**Problem Management Plus (PM+): Pilot trial of a new, WHO transdiagnostic psychological intervention for common mental disorders in conflict-affected Pakistan**

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**Abstract:**

The short and long-term mental health consequences of war and conflict on the affected population are wide-ranging and pervasive. There is an urgent need for psychological interventions delivered by non-specialist front-line workers that can address a range of mental health problems. The World Health Organization’s Problem Management Plus (PM+) is a brief transdiagnostic intervention employing evidence-based strategies of problem solving, behavioural activation, strengthening social support, and stress management. We conducted a mixed-methods pilot study to explore the feasibility and acceptability of the WHO PM+ intervention in a low-income conflict-affected setting in Peshawar, Pakistan. The results show that the non-specialists (lay-helpers) with no prior experience of mental health care delivery were successfully trained and supervised to deliver the intervention. The intervention had a high uptake-rate, was perceived to be useful by clients and their families, and was successfully integrated into primary care centres. The randomized outcome evaluation indicated improvement in disability and post-traumatic stress symptoms but no change in levels of general psychological distress. Barriers identified included access for women and those living at distance; suggestions for improvement included more visual aids for non-literate clients. The pilot study paves the way for further adaptation, larger-scale implementation and definitive RCTs of the intervention in Peshawar and similar challenging settings.

**Introduction**

In recent decades there has been an unprecedented rise in the number of humanitarian emergencies due to conflict and natural disasters. Although estimated rates of mental disorder after conflict vary due to differences in context and study methodology, a meta-analysis shows that the average rates for depression and posttraumatic stress disorder (PTSD) range between 15-20% (1). The magnitude of psychosocial distress may be higher, affecting over half the people living in such situations (2). The World Health Organization (WHO) along with other agencies stress the need for a broader intervention framework in humanitarian emergencies that not only incorporates PTSD, anxiety and depression but that also includes non-pathological distress (3-6).

Psychological interventions are among the first line treatments for such conditions and many studies have demonstrated the effectiveness of psychological interventions in reducing these conditions (7). Key barriers to sustainable delivery of psychological interventions in LMIC, and in emergency settings particularly, include the complexity of and resistance to decentralisation of mental health services; challenges to implementation of mental health care in primary-care settings; the low numbers and few types of workers who are trained and supervised in mental health care (8). Implementation of adapted psychological interventions by trained lay-workers is one potential solution to this problem, which is receiving significant attention as part of global mental health research agenda (9).

WHO as part of its Mental Health Gap Action Programme (mhGAP) has begun to develop guidelines and test psychological interventions adapted for delivery by non-specialists (10). Problem Management Plus (PM+) is one such intervention (11), developed specifically for adults suffering from symptoms of common mental health problems (e.g., depression, anxiety, stress), as well as self-identified practical problems (e.g., unemployment and interpersonal conflict). The intervention has been developed with particular attention to the needs of populations affected by adversity such as conflict. PM+ is brief, consisting of 5 face-to-face sessions, with a key feature of being deliverable by trained and supervised lay people. The PM+ manual has been translated into Urdu and adapted to the local culture in the Peshawar District.

The aim of this study was to pilot the PM+ intervention in peri-urban Peshawar, one of the most severely conflict-affected cities in Pakistan. A key feature of this mixed-methods study was to explore the feasibility of integrating the intervention into primary healthcare settings, delivered by non-specialist lay delivery agents (hereafter referred to as “lay helpers”) working under supervision of a mental health specialist.

**Methods**

**Study design**

A mixed-methods study with a quantitative component consisting of a two arm randomised controlled pilot trial and qualitative evaluation of the acceptability of PM+.

**Settings and participants**

The Peshawar District is located in the Khyber Pakhtunkhwa province of Pakistan, 40 km from the eastern border of Afghanistan. In the last three decades Peshawar has witnessed an unprecedented rise in militancy, leading to loss of human lives, destruction of property and infrastructure, and curtailment of economic activity (12). In 2009 Peshawar experienced 170 militant attacks, which left 445 dead and 1520 injured. Such attacks have escalated in the last 5 years – 2014 witnessed one of the worst incidents on children in modern history when 132 school children were killed in a single attack on an army school by militants (13). Surveys of psychological distress from adjoining areas have shown rates of up to 65%, with the majority presenting at primary care centers (132). Primary care centers are currently ill equipped to deal with such high level of need (13). Pakistan has a dearth of trained specialists to deliver psychological interventions (14).

