18 (18.8%)	43 (22.6%)
Who do you live with			
Extended family with spouse	101 (33.0%)	81 (26.6%)	182 (29.8%)
Extended family without spouse	15 (4.9%)	23 (7.5%)	38 (6.2%)
With parents	10 (3.3%)	9 (3.0%)	19 (3.1%)
Maternal home (Nepali: Maiti)	6 (2.0%)	5 (1.6%)	11 (1.8%)
Spouse only	20 (6.5%)	17 (5.6%)	37 (6.1%)
Spouse and children only	107 (35.0%)	116 (38.0%)	223 (36.5%)
Other	47 (15.4%)	54 (17.7%)	101 (16.5%)
Indicators of Economic Status (yes)			
Concrete Building	39 (12.7%)	48 (15.7%)	87 (14.2%)
Electricity	271 (88.6%)	277 (90.8%)	548 (89.7%)
Drinking water	276 (90.2%)	270 (88.5%)	546 (89.4%)
Radio	85 (27.8%)	78 (25.6%)	163 (26.7%)
Television	186 (60.8%)	190 (62.3%)	376 (61.5%)
Simple mobile phone	252 (82.4%)	242 (79.3%)	494 (80.9%)
Smart mobile phone	151 (49.3%)	163 (54.5%)	314 (51.9%)
Bicycle	202 (66.0%)	226 (74.1%)	428 (70.0%)
LP Gas	224 (73.2%)	231 (75.7%)	455 (74.5%)
Ever taken medication for mental health problems			
No	263 (85.9%)	287 (94.1%)	550 (90.0%)
Yes	31 (10.1%)	10 (3.3%)	41 (6.7%)
Don't know	12 (3.9%)	8 (2.6%)	20 (3.8%)
Ever received counselling services (e.g., counselor, doctor, religious advisor)			
0 times	291 (95.1%)	297 (97.4%)	588 (96.2%)
1 – 4 times	7 (2.3%)	2 (0.7%)	9 (1.5%)
5 – 10 times	6 (1.9%)	4 (1.3%)	10 (1.6%)
>10 times	2 (0.7%)	2 (0.7%)	4 (0.7%)

Traumatic and Natural Disaster Exposures			
Ever experienced a natural disaster (yes)	163 (53.3%)	145 (47.5%)	308 (50.4%)
When did the natural disaster occur?			
0 to 3 years ago	22 (13.5%)	31 (21.4%)	53 (17.2%)
Over 3 years ago	141 (86.5%)	114 (78.6%)	255 (82.8%)
Been in a serious accident	65 (21.2%)	51 (16.7%)	116 (19.0%)
Had a serious sickness	227 (74.2%)	216 (70.8%)	443 (72.5%)
Been in the military or war zone	26 (8.5%)	20 (6.6%)	46 (7.5%)
Seen/had a death/murder of close family or friend	63 (20.6%)	64 (21.0%)	127 (20.8%)
Seen/had close friend/family member commit suicide	114 (37.3%)	91 (29.8%)	205 (33.6%)
Been attacked with a gun/knife	30 (9.8%)	37 (12.1%)	67 (11.0%)
Been attacked without weapon	40 (13.1%)	48 (15.7%)	88 (14.4%)
Beaten as a child	77 (25.2%)	73 (23.9%)	150 (24.5%)
Had adult sexual contact before age 13	7 (2.3%)	8 (2.6%)	15 (2.5%)
Had unwanted sexual contact after age 13	22 (7.2%)	25 (8.2%)	47 (7.7%)

Treatment exposure and enhanced usual care

Median competency of the 12 facilitators in common factors as measured with ENACT after training was 81% (range 61-100%). Average fidelity during Group PM+ delivery was 2.4 (scale of 0 to 3, **Table 2**).

TABLE 2: Summary of fidelity checklist (FC) score by session[a]

	n[b]	Mean	SD	Median	Min	Max
Session 1	18	2.8	0.2	2.8	2.4	3.0
Session 2	13	2.8	0.1	2.8	2.4	3.0
Session 3	11	2.9	0.2	3.0	2.6	3.0
Session 4	15	2.7	0.1	2.8	2.4	2.9
Session 5	20	2.8	0.1	2.9	2.7	3.0

[a] Average values of FC are computed for each session of each ward, and then summarized here for each session across wards.

[b] 79 sessions total were evaluated in-person by the Clinical Supervisors. Clinical Supervisors evaluated at least 2 sessions per PM+ group. Clinical Supervisors attempted to evaluate at least one of each session (session 1, 2, 3, 4, and 5) for each facilitator. However, facilitators were evaluated during different sessions depending on which sessions they needed the most support on and the time schedule of the Clinical Supervisor. FC data is unavailable for session 5 of ward S9 and session 5 of ward P1.

In the Group PM+ arm, 238 (78%) participants completed treatment, defined as attending 4 (N=72) or 5 sessions (N=166) (**Table 3**).

TABLE 3. Intervention participation

Number of sessions attended	Total (N = 305)
0	15 (4.9%)
1	5 (1.6%)
2	21 (6.9%)
3	26 (8.5%)
4	72 (23.6%)
5	166 (54.4%)
Completer (attended 4 or 5 sessions)	
No	67 (22.0%)
Yes	238 (78.0%)
Session 1	
No	40 (13.1%)
Yes	265 (86.9%)
Session 2	
No	59 (19.3%)
Yes	246 (80.7%)
Session 3	
No	67 (22.0%)
Yes	238 (78.0%)
Session 4	
No	60 (19.7%)
Yes	245 (80.3%)
Session 5	
No	56 (18.4%)
Yes	249 (81.6%)

Primary outcome

In intention-to-treat analyses, the Group PM+ arm was associated with lower GHQ-12 scores at both midline and endline compared to the control arm (**Table 4**). At 3-months, this effect is significant at the 5% level with an estimated GHQ-12 score of 1.4 units (95% CI: 0.3, 2.5) lower in Group PM+ compared to control when adjusting for the baseline GHQ-12, SMD=-0.2 (95% CI: -0.4, -0.0). Using the primary analytic model, the ICC for the control arm was 0.00 at midline and 0.08 at endline; and, for the Group PM+ arm, 0.10 and 0.12. When additional pre-specified covariates were adjusted for (e.g., age, caste, exposure to disasters, baseline WHODAS, baseline PHQ-9), similar results were obtained. Likewise, similar results were obtained for the completers population (**Table 4**). There was minimal missing outcome data (98.8% completed endline). There was no indication of baseline covariates differing by study arm and midline or endline data availability so we did not perform other sensitivity analyses to account for missing outcome data. There was no evidence of an interaction between gender and the treatment effect; and there was no suggestion of a benefit of Group PM+ for men in gender-specific sub-analyses (**Table 4**).

TABLE 4: Intervention effects (mean differences and 95% confidence intervals) on primary outcome: psychological distress measured with the General Health Questionnaire GHQ-12)

Primary Outcome (GHQ-12)	Mean (SD), n			Estimated Treatment Effect			Variance Components[e]			
	Control (N = 306)	PM+ (N = 305)	Total (N = 611)	Mean Difference (95% CI)	*P*-value	Standardized Mean Difference (95% CI)[f]	Cluster (residential ward)		Person	Residual
							Control	PM+		
ITT[a]										
Baseline	20.9 (6.0), n = 306	21.2 (6.3), n = 305	21.0 (6.1), n = 611	-	-	-	-	-	-	-
Midline	20.3 (6.6), n = 301	17.7 (6.9), n = 303	19.0 (6.9), n = 604	-2.7 (-3.7, -1.7)	< 0.001	-0.4 (-0.5, -0.2)	< 0.001	2.0	13.9	17.8
Endline	19.3 (6.5), n = 301	18.1 (7.0), n = 301	18.7 (6.7), n = 602	-1.4 (-2.5, -0.3)	0.014	-0.2 (-0.4, -0.0)	1.6	2.4		
ITT Sensitivity[b]										
Baseline	20.9 (6.0), n = 306	21.2 (6.3), n = 305	21.0 (6.1), n = 611	-	-	-	-	-	-	-
Midline	20.3 (6.6), n = 301	17.7 (6.9), n = 303	19.0 (6.9), n = 604	-2.9 (-4.0, -1.9)	< 0.001	-0.4 (-0.6, -0.3)	< 0.001	2.4	12.2	17.7
Endline	19.3 (6.5), n = 301	18.1 (7.0), n = 301	18.7 (6.7), n = 602	-1.6 (-2.8, -0.5)	0.005	-0.2 (-0.4, -0.1)	2.5	2.3		
ITT Female[c]										
Baseline	20.9 (5.9), n = 251	20.8 (6.0), n = 251	20.8 (5.9), n = 502	-	-	-	-	-	-	-

Midline	20.6 (6.5), n = 249	17.3 (6.8), n = 250	18.9 (6.8), n = 499	-3.0 (-4.1, -1.9)	< 0.001	-0.4 (-0.6, -0.3)	< 0.001	1.9	13.9	17.8
Endline	19.6 (6.5), n = 248	18.0 (6.5), n = 249	18.8 (6.6), n = 497	-1.5 (-2.8, -0.3)	0.017	-0.2 (-0.4, -0.0)	1.7	2.6		
ITT Male[c]										
Baseline	20.9 (6.4), n = 55	23.3 (7.2), n = 54	22.1 (6.9), n = 109	-	-	-	-	-	-	-
Midline	19.1 (7.1), n = 52	19.5 (7.3), n = 53	19.3 (7.2), n = 105	-1.1 (-3.5, 1.3)	0.359	-0.2 (-0.5, 0.2)	< 0.001	1.9	13.9	17.8
Endline	18.1 (6.3), n = 53	18.7 (8.7), n = 52	18.4, (7.6), n = 105	-0.9 (-3.5, 1.8)	0.529	-0.1 (-0.5, 0.2)	1.7	2.6		
Completers[d]										
Baseline	20.9 (6.0), n = 306	21.1 (6.4), n = 238	21.0 (6.2), n = 544	-	-	-	-	-	-	-
Midline	20.3 (6.6), n = 301	17.3 (6.7), n = 238	19.0 (6.8), n = 539	-3.0 (-4.1, -1.9)	< 0.001	-0.4 (-0.6, -0.3)	< 0.001	2.7	12.7	17.9
Endline	19.3 (6.5), n = 301	18.1 (6.8), n = 238	18.8 (6.7), n = 538	-1.4 (-2.6, -0.3)	0.015	-0.2 (-0.4, -0.0)	1.7	2.6		

Abbreviations: CI, confidence interval; ITT, intention to treat; PM+, Problem Management plus.

a Primary analytic model (see methods).

b Primary analytic model with 5 additional baseline covariates: age categories, caste categories, exposure to natural disasters, baseline World Health Organization Disability Assessment Schedule (WHODAS), and baseline Patient Health Questionnaire (PHQ-9).

c Gender effects obtained by adding 3 interactions to primary analytic model: arm-by-gender, time-by-gender, arm-by-time-by-gender.

d Primary analytic model applied to the completer population.

e In units^2. Can be used to obtain intraclass correlation coefficient (ICC) for each treatment group at each time-point using arm-time specific variance/ residual variance. ICC estimates for ITT the analysis is: < 0.001 and 0.082 for control at midline and endline, respectively; 0.101 and 0.119 for PM+ at midline and endline, respectively.

f Standardized mean differences (SMD) calculated by dividing the estimated mean difference by the overall standard deviation across the two arms combined.

Secondary outcomes

The Group PM+ arm was associated with lower depression symptoms (PHQ-9 mean difference=-1.0, 95% CI: -1.8, -0.1, p=0.028). Group PM+ was not associated with lower functional impairment (WHODAS mean difference=1.5, 95% CI: -3.4, 0.4, p=0.118), PTSD symptoms (PCL-C mean difference=-1.0, 95% CI: -2.2, 0.1, p=0.084), perceived social support (MSPSS mean difference=1.0, 95% CI: -0.3, 2.3, p=0.138), nor somatic symptoms (SSS mean difference=-1.0, 95% CI: -2.2, 0.2, p=0.105), see **Table 5**. For secondary binary outcomes (**Table 6**), at endline, 29.9% of the Group PM+ arm participants showed a 50% reduction in PHQ-9 from baseline compared to 17.3% in the control arm , risk ratio=1.7 (95% CI: 1.2, 2.4, p=0.002). Similarly, 58.8% of participants in the Group PM+ arm had "heart-mind" problems at endline compared to 69.4% of participants in the control arm, risk ratio=0.8 (95% CI: 0.7, 1.0, p=0.042).

TABLE 5: Intervention effects[a] on secondary and mediator score outcomes (mean differences and 95% confidence intervals for the ITT population)

Outcomes	Mean (SD), n			Estimated Treatment Effect			Variance Components			
	Control (N = 306)	PM+ (N = 305)	Total (N = 611)	Mean Difference (95% CI)	P-value	Standardized Mean Difference (95% CI)	Time		Person	Residual
							Control	PM+		
Secondary Score Outcomes										
WHODAS										
Baseline	24.6 (6.5), n = 306	26.0 (6.8), n = 305	25.3 (6.7), n = 611	-	-	-	-	-	-	-
Midline	19.2 (9.6), n = 301	17.1 (8.8), n = 303	18.2 (9.3), n = 604	-3.0 (-4.6, -1.4)	< 0.001	-0.3 (-0.5, -0.2)	5.7	3.5	32.6	28.2
Endline	16.5 (8.6), n = 301	16.0 (9.6), n = 301	16.2 (9.1), n = 602	-1.5 (-3.4, 0.4)	0.118	-0.2 (-0.4, 0.0)	5.1	12.6		
PHQ-9										
Baseline	11.9 (5.0), n = 306	12.7 (4.9), n = 305	12.3 (5.0), n = 611	-	-	-	-	-	-	-
Midline	10.9 (5.2), n = 301	9.6 (5.0), n = 303	10.2 (5.1), n = 604	-1.7 (-2.5, -0.9)	< 0.001	-0.3 (-0.5, -0.2)	1.3	0.7	7.4	9.6
Endline	10.0 (4.4), n = 301	9.5 (5.2), n = 301	9.8 (4.8), n = 602	-1.0 (-1.8, -0.1)	0.028	-0.2 (-0.4, -0.0)	0.4	2.5		
PCL										
Baseline	21.8 (7.0), n = 306	23.0 (6.8), n = 305	22.4 (6.9), n = 611	-	-	-	-	-	-	-
Midline	21.4 (6.9), n = 301	20.4 (6.9), n = 303	20.9 (6.9), n = 604	-1.7 (-2.6, -0.8)	< 0.001	-0.2 (-0.4, -0.1)	< 0.001	0.2	13.7	15.8
Endline	20.5 (6.6), n = 301	20.2 (7.1), n = 301	20.3 (6.9), n = 602	-1.0 (-2.2, 0.1)	0.084	-0.2 (-0.3, 0.0)	2.3	3.6		

MSPSS										
Baseline	30.7 (9.5), n = 306	32.5 (9.9), n = 305	31.6 (9.7), n = 611	-	-	-	-	-	-	-
Midline	30.8 (9.5), n = 301	32.9 (8.7), n = 303	31.9 (9.1), n = 604	1.0 (-0.2, 2.1)	0.097	0.1 (-0.0, 0.2)	2.3	< 0.001	17.8	25.1
Endline	31.0 (9.2), n = 301	33.2 (9.0), n = 301	32.1 (9.2), n = 602	1.0 (-0.3, 2.3)	0.138	0.1 (-0.0, 0.2)	3.1	1.9		
SSS										
Baseline	23.0 (6.7), n = 306	23.8 (6.9), n = 305	23.4 (6.8), n = 611	-	-	-	-	-	-	-
Midline	23.1 (6.9), n = 301	21.5 (6.9), n = 303	22.3 (7.0), n = 604	-2.1 (-3.1, -1.2)	< 0.001	-0.3 (-0.4, -0.2)	1.1	1.4	12.7	14.5
Endline	22.1 (7.0), n = 301	21.6 (7.5), n = 301	21.8 (7.3), n = 602	-1.0 (-2.2, 0.2)	0.105	-0.1 (-0.3, 0.0)	2.8	4.1		
Mediator										
RTC										
Baseline	26.3 (6.4), n = 306	27.5 (6.5), n = 305	26.9 (6.5), n = 611	-	-	-	-	-	-	-
Midline	25.9 (6.2), n = 301	28.5 (6.2), n = 303	27.2 (6.3), n = 604	2.1 (1.0, 3.2)	< 0.001	0.3 (0.2, 0.5)	0.3	4.8	11.3	14.8
Endline	25.5 (5.5), n = 301	27.4 (6.3), n = 301	26.4 (6.0), n = 602	1.5 (0.3, 2.7)	0.016	0.2 (0.0, 0.4)	1.5	5.8		

Abbreviations: WHODAS, World Health Organization Disability Assessment Schedule; PHQ-9, Patient Health Questionnaire; PCL, Posttraumatic stress disorder Checklist; MSPSS, Multi-dimensional Scale of Perceived Social Support; SSS, Somatic Symptom Scale 8; RTC, Reducing Tension Checklist.

[a] *Based on the primary analytical model.*

TABLE 6: Intervention effects[a] on secondary binary outcomes (risk ratios and risk differences with 95% confidence intervals for the ITT population)

Secondary Binary Outcomes	n/N (%)		Estimated Treatment Effect			
	Control	PM+	Risk Ratio (95% CI)	*P*-value	Risk Difference in percentage points, pp, (95% CI)	*P*-value
Heart-Mind Problems						
Baseline	306/306 (100.0%)	305/305 (100.0%)	-	-	-	-
Midline	229/301 (76.1%)	184/303 (60.7%)	0.8 (0.7, 0.9)	0.004	-14.5pp (-24.4, -4.6)	0.004
Endline	209/301 (69.4%)	177/301 (58.8%)	0.8 (0.7, 1.0)	0.042	-10.2pp (-20.4, 0.0)	0.051
50% Reduction in PHQ-9 from Baseline						
Baseline	-	-	-	-	-	-
Midline	46/301 (15.3%)	74/303 (24.4%)	1.6 (1.0, 2.4)	0.041	9.2pp (0.9, 17.4)	0.029
Endline	52/301 (17.3%)	90/301 (29.9%)	1.7 (1.2, 2.4)	0.002	12.3pp (4.1, 20.4)	0.003

Abbreviations: PHQ-9, Patient Health Questionnaire.
[a] Using the modified Poisson approach (Zou & Donner, 2013)

Mediation analyses

The hypothesized mediator (skill use aligned with the treatment's mechanisms of action measured with the RTC) was greater in the Group PM+ arm at midline (RTC mean difference=2.1, 95% CI: 1.0, 3.2, p<0.001) and endline (RTC mean difference=1.5, 95% CI: 0.3, 2.7, p=0.016), see **Table 5**. The mediation analysis of RTC at midline mediating GHQ-12 reduction at endline, shows an estimated mediation effect of -0.4 relative to the estimated intervention effect of -1.3 (see **Figure 2**) so that the estimated relative portion of the Group PM+ effect on endline GHQ-12 that is mediated by midline RTC is 31%.