The study was conducted from June 2013 to May 2014 in three primary care centres in Gulbahar Union Council, a low-income peri-urban locality in Peshawar District. Participants were primary care attenders aged 18 or above, referred for screening by the primary care physician. Screening was conducted by trained members of the research team following informed consent. Invited participants scored: (a) Three or above on the General Health Questionnaire (GHQ-12), a screening questionnaire for common mental disorders (15) *and* (b) Five or above on WHO Disability Assessment Schedule (WHODAS), a screening questionnaire for functional impairment (16). We excluded individuals with imminent suicide risk, severe cognitive impairment (eg., severe intellectual disability or dementia) or with expressed acute needs/protection risks (eg recent abandonment by husband and his family). We also excluded individuals who reported having experienced a major traumatic event during the past month and individuals with severe mental disorder (psychotic disorders, substance-dependence) . Individuals meeting the exclusion criteria were referred to a specialist centre, depending upon their needs.

All eligible and consenting participants were randomized by an independent researcher not involved in the assessments, to either the PM+ intervention or enhanced treatment as usual (TAU) groups. Randomization was performed at an independent centre using computerized software on a 1:1 basis, stratified for gender.

**Intervention**

**Problem management plus:** PM+ is an innovative low intensity, trans-diagnostic intervention that aims to provide support to adults exposed to adversity. Specifically, it aims to address both common symptoms of mental health problems such as anxiety , depression and stress; and, where possible, associated practical problems, such as livelihood and financial problems and interpersonal conflict. This is achieved through the provision of five, 90-minute sessions, that combine evidence-based strategies of problem solving counselling with selected behavioural strategies including behavioural activation, strengthening social support, and stress management (11).

The PM+ intervention was adapted for the culture and context of Peshawar using a framework developed for this purpose (17,18). The framework contains 8 adaptation principles: (1) language; (2) persons; (3) metaphors; (4) content; (5) concepts; (6) goals; (7) methods and (8) context. A ninth principle of *security* was added to recognise potential complexities associated with adapting interventions for delivery in humanitarian contexts. Adaptations were made to the PM+ intervention material that included: a training manual; a reference manual for lay counsellors; and supporting worksheets for clients. The English and Urdu manual are available on request.

The training and supervision of lay-helpers followed an apprenticeship model (19). This model involves moving the primary delivery of healthcare from specialists such as psychiatrists and psychologists to lay-helpers, and follows the format of building skills through on-the-job training. In this study, lay-helpers were defined as those with at minimum 10 years of education, and with no training or experience of mental health (encompassing counselling, psychology or psychiatry). The apprenticeship model required an initial 6-day training programme by the Master Trainer (KD) to local mental health specialists (NA, MT) who in turn provided an 8-day training programme to six lay-helpers. Training of both supervisors and lay-helpers was followed by four weeks of practice cases with supervision. The lay-helpers were supervised by the 2 in-country trainers. The in-country trainers were supervised by the Master Trainer, building skills in the PM+ intervention as well as in training and supervision of others. Thus, supervision was cascaded from specialist to local experts, and onwards to lay-helpers. Following training and practice cases, the lay-helpers were placed at 2 primary care centres to offer intervention to randomised participants.

**Treatment as usual:** Treatment-as-usual in primary healthcare centres (PHCs) in Peshawar, Pakistan to individuals with common mental disorders usually consists of (a) no treatment, (b) placebo-based care (eg vitamin injections) as evidence-based mental health care is currently not available in PHCs or (c) referral to Lady Reading Hospital specialised psychiatric care. For this study, TAU was enhanced; participants in the TAU group were managed by their primary care physician who received – specifically for this study - refresher training in recognition and treatment of common mental disorders routinely taught in Pakistan by our partner Lady Reading Hospital (20).

**Measures**

Assessments were conducted at baseline and one week after the scheduled 5th session of intervention. The instruments have been adapted and validated for use in Pakistan. All measures were administered by trained research staff blind to the allocation status of the participants.

*Psychological distress*: This was measured by the GHQ (15, 21). The GHQ-12 consists of 12 questions that are scored on a 4-point Likert scale ranging from 0 to 3. When used as a screening tool, the GHQ-12 is usually scored bi-modally (i.e., 0-0-1-1), with scores ranging from 0-12. In a previous study in Pakistan, a cut-off of 3 or higher has been reported to indicate clinically significant psychological distress (21).