FIGURE 2. **Mediation Analysis**

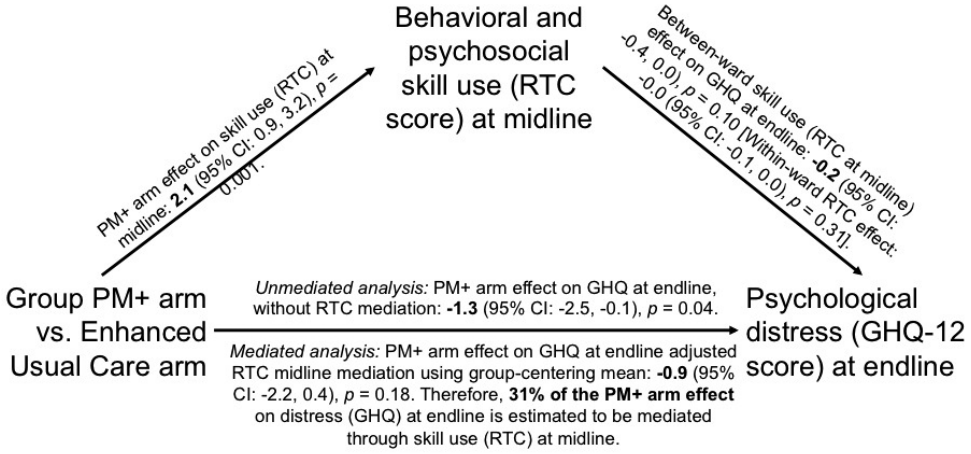

Figure 2: *Hypothesized pathway with model-estimated effects for mediation of behavioral and psychosocial skill use at midline on psychological distress at endline. Midline is 7 weeks post-baseline (after completion of the intervention in the Group PM+ arm). Endline is 20 weeks post-baseline (three months after completion of the intervention in the Group PM+ arm). Abbreviations: GHQ-12, General Health Questionnaire; PM+, Problem Management plus; RTC, Reducing Tension Checklist.*

Harms

There were 3 serious adverse events: 1 referral for domestic violence, 1 suicide death in the control arm, and 1 death due to a physical illness in the Group PM+ arm. No harms were attributable to participation in Group PM+ or study trial procedures based on reviews by the Data and Safety Monitoring Board.

DISCUSSION

This study evaluated effectiveness of Group PM+ for people with psychological distress in disaster-prone communities. Results show initially moderate treatment effects (SMD=0.40 post-treatment) and smaller benefits at 3-month follow-up (SMD=0.20) in reducing psychological distress. There were benefits in depression symptom reduction at 3-month follow-up (29.9% response rate in Group PM+ compared to 17.3% among controls), which translates to a 70% greater likelihood of reducing symptoms by half due to receiving Group PM+. Similarly, "heart-mind" problems (local idiom of distress) were present in 58.8% of Group PM+ participants compared to 69.4% of controls at 3-months follow-up. There were no significant between-group differences for other secondary outcomes at endline.

When comparing these results to other psychological treatments studies in low- and middle-income countries, the immediate reduction on psychological dis-

tress post-intervention (midline SMD of 0.40) is comparable to the pooled effect for treatments for common mental disorders (SMD=0.49) (Singla et al., 2017). It was lower than the pooled effect for treatments for depression in humanitarian settings (SMD=0.87) (Campbell et al., 2012). A cRCT similar to ours evaluating Group PM+ among women in Pakistan demonstrated larger effect sizes on all outcomes (Rahman et al., 2019).

A unique contribution of this study was evaluating potential mechanism of action: skill use aligned with the treatment's mechanism of action. We found that 31% of the treatment effect in reducing psychological distress at endline is mediated by participants' utilization of the therapeutic strategies underlying Group PM+. This suggests that efforts to increase and maintain skill use, such as giving booster sessions, could further enhance the benefit. Studying mechanisms of action may also determine who will most benefit from the intervention. For example, psychosocial and behavioral skills were high in this population at baseline (RTC mean of 26.9) compared to the population in the Group PM+ pilot study in a different district in Nepal (RTC baseline of 12.9) (Sangraula et al., 2020). Use of these skills may be greater in settings with higher education levels and greater access to resources, which were differences between our pilot and full trial site, possibly impacting the magnitude of treatment effect.

Another study strength was measuring competency of facilitators. Because non-specialist interventions are delivered by different cadres across settings, ranging from college graduate nurses to persons with only a high-school education (Kohrt et al., 2018), it is important to establish minimum criteria on standardized competency measures across settings and facilitator types. In this trial, we used ENACT, which is publicly available in a digital format through the WHO EQUIP project (Kohrt et al., 2020). By employing competency assessments, we excluded facilitators who had low skill levels, and supplemented skill gaps for those who were retained. By reporting competency levels achieved by facilitators in this trial, future programs implementing Group PM+ can compare the competency of their facilitators to determine if their skills are adequate for safe and effective intervention delivery.

The study demonstrated change in a locally meaningful outcome, "heart-mind" problems. Few prior studies have included locally salient outcomes (Cork et al., 2019), which are important to promote engagement, adherence, and scale-up, as well as minimize stigma (Kohrt et al., 2014; Kohrt & Harper, 2008). The study also included detailed documentation of services received by the control condition and reasons for dropout throughout the study, strict blinding, high retention, and rarity of missing data.

Limitations include lack of power to evaluate gender specific effects, as well as clustering of all male participants in one area of the district. Moreover, male participants on average were older. Therefore, we cannot make gender-specific conclusions about effectiveness. Future studies will need to adapt PM+ and test effectiveness for men. This is important because of the gap in interventions with

demonstrated effectiveness specifically for men (Singla et al., 2017). Future studies should also consider more objective measures of mechanisms of action that are less subject to self-report bias.

CONCLUSION

A rigorously conducted cRCT evaluated effectiveness of a brief group psychological intervention delivered by non-specialists without prior mental health training and a high-school education level. We found modest benefits of Group PM+ compared to enhanced usual care. To increase the public health benefit of Group PM+, additional effort should be placed on strengthening PM+ skill use. Future global mental health research should similarly attend to both competency and mechanisms of action to determine what works, how it works, and use this information to inform scaling up of psychological interventions in humanitarian emergencies and low-resource settings around the world.

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BENEFITS OF GROUP-BASED INTERVENTIONS

CHAPTER 7

The impact of group-based interventions: between and within group level effects

This chapters is based on: Sangraula, M., Wang, X., Turner, E.L., Ghimire, R., Shrestha, P., Luitel, N., Jordans, M.J.D., & Kohrt, B.A. (Under Review) Between and within group level effects for a brief group psychological intervention delivered by non-specialist providers in a humanitarian setting

ABSTRACT

Background

Group-based task-sharing psychological interventions are increasingly utilized in low- and middle- income countries (LMICs) to increase population reach and close the treatment gap. However, mechanisms that impact differences in outcomes between groups, such as rural vs. urban location, facilitator competency, and group cohesion, alongside the benefits of group interventions have rarely been studied in this context. These mechanisms were explored within a cluster randomized controlled trial (c-RCT) in Nepal for Group Problem Management Plus (PM+), a brief trans-diagnostic intervention delivered by lay-health workers.

Methods

This exploratory analysis was conducted with 36 clusters that received Group PM+ in Nepal. We utilized a four part methodology for this analysis: 1) adapted and tested a group cohesion scale with participants that received Group PM+, 2a) statistically explored impacts of facilitator competency, context (rural vs. urban setting), and group cohesion on between-group differences in general distress, participant skill use, and group cohesion using Intraclass Correlation Coefficient (ICC) scores and linear modeling, 2b) statistically explored potential impacts of facilitator competency and group cohesion on individual level changes in general distress outcomes using multi-level modeling, 3) identified participants' perceptions of group level processes using qualitative data. Facilitator competency was measured with various competency scales, including ENACT, GroupACT and a Fidelity Checklist.

Results

The average group size was 8.14 participants. There were 2 male and 10 female facilitators for a total of 251 female and 54 male Group PM+ participants. Between-group differences were greater for perceptions of group cohesion ($\rho = 0.32$) than between-group differences for changes in levels of general distress ($\rho = 0.06$) or uptake of skills ($\rho = 0.13$). Between-group differences were also greater for women's groups compared to men's groups. Facilitator competency contributed the most to between-group variance of group cohesion ($R^2 = 28.46\%$) and uptake of PM+ skills ($R^2 = 13.68$). Rural vs. urban cluster contributed the most to between-group variance of changes in general distress ($R^2 = 20.21$). Variables tested in the multilevel modeling for fixed effects on changes in general distress were not significant. The qualitative evaluation supported prior findings that group members have the potential to act as therapeutic agents for one another.

Conclusion

Findings highlight that facilitator competency, rural vs. urban context, and group cohesion has the potential to contribute to differences in outcomes between groups. These findings have practical implications on strengthening facilitator competency measurements and fostering group processes, such as cohesion, in group-based psychological

treatments. Future research is needed to confirm how much group-based mechanisms contribute to individual psychological outcomes in group intervention participants.

BACKGROUND

Group-based psychological interventions are increasingly utilized in low- and middle-income countries (LMICs) and often apply task-sharing methods, where non-specialists are trained to deliver the treatment. Group interventions are cited to have several benefits over individual treatment. They can reach a greater number of people at once, while training fewer non-specialists for service-delivery, which is especially beneficial for humanitarian and LMIC settings that have limited human and financial resources. The cost of group therapy is also considerably lower than the cost of individual therapy (Chiumento et al., 2017), though they are similar in long-term effectiveness (Cuijpers et al., 2008). Group interventions also have some inherent benefits, such as social support and the potential for group members to be therapeutic agents for one another (Yalom, 1995).

The effectiveness of most group interventions is measured by individual outcomes rather than analyzing between-group differences, though group interventions are inherently clustered (Krull & Mackinnon, 1999). Between-group differences refer to how two or more groups are different from one another. It is likely that participants in the same group share similarities because they reside within similar contexts, have non-randomly distributed background variables and share group experiences, which may also contribute to between-group differences (Krull & MacKinnon, 2001). However, group-based mechanisms that lead to change have rarely been studied within task-sharing interventions in LMICs. For example, the relationship between patient and therapist may be a predictive factor in individual treatment. For group-based interventions, group-level mechanisms such as geographical context, facilitator competency, and group cohesion may be more impactful (Cuijpers et al., 2008).

The first potential mechanism that is especially relevant for task-sharing group-based interventions is facilitator competency, which is defined as non-specific factors (such as warmth, empathy, listening skills) and specific skills unique to the intervention (Pedersen et al., 2020). Non-specialists (or group facilitators) have varying backgrounds, education levels, and prior experiences that could contribute to differing levels of facilitator competency even within a site. Differences in facilitator competency may also directly impact treatment outcomes (Kohrt et al., 2015), and contribute to between-group differences in outcomes.

The second potential mechanism of change is the geographical context in which the intervention takes place. Rural versus urban areas and their coinciding structural factors, such as population density and exposure to violence, result in differences in prevalence of mental illness (Peen et al., 2010). Geographical differences and the built environment also impact the quality of existing resources and sup-

port to cope with these stressors (Lund et al., 2018), and in turn may also impact how participants respond to treatment.

The third potential mechanism of change in a group-based intervention is group cohesion, described as a sense of connectedness and belonging to a therapeutic group (Yalom, 1995). From the perspective of a group member, group cohesion occurs on three structural levels: member- member, member-group, and member-facilitator (Burlingame et al., 2018). The quality of these three structural relationships sets the stage for group processes that allow members to engage in self-disclosure and personal exploration that could ultimately lead to therapeutic change (Burlingame et al., 2018; Tschuschke & Dies, 1994). Though studies in LMICs have noted that group cohesion may lead to different outcomes between groups (Murray et al., 2014), our study is the first to measure it within this context.

This study is part of a larger endeavor to increase the quality of care for LMIC populations by identifying how group psychological interventions can deliver the best results to participants that often lack access to other mental health care. Considering the existing lack of tools and statistical methods to investigate mechanisms of change in group-based interventions, our main objectives focus on addressing this gap in research. We employ a three part objective: 1) adapt and test a scale that measures individual participants' perception of group cohesion, 2a) statistically explore impacts of facilitator competency, context (rural vs. urban setting), and group cohesion on between-group differences in general distress, participant skill use, and group cohesion, 2b) statistically explore potential impacts of facilitator competency and group cohesion on individual level changes in general distress outcomes, 3) identify participants' perceptions of group level processes using qualitative data.

This analysis will be completed with the Group Problem Management Plus (Group PM+) intervention, which was tested for feasibility and acceptability as well as effectiveness in Nepal (Sangraula et al., 2020; van't Hof et al., 2020). Group PM+ is a brief intervention that trains non-specialists to deliver five trans-diagnostic sessions to participants with general distress symptoms (Dawson et al., 2015). Individual PM+ was tested in Pakistan and Kenya (Bryant et al., 2017; Rahman et al., 2016) and the group version has previously been tested in Pakistan (Rahman et al., 2019). Aside from evaluating the cost-effectiveness of group-based PM+ compared to individual (Chiumento et al., 2017), secondary analysis on additional benefits of the group-based version or further mechanisms that effect outcomes have not been conducted.

METHODS

Setting and Research Design

We conducted a two-arm, single-blind cluster randomized controlled trial (cRCT) in Morang, a district in Eastern Nepal (van't Hof et al., 2020). The Group PM+ arm

was compared to enhanced usual care (EUC) in participants with psychological distress. Of the 72 clusters, 14 were allocated to enroll only male participants and 56 for female, allowing for single-gender groups. Covariate constrained randomization was implemented to account for binary cluster-level covariates: rural/urban status, far/close proximity to health care, and high/low frequency flooding risk. We will only include the 36 clusters, and a total of 305 participants, that received the Group PM+ treatment for this group-based analysis.

Facilitator Supervision

Prior to intervention delivery, the Enhancement Assessment of Common Therapeutic Skills (ENACT) was administered to facilitators to assess for common therapeutic factors (Kohrt et al., 2015). The two male facilitators led a total of seven groups and the ten females facilitators led 29 groups. Each facilitator led a maximum of four groups and a minimum of three groups. Clinical supervisors attended at least two sessions out of every PM+ group and evaluated facilitator competency using various competency tools. Office supervision settings were also held twice a week to review facilitator competencies, discuss success, and address challenges (van't Hof et al., 2020).

Instruments and Tool Development

Outcome measures were administered at baseline (before the treatment), 7 weeks after baseline (mid-line or one-week post-treatment), and 20 weeks after baseline (end-line, 12 weeks after treatment) (van't Hof et al., 2020). Though many outcome measures were administered, this analysis will only focus on two outcomes: 1) individual psychological distress at end-line, the primary outcome in the effectiveness trial, measured using the General health Questionaire-12 (GHQ-12) (Goldberg, 1988), 2) uptake of PM+ psychosocial coping skills measured using the Reducing Tension Checklist (RTC), which was developed prior to the feasibility and acceptability Group PM+ trial (Sangraula et al., 2020). The RTC was also evaluated as a mediator to the primary outcome in the effectiveness trial (under review, Kohrt, Jordans).

A fidelity checklist (FC) and the Group Facilitation Assessments of Competencies Tool (GroupACT) were developed for clinical supervisors to evaluate facilitator competency during observed sessions. The fidelity checklist measured PM+ specific facilitator competencies. Though these competencies vary by session, examples include setting ground rules, reading case stories, and introducing and reviewing PM+ skills. Minimal research exists on identifying the key common factors that a group facilitator needs to successfully deliver a group-based intervention. The GroupACT was developed to fill this gap and measures the common factors necessary for facilitators to successfully deliver a group-based intervention (under review, Pederesen 2020). This included encouraging group participation, fostering empathy amongst group participation, and encouraging group confidentiality. Each competency on the GroupACT ranged from a score of 1 to 4 compared to 1 to

3 for the FC. The facilitators also used these tools as "cheat sheets" to ensure that they were addressing the required competencies during the sessions, and to reflect on successes and challenges.

To measure group cohesion, we adapted the Group Cohesion Scale Revised (GCS-R), a 25-item instrument with established reliability and validity (Treadwell et al., 2001; Veeraraghavan et al., 1996). To adapt the questionnaire, we removed several items that were not relevant to the Group PM+ intervention ("Group members are receptive to feedback and criticism") or did not fit into the Nepal context ("I feel vulnerable in this group"). We also removed items that were repetitive and vague ("Group members influence one another"). We conducted several rounds of cognitive interviewing with participants from practice groups and garnered their feedback to finalize a translated 12-item instrument. Ultimately, the questionnaire addressed three dimensions of group cohesion: member's own comfort and engagement in the group, member to member relationship, and group functioning as a unit (Burlingame et al., 2018). Research assistants were blinded to treatment arm throughout the study and administered the GCS-R to only the treatment arm (n=305), after conducting end-line assessments with all assigned clusters.

Statistical Analysis

For descriptive statistics, mean with standard deviation, median with lower quantile and upper quantile, range, as well as number of non-missing values with percentage of non-missing values were used to describe continuous variables, for the whole PM+ population, and for each gender; frequency of each category for the whole PM+ population, together with frequency of each category for each gender, were used to describe categorical variables.

For cluster randomized trials, individuals within the same cluster tend to be similar, and intraclass correlation coefficient (ICC) is commonly used to quantify the degree of similarities within clusters, with larger ICC (ρ) meaning more similarities within clusters (Brown et al., 2015). Specifically,

$$ICC = \frac{\tau^2}{\tau^2+\sigma^2},$$

where τ^2 is between-cluster variance and σ^2 is within-cluster variance (Singer, 1998; Snijders & Bosker, 1994). That is, ICC assesses the proportion of total variance that can be attributed to between-clusters. In this study, cluster is ward/group. Boxplots of each ward, with estimated ICC due to clustering by ward for the whole PM+ population and for each gender, were generated to display the distribution of outcome variables.