*Functioning:* Disability was assessed using the 12-item interviewer-administered screener version of the World Health Organization Disability Assessment Schedule – version II (WHODAS II) (16). It is used across all diseases, including mental disorders. It is simple to administer and applicable across cultures in adult populations. WHODAS II covers six domains (cognition, mobility, self-care, getting along, life activities, participation). It assesses difficulties people have due to their illness across these domains during the last 30 days. Difficulties are scored on a 5-point Likert scale as none, mild, moderate, severe, or extreme. WHODAS II has been used cross-culturally and is valid both as a screening as well as outcome measure, displaying good sensitivity to change (22,23). For screening participants for inclusion in the study, we used a cut-off of five or above using a simple-sum of scores (23).

*Post-traumatic stress symptoms:* Posttraumatic stress disorder (PTSD) symptoms was measured using the PTSD Checklist–Civilian Version (PCL-C) (24), which is a 17-item checklist corresponding with the 17 DSM IV PTSD symptoms. Items are rated on a 1-5 scale and add up to a total severity score of 85. The PCL-C has been used previously in Pakistan (25) and has been found to have acceptable psychometric properties.

**Process evaluation**

The process evaluation involved mixed-methods process monitoring and semi-structured process evaluation interviews. Process monitoring involved analysis of supervision records, and lay-helper competency assessments. For these all 6 lay-helpers were assessed for their competency in delivering PM+ by 2 independent assessors using a competency rating tool that evaluated a) basic counselling skills, and b) use of PM+ strategies with clients through direct observation of specially designed role plays. Competency was rated using a 5-point Likert scale ranging from 0=not done to 5=excellent.

 The qualitative evaluation involved targeted semi-structured interviews with key informants following an established approach for applied mental health research in humanitarian settings (26), exploring questions relating to intervention acceptability. Interviews followed a semi-structured topic guide developed for each category of key informant including 5 intervention clients, 5 lay-helpers, and 5 Primary Healthcare Centre clinical staff (PHC-CS). Interviews were conducted following voluntary informed consent and documented verbatim in a written transcript for subsequent analysis.

**Sample size estimations and analysis**

Since this was a small exploratory RCT that did not aim to detect statistically significant differences in effectiveness, no power calculations were carried out (27). We delivered the intervention to 30 participants in each arm, allowing us to test the feasibility and acceptability of the intervention and trial procedures in the proposed setting and inform the sample size for a future definitive trial (27).

We carried out intention to treat analysis to assess the difference between the two treatment arms. The baseline characteristics were first evaluated to determine the success of randomisation. The adjusted mean difference between the two groups was assessed using log-linear regression models with outcome variables transformed on log scale. The model was adjusted for the baseline scores of each outcome variable.

All qualitative data was analysed thematically following the Framework approach (28) relevant to applied research. This involved researchers familiarising themselves with interview transcripts, coding transcripts by themes and sub-themes, and finalising the coding through consensus. A document containing the finalised thematic categories was then reviewed alongside interview transcripts to identify quotes to illustrate key themes. Finally, the transcripts were re-visited to ensure that coding had reached saturation. All analysis was conducted in the original language, with only the quotes presented here translated into English.

**Ethical considerations**

Ethical approvals were obtained from the local Ethics Review Board at the Lady Reading Hospital and the WHO Ethical Review Committee. Approval was also obtained from primary care administration prior to implementation. Participants were interviewed after providing voluntary written consent.

**Results**

All 60 participants referred by the primary care physician were eligible to take part in the trial and consented to participating. Eleven participants from 60 randomized (18%) – 6 from the intervention arm and 5 from the control arm – were lost to follow-up. Table 1 shows the sample characteristics, and demonstrates the treatment groups were well balanced at baseline for demographic and clinical variables.

*Table 1 about here*

Table 2 summarizes results for the outcomes measured in the participants on intention to treat analysis. On disability scores, there was a significant positive treatment effect in favour of the PM+ intervention; with mean difference 57% less in the intervention arm compared to the control arm (95% CI: -1.11 to -0.03, p=0.04). There was also a positive treatment effect on post traumatic stress symptoms, with a mean difference of 59% reduction in favour of the intervention group. (95% CI: -1.09 to -0.09; p=0.02). On the third outcome of general psychosocial distress there was no significant change.

**Process evaluation**

*Process monitoring* demonstrated that participants showed high levels of intervention adherence with 22/30 (73%), overall completing the 5-session intervention and 4/30 (13%) completing 2 sessions. Competency assessments found that the lay-helpers achieved satisfactory levels of competency with 4/6 (67%) achieving scores of 2 or above on competence in all of the basic counseling skills assessed, and 5/6 (83%) achieving these competence scores on PM+ strategies assessed. Additional targeted training and supervision was provided to the lay-helpers in areas where their scores were low.