To evaluate the percentage of between-cluster variance in GHQ delta, RTC delta, and GCS that can be attributed to each fixed effect, i.e., ENACT, GroupACT, fidelity checklist (FC), rural vs. urban cluster, socio-demographics (including age, gender, education, occupation, caste group, religion, marital status, most used language, number of members in household, chronic disease, and persons living with), participant attendance, and GHQ/RTC baseline, the approach applied by Hruschka et

al. (2005) and described by Snijders and Bosker (1994) were used. Specifically, the percentage was estimated by the relative reduction in between-cluster variance after adding fixed variable(s) into analysis, and the formula is:

$$R^2_{Between} = 1 - \frac{\tau_1^2 + \frac{\sigma_1^2}{n}}{\tau_2^2 + \frac{\sigma_2^2}{n}},$$

where τ_1^2 and τ_2^2 are the between-cluster variances from analysis (1) containing the fixed variable(s) and (2) not containing the fixed variable(s) respectively, σ_1^2 and σ_2^2 are the residual variances from analysis (1) and (2) respectively, and n is the harmonic mean of cluster size (i.e., number of participants in each ward). For each analysis, the linear mixed model was used to model the outcome variable, with corresponding fixed variable(s) as fixed effect, and with ward as random effect to account for clustering by ward. In addition, since random variations and model misspecifications can affect the estimates of between-cluster variances, this approach can sometimes lead to a negative R^2. As pointed by Hruschka et al. (2005), when the fall below zero is small, it can indicate random variations, and demonstrate the fixed effect explains little of between-cluster variance in outcome variable.

Linear mixed models were fit using Stata multilevel mixed-effects linear regression procedure MIXED. All analyses were performed using Stata 15 (StataCorp, 2017). All boxplots were generated using R 4.0.2 (R Core Team, 2020).

Qualitative evaluation

Qualitative interviews followed a semi-structured interview guide. Key informant interviews were conducted with 4 male and 4 female non-completer participants (participants that did not complete 5 sessions), 4 male and 4 female completer participants (participants that completed 5 sessions), 8 family members of participants, and clinical supervisors (n=2). Two focus groups were conducted with program facilitators (n=6 in each group) and a focus group was conducted with a group that continued to meet after sessions were completed. All qualitative interviews were conducted after participants completed their end-line assessments. Though the interviews explored a variety of questions on program utility, acceptability and perceived intervention effectiveness, this analysis focused specifically on exploring group-based mechanisms and participants' personal experiences participating in a psychological group intervention. Data was analyzed using a thematic content analysis approach, to understand patterns in participants' experiences. Interviews were first recorded, and the focus groups were transcribed verbatim. All interviews were then translated into English for subsequent analysis. Researchers coded interviews based on themes identified in the semi-structured interview guide and along with other group-based themes from the data. Data were then reviewed by code and quotes were identified that illustrated significant themes.

Ethics

Ethical approval was obtained from the National Health Research Council (NHRC, reg #371/2016) and the WHO Ethical Review Committee (ERC.0002817). All study

participants were enrolled to the study only after voluntary consent and all participants provided a separate written consent prior to conducting qualitative interviews.

RESULTS

Descriptive statistics: Socio-demographics and Individual Level Outcomes

The individual level descriptive statistics were analyzed separately by gender because single-gender groups represent each cluster **[Table 1].** 17.5% (n=54) of the 305 participants were men compared to 82.3% (n=251) women. Male and female participants were distributed almost evenly between rural (women = 50.6%, men = 46.3%) and urban (women = 49.4%, men = 53.7%) clusters, with a slightly higher proportion of men in urban clusters. Male participants (54.0 [SD 17.1]), on average, were older than female participants (43.6 [SD 13.6]) by approximately 11 years. Female participants ranged from 18 to 91 years and male participants ranged from 21 to 85 years. Majority of both male and female participants were Brahmin/Chhetri (male = 44.4% and female = 34.3%). Males and females were distributed evenly amongst Janajati and Other caste categories but there was a greater proportion of local indigenous females (20.7%) compared to males (9.3%). Males and females had similar average GCS-R scores (20.9 [SD=4.4] and 20.2 [SD=4.6] respectively). GHQ-12 (women = -2.8 [SD=6.5] and men = -4.5 [SD=7.6]) and RTC delta (women= -0.7 [SD=6.9] and men = 2.6 [7.0]) average scores were slightly greater for men compared to women.

TABLE 1. Characteristics for females vs. males of PM+ groups

	Female (N = 251)	**Male** (N = 54)	**Total** (N = 305)
GHQ-12 BL			
Mean (SD) Median (Q1, Q3) Min, Max N (% Non-missing)	20.8 (6.0) 20.0 (16.0, 25.0) 4.0, 35.0 251 (100.0%)	23.3 (7.2) 24.5 (20.0, 27.0) 5.0, 35.0 54 (100.0%)	21.2 (6.3) 21.0 (17.0, 26.0) 4.0, 35.0 305 (100.0%)
GHQ-12 EL			
Mean (SD) Median (Q1, Q3) Min, Max N (% Non-missing)	18.0 (6.5) 18.0 (13.0, 22.0) 3.0, 36.0 249 (99.2%)	18.7 (8.7) 18.5 (12.5, 25.0) 0.0, 34.0 52 (96.3%)	18.1 (7.0) 18.0 (13.0, 22.0) 0.0, 36.0 301 (98.7%)
GHQ-12 delta (BL to EL)			
Mean (SD) Median (Q1, Q3) Min, Max N (% Non-missing)	-2.8 (6.5) -2.0 (-7.0, 1.0) -22.0, 18.0 249 (99.2%)	-4.5 (7.6) -3.0 (-8.5, -0.5) -28.0, 8.0 52 (96.3%)	-3.1 (6.7) -3.0 (-7.0, 1.0) -28.0, 18.0 301 (98.7%)

RTC BL1			
Mean (SD) Median (Q1, Q3) Min, Max N (% Non-missing)	27.7 (6.4) 28.0 (23.0, 32.0) 10.0, 46.0 251 (100.0%)	26.3 (6.8) 27.5 (20.0, 32.0) 13.0, 40.0 54 (100.0%)	27.5 (6.5) 28.0 (23.0, 32.0) 10.0, 46.0 305 (100.0%)
RTC EL			
Mean (SD) Median (Q1, Q3) Min, Max N (% Non-missing)	27.1 (6.2) 27.0 (23.0, 31.0) 10.0, 46.0 249 (99.2%)	29.1 (6.5) 29.0 (26.0, 33.5) 14.0, 41.0 52 (96.3%)	27.4 (6.3) 27.0 (24.0, 32.0) 10.0, 46.0 301 (98.7%)
RTC delta (BL to EL)			
Mean (SD) Median (Q1, Q3) Min, Max N (% Non-missing)	-0.7 (6.9) -1.0 (-5.0, 3.0) -27.0, 29.0 249 (99.2%)	2.6 (7.0) 3.0 (-3.0, 7.5) -13.0, 21.0 52 (96.3%)	-0.2 (7.0) 0.0 (-4.0, 4.0) -27.0, 29.0 301 (98.7%)
GCS-R1			
Mean (SD) Median (Q1, Q3) Min, Max N (% Non-missing)	20.9 (4.4) 21.0 (18.0, 24.0) 3.0, 31.0 241 (96.0%)	20.2 (4.6) 20.0 (17.0, 23.0) 10.0, 30.0 47 (87.0%)	20.8 (4.5) 21.0 (18.0, 24.0) 3.0, 31.0 288 (94.4%)
Age (years)			
Mean (SD) Median (Q1, Q3) Min, Max N (% Non-missing)	43.6 (13.6) 42.0 (34.0, 52.0) 18.0, 91.0 251 (100.0%)	54.0 (17.1) 53.5 (38.0, 65.0) 21.0, 85.0 54 (100.0%)	45.5 (14.8) 44.0 (35.0, 55.0) 18.0, 91.0 305 (100.0%)
Gender			
Male Female	0 (0.0%) 251 (100.0%)	54 (100.0%) 0 (0.0%)	54 (17.7%) 251 (82.3%)
Rural/Urban			
Rural Urban	127 (50.6%) 124 (49.4%)	25 (46.3%) 29 (53.7%)	152 (49.8%) 153 (50.2%)
Caste groups			
Brahmin/Chhetri Local indigenous Janajati Other	86 (34.3%) 52 (20.7%) 61 (24.3%) 52 (20.7%)	24 (44.4%) 5 (9.3%) 12 (22.2%) 13 (24.1%)	110 (36.1%) 57 (18.6%) 73 (23.9%) 65 (21.3%)

Abbreviations: General Health Questionnaire-12 (GHQ-12), Reducing Tension Checklist (RTC), Group Cohesion Scale Revised (GCS-R), Baseline (BL), Endline (EL)

Descriptive Statistics: Facilitator Competency

GroupACT and FC scores were evaluated by the Clinical Supervisors for 77 of the 180 sessions delivered by the facilitators. Average GroupACT and FC competency scores were similar across evaluated sessions **[Table 2].** Average GroupACT score

per facilitator ranged from 3.0 to 3.9 with a total average across facilitators of 3.4 (SD=0.4), and min/max of 2.6 and 4.0 **[Table 3].** Average FC score per facilitator ranged from 2.8 to 3.0 with a total average across facilitators of 2.8 (SD=0.1), and min/max of 2.5 and 3.0. ENACT scores ranged 30.0 to 50.0, with a total average of 40.0 across the 12 facilitators. The scatter plots show variability of competency outcomes according to clusters and illustrate that facilitators had different average ENACT scores and GroupACT and FC scores for the different groups they led **[Figures 1, 2, and 3].**

TABLE 2: Average GroupACT and FC for each session[a]

	n[b]	Mean	SD	Median	Min	Max
GroupACT						
Session 1	16	3.5	0.4	3.6	2.6	4.0
Session 2	14	3.3	0.4	3.3	2.6	4.0
Session 3	13	3.4	0.5	3.6	2.7	4.0
Session 4	16	3.4	0.5	3.4	2.6	4.0
Session 5	16	3.5	0.4	3.6	2.7	4.0
FC						
Session 1	18	2.8	0.2	2.8	2.4	3.0
Session 2	13	2.8	0.1	2.8	2.4	3.0
Session 3	11	2.9	0.2	3.0	2.6	3.0
Session 4	15	2.7	0.1	2.8	2.4	2.9
Session 5	20	2.8	0.1	2.9	2.7	3.0

a Average values of GFS and FC are computed for each session of each ward, and then summarized here for each session across wards.

b GFS and FC data is unavailable for session 5 of ward S9; GFS data is unavailable for session 1 of ward P1; FC data is unavailable for session 5 of ward P1. Thus, the number (n) of sessions included to generate summary statistics in Table 4 is different from the number (N) of supervision sessions listed in Table 3.

TABLE 3: **Summary Statistics of Facilitator Competency Measures: GroupACT/FC/ENACT**

Facilitator	Number of Wards	GroupACT			FC			ENACT
		Mean (SD)	Median (Q1, Q3)	Min, Max	Mean (SD)	Median (Q1, Q3)	Min, Max	
1	N = 4	3.5 (0.4)	3.6 (3.3, 3.8)	3.0, 3.9	2.8 (0.2)	2.9 (2.7, 2.9)	2.6, 3.0	50.0
2	N = 4	3.9 (0.2)	3.9 (3.8, 4.0)	3.6, 4.0	2.9 (0.1)	2.9 (2.9, 3.0)	2.8, 3.0	47.0
3	N = 3	3.3 (0.5)	3.0 (3.0, 3.9)	3.0, 3.9	2.9 (0.2)	3.0 (2.7, 3.0)	2.7, 3.0	37.0
4	N = 3	3.6 (0.3)	3.8 (3.2, 3.8)	3.2, 3.8	2.9 (0.1)	2.9 (2.9, 3.0)	2.9, 3.0	30.0
5	N = 2	3.1 (0.6)	3.1 (2.6, 3.5)	2.6, 3.5	2.5 (0.1)	2.5 (2.5, 2.6)	2.5, 2.6	35.0
6	N = 4	3.6 (0.3)	3.6 (3.5, 3.8)	3.4, 4.0	2.8 (0.1)	2.8 (2.7, 2.8)	2.7, 2.8	48.0
7	N = 2	3.4 (0.6)	3.4 (3.0, 3.9)	3.0, 3.9	2.7 (0.1)	2.7 (2.6, 2.7)	2.6, 2.7	35.0
8	N = 4	3.3 (0.6)	3.4 (2.8, 3.8)	2.6, 3.8	2.8 (0.2)	2.8 (2.6, 2.9)	2.5, 3.0	33.0
9	N = 3	3.5 (0.3)	3.6 (3.2, 3.7)	3.2, 3.7	2.8 (0.1)	2.8 (2.8, 2.9)	2.8, 2.9	38.0
10	N = 3	3.1 (0.4)	2.9 (2.9, 3.5)	2.9, 3.5	2.7 (0.1)	2.8 (2.6, 2.8)	2.6, 2.8	39.0
11	N = 2	3.1 (0.4)	3.1 (2.9, 3.4)	2.9, 3.4	2.8 (0.1)	2.8 (2.7, 2.8)	2.7, 2.8	31.0
12	N = 2	3.0 (0.5)	3.0 (2.6, 3.3)	2.6, 3.3	2.8 (0.0)	2.8 (2.8, 2.8)	2.8, 2.8	47.0
Total	N = 36	3.4 (0.4)	3.5 (3.0, 3.8)	2.6, 4.0	2.8 (0.1)	2.8 (2.7, 2.9)	2.5, 3.0	40.0

FIGURE 1. **Scatterplot of GroupACT**

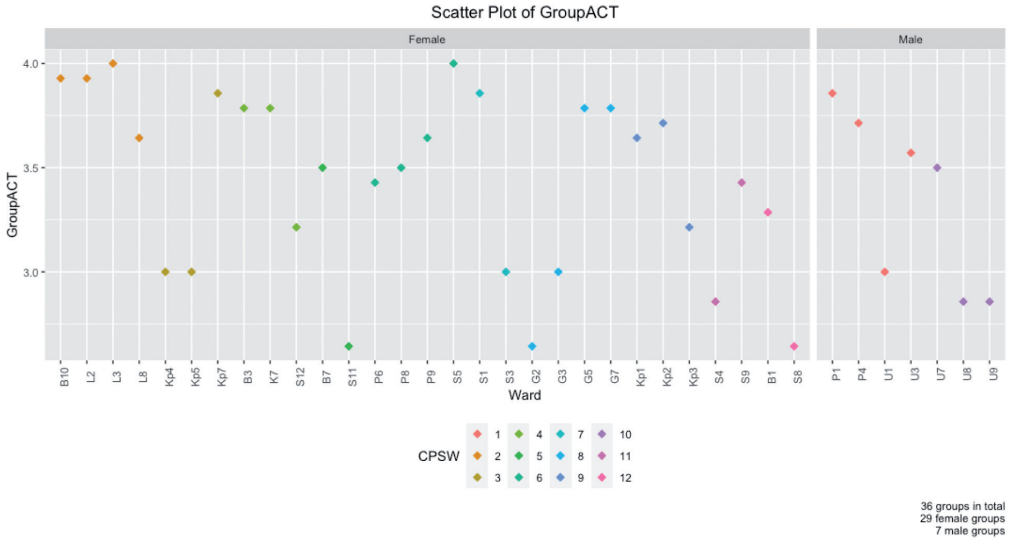


FIGURE 2. **Scatterplot of Fidelity Checklist**

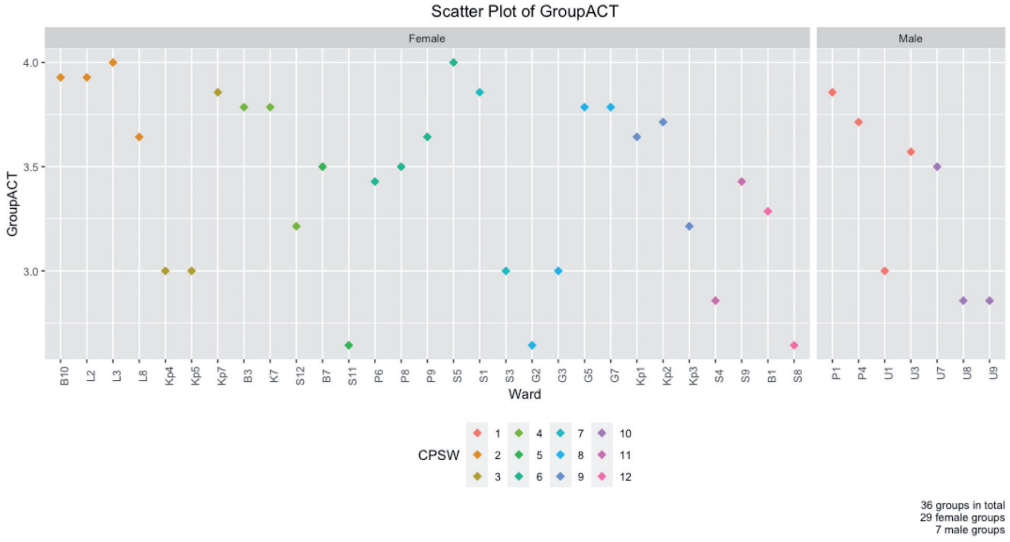
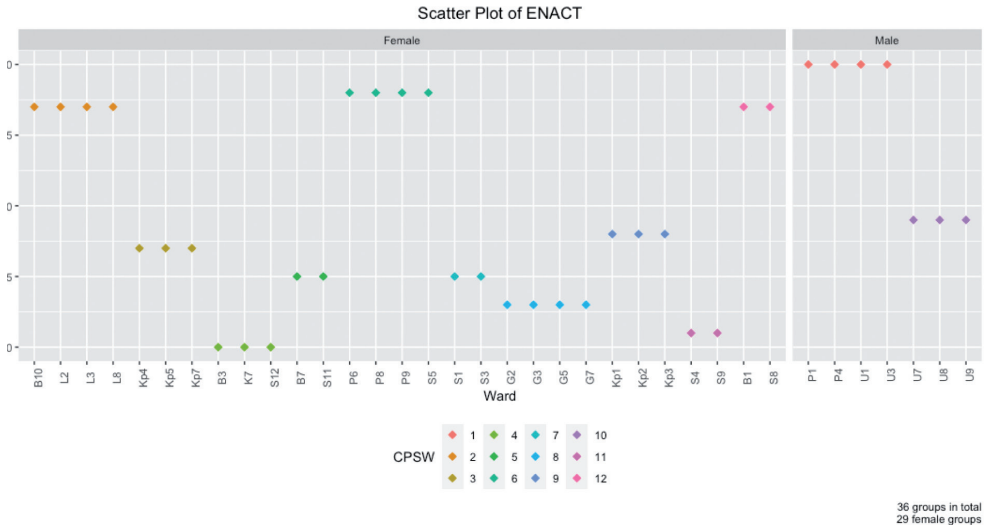


FIGURE 3. Scatterplot of ENACT



Intraclass Correlation Coefficient (ICC)

ICCs (ρ) were calculated for male and female groups separately and all groups together for three outcomes (GHQ delta, RTC delta, and GCS-R) to assess the proportion of total variance that can be attributed to between-group differences. Overall, the analysis determined that individual participant outcomes for GHQ-12 delta, RTC delta, and GCS-R were more similar to the outcomes of other individuals in the same group in the women's PM+ groups compared to men's groups. For changes in levels of general distress (GHQ-12 delta) average $\rho = 0.09$ for the 29 women's groups compared to $\rho = <0.001$ for the 7 men's groups, with an average $\rho = 0.07$ for all 36 groups. For changes in levels of skill use uptake (RTC delta) the average $\rho = 0.12$ for the 29 women's groups compared to $\rho = 0.04$ for the 7 men's groups, with an average $\rho = 0.13$ for all 36 groups. GCS-R scores demonstrated the largest between-group differences, with $\rho = 0.34$ for women's groups and $\rho = 0.28$ for men's groups, with an average of $\rho = 0.24$. **Figures 4, 5, and 6** represent box plots with clusters (wards, or PM+ groups) on the *x* axis and outcome scores on the *y* axis. The twelve non-specialists and the single-gender groups they facilitated are color-coded within the box plots to visually note the differences in range of outcomes and any outliers, that lead to differences in ICC scores.

FIGURE 4. **Boxplots of GHQ delta from Baseline to Endline**

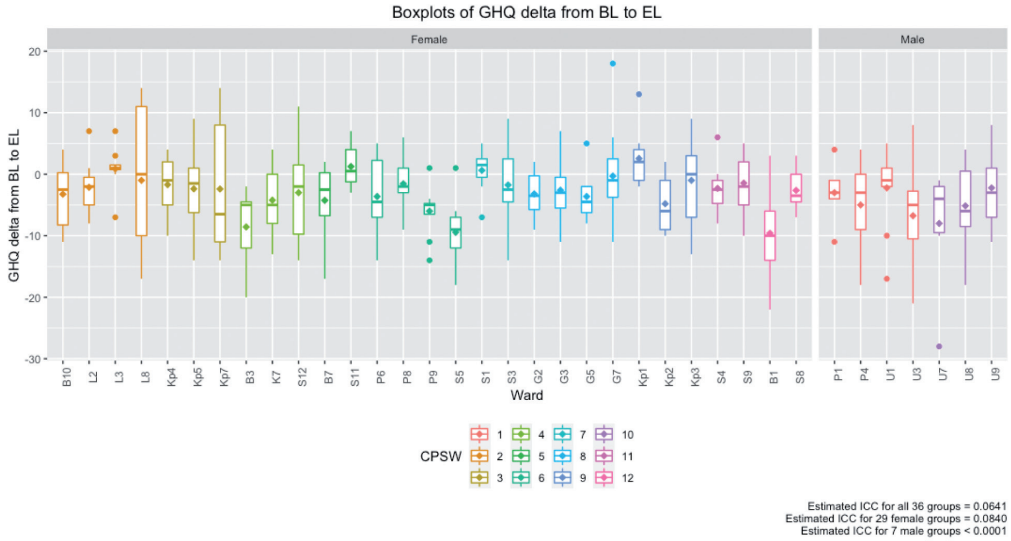


FIGURE 5. **Boxplots of RTC delta from Baseline to Endline**

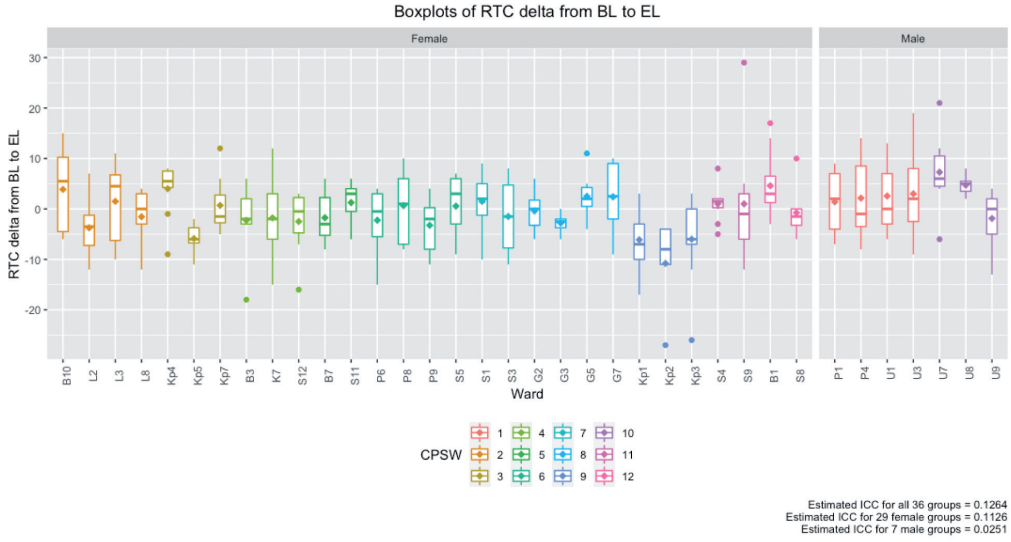
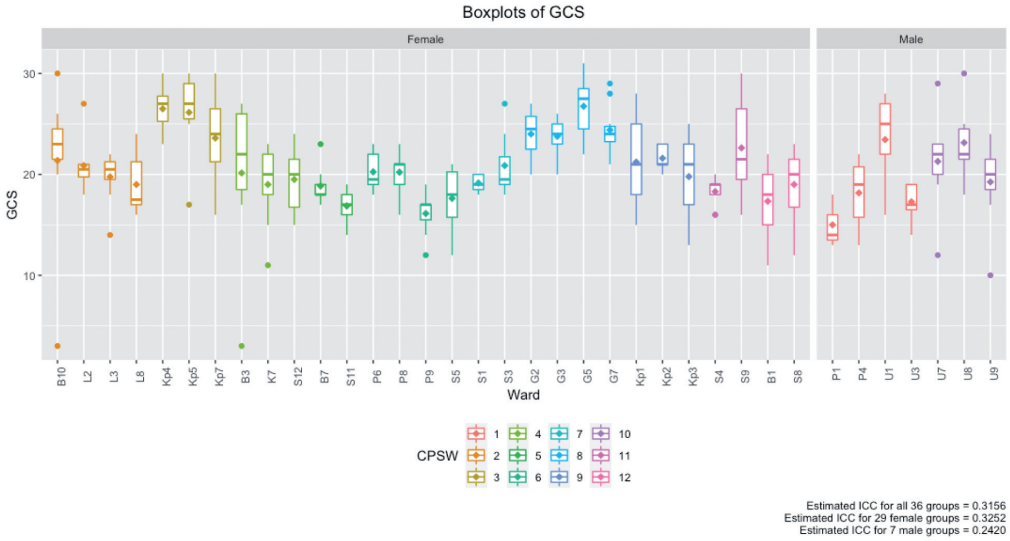


FIGURE 6. **Boxplots of GCS-R**



Model-based Results

6.12% of the between-group variance (R^2) in changes in levels of general distress was attributed to facilitator competency (which included three fixed variables: ENACT, GroupACT, and Fidelity Checklist) and 20.21% of the variance was attributed to rural vs. urban cluster **[Table 4].**

TABLE 4: Between-group variation in GHQ delta, RTC delta, and GCS

Fixed Effect(s)[d]	GHQ Delta[a]			RTC Delta[b]			GCS-R[c]		
	Variance Components		Estimated Percentage[e] of Between-Group Variance in GHQ Delta Attributed to Fixed Effect	Variance Components		Estimated Percentagec[f] of Between-Group Variance in RTC Delta Attributed to Fixed Effect	Variance Components		Estimated Percentage[g] of Between-Group Variance in GCS-R Attributed to Fixed Effect
	Between-Group	Residual		Between-Group	Residual		Between-Group	Residual	
Between-Group Variables[h]									
ENACT (Facilitator Level)	2.46	42.53	5.48%	5.85	43.04	3.24%	5.13	13.53	14.01%
Group Facilitation Scale	2.77	42.46	1.77%	6.23	43.04	0.00%	6.09	13.55	1.98%
Fidelity Checklist	2.82	42.46	1.10%	5.34	43.08	7.64%	5.85	13.54	5.06%
Facilitator Competency[i]	2.41	42.51	6.12%	4.65	43.08	13.68%	3.97	13.50	28.46%
Rural vs. Urban Cluster	1.26	42.53	20.21%	5.79	43.01	3.78%	5.55	13.55	8.68%
Within-Group Variables									
Socio-demographics[j]	2.02	35.71	21.20%	5.58	34.90	14.33%	4.74	10.87	23.17%
Participant Attendance	2.95	42.45	-0.41%	6.56	42.63	-2.48%	5.45	12.08	12.34%
GHQ/RTC Baseline	2.97	33.98	12.12%	7.64	25.77	6.16%	6.41	13.44	-1.75%
GCS	3.45	42.06	-5.98%	7.22	42.29	-7.87%	-	-	-

[d] *Each row indicates one model with fixed effect presented in the first column and ward as random effect to account for clustering by ward. Results in column 2-4 are from data of all 36 PM+ groups for GHQ delta; results in column 5-7 are from data of all 36 PM+ groups for RTC delta; results in column 8-10 are from data of all 36 PM+ groups for GCS.*

[e] *I used the approach applied by Hruschka et al. (2005) and described by Snijders and Bosker (1994) to estimating the percentage of between-group variance in GHQ delta attributed to corresponding fixed effect. Specifically, the percentage was estimated by the relative reduction in between-cluster variance after adding fixed variable(s) into analysis, and the formula is:* $R^2_{Between} = 1 - \frac{\tau_1^2 + \frac{\sigma_1^2}{n}}{\tau_2^2 + \frac{\sigma_2^2}{n}}$ *, where* τ_1^2 *and* τ_2^2 *are the between-cluster variances from analysis (1) containing the fixed variable(s) and (2) not containing the fixed variable(s) respectively,* σ_1^2 *and* σ_2^2 *are the residual variances from analysis (1) and (2) respectively, and n is the harmonic mean of cluster size (i.e., number of participants in each ward). In this case for GHQ delta,* τ_2^2 *and* σ_2^2 *are values presented in [a],* τ_1^2 *and* σ_1^2 *are values presented in the 2nd and 3rd column of Table 2 for corresponding fixed variable(s). There are 301 participants with available GHQ delta, and the harmonic mean of group size is 8.14. In addition, since random variations and model misspecifications can affect the estimates of between-cluster variances, this approach can sometimes lead to a negative* R^2*. As pointed by Hruschka et al. (2005), when the fall below zero is small, it can indicate random variations, and demonstrate the fixed effect explains little of between-cluster variance in outcome variable.*

[f] *Same approach was used as described in [e]. In this case for RTC delta* τ_2^2 *and* σ_2^2 *are values presented in [b],* τ_1^2 *and* σ_1^2 *are values presented in the 5th and 6th column of Table 2 for corresponding fixed variable(s). There are 301 participants with available RTC delta, and the harmonic mean of group size is 8.14.*

[g] *Same approach was used as described in [e]. In this case for GCS,* τ_2^2 *and* σ_2^2 *are values presented in [c],* τ_1^2 *and* σ_1^2 *are values presented in the 8th and 9th column of Table 2 for corresponding fixed variable(s). There are 288 participants with available GCS, and the harmonic mean of group size is 7.61.*

[h] *For between-group variables, only ENACT is at facilitator level, i.e., each facilitator has one ENACT score that applies to all of the wards within that facilitator. All other between-group variables (i.e., group facilitation scale, group facilitation scale, and rural vs. urban cluster) are at group level., i.e., each ward has one score for each of these variables.*

[i] *The facilitator competency includes: ENACT, group facilitation scale, and fidelity checklist. In contrast to the first three rows, which includes only one fixed variable in each model, this model includes three fixed variables, i.e., ENACT, group facilitation scale, and fidelity checklist. As a consequence, the estimated percentage of variance explained in this model doesn't equal to the sum of the three numbers obtained from the first three models.*

[j] *The socio-demographics includes age category, gender, education, occupation, caste group, religion, marital status, most used language, number of members in household, chronic disease, and persons living with.*

For changes in level of PM+ skill use uptake, R^2= 13.68% for facilitator competency and R^2 = 3.78% for rural vs. urban cluster. For changes in level of PM+ skill use uptake, R^2 = 13.68% for facilitator competency and R^2 = 3.78% for rural vs. urban cluster. For fixed level effects on the individual perceptions of group cohesion, R^2 = 28.46% for facilitator competency and R^2 = 8.68% for rural vs. urban cluster. Facilitator competency attributed the highest between-group variance for GCS-R and rural vs. urban cluster for GHQ-12 delta. Of the within-group fixed effects, the R^2 for participant attendance and GCS-R for GHQ and RTC delta were below 0, meaning random variations and that the fixed effect explains little of between-cluster variance in outcome (Hruschka et al., 2005). Socio-demographics contributed to higher between-group variations for all three measures compared to the other within-group variables. Of the variables tested in the multilevel modeling for fixed effects on GHQ delta, all five were not significant **[Table 5].**

TABLE 5: Fixed effects on GHQ-12 delta[a]

Variable	Estimated Fixed Effect	
	Point Estimate (95% CI)	***P*-value**
ENACT (Facilitator Level)	-0.08 (-0.24, 0.08)	0.325
FC (Group Level)	-2.44 (-11.64, 6.75)	0.602
GroupACT (Group Level)	-1.17 (-4.09, 1.74)	0.430
GCS-R	-0.08 (-0.28, 0.12)	0.447
RTC Baseline	0.09 (-0.03, 0.22)	0.150

[a] *The following variables were included as fixed effects: socio-demographics (including age category, gender, education, occupation, caste group, religion, marital status, most used language, number of members in household, chronic disease, and persons living with), ENACT, FC, GroupACT, GCS, RTC baseline. Ward was included as random effect to account for clustering by ward*

Qualitative Findings

Because of existing cultural stigma around mental health issues, participants noted entering the group sessions feeling as if they were the only ones who suffered from mental health problems. The group intervention facilitated a space for the participants to share their personal stressors that they previously may not have discussed with others. Both male and female participants noted that the act of sharing their problems with others in the group led them to feel less stressed. Because each group had participants with a range of adversity levels and stressors, participants were able to compare their problems with others in their groups, which allowed them to gain perspective of their own problems in comparison. Some participants also noted specific members of the group whose stories had an impact on them. Through these group processes, participants acted as therapeutic agents for one another (Yalom, 1995).

Participants had varied responses about their preference for group composition. Most participants noted that groups with participants of different ages was beneficial to group processes because they were able to learn from each other. Few participants noted that they initially felt uncomfortable sharing a space with people from different backgrounds (i.e. caste or class) at first, but these feelings eased throughout the intervention. Others noted that group processes, such as learning the PM+ techniques, would have been easier if members of a group were similar in age and in language fluency, so that all participants could learn at the same speed. Participants also mentioned that when some group members were not engaged throughout the session, it changed the group dynamic and made the sessions less engaging. While some participants noted that they enjoyed attending the sessions with friends and neighbors, others noted that they would feel more comfortable with group members who they did not know prior to the intervention. This is in line with previous findings (Khan et al., 2019; Sangraula et al., 2020).

Participants also noted additional benefits from group-based interventions beyond the normalization of mental health problems, such as recognizing the importance of social support. For example, a female participant also noted gaining the confidence to speak in front of a group. One group formally met with almost all participants at least four times after the intervention. During these meetings, participants would review the PM+ techniques and share their "happiness and sorrows". Participants in the post-intervention group meetings found it especially helpful to discuss the problem-solving skills with a group, because they were able to receive many possible solutions to their problems from other group members. Some participants noted making new friends that they informally meet with outside of the intervention and noted supporting one another through challenges, such as health problems or unemployment. These findings demonstrate that group-based interventions may lead to longer term social support to lower psychological distress over time.