*Semi-structured interviews:* Key objectives of the process evaluation were to explore: the acceptability of the intervention to key stakeholders, the feasibility of integrating it within the PHC centres, and to identifying barriers and challenges to further scale-up. Interviewees across all groups of stakeholders discussed common themes which are summarised with illustrative quotes in Table 3. Overall lay-helpers, clients, and their families expressed satisfaction with the PM+ intervention, identifying the benefits of this programme for addressing problems related to their perceived psychological well-being and daily functioning. A barrier identified by all groups of interviewees was the accessibility of a clinic-based treatment programme. This recognised that following a clinic-based design the intervention will only ever reach those clients who attend clinics. Other challenges were also discussed such as logistical issues of the space required for PM+ sessions, as well as the cost and inconvenience of travelling to PHC centres, particularly the sociocultural barrier for females travelling alone to attend sessions. It was suggested this could be addressed through a community-based approach to intervention delivery, with helpers visiting clients at home rather than requiring travel to clinical facilities.

A barrier to implementing the PM+ strategies was client literacy that prevented full use of the client worksheets. To overcome this barrier lay-helpers suggested the incorporation of further visual aids.

**Discussion**

This mixed-methods pilot study explored the feasibility and acceptability of the WHO PM+ intervention in a low-income conflict-affected setting in Peshawar, Pakistan. In summary, the results show that lay-helpers with no prior experience of mental health care delivery were successfully trained and supervised to deliver the intervention. The intervention had a high uptake-rate, was perceived to be useful by clients and their families, and was successfully integrated into primary care centres. The outcome evaluation indicated improvement in functioning and PTSD symptoms but no change in levels of general psychological distress. Barriers identified included access for women and those living at distance, and suggestions for improvement included more visual aids for non-literate clients.

Our study had a small sample size and recruited participants through primary care physician referral; thus the validity and generalizability of the findings have to be interpreted with caution. In line with current recommendation, we therefore focused on the descriptive aspects of the study instead of hypothesis testing (27, 29).

 A key strength of the study was that it was successfully conducted in a highly challenging and insecure real-life setting. Our high enrolment rate, low drop-out rate, and good balance in baseline characteristics between intervention and control groups show that larger scale randomised trials are feasible in such settings. Furthermore, the intervention was successfully delivered by the most widely (and in many cases, the only) available human resource for health in such settings: lay-helpers with no prior mental health experience. The results of this trial demonstrate the feasibility of the task shifting approach, and are consistent with what our groups and others have found in the context of other task shifting interventions (30,31).

In conflict or post-conflict settings, very few studies have been conducted on targeted non-specialist interventions in adults. A naturalistic study using brief client-centered problem-focused counseling in war-trauma survivors in Nepal (32) found modest improvements in somatic symptoms, subjective well-being, disability and functioning. A study in Aceh, Indonesia (33) found that group-counselling by trained counselors led to improvement in functioning and coping but no effect on anxiety, depression and PTSD symptoms. Systematic reviews of such interventions (7,34) have found a dearth of evidence-based scalable interventions for mental health and psychosocial support in humanitarian settings. They proposed that further research was needed, especially in terms of moving beyond PTSD and severe mental disorder.

The lay-helpers were recruited from the local population and this had several advantages for potential scale-up. They were from the same culture and had experienced similar circumstances and therefore could relate well to their clients. Studies have shown that clients often prefer such delivery-agents over specialists, especially when they are embedded within primary-care because they are more accessible and also help reduce stigma attached to help-seeking for such conditions (35). In this study, higher education was not a requirement to become a lay-helper, thus there was a large pool of eligible persons able to take on this role. These factors are important for sustainability and scale-up of such interventions.

Supervision is a key aspect of ensuring fidelity and quality. The brief training and cascade model of supervision were designed to support sustainability and scale-up of the model. Thus relatively few specialists based in a specialist centre can provide group-supervision to many lay-helpers. Additionally, the lay-helpers can utilize peer-supervision, with the more experienced lay-helpers taking on a supervisor’s role as they become more confident in their skills. Such close supervision also ensures that the lay-helpers are more likely able to deal difficult situations and care for their own emotional health while working in a challenging environment. They would also be more aware than outsiders of local security concerns and adapt their practice accordingly.