TABLE 6. **Qualitative Outcomes**

Themes	Quotes
Group composition (age, caste, etc.)	*"I think it would have improved [if people of same age were in a group]. There were some people in the group who did not understand what we discussed in the program while other understood it easily…because of age and language."* Male participant *"People living in a same age have very different problems. I don't care about age. I like to sit with elder people as I get to learn from their experiences. I seek advice from them… I felt awkward at first [sitting with people from different castes]. Later, I was comfortable."* Female participant *"I feel comfortable in the same group with the people living far. Neighbors backbite and might talk nonsense with others so we cannot speak openly in front of them. While sharing sorrows, everyone listens but at the time of anger, they may bring out what we shared. I would not attend the program [if the participants were neighbors] because we often meet them. We do not meet the people living far [outside of the sessions]"* Female participant *"There were 2-3 participants who did not show interest in the group. It changes the environment. Time is wasted in the following up with them."* Female participant
Normalization of MH issues in a group	*"Everyone shared their feelings and problems. At home I used to think only I have the stress in my life. The discussion made me realize that I am not only person. My problems seemed smaller while listening to the disheartening story of the other people."* Female participant *"At home, we are helpless staying alone. We don't find anyone to share problems with because of our fear of stigma. But if we get to meet people we don't know, we can share our problems and listen to their problems. While listening to others' problems our stress relieve itself. Earlier I used to think I was the only person living stressful life, Nowadays I don't think so… There is pain deep inside my heart. Anyway, I must face the problems. I am not alone."* Female participant *"After sharing my pain and suffering, I got help from them and also by sharing problems [with others] I felt like my problems were decreased to some extent."* Male participant *"I used to listen to the problems of one sister [in the group]. She had lots of problems. She is courageously living despite of all these problems…Compared to her problems, there is no problem in my life…Whenever I am in trouble, I remember her. She has lots of problems but still she keeps smiling. It helps me to stop my thoughts on my problems."* Female participant

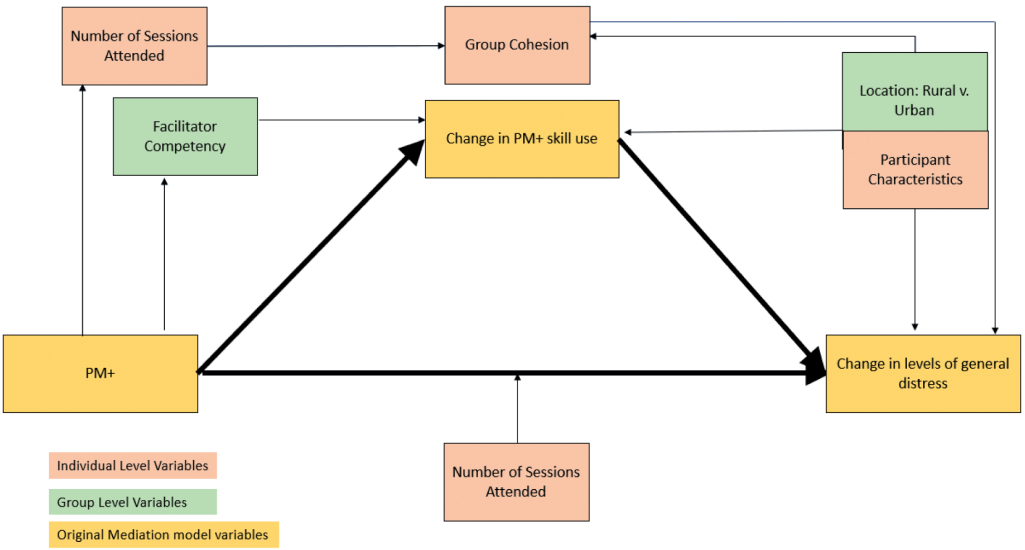
Additional benefits of a group intervention	*"If someone says something to us then group of five/six people can come up with the ideas to solve the problem. If we have our hard time, our group can help us. We can help each other; this was the lesson we learned from the program. Even for problems at home and if we get sick, we need a group…the program made this clear"* Male participant *"She [facilitator] taught us the ways of giving introduction and skills of communication in the first class. By seeing the fellow participants, I was motivated, and I learnt the way of giving an introduction…Now I can give my introduction. If there is any program, I can speak Infront of the audience."* Female participant *"I was feeling odd at first…I had never done this before…Its difficult to face strangers. I had a fear that they might judge me and understand my words in a negative sense. Gradually I felt comfortable after the program proceeded. I am happy to overcome my fear."* Female participant
Support beyond intervention	*"I find this program quite satisfying and also I made some new friends…we are supposed to meet on Tuesday… we are just planning to have some snacks and talk with each other."* Male participant *"She told me that she made friends in there [the program]…So, my mother said she also wanted to go there because they can talk about their problems and share all their troubles. She also liked the attitude of the peoples in program. She told that it is good to share problems and make new friends…they learned about how to move forward in life, how to recover from troubles."* Family member of female participant *"If someone is in trouble. If he is very sick or he needs support. We should give support to them…He [a group member] said he was unemployed. He was poor. We [the group] went to the nearby poultry farm and helped him to get the job. He is working now."* Male participant *"Some are further away so they can't come [to the group meetings after sessions ended]. Everyone leads. First, we talk. Then we go over the exercises. Then we discuss our happiness and sorrow. Then we go home. We have met every month since it ended. We have met about three or four times…it has really helped us."* Female participant

DISCUSSION

To the best of our knowledge, this is the first study that explores specific group-based mechanisms in task-sharing group psychological interventions in an LMIC setting. Our analysis demonstrates that mechanisms, such as facilitator competency and contextual settings attribute to between-group differences in group cohesion and psychological outcomes. Male participants' changes in general distress, changes in uptake of therapeutic techniques, and perceptions of group cohesion were consistently less attributed to what group they were in when compared to female participants. One interpretation of this finding could be that males are less impacted by group level effects and processes, such as who else is in their thera-

peutic group. However, this interpretation should be taken with caution because the sample size of men was much smaller than women. We developed a conceptual model, by adding on the mediation model established in the Group PM+ effectiveness trial (under review, Kohrt, Jordans), to visualize the potential relationships between the group and individual level variables explored in this analysis **[Figure 7].** The conceptual model includes both individual and group level variables and highlights that facilitator competency, participant's individual characteristics, and rural vs. urban location may mediate changes in PM+ skill use. The number of sessions attended may impact group cohesion which may in turn impact changes in general distress. This conceptual model provides a basis for future research, which is necessary to confirm the proposed relationship between variables.

FIGURE 7. **Conceptual Model**



Our findings show that context of intervention delivery is important. 20% of the between-group differences in general distress changes were attributed to whether the intervention group was in a rural or urban cluster. The multilevel model showed that the setting was more influential than facilitator competency on between-group variance in general distress changes. Our findings are also supported by prior studies where urban settings have lower effect sizes for mental health treatments when compared to rural settings (Arjadi et al., 2015). Urban versus rural location of the intervention may also correlate with other contextual factors, such as participant education level, resources available in the area or stigma for receiving treatment, that could act as potential moderators (Jones et al., 2011; Thornicroft, 2008).

Consistent with prior findings, our analysis shows that facilitator competency is important in care delivered by non-specialists (Kohrt et al., 2015; Singla et al., 2014),

though has received little attention and progress (Jordans et al., 2013). Facilitator competency, especially the ENACT scores of facilitators, had the largest impact in between-group variation for group cohesion (R^2 =28.69%). Common factors in group interventions have been previously linked with better mental health outcomes (Burlingame et al., 2018) and our findings suggest that facilitators' use of common factors in group interventions could foster group cohesion. Group management skills, as measured by the GroupACT, did not have a measurable impact on between-group variance in the uptake of therapeutic skills. Uptake of skills was more attributed to how much facilitators were adherent to the intervention, as measured by the fidelity checklist.

Though our analysis detected a relationship between changes in general distress and facilitator competency, these effects were not statistically significant. Because the competency scales were measured at the group or facilitator level, they had the same values for multiple participants, which led to a lack of variation in facilitator competency outcomes. Both the ENACT and fidelity checklist were measured on a three-point scale (i.e. needs improvement, done partially, done well) (Kohrt et al., 2015; Sangraula et al., 2020), whereas the GroupACT was measured on a four-point scale (Pedersen, under review). Including scales with more options that capture facilitator competency in greater detail may be useful in assessing effects on outcome levels in the future. Our findings show that a relationship exists between facilitator competency and group-level outcomes, but greater work is necessary on the psychometrics and implementation of measurements to more precisely capture facilitator competency.

To our knowledge, this was the first time a group cohesion measure was administered in a task-sharing psychological intervention in an LMIC. Group cohesion had the highest ICC scores, amongst the tested variables, even for male groups. Consistent to prior findings, these results demonstrate that group members' perceptions of group cohesion are impacted by the experiences of others in the group and overall group functioning (Burlingame et al., 2018). Though our analysis showed a potential relationship between group cohesion and changes in general distress, these effects were not statistically significant. Meta-analysis of prior studies have concluded that 53% to 80% of studies have demonstrated a statistically significant positive association between group cohesion and treatment outcome (Burlingame et al., 2001, 2018; Tschuschke & Dies, 1994). However, the cohesion-outcome relationship is complex. Interpersonal therapies are more likely to have higher cohesion-outcome correlation when compared to "skills based" interventions (Burlingame et al., 2018), such as Group PM+ (Dawson et al., 2015). This is supported by our finding that facilitators' competency of common factors contributed more than other tested variables to the between-group variation on group cohesion. Dose is another moderator that could impact the cohesion-outcome relationship. Groups that met more than 20 times had the highest correlation and those that met less than 13 times had the lowest correlation (Burlingame et al., 2018). In comparison, Group PM+ participants met for a maximum of only 5 times. Interestingly, our results showed that 13% of within-group differences in group cohesion scores were attributed to participant attendance compared to an undetectable impact on the other tested outcomes.

The qualitative findings highlight that group-based factors and processes, such as the normalization of mental health issues, group composition and increased social support, all impact participants' satisfaction and perceived utility of the treatment. Participants reported the benefits of discussing and listening to each other's problems in a group setting and, in some cases, finding support systems that lasted beyond the intervention. These findings support the quantitative analysis by highlighting the importance of facilitator competency, especially their role in creating supportive environments that allow group members to comfortably engage in therapeutic group-based processes (Yalom, 1995). Though participants had different opinions on their preferred group composition, the facilitator's ability to keep all members equally engaged may impact participants' perceptions of group cohesion and their overall treatment experience. These conclusions further support the use of competency scales, such as ENACT and GroupACT, to address both the common factors and group-specific facilitation skills necessary to successfully deliver a group-based intervention.

Our study acknowledges that group-based mechanisms and process are different from those underlying individual therapy and develops a pathway and tools for future research. Because greater attention to group cohesion by the facilitator has shown to increase correlations to outcomes (Lecomte et al., 2015), facilitator trainings and supervision should incorporate focus on such group processes and strengthen facilitators' common factors and interpersonal skills development, even for skills-based interventions such as Group PM+. There is also a lack of research on group member variables, such as gender, age, symptom severity, and their impact on psychological outcomes and cohesion-outcome correlations (Burlingame et al., 2018). Further research is also necessary to clarify the impact of group-based mechanisms on individual psychological outcomes.

There are several limitations to this study. Our sample size of male groups was smaller than female groups. Facilitators were assessed on the GroupACT and the fidelity checklist by clinical supervisors, who also train facilitators and conduct regular supervision. This could lead to possible biases in assessments. Because the GroupACT and fidelity checklist are conducted in every supervised session, average rating may also regress to the mean over the duration of the trial. This was the first attempt to measure group cohesion for a mental health intervention in Nepal. Therefore, this cohesion scale has not been validated in Nepal and could be a potential next step.

CONCLUSION

Because group-based interventions are increasingly utilized in LMIC settings, it is important to consider what underlying factors and mechanisms may impact participant outcomes. Outcomes from this study demonstrate that group-based mechanisms such as facilitator competency, group cohesion, and rural vs. urban setting has the potential to impact between-group differences in task-sharing group psychological interventions.

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EPILOGUE

CHAPTER 8

Epilogue: Key areas of attention for the adaptation and implementation of psychological interventions in low-resource settings

INTRODUCTION

Scalable and task-sharing psychological treatments are increasingly used to address the burden of mental health problems in low- and middle-income countries (LMICs). The dissertation presents an example of the necessary steps in testing a psychological intervention in an LMIC setting. These steps include a) cultural adaptation, b) testing for feasibility and acceptability, c) testing for effectiveness, and d) clarifying and testing the mechanisms for intervention effectiveness. This implementation process was conducted with World Health Organization's Group Problem Management Plus (PM+), a trans-diagnostic, task-sharing psychological intervention in Nepal. Prior PM+ trials followed a similar process when testing for intervention effectiveness (Bryant et al., 2017; Chiumento et al., 2017; Rahman et al., 2019). This dissertation presents the first time that Group PM+ was tested in the Nepal context and the first trials that also included male participants. Group PM+ met feasibility and acceptability requirements when tested in Nepal's Sindhuli district and was then tested for effectiveness in Morang district.

The dissertation begins with an introduction (**chapter one**) to the field of global mental health (GMH), the existing treatment gap in access and use of mental health care, and task-sharing interventions, such as Group PM+, as a potential mitigating strategy. The introduction also describes ongoing challenges in global mental health research around the cultural adaptation process, program implementation, and research design in randomized controlled trials (RCTs).

Chapter two details a rigorous cultural adaptation process that was conducted prior to the first trial. Adaptations were evaluated for feasibility and acceptability during the pilot trial and experiences from the pilot trial informed further adaptations before testing the intervention for effectiveness. The adaptation framework and tools were designed to be easily replicated in other contexts, paying special attention to low-resource settings. This chapter introduces several themes relevant throughout the dissertation: 1) Balancing *fidelity* to the original intervention with the *fit* to the cultural context, 2) Identifying and measuring the intervention's mechanisms of actions, and 3) Importance of recruitment procedures and quality monitoring (i.e. measuring competency of facilitators). Local concepts of mental health problems including *tension,* a common idiom of distress, were combined with the mechanisms of action to create a conceptual model that could be used by the lay facilitators.

The intervention met all predefined feasibility and acceptability criteria when tested in Sindhuli district, Nepal (**chapters three and four**). Assessments and trial procedures were found to be feasible and only a few participants were lost to follow-up. High rates of participation in the Group PM+ sessions indicated intervention acceptability. Though this study was not powered, the Group PM+ arm indicated more improvements, especially in daily functioning and general distress, when compared to the enhanced usual care (EUC) arm. The main strengths of this trial included the addition of the facilitator fidelity checklists to assure quality in

the delivered program and the Reducing Tension Checklist (RTC) questionnaire to measure participants' uptake of Group PM+ skills. Though recruiting men into the trial was challenging, we were able to successfully recruit and administer Group PM+ sessions with male groups. Qualitative findings also highlighted the inherent benefits of group interventions including social support and validation of mental health problems. Adaptations, such as the inclusion of devices to support participants outside of the sessions, were necessary before the effectiveness trial and are highlighted in chapter two.

The effectiveness cluster randomized controlled trial (c-RCT) was conducted in Morang, a district in eastern Nepal annually affected by floods (**chapters five and six**). This trial included 72 clusters and over 600 participants across the two arms. The reduction of psychological distress post-intervention was similar to the pooled effect for common mental disorders treatment (Barbui et al., 2019). Results showed short-term modest treatment effects directly after the treatment but were no longer significant at the three-month follow-up. Results also showed differences in favor of Group PM+ for PTSD, functioning, depression, somatic symptoms, and social support directly after the intervention. Because these findings were different from our feasibility trial, understanding *why* these differences occurred becomes especially important.

Chapter seven analyses if there are differences in outcomes attributed to which group participants were in. The chapter then explores several group-based domains that clarify differences these between-group outcomes to consider for future implementation of psychological interventions. These group-based domains include considering the context (rural vs. urban), evaluating competency of facilitators, and perceptions of group cohesion.

While the dissertation focused on testing the Group PM+ intervention, the implementation process and lessons learned from this experience can be applied to the testing of global mental health interventions across LMICs. In this epilogue, I aim to reflect on these insights and highlight best practices for the implementation, delivery, and scalability of global mental health intervention trials in low-resource settings. Specifically, I will discuss where global mental health trials are conducted, how participants are identified for psychological interventions, what is delivered, how to ensure quality of care in research trials, and how to address methodological challenges in RCTs. I will also provide possible future directions for global mental health intervention implementation and recommendations linked to the findings from the Group PM+ trials in Nepal.

This epilogue will be structured in three sections, 1) Culture and Contest, 2) Feasibility and Acceptability, and 3) Evaluating Effectiveness, that correspond to the chapters in the dissertation. This epilogue will use a culture and context lens. Similar to prior GMH intervention trials, the cultural adaptation of Group PM+ was conducted before program implementation. Conducting adaptation procedures only once before implementation demonstrates that we often consider culture and context as pre-conditions that should be considered during the planning

phase. However, culture is complex and constantly evolving. The cultural adaptation process should be reflective of this fluidity and should be an ongoing process throughout the entirety of the research rather than a checkbox to be completed before implementation. Culture and context should be considered in each aspect of the research and the *fidelity* vs. *fit* dichotomy should be constantly addressed when implementing an intervention in a new location or with a new population. The examination of what we consider to be "effective" is also a recurring lens that I will use in this discussion. Effectiveness is usually determined by effect sizes and changes in measured outcomes. However, it is necessary to dissect how effectiveness is measured and what implementation and socio-cultural factors impact intervention effectiveness. We must also examine what components of the intervention strengthen its effectiveness and the populations the intervention benefits and why. The conclusion will also explore future directions of research to clarify this understanding, especially for scalability and implementation purposes. **Table 1** highlights critical implementation questions to assess and reflect on when conducting a randomized controlled trial in a low resource setting.

SECTION 1: CULTURE AND CONTEXT

Where: Location of Global Mental Health trials

The field of GMH places priority on improving mental health worldwide, with a focus on low-and middle- income countries (LMICs) which are home to over 80% of the global population but have "less than 20% of the mental health resources" (Koplan et al., 2009; Saxena et al., 2007). Under the larger umbrella of LMICs, different descriptive terms are used for countries and settings with varying levels of political conflict, violence, ethnic fragmentation, government stability, and exposure to natural disasters (De Jong, 2010). These terms include 'humanitarian settings', 'complex humanitarian emergencies', 'fragile states', 'post-conflict settings', and 'post-disaster settings' amongst others. A complex web of predisposing factors, such as politics and the social fabric, before the initial emergency, conflict and/or disaster, may determine mental health indicators and access to services to address these needs. Because the "road to recovery" from a conflict is not a linear process and is often compounded with additional conflicts and disasters (Collier & Sambanis, 2005), many of the distinctions between these descriptive terms have become increasingly unclear. However, the blurring of these distinctions may lead to consequences in funding and applicability of research and programming. A recommendation after conducting the Group PM+ studies in Nepal is that a critical understanding of the designated study site and the corresponding terms used to describe the site is important in determining if a given intervention is a proper fit for the population.

Given Nepal's history of civil war, political instability, earthquakes in 2015, annual flooding, and low development indicators, the country is unequivocally categorized as a low-income country with a developing economy, and is classified as

one of the least developed economies in South Asia (*World Economic Situation and Prospects 2020*, n.d.). In 2015, Nepal was also categorized as a "fragile state" though international development literature increasingly recognizes the complexity of this category due to the diversity in fragile situations (OECD, 2015). The complex reality is also that low-income countries are plagued with extreme inequity (Jones, 2009). Different areas of a country may be predisposed to natural disasters and conflict, depending on the geography and local populations. Distribution of goods and services may also vary throughout a country, as a result of political, economic, and social imbalances, that may be upheld and reinforced by formal and informal institutions. For example, in Nepal conflict related deaths during the civil war were significantly higher in poorer districts in the mid-western hills region (Do & Iyer, 2010). Wealth, access to health and education resources, and geographic accessibility could function as both protective factors to shield a community from conflict/trauma and as resources to cope with its aftereffects. Therefore, there is no one "Nepal context" that is fully representative of the country and this terminology should also be avoided when conducting research trials.

Considerable research evidence shows that mental health problems are socially determined (Allen et al., 2014; Lund et al., 2018). Though global mental health research continues to seek innovative treatments, there are increasing calls to acknowledge the "inseparability of mental health outcomes from macro-level social challenges and inequalities" that affect how these treatments may impact different populations (Burgess et al., 2020). Specifically, exposure to natural disasters, access to health services, low educational attainment, and unemployment are some social inequalities that contribute to negative mental health outcomes (Allen et al., 2014; Fryers et al., 2005). This social determinants of mental health conceptual framework (Lund et al., 2018) can be used to explore and compare the findings from Nepal's Group PM+ feasibility trial, effectiveness trial, and Group PM+ effectiveness trials conducted in other countries.

Nepal's Group PM+ feasibility trial reported three times higher effect sizes when compared to Nepal's effectiveness trial and the effectiveness trial reported significantly lower effect sizes when compared to previous trials in Kenya and Pakistan (Bryant et al., 2017; Rahman et al., 2019). When comparing the two research sites in Nepal, it is important to note the research methodological differences; the sample size of the feasibility trial was much smaller than the effectiveness trial and the feasibility trial was also not powered. Because of these methodological differences, feasibility trials across sites often show greater effect sizes compared to effectiveness trials and should be used to inform trial procedures rather than treatment effect (Sim, 2019). Therefore, the aim of highlighting the different outcomes between the two trials is to explore underlying contextual factors that can further inform *how* locations are chosen for future research and program implementation. Amongst many explanations, the connection between adversity, access to mental health services outside of the research study, and mental health outcomes is one possible hypothesis for interpreting the range of results.

TABLE 1. **Checklist for Key Cultural Adaptation and Implementation Processes for Conducting Randomized Controlled Trials in Low-Resources Settings**

Who?	**Where?**
· Community Informants - What qualities of community informants are necessary identify participants for the trial? - Who will be trained to recruit participants into the trial or identify cases for service delivery? What will be included in the training for community informants? · Research Participants - Who is the target population for the intervention? Is the intervention a good fit for the target population? What factors would - How is the intervention adapted to be inclusive of participants of different backgrounds that may participate in the intervention (men, women, etc.)?	· Study site - How is the specific study site defined? (Humanitarian, LMIC, fragile state etc.) Is this terminology reflected in the local data? - What types of adversity affect the targeted population in the study site? - Who is the most affected by adversity in the study site? How can they be reached by the research study? - What are demographics of the population at the study site? Do they match the targeted population that are most in need of the intervention? - What pre-existing mental health and social service resources are available for intervention participants?

What?	How?
· Intervention - What type of intervention is best fit for the needs of the population (e.g. individual or group intervention, family therapy etc.)? - How are changes in the use of mechanisms of action measured before and after the intervention? - How have adaptations to the intervention addressed socio-cultural challenges? - What tools and mechanisms facilitate long-term change within intervention participants? - Does the intervention encourage any changes beyond mental distress symptoms (ex. Social inclusion, resilience etc.)? Are these domains measured? - If it is a task-sharing intervention, is the dose of the intervention a good fit for the targeted population?	· Case-identification - Are socio-cultural challenges and symptoms incorporated into the case-identification method? - Who is trained to be a community informant? - How are cases referred? - How is supervision conducted for community informants? - How is stigma addressed when community informants approach potential cases? - Are there greater efforts to reduce stigma amongst community members? How? · Methodological considerations - What is the control condition? What potential biases does this control condition hold? Are the two arms comparable? - What are other existing services outside of the study and how are participants referred? - How are the services that participants (in both arms) receive during the study documented? - What dissemination strategies will be used to increase uptake of the intervention after the research trial? · Training and Supervision - What trainings are conducted before the start of the trial? Do the trainings account for the background and skill level of the non-specialists? - How is non-specialist competency measured (including common factors, intervention fidelity, and group management, if a group intervention)? - What are the ongoing supervision practices during the intervention?

Though within the same low-income country, the culture, context, and existing inequities within our two study sites in Nepal were notably different. The pilot research site in Sindhuli district was affected by earthquakes in 2015 (Khatri, 2018) and had access to local health posts but was located several hours from the nearest hospital. In contrast, Morang, a *terai* district in the eastern flatlands of Nepal, was close in proximity to four major urban areas and there were three primary health care centers (PHCCs) with mh-GAP trained health workers within the study site. Areas of Morang district are affected by annual floods (Sharma et al., 2019). Though participants in the two trials were similar in their levels of distress at baseline, contextual differences between the two districts were also reflected by the sample population's demographics. Approximately 29% of effectiveness trial participants were illiterate compared to 70% in the feasibility trial. 7% of feasibility trial participants completed primary education compared to 25% in the effectiveness trial. Other factors, such as employment status and caste composition, also reflect a more well-resourced sample size in Morang. Higher education and access to resources also create strong pathway to acquiring mental health and coping skills (Jorm, 2012). This is echoed in the effectiveness trial where PM+ related skill use, measured by the Reducing Tension Checklist (RTC), was much higher at baseline when compared to the feasibility trial (26.3 for control and 27.5 for intervention arm, compared to 10.1 and 15.6 respectively). This suggests that participants in the effectiveness trial were already using the PM+ skills prior to the intervention, possibly because of higher educational attainment and greater access to resources. It also provides a compelling argument for why it is necessary to closely examine a context and determine the contextual *fit* of an intervention before implementation. Using the social determinants framework (Lund et al., 2018), one could conclude that though both districts were inflicted with natural disasters, Morang district had greater access to pre-existing resources to cope when compared to Sindhuli district. This may have led participants to respond differently to the treatment.

Group PM+ has been tested in several settings prior to Nepal, including in Kenya and Pakistan. The primary outcome effect sizes were greater in both Kenya and Pakistan, when compared to the effectiveness trial in Nepal (Bryant et al., 2017; Rahman et al., 2019). While noting potential implementation and methodological differences in the three trials, a social determinants framework, similar to the previous within-country comparison, can be used to further understand what location the intervention is best fit for. Though participants in all three trials reported comparable levels of distress at baseline, Group PM+ trials in Kenya and Pakistan also reflect a less-resourced population compared to Morang, in regard to education status, employment, and adversity. For example, less than 20% of the sample in the Pakistan trial attained formal education compared to approximately 45% in the Morang trial. In Kenya, over 72% of the participants had experienced assault compared to 13% of participants in the Morang trial.

Though considered a post-humanitarian context, the sample size of Nepal's effectiveness trial exposure to adversity was arguably less compared to previous trials. In a questionnaire about exposure to natural disasters, half of the Nepal trial's par-

ticipants had experienced a natural disaster in their lifetime and over 80% of these participants noted that it occurred over three years ago. Participants however noted experiencing other forms of adversity, such as suicide of a loved one, physical illness, and physical/sexual assault. The trial in Kenya focused specifically on women with a history of gender-based violence and the Pakistan trial was conducted in an area with severe armed conflict till 2011, and as a result, the location had major damage to the economy, infrastructure, and social fabric (Bryant et al., 2017; Rahman et al., 2019).

Differences in the participants' social determinants and levels of adversity between the three trials further highlight the necessity to clarify descriptive terminology in mental health research. First, it is necessary to define terms, such as 'humanitarian setting', 'post-conflict setting', and 'fragile state', in the context of mental health research rather than only in the field of development. This includes increasing the number of prevalence-based mental health studies in various settings and analysis of the social determinants and forms of adversity that affect varying populations (e.g. youth, women) within each of these settings (Patel et al., 2007). Second, these umbrella terms must be distinctively reviewed when conducting meta-analyses. For example, Barbui and colleagues explicitly group interventions conducted in humanitarian settings separately from LMIC settings when conducting their analysis (Barbui et al., 2020). Third, a full description of humanitarian conditions, such as poverty, stigma, and access to resources, must be included in studies to provide greater cultural context to factors that may impact treatment outcomes (Purgato et al., 2018). Data on participants' exposure to trauma and natural disasters should also be included in published studies. This is a strength of our study. A separate aggregated analysis can be conducted for participants facing different levels of adversity to further understand if interventions lead to different outcomes for those exposed to higher levels of adversity. Research studies can also broaden what it means to face adversity within the specific cultural context, and include measurements for contextually appropriate concepts, such as social inclusion (Baumgartner & Burns, 2014).

Though a country may be classified using one of these terms, an in-depth needs assessment of the potential site prior to research implementation is needed to clarify whether the community fits the level of adversity and social determinants targeted by the research. The following questions can be used as a foundation to guide such a needs assessment:

- → What forms of adversity do local communities face?
- → Which communities in the area are most affected by the humanitarian crisis, natural disaster, or other forms of adversity?
- → What is the local population's primary language, educational level, occupation, and overall health status?
- → What are existing mental health resources in the area and are the resources offered by the intervention already accessible to the targeted communities?
- → How do these communities perceive their mental health challenges?
- → What methods can be used to reach the communities most affected by crisis and adversity?

As recommended in chapter two, a needs assessment can be integrated into the cultural adaptation process and is necessary to select a research/program site where communities, that are especially suffering from adversity, can be reached. Similarly, sites with limited access to mental health care should be selected for program implementation to work towards closing the treatment gap. Before our feasibility and acceptability trial, we used a needs assessment to adapt the content and implementation of the intervention. However, an assessment to assure that the research site is a good fit and to re-evaluate how the most adverse-affected communities will be reached is necessary before implementation in a new location even within the same country. During implementation, it is also necessary to have an ongoing evaluation to ensure that the target population is being recruited into the intervention study. Integrating this step as a fundamental aspect of research implementation acknowledges that cultural adaptation is an ongoing process and that a diversity in mental health experiences can exist even within a single country.

SECTION 2: FEASIBILITY AND ACCEPTABILITY

How: Conducting feasible and acceptable case-detection

Though task-sharing interventions have proven to be effective and are a critical step in increasing access to care, issues that impact the demand of these services in LMIC settings should be addressed alongside increasing the availability of effective treatments (Jordans et al., 2015). Even as the availability of mental health care increases, factors such as social and cultural norms and knowledge of existing services can impact their demand and utilization (Jordans et al., 2020). Community case-detection is a method to increase the utilization of mental health care. It includes the process of identifying community members that may be have mental health problems and referring them to available services.

While the procedures and accuracy of case-detection has mostly been explored for service delivery, experiences from the Group PM+ trials revealed that exploring issues around the quality of case-detection is also crucial in RCTs. Participants' initial experiences with case-detection for service delivery and trial recruitment sets the foundation and can impact all subsequent research and implementation activities. However, the process of case-detection is complex, especially in LMIC settings where stigma is intertwined with the lack of awareness about mental health issues and lack of demand for services (Hanlon et al., 2014). Thus, innovative case-detection procedures that integrate a socio-cultural understanding of mental health are necessary to effectively address the barriers of receiving care.

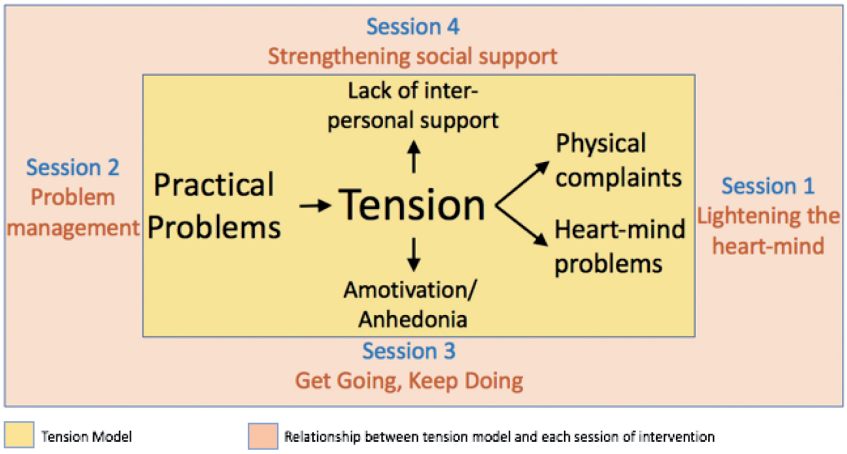
LMICs face a unique set of barriers in case-detection that are not as applicable to high-income country (HIC) settings (Jordans et al., 2015). For example, HICs often use self-reported tools for case identification but low literacy rates in LMICs make it difficult for the general population to use such tools. The use of psychiatric

labels to describe mental distress may also discourage community members, with a range of cultural attitudes towards mental health, from seeking care (Kohrt & Harper, 2008). Stigma against mental health problems and utilizing mental health services is associated with a lack of recognition of mental health problems and lack of knowledge around where to receive mental health services (Hanlon et al., 2014; Joseph & Hermann, 1998). To reduce stigma against mental health and taking part in the Group PM+ study, the Community Informant Detection Tool (CIDT) was adapted before the feasibility trial to include pictorial representations and vignettes of persons with general distress symptoms (Jordans et al., 2015). Despite the culturally appropriate adaptations that were made to the CIDT, many community members initially in the feasibility PM+ trial believed that the Group PM+ intervention only addressed severe mental illness and refused to be screened into the study for this reason. This experience revealed the importance of an ongoing cultural adaptation process and how necessary adaptation is not only for program materials but also for scalability and implementation processes.

In conjunction with considering mental distress symptoms to identify community members in need of care, understanding the explicit link between socio-cultural challenges and an individual's distress was a crucial aspect of case-detection in the Group PM+ trials (Burgess et al., 2020). Stressors are often interconnected, especially in humanitarian and LMIC settings, and individuals may experience adversity at the personal, familial, community, or societal level (Morgan & Kleinman, 2010). Societal conditions, such as poverty and migration, increase mental health problems through increases in daily stress, social exclusion, malnutrition and trauma (Lund et al., 2011). These stressful situations have both physiological and psychological impacts, such as sleeplessness, fatigue, disinterest, and hopelessness. Because the expression of these symptoms can vary depending on context, the cultural adaptation process must explicitly explore and integrate socio-cultural challenges and a contextual understanding of mental distress into the intervention and its implementation methods.

Prior to the feasibility trial, we developed an ethno-psychological conceptual model based on *tension* (Figure 1), one of the most prevalent and non-stigmatizing idioms of distress in Nepali language (Rai et al., 2017). This model highlighted the pathway from adversity, to distress, to physiological and psychological symptoms and represented the conceptual foundation of the intervention by linking socio-cultural challenges to mental health problems. The model demonstrated that practical problems, or adversity, led to stress, which increased physical and emotional problems, lack of interpersonal support, and amotivation. These linkages were based on evidence gathered during the cultural adaptation process about how local populations conceptualized their stress and the problems they faced. Rather than only focusing on visible physiological or psychological distress symptoms, this model was also used to deliver a non-stigmatizing case-detection process focused on identifying community members with socio-cultural challenges, along with using the CIDT.

FIGURE 1. **Tension Model**



The case-detection process utilized in the Group PM+ trials further advanced guidelines for the existing case referral system. Active case-finding has been previously used to successfully increase demand for mental health services (Cohen et al., 2011; Jordans et al., 2020; Patel et al., 2011) and often includes a two-step process: 1) identification of cases and referral, and 2) diagnostic interview by trained health worker (Patel & Thornicroft, 2009). The CIDT further defined the first step of this process by developing a structured approach, along with assessing willingness to seek care and highlights a clear referral pathway to service utilization (Subba et al., 2017). However, during the feasibility Group PM+ trial, we faced several challenges even before the identification process (Sangraula et al., 2020). Initially, community informants identified persons with severe mental illness, because their symptoms had greater visibility, than those with general distress who were targeted for the study. Because of the high levels of community stigma towards mental health, some referred community members did not want to complete the diagnostic screening. In order to normalize recruitment into the study and more easily identify persons with potential general distress symptoms, we explicitly addressed the link between sociocultural challenges and mental health problems in our case-detection process.

Further adaptations were made to the case-identification process to include community sensitization efforts that addressed the social determinants of mental health. Non-specialists and community members trained in case-detection conducted interactive events with locals about mental health and used the *tension* model as the foundational basis. During these events, practical problems, such as losing a loved one, physical health problems, and migration, were explicitly linked to *tension* and in turn, non-stigmatizing physiological and psychological symptoms. Similarly, it was highlighted that the lack of interpersonal support and isolation could also lead to increased tension. Community sensitization events normalized mental distress by establishing a pathway

from socio-cultural challenges, which were regarded as common and a part of life. While informants may also have known people in their local communities with distress symptoms, understanding mental health through the lens of social suffering made it easier for informants to identify individuals who were more likely to have symptoms.

After the initial identification, informants used the vignettes and pictorial depictions in the CIDT to discuss if the identified individuals were experiencing mental health symptoms and if they were interested in screening for the study. These adaptations and additions to the existing case-detection process highlight the importance of addressing mind-body-social relations with a deep understanding of the cultural context in every aspect of an intervention trial or community-based program (Kohrt & Harper, 2008). The inseparability of mental health outcomes from social challenges and inequities need to be further integrated into interventions and their implementation processes (UNHRC, 2017).

The selection, hiring, and training of community informants for case-detection influences the referral process into the research trial along with the community's understanding of mental health. Benefits of utilizing non-specialists or lay-community health workers for program delivery include their wide population coverage, rates of acceptance from program participants and their families when compared to mental health specialists, and a depth in knowledge of the local population's culture and health needs (de Menil & Underhill, 2010; Kagee et al., 2013; Thara & Padmavati, 1999). As collaborative care models gain popularity, there have been increasing calls to train non-specialists in both the detection and service delivery (Kagee et al., 2013). Though non-specialists may be an ideal for conducting case-detection, we found it a necessity to train a separate cadre of lay workers that were solely focused on recruiting participants into the Group PM+ case study, especially because of the accuracy and sensitivity required by the case-detection process. Therefore, this approach consisted of two tiers of non-specialists with varying objectives, trainings, and supervision systems: 1) Community Informants (CIs) who focused on identifying persons with mental health problems, conducting referrals, and addressing sociocultural concerns such as stigma within their own communities, 2) Non-specialists who focused their efforts on delivering Group PM+ with the highest quality of care. This tiered approach tackled community and individual stigma at multiple levels and supported in reducing burnout by avoiding the shifting of too many tasks onto non-specialists (Hoeft et al., 2018).