Over two-thirds of the total participants referred to the study were women. This was expected, given the much higher rate of women presenting to primary care centers with emotional symptoms compared to men (36,37). However, only a small proportion of women with emotional problems access primary care centres, and the process evaluation demonstrated that cultural issues (e.g., women require male chaperones to visit a center) and distances would preclude many women from accessing weekly sessions. As the delivery agents are locally employed lay-persons, this offers the possibility of delivering the intervention nearer the homes, possibly through partnerships with local community-health workers. Such approaches have been found to be useful in delivering psychosocial intervention to mothers in rural Pakistan (35,38).

In conclusion, this pilot study provides very encouraging results about the feasibility, acceptability and potential effectiveness of this brief manualized psychological intervention that can be delivered by persons with no prior experience of mental health care delivery. It has paved the way for further larger-scale implementation and evaluation programmes in Peshawar and similar challenging settings. It confirms that low-intensity, transdiagnostic psychological interventions hold potential to reduce the global burden of disease.

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Table 1: Comparison of baseline demographics between control and intervention groups

|  |  |  |
| --- | --- | --- |
| **Variables** | **Control group (N=30)****(N%)** | **Intervention group (N=30)****(N%)** |
| **Gender** |  |  |
| Male | 7(23.3) | 6(20) |
| Female | 23(76.7) | 24(80) |
| **Marital Status** |  |  |
| Married | 23(76.6) | 21(70) |
| Single | 6(20) | 6(20) |
| Other | 1(3.3) | 3(10) |
| **Education**  |  |  |
| None | 18(60) | 16(53.3) |
| Primary | 3(10) | 5(16.7) |
| Secondary | 5(16.3) | 8(26.7) |
| University | 0(0) | 1(3.3) |
| **Occupation** |  |  |
| Unemployed | 3(8.0) | 2(6.6) |
| Housewife | 18(60) | 16(53.3) |
| Skilled worker | 2(6.7) | 1(3.3) |
| Unskilled worker | 6(20) | 9(30) |
| Student | 1(1.3) | 2(6.7) |

**Table 2. Comparison of outcomes between control and intervention groups on intention to treat analysis**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Outcome** | **Time** | **Control** | **Intervention** |  |  |  |
| **Mean** | **SD** | **N** | **Mean** | **SD** | **N** | **Coef** | **95%CI** | **P value** |
| Disability | T1 | 17 | 10.51 | 30 | 17.70 | 9.21 | 30 | -0.57 | -1.11, -0.03  | 0.04 |
| T2 | 11.31 | 10.36 | 26 | 6.60 | 6.14 | 25 |
| PTSD symptoms | T1 | 32.33 | 17.05 | 30 | 34.17 | 20.07 | 30 | -0.59 | -1.09, -0.09 | 0.02 |
| T2 | 19.54 | 18.45 | 26 | 9.84 | 9.05 | 25 |
| General psychological distress | T1 | 20.77 | 4.12 | 30 | 19.57 | 4.90 | 28 | -0.04 | -0.17, 0.08 | 0.49 |
| T2 | 19.50 | 3.61 | 26 | 18.60 | 3.80 | 26 |

**Table 3: Qualitative interview results:**

|  |  |  |
| --- | --- | --- |
| **Objective** | **Theme** | **Quote (source)** |
| Acceptability to clients | Clients find the programme useful | *I have changed a lot…like a burden lifted from my mind….and I can control my anxiety and fear (Client)**I feel good after sessions. ..., I was able to get back to work. ... I recommend it to others like me (Client)**I am very happy with my helper, he worked with me to re-start my life... he put in a lot of effort in guiding me (Client)* |
| Acceptability to families | Families positive about the programme  | *My family is positive about this programme. My husband has also noticed a change in me and has begun to support me (Client)**I had good rapport with family members. They listen to me and support the client (Lay-helper)* |
| Acceptability to lay-helpers | Lay-helpers confident about their skills | *I could help them because I’ve been through similar experiences (Lay-helper)**I feel I can help clients and they benefit. My clients who were limited to bed have become active again… (Lay helper)**I felt confident after my training and practice-cases. I can always discuss my cases with the other helpers and supervisors (Lay helper)* |
| Feasible for Primary health | Primary health care staff views about the programme | *The community has benefited…. it is an excellent programme. (PHC doctor)**They helped our work, and we had no complains from anyone (PHC administrator)* |
| Barriers and challenges | Accessibility of the programme and programme materials | *Women cannot go outside unescorted…we can only help those who make it here…it would be more helpful for women if it could be delivered in the homes (PHC doctor)* *Some clients who are not literate find it hard to understand….some nice illustrations could help them understand (Lay helper)* |

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