SECTION 3: EVALUATING EFFECTIVENESS

What is included in psychological interventions?

Because task-sharing interventions have demonstrated overall effectiveness in various low- and middle- income country settings (Singla et al., 2017), there is a need to increase focus on strengthening the components of the intervention that lead to high quality care and beneficial outcomes for participants. This includes further

consideration of socio-cultural challenges faced by the population served, implementing innovations *within* task-sharing interventions to increase fit with the population, and strengthening the tried-and-tested mechanisms of action. In the PM+ intervention, the mechanisms of action, or the processes and events that are predicted to be responsible for change in levels of distress (Kazdin, 2007), are the skills shared with participants in each session of the intervention (i.e. deep breathing, behavioral activation, problem solving, and social support) (Dawson et al., 2015).

As a method to increase focus on strengthening the components of the intervention that lead to high quality care, my take is that a necessary innovation in global mental health research is to identify how task-sharing interventions can be more sensitive to participants' individual needs as a method to increase quality of care. For example, participants of Group PM+ reported a range of different life experiences such as natural disasters, sexual trauma, and having a close family member/friend die by suicide, all of which may have contributed to mental distress and a range of symptom severity. One approach is to group participants with similar symptom severity together and train non-specialists to provide corresponding levels of care. Another approach is to increase treatment dose. Though short and effective sessions are an important aspect of interventions such as Group PM+, the length of treatment must also be balanced with population fit. Higher treatment dose (i.e. increasing the number of sessions) has led to better outcomes for participants compared to lower doses (Selohilwe et al., 2019) and may be especially beneficial for participants with greater mental health distress. Though task-sharing interventions are already regarded as highly innovative, using a stepped-care approach within task-sharing interventions could be a necessary innovation to increase quality of care (Hoeft et al., 2018).

In addition to focusing on overall intervention effectiveness, identifying *how* interventions lead to desired outcomes is important to consider when testing future task-sharing interventions. Identifying pathways for how interventions work can be helpful for strengthening the components that lead to beneficial outcomes for participants (Purgato et al., 2020). We identified *participant skill use* as a potential mediator and developed a ten-item Reducing Tension Checklist (RTC) to measure the use of behavioral and psychosocial skills (i.e. the mechanisms of action) associated with the PM+ sessions. As shown by the mediation analysis in the Group PM+ effectiveness trial, participants' skill use outside of the sessions explained 31% of the variance in the primary outcome (General Health Questionnaire, GHQ) at endline. This suggests that strengthening the mechanisms of action within the intervention could potentially increase beneficial results for the participants. If potential pathways between intervention and outcomes are further strengthened, possible moderators, such as education and access to resources, can also be identified (Tol et al., 2010).

Measuring the mechanisms of action, using the RTC, revealed that further adaptations may be necessary to refine skill use especially for well-resourced populations. Median baseline RTC scores were higher in the effectiveness trial than the end line RTC scores of feasibility trial participants. The use of the RTC in the two trials revealed that some populations, especially those with higher education and more access

to resources, may already employ the skills presented in the intervention. This highlights that well-resourced populations may need further adaptations in task-sharing interventions to receive greater benefit from the intervention. Increasing the dose or further strengthening the mechanisms of action as part of the cultural adaptation process could be helpful to already well-resourced populations. The ongoing cultural adaptation process in the Group PM+ trial centered around identifying and strengthening the mechanisms of action. Though adaptations to refine skill use, such as devices, were added to the intervention before the effectiveness trial, the adaptations were based on the feasibility study population. A needs assessment with an exploration of what coping skills were already in practice by those in the new trial site would be a helpful addition to the cultural adaptation process. If the needs assessment finds that some of the skills are already in use, it can then be decided if the location is the correct fit for the task-sharing intervention or if further adaptations could be made to strengthen the mechanisms of action for population fit.

Task-sharing interventions are designed to be simple enough for delivery by non-specialists and yet are intended for implementation in settings with inherently complex socio-cultural, political, and economic roots underlying common mental health disorders (Lund et al., 2018; Patel et al., 2018). Though a rigorous and ongoing cultural adaptation process may incorporate some in-depth content that addresses these contextual factors, it is necessary to question if that is enough to lead to long-term change. While noting that trans-diagnostic interventions led by non-specialists may not fully address the complex nature of mental health problems in LMICs, it is necessary to also further consider *how* task-sharing interventions could facilitate long-term change for participants who face the daily impact of complex social challenges (Burgess et al., 2020). Evidence is increasing on the potential of task-sharing interventions to not only address intrapersonal dynamics, such as reducing self-stigma and self-isolation, but also to motivate individuals to access income-generating opportunities and therefore, tackle social risk factors (Selohilwe et al., 2019). Thus, task-sharing intervention trials should include measurements beyond symptoms of depression and anxiety, and measure relevant socio-cultural domains, such as resilience and social inclusion (Baumgartner & Burns, 2014; Lund et al., 2018).

How: Quality Assurance and Facilitator Competency

There is strong evidence that trained non-specialists without a mental health background can deliver effective psychological treatment with adequate training and supervision (Singla et al., 2017). Because mental health care outside of intervention studies might often be lacking in LMIC settings, task-sharing approaches have a unique responsibility to provide the highest quality of care possible to program participants. Proper competency of non-specialists contributes to quality and though quality mental health care is often cited as a goal in global mental health (Group, 2007), there is a lack of formal tools to evaluate the competency of non-specialists (Kohrt et al., 2018). Establishing competency scales and reporting competency scores in research studies is necessary because task-sharing trials often

employ non-specialists from various backgrounds with different levels of prior education, making it difficult to compare the impact of competency on outcomes across studies. Though it is agreed upon that competency requires in-depth knowledge of the treatment and skill in delivering procedures and strategies (McHugh & Barlow, 2012), evaluating for competency is complex because of the multiple and often interconnected skills required for intervention delivery (Cooper et al., 2017).

Issues of measuring competency were addressed in our Group PM+ trials by developing multiple scales to assess the wide range of skills required for delivering the intervention. Non-specific factors (also known as common factors), such as empathy, warmth, listening skills, effect outcomes particularly in brief interventions (Wampold, 2010). These common factors were measured before and after non-specialist training using ENACT (Kohrt et al., 2015). Non-specialists with ENACT scores below the cut-off were discontinued or required to complete additional training and practice to build their skills in common factors. While common factors have demonstrated to be impactful in psychological interventions (Pim Cuijpers et al., 2019), short-duration and manualized interventions, such as Group PM+, require tools that also measure to what extent non-specialists are retaining fidelity to the intervention and how well they deliver these intervention-specific factors. We developed a fidelity checklist by extracting the core skills and procedures required in each of the five intervention sessions.

Group-based interventions are increasingly utilized in LMIC settings and participants have noted the key role that the facilitators play in creating a safe space to share personal problems and learn to manage general distress (Dickson & Bangpan, 2018). Though there is overlap between common factors and proficiencies necessary to manage a group, non-specialists require an additional and more extensive set of skills to deliver group-based interventions. By recognizing the importance of group-based management and processes separate from competencies for individual level therapy, the GroupACT was developed to measure group-specific competencies, such as facilitating collaboration and fostering group empathy, as part of the Ensuring Quality in Psychological Support (EQUIP) platform (Kohrt et al., 2020). We noted during process evaluations that the competency scales, particularly the fidelity checklist and GroupACT were utilized as more than just simply tools for measurement and reporting. They assisted in providing intensive support to clinical supervision, acted as a device for personal reflection amongst the non-specialists and were a necessity, along with the manual, to guide session delivery (Ottman et al., 2020). Rather than only conducting assessments to assure that competency scores are up to par before the trial, integration of these competency measures into intervention delivery can help assure that therapy quality is a core element of the implementation process. Our exploratory analysis of group-based mechanisms demonstrated that competency scales, including the ENACT, GroupACT, and Fidelity Checklist, that were evaluated in the study were not precise enough to detect potential relationships between facilitator competency and outcomes. Therefore, it is recommended to continue work on such measures to more accurately capture facilitator competency.

Adapting and applying best practices to training and clinical supervision for non-specialists was an ongoing process throughout the Group PM+ trials. Prior to the feasibility study, the non-specialists received a 20-day Community Psychosocial Worker (CPSW) training, as is standard for this cadre of health worker in Nepal, before the 10-day Group PM+ training. However, the process evaluation showed that some non-specialists felt that aspects of the CPSW training provided more information than necessary to deliver Group PM+. For the effectiveness trial, the CPSW training was reduced to 10-days and followed by the same 10-day Group PM+ training. Therefore, contextual factors, such as the information included in pre-existing local trainings and the educational levels of the non-specialists, must guide the length and content of psychosocial trainings.

Though one of the most appealing aspects of task-sharing interventions is the short duration of training for non-specialists, it can often be difficult for non-specialists without prior mental health experience to confidently conduct a psychological intervention with only brief classroom-based training (Dickson & Bangpan, 2018). In a prior study, non-specialists reported feeling that they lacked enough time to learn during the trainings and lacked proper supervision and support before implementation (Shahmalak et al., 2019). After the initial 10-day Group PM+ training, non-specialists conducted several rounds of practice groups to gain confidence using common factors skills, while retaining fidelity to the intervention. Non-specialists met weekly for office supervision led by the clinical supervisors to discuss successes, challenges, and to review the fidelity checklist and GroupACT that clinical supervisors rated during field supervision. They also rated themselves on the fidelity checklist and GroupACT after every session to gain personal insights on their session delivery. Thus, the competency scales contributed to scalability and implementation rather than just reporting purposes. This form of continuous group supervision, field supervision along with extra support for difficult participants (Jordans et al., 2007), should be the backbone of task-sharing trials.

How: Methodological Challenges in RCT Implementation

Randomized controlled trials (RCTs) are considered the "gold standard" in research and often inform a range of policy and implementation decisions (Newcomer et al., 2015). Treatment guidelines, based on the results of RCTs, are used to make recommendations about implementation of interventions and which programs to fund (Cuijpers & Cristea, 2016). Because of these high stakes, methodological challenges must be addressed critically so the outcomes of RCTs best reflect the effectiveness of the intervention. This is especially relevant in LMIC settings that have less resources to conduct RCTs when compared to HICs (Purgato et al., 2018). Ongoing discussion in global mental health research has focused on how to address methodological challenges, such as limiting bias and implementing the most appropriate control conditions (Cuijpers & Cristea, 2016; Munder et al., 2019; Purgato et al., 2018). Addressing these issues can support in conducting RCTs with the highest ethical standards (Sumathipala & Fernando, 2014). Methodological challenges,

especially in the precise measurement of the control group, were encountered and addressed during our Group PM+ trials.

The choice of control groups is especially relevant in LMIC settings. The best comparison control group design has been widely debated (Cuijpers & Cristea, 2016; Purgato et al., 2019). Enhanced usual care (EUC) control condition was used in the Group PM+ trials. It is recognized that the EUC condition is vastly different according to populations and contexts, especially in LMIC settings with little to no treatment available outside of the intervention (Purgato et al., 2019). This control condition can also differ within a single country based on location and geography. The availability of treatment outside of the intervention differed between our feasibility and effectiveness trials. The effectiveness trial encompassed a larger area with access to several primary health care centers (PHCCs) within the study site compared to the feasibility trial which only had one health post in each arm with limited health services. While the number and quality of preexisting services could not be altered, mhGAP training was given to providers in health posts that did not have previous mental health training.

In the effectiveness trial, participants in both arms were asked a series of questions about what services they received during the trial, including any medication or counseling services received before initial screening and continued throughout the study. Culturally relevant forms of care, such as talking to friends, prayer, and traditional healing, were also included in these questions. We encountered several challenges while administering these questions, such as participants forgetting exactly what services they received in health care settings, how often, and if the medications they were taking were for mental health problems. Another method to gather this data is to obtain service user information from local health posts and mental health providers. However, this method could only be conducted if it respects the confidentiality of patients outside the study that received care and if health posts kept detailed written accounts of all service users. Regardless, this method would still miss the participants that sought traditional and other healing methods during the trial.

Collecting service use data is not only important to account for the control arm but is also crucial for the treatment arm. Though we document the 'dose', or the number of sessions, that a participant receives along with any traumatic events or changes in lifestyle in the duration of the trial, it is also necessary to collect information about what other services they have received outside of the intervention. It may be that some participants started taking psychotropic medications or receiving counseling and these treatments are contributing to positive changes in the participant rather than the psychological intervention itself. Influences of these external treatments need to be accounted for to most accurately measure the effectiveness of the intervention. The plan for how to best collect this data depends on contextual factors, such as reliability of participants and available resources to collect data from services directly. Plans to collect additional service use data along with a plan for analysis should be critically discussed, decided upon before the trial

and written as part of the data analysis protocol. The analysis protocol should also clarify how service use data will be integrated into the final effectiveness findings of the trial.

Furthermore, there is a need for randomized controlled trials and other intervention-based trials to prioritize working towards systems level changes in conjunction to testing scalable interventions for effectiveness. Despite growing evidence to support the effectiveness of task-sharing and other mental health interventions, uptake of these treatments by local health systems is lagging (Murray et al., 2014). Bridging the gap between science and practice in real-world settings should be a focal point for future research. Though the original objectives of the research trial may focus solely on testing effectiveness, time and effort should be integrated within the research design for consistent advocacy and should be prioritized similarly to other aspects of the research. This includes advocating for the rights of mental health service users, integration of effective interventions into governmental health systems, and expansion of national and local budgets for mental health services.

Therefore, clear plans and methods should be developed prior to implementation on how the trial will simultaneously work towards uptake of the intervention or mental health services by community-based organizations (CBOs), local health facilities, and the government, depending on the context (Proctor et al., 2009). This is especially true for task-sharing interventions where after the trial, a number of delivery agents are qualified to provide quality care through brief interventions. Dissemination practices in such trials should include linking qualified mental health workers from the research trial to CBOs, NGOs and government health services to continue delivering mental health services in some capacity. This is extremely challenging especially in low income country settings where systematic policies, funding, and facilities are lacking (Murray et al., 2014). Despite these challenges, dissemination needs to be a priority especially in task-sharing interventions where the ultimate goal is to increase the number of qualified mental health workers and access to care. Only then will we have a real reduction in the treatment gap.

KEY RECOMMENDATIONS AND IMPLICATIONS

This epilogue discussed reflections from the implementation and evaluation of a task-sharing psychological intervention in a low-income country. The recommendations and implications for future research from these trials can be applied to global mental health research and programming beyond randomized controlled trials. The foundation of this epilogue is based on the importance of an ongoing cultural adaptation process that constantly evaluates whether the intervention is the right fit for the targeted population. The cultural adaptation process should also address how this fit can be improved, while maintaining fidelity, and evaluate *how* interventions could be strengthened to increase effectiveness. The following are key recommendations and implications for future global mental health research.

First, prior to study or program implementation, it is necessary to locally define vague descriptor terms, such as 'humanitarian setting', 'LMIC' and 'low-resource setting', and conduct an in-depth needs assessment to determine if the potential site fits the level of adversity and social determinants targeted by the intervention and research. The needs assessment should include a detailed understanding of local adversity levels and the existing available mental health and other resources. Such assessments should be conducted before program implementation in a new location even within the same country. Ultimately, needs assessments should identify a community that faces significant adversity, relative to other potential implementation sites, and needs mental health services that otherwise would not be available. Implementing research and programming in such areas supports in decreasing the mental health treatment gap, which is one of the aims of global mental health research. Afterwards, ongoing evaluation of if the target population is being reached and recruited into the intervention study is also necessary. The field of global mental health research needs to move towards explicitly providing clear indicators for and defining terminology such as 'humanitarian setting', 'fragile state', 'post humanitarian setting' and others. These umbrella terms must also be distinctively reviewed when conducting meta analyses. A full description of socio-cultural conditions and indicators, determined from the needs assessment or otherwise, should also be included in studies to provide contextual background to the factors that may impact treatment outcomes. These indicators include, but are not limited to, measures of poverty, mental health stigma, socio-economic status, and access to resources.

Second, a conceptual model that addresses how the intervention links with the local cultural concepts of distress is necessary to be developed as part of the adaptation process. The conceptual model should use local idioms of distress and should capture how local populations conceptualize their stress and the stressors that they face. In our conceptual model, practical problems, such as physical health problems and natural disasters, were explicitly linked to *tension,* which was linked to physiological and psychological problems. Connecting mental and emotional problems directly as a result of adverse events made recruitment into the study less stigmatizing for participants. The conceptual model was used during community sensitization events to prompt open discussions on mental health amongst local community members to decrease stigma during the case-detection process. It was also used during the facilitator trainings to elaborate on the pathways to *tension* and to provide a method for discussing mental health with local communities without stigmatization. Conceptual models are also necessary for future interventions to reiterate the explicit link between socio-cultural challenges and levels of distress and to address the pathways between social determinants and mental health problems in relation to the specific cultural context.

Third, it is necessary to advance global mental health by further innovating task-sharing interventions to increase quality of care and potency to make long-term changes in levels of distress for participants. Global mental health research studies should identify pathways for

how interventions work rather than just measuring for their effectiveness. Mediation analysis and identifying pathways that lead to changes in levels of distress, can be used to strengthen future psychological interventions. Furthermore, this includes strengthening focus on the components of the intervention that lead to high quality care, while adapting interventions to be more sensitive to participants' individual needs. A recommended approach is to group participants with similar symptom severity together and train non-specialists to provide corresponding levels of care. A separate aggregated analysis can then be conducted for participants facing different levels of adversity to further understand if interventions lead to different outcomes for those exposed to higher levels of adversity. Though an appeal of task-sharing brief interventions is the minimal number of sessions, an increase in treatment dose may be supportive for participants with higher levels of distress. Relatively well-resourced populations, with prior exposure to the coping skills taught in the intervention, may benefit from further adaptations in dose and strengthening of mechanisms of action.

Fourth, it is recommended to more critically analyze intervention effectiveness by considering the impact of factors, such as competency levels of facilitators and research design, on participant outcomes. Because non-specialists across study sites have varying levels of formal education, it is currently difficult to fully compare the impact of facilitator competency on intervention outcomes. Global mental health research should work towards developing more precise competency assessments and utilizing the same competency measures for facilitators across study sites. Because evidence is increasing on the potential of task-sharing interventions to also tackle social risk factors, such as motivating participants to access income-generating opportunities, relevant sociocultural domains such as resilience and social inclusion should also be included studies. Measuring beyond symptoms of depression, anxiety, and other mental health outcomes, also helps to integrate the intervention into the local cultural context and points to social factors that may have potential long-term mental health benefits as well. It is also recommended for future intervention studies to carefully consider how the design of the control conditions could vary the relative benefit of the intervention compared to the control arm. This must be considered before implementation in every research site, even within the same country. Furthermore, service use data must be collected for both arms to determine what services participants received outside of the intervention to analyze the true impact of the intervention, rather than the intervention supported by outside services used.

Ultimately, this dissertation aims to clarify the theoretical and implementation methodologies and lens necessary to establish the effectiveness of a psychological treatment in a low-income country setting. The valuable lessons learned, from multiple phases of contextualizing, implementing, analyzing, and reviewing the Group PM+ methodology and outcomes, can be applied to future global mental health research and implementation.

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ENGLISH SUMMARY
CULTURAL ADAPTATION, IMPLEMENTATION, AND ANALYSIS OF A TASK-SHARING GROUP-BASED PSYCHOLOGICAL INTERVENTION IN NEPAL

Low- and middle-income countries (LMICs) and humanitarian settings often have a high burden of psychological distress but also lack access to mental health care. This gap in treatment has led to the increasing use of task-sharing interventions that utilize non-specialists to deliver quality care. Before wide-scale dissemination, it is necessary for these interventions to be tested for feasibility, acceptability, and effectiveness. The dissertation presents an example of the necessary steps in testing a psychological intervention in an LMIC setting. These steps include a) cultural adaptation, b) testing for feasibility and acceptability, c) testing for effectiveness, and d) clarifying and testing the mechanisms for intervention effectiveness. This implementation process was conducted with World Health Organization's Group Problem Management Plus (PM+), a trans-diagnostic, task-sharing psychosocial intervention in Nepal. Prior PM+ trials followed a similar process when testing for intervention effectiveness. This dissertation presents the first time that Group PM+ was tested in the Nepal context and the first trials that also included male participants.

Chapter one sets the stage for the dissertation. It includes an introduction to the field of global mental health, the existing treatment gap in access and use of mental health care, and task-sharing interventions, such as Group PM+, as a potential mitigating strategy. Ongoing challenges in the cultural adaptation process, program implementation, and research design in randomized controlled trials (RCTs) are also described in depth. The chapters that follow in the dissertation aim to address these challenges and clarify implementation processes and methods that can be applied to future psychological research trials.

Chapter two details a rigorous cultural adaptation process that was conducted prior to the feasibility trial. The Ecological Validity Model (EVM) and the Replicating Effective Programs (REP) framework informed the development of a clear contextualization guide for low-resource settings. The resulting procedure is called the Mental Health Cultural Adaptation and Contextualization for Implementation (mhCACI) and consists of 10-steps. These steps include: 1) Identify mechanisms of action, 2) Conduct a literature desk review for the culture and context, 3) Conduct a training-of-trainers, 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. For Group PM+, key adaptations were harmonizing the mechanisms of action with cultural models of 'tension'; modification of recruitment procedures to assure fit; and development of a skills checklist. Adaptations were evaluated for feasibility and acceptability during the pilot trial and experiences from the pilot trial informed further adaptations before testing the intervention for effectiveness. This chapter introduces

several key themes relevant throughout the dissertation: 1) Balancing *fidelity* to the original intervention with the *fit* to the cultural context, 2) Identifying and measuring the intervention's mechanisms of actions, and 3) Importance of recruitment procedures and quality monitoring (i.e. measuring competency of facilitators).

Chapter three presents a protocol for a feasibility trial of Group PM+. Testing for feasibility and acceptability is a critical step prior to a trial to determine effectiveness. This chapter describes in detail the implementation methods for the feasibility trial in Sindhuli district, Nepal. This includes the randomization process between the intervention and enhanced usual care arm as well as the time points for measuring changes in psychological distress and other mental health outcomes. Criteria for determining feasibility and acceptability are also outlined in this chapter. Some feasibility and acceptability requirements include fidelity to Group PM+ elements at the level of 75% or greater, retention of at least 67% of participants, and presence of adverse events among fewer than 10% of participants. If the feasibility trial is able to meet these requirements, an additional trial can be conducted to test for intervention effectiveness.

Chapter four presents the outcomes from the feasibility and acceptability Group PM+ trial. The intervention met all predefined criteria and assessments. Trial procedures were found to be feasible and only a few participants were lost to follow-up. High rates of participation in the Group PM+ sessions indicated intervention acceptability. Though this study was not powered, the Group PM+ arm indicated more improvements, especially in daily functioning and general distress, when compared to the enhanced usual care (EUC) arm. The main strengths of this trial included the addition of the facilitator fidelity checklists to assure quality in the delivered program and the Reducing Tension Checklist (RTC) questionnaire to measure participants' uptake of Group PM+ skills. Qualitative findings also highlighted the inherent benefits of group interventions including social support and validation of mental health problems. Adaptations, such as the inclusion of devices to support participants outside of the sessions, were necessary before the effectiveness trial and are highlighted in chapter two.

Chapter five presents a protocol for an effectiveness cluster randomized controlled trial (c-RCT) in Morang, a district annually affected by floods in Eastern Nepal. This chapter outlines the rigorous implementation methodology to be used in the c-RCT, which includes comparing 36 Group PM+ clusters to 36 enhanced usual care (EUC) clusters with participants with high levels of psychological distress recruited from their communities. The chapter also highlights individual psychological distress, as the primary outcome, and levels of functioning, depressive symptoms, and post-traumatic stress disorder symptoms as secondary outcomes. Plans for mediation analysis are also detailed in this chapter.

Chapter six presents the effectiveness c-RCT for Group PM+ in Morang district, Nepal. Participants in the intervention and enhanced usual care arms were assessed at baseline, midline (7-weeks post-baseline; after treatment in the experimental arm) and endline (20-weeks post-baseline). 324 participants were enrolled in the control arm (36 wards) and 319 in the Group PM+ arm (36 wards). Group PM+ was associated at endline with a larger proportion attaining more than 50% reduction in depression symptoms

but was not with lower PTSD symptoms or functional impairment. It was determined from this trial that in humanitarian emergencies with a lack of mental health specialists, a 5-session group psychological treatment delivered by non-specialists can be used to modestly reduce psychological distress and depression symptoms. These benefits can partly be explained by the degree of psychosocial skill use in daily life. Psychosocial skill-use immediately after the intervention explained 31% of the PM+ effect on general distress scores three months after the intervention. Enhanced skill use by PM+ participants showed to be especially important in reducing symptoms.

Chapter seven utilizes mixed methods to explore the between-group effects of the context, facilitator competency, and group cohesion amongst PM+ groups in the effectiveness trial. These mechanisms that impact the differences in outcomes between groups, alongside the benefits of group interventions, have rarely been studied in the low-income country context. Across the 36 groups, between-group differences were greater for group cohesion than changes in levels of general distress or uptake of skills. Facilitator competency impacted group cohesion and participant's uptake of PM+ skills. The qualitative evaluation supported prior findings that group members have the potential to act as therapeutic agents for one another. These findings have practical implications on strengthening facilitator competency measurements and fostering group processes, such as cohesion, in group-based psychological treatments.

Chapter eight, the epilogue, aims to reflect on key findings from the dissertation and provide key recommendations for future psychological trials and program implementation. This chapter is structured in three sections, 1) Culture and Contest, 2) Feasibility and Acceptability, and 3) Evaluating Effectiveness, that correspond to the chapters in the dissertation. Key recommendations include: conducting in-depth needs assessments and utilizing the social determinants framework to identify potential research sites, developing psychological conceptual models specific to the research site, adding further innovations to task-sharing interventions, and critically assessing the impacts of factors such as facilitator competency and research design on participant outcomes.

DUTCH SUMMARY
CULTURAL ADAPTATION, IMPLEMENTATION, AND ANALYSIS OF A TASK-SHARING GROUP-BASED PSYCHOLOGICAL INTERVENTION IN NEPAL

In lage- en middeninkomenslanden en humanitaire *settings* komt psychologische *distress* in hoge mate voor, en toch er is vaak slechte toegang tot geestelijke gezondheidszorg. Deze behandelingskloof heeft geleid tot een toenemend gebruik van *task-sharing* interventies, die non-specialisten inzetten om kwaliteitszorg te leveren. Voordat deze interventies op grote schaal worden verspreid, moeten ze eerst worden getest op haalbaarheid, aanvaardbaarheid en effectiviteit in een lage- en middeninkomens setting. De benodigde stappen hiervoor zijn: a) culturele adaptatie, b) het testen op haalbaarheid en aanvaardbaarheid, c) het testen op effectiviteit, en d) de onderliggende mechanismen voor de effectiviteit van de interventie nader toelichten en testen. Dit implementatie proces is uitgevoerd met de World Health Organization's Group Problem Management Plus (PM+): een trans-diagnostische, *task-sharing* psychosociale interventie in Nepal. Eerdere PM+ trials volgden een soortgelijk proces voor het testen van effectiviteit van de interventie. Dit proefschrift beschrijft de eerste keer dat Group PM+ in de Nepalese context werd getest, zowel als de eerste trials waar ook mannelijke participanten aan deelnamen.

Hoofdstuk één zet de toon voor het proefschrift. Het bevat een inleiding op het gebied van wereldwijde geestelijke gezondheid, de bestaande behandelingskloof in de toegang tot en het gebruik van geestelijke gezondheidszorg, en *task-sharing* interventies, zoals Group PM+, als een potentiële mitigerende strategie. Daarnaast worden de voortdurende uitdagingen in het culturele adaptatieproces, programma-implementatie, en de onderzoekopzet voor *Randomized Controlled Trials* ook uitgebreid omschreven. De hoofdstukken die volgen hebben als doel deze uitdagingen aan te pakken en implementatieprocessen en –methoden die kunnen worden toegepast op toekomstige psychologische trials te verhelderen.

In hoofdstuk twee wordt een rigoureus cultureel adaptatieproces beschreven dat voorafgaand aan de haalbaarheids onderzoek is uitgevoerd. Het *Ecological Validity Model (EVM)* en het *Replicating Effective Programs (REP)* framework zijn gebruikt om de ontwikkeling van een overzichtelijke contextualisatiegids voor *low resource settings* te begeleiden. De resulterende procedure wordt de *Mental Health Cultural Adaptation and Contextualization for Implementation (mhCACI)* genoemd en bestaat uit 10 stappen. Deze stappen zijn: 1) Identificeer de actiemechanismen, 2) Voer een literatuurstudie uit met betrekking tot de cultuur en context, 3) Voer een training-voor-trainers uit, 4) Vertaal het interventiemateriaal, 5) Laat een expert het materiaal doorlezen, 6) Beoordeel de interventiepopulatie en de locatie kwalitatief, 7) Voer oefenrondes uit, 8) Voer een adaptatieworkshop uit met experts en implementeerders, 9) Pilot de training, supervisie en de implementatie, en 10) Voer een process evaluatie uit. Voor Group PM+ waren de belangrijkste aanpassingen het harmoniseren van de actiemechanismen met behulp van culturele modellen voor 'spanning'; het aanpassen van wervingsprocedures om geschiktheid van participanten te garanderen; en het ontwikkelen van een vaardigheden-

checklist. De aanpassingen werden geëvalueerd op haalbaarheid en aanvaardbaarheid tijdens de pilot en ervaringen die naar voren kwamen tijdens de pilot hebben geleid tot verdere aanpassingen, voordat de interventie op effectiviteit werd getest. Dit hoofdstuk introduceert een aantal hoofdthema's die relevant zijn voor het gehele proefschrift: 1) De balans vinden tussen de getrouwheid aan de oorspronkelijke interventie en het passend maken voor de culturele context, 2) Het identificeren en meten van de actiemechanismen van de interventie, en 3) Het belang van wervingsprocedures en kwaliteitsmonitoring (i.e. het meten van de competentie van de facilitators).

In hoofdstuk drie wordt een protocol gepresenteerd voor een trial die haalbaarheid bepaalt van Group PM+. Het testen op haalbaarheid en aanvaardbaarheid is een belangrijke stap voorafgaand aan de trial die de effectiviteit bepaalt. Dit hoofdstuk beschrijft in detail de implementatiemethoden voor de trial die haalbaarheid bepaalt in het Sindhuli district, Nepal. Dit omvat het randomisatieproces tussen de interventie en de verbeterde gebruikelijke zorg arm en de tijdspunten voor het meten van veranderingen in psychologische *distress* en andere geestelijke gezondheidsuitkomsten. In dit hoofdstuk worden ook de criteria voor het bepalen van de haalbaarheid en de aanvaardbaarheid uiteengezet. Sommige haalbaarheids- en aanvaardbaarheidsvereisten betreffen getrouwheid aan Group PM+ elementen op het niveau van 75% of meer, behoud van ten minste 67% van de participanten, en aanwezigheid van ongewenste voorvallen onder minder dan 10% van de participanten. Als de trial die haalbaarheid bepaalt aan deze eisen kan voldoen, kan een extra trial worden uitgevoerd om de effectiviteit van de interventie te testen.

In hoofdstuk vier worden de resultaten van de haalbaarheids- en aanvaardbaarheidstrial van de Group PM+ gepresenteerd. De interventie voldeed aan alle vooraf vastgestelde criteria en beoordelingen. De trial procedures werden haalbaar bevonden en slechts enkele participanten vielen uit vóór follow-up. De hoge participatiegraad in de Group PM+-sessies duidde op aanvaardbaarheid van de interventie. Hoewel deze studie niet *"powered"* was, gaf de Group PM+ arm meer verbeteringen aan, met name in het dagelijks functioneren en wat betreft algemene *distress*, in vergelijking met de controle groep. De sterkste punten van dit onderzoek waren de toevoeging van de *Facilitator Fidelity checklists* om de kwaliteit van het programma te verzekeren en de *Reducing Tension Checklist* (RTC) vragenlijst om het gebruik van Group PM+ vaardigheden door participanten te beoordelen. Kwalitatieve bevindingen benadrukten daarnaast de inherente voordelen van groepsinterventies, waaronder sociale support en validatie van geestelijke gezondheidsproblemen. Aanpassingen, zoals het opnemen van technieken om deelnemers ook buiten de sessies te ondersteunen, waren noodzakelijk vóór de effectiviteitstrial kon plaatsvinden en zijn uiteengezet in hoofdstuk twee.

Hoofdstuk vijf beschrijft het protocol voor een *effectiveness cluster Randomized Controlled Trial (c-RCT)* in Morang, een district in Oost Nepal dat jaarlijks wordt getroffen door overstromingen. Dit hoofdstuk zet de rigoureuze implementatiemethoden uiteen die worden gebruikt in de c-RCT, die onder meer bestaat uit een vergelijking van de 36 Group PM+ clusters met de 36 verbeterde gebruikelijke zorg clusters onder participanten, en hoge mate van psychologische *distress* vertonen. Daarnaast gaat dit hoofdstuk in op individuele psychologische *distress,* als primaire uitkomstmaat, en

post-traumatische stress disorder (PTSD) symptomen als secundaire uitkomstmaat. Plannen voor mediatie analyses worden ook nader uitgewerkt in dit hoofdstuk.

Hoofdstuk zes beschrijft de effectiviteit van c-RCT voor Group PM+ in Morang district, Nepal. Participanten in de interventie- en verbeterde gebruikelijke zorg armen worden beoordeeld op de baseline, midline (7 weken na de baseline; na behandeling in de experimentele arm), en endline (20 weken na de baseline). 324 participanten namen deel in de controle arm (36 afdelingen), en 319 in de Group PM+ arm (36 afdelingen). Group PM+ werd op de endline geassocieerd met een groter deel dat meer dan 50% vermindering van depressieve symptomen vertoonde, maar niet geassocieerd met verminderde PTSD symptomen of functionele beperkingen. Uit deze trial bleek dat in humanitaire noodgevallen, waarbij er een tekort is aan geestelijke gezondheidsspecialisten, een psychologische groepsbehandeling van 5 sessies die wordt geleverd door een non-specialist gebruikt kan worden om psychologische *distress* en depressieve symptomen te verminderen. De gevonden voordelen kunnen deels worden toegeschreven aan het gebruik van psychosociale vaardigheden in het dagelijkse leven. Het gebruik van psychosociale vaardigheden direct na de interventie verklaarde 31% van het PM+ effect op algemene distress-scores drie maanden na de interventie. Verbeterd gebruik van vaardigheden door PM+ participanten bleek vooral belangrijk te zijn voor het verminderen van symptomen.

Hoofdstuk zeven maakt gebruik van mixed methods om in de effectiviteitstrial het *between-groups* effect van de context te onderzoeken, zowel als de competentie van de facilitator en de groepscohesie tussen PM+ groepen. De mechanismen die verschillen in uitkomsten tussen de groepen beïnvloeden, samen met de voordelen van groepsinterventies, zijn zelden onderzocht in de context van lage inkomenslanden. In de 36 groepen waren de *between-groups* verschillen groter voor groepscohesie dan voor verandering in levels van algemene *distress* of gebruik van vaardigheden. De competentie van facilitators beïnvloedde groepscohesie en het gebruik van PM+ vaardigheden door participanten. De kwalitatieve evaluatie ondersteunde eerdere bevindingen dat groepsleden potentieel therapeutische agenten voor elkaar kunnen zijn. Deze bevindingen hebben praktische implicaties voor het versterken van facilitator competentie metingen en het bevorderen van groepsprocessen, zoals cohesie, in groepsgewijze psychologische behandelingen.

Hoofdstuk 8, het epiloog, beoogt te reflecteren op de belangrijkste bevindingen van dit proefschrift en belangrijke aanbevelingen te geven voor toekomstige psychologische trials en programma implementatie. Het hoofdstuk is opgedeeld in drie secties: 1) Cultuur en context, 2) Haalbaarheid en aanvaardbaarheid, en 3) Evalueren van Effectiviteit, overeenkomend met de hoofdstukken in dit proefschrift. De belangrijkste aanbevelingen zijn: het uitvoeren van verdiepende needs assessments en het gebruik maken van het social determinants framework om potentiële onderzoekslocaties te identificeren, het ontwikkelen van psychologische conceptuele modellen die specifiek zijn voor de onderzoekslocatie, verdere innovaties toevoegen aan task-sharing interventies, en het kritisch beoordelen van de invloed van factoren zoals competentie van de facilitator en de onderzoeksopzet op resultaten van participanten.

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