End report on process and outcomes of PM+ implementation in Jordan

DELIVERABLE 4.2
DELIVERABLE 4.3

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1. Executive summary

Worldwide over 100 people are forcibly displaced by war and conflict, with over 27 million formally registered refugees and many more who are not registered [1]. People exposed to this form of adversity are at greater risk for common mental disorders, including anxiety, depression, and posttraumatic stress disorder (PTSD) [2]. This is not surprising considering the exposure to violence, traumatic death, forced separation from family and social networks, poverty and hardship that people in these situations endure. Refugees displaced from war-affected settings are often hosted in directly-adjacent low-and middle-income countries (LMIC) that lack sufficient resources to provide adequate mental health services. The recent Lancet Commission on global mental health highlighted the marked gap between mental health need and provision of services in LMICs [3]. The major barriers to providing evidence-based mental health programs in LMICs include the lack of mental health specialists, most treatment programs being disorder-specific which results in health providers needing to master multiple programs, and lengthy programs that are costly for health services and demanding on recipients.

In response to these challenges, a range of task-shifting approaches has been developed in which non-specialists are trained and supervised to deliver mental health programs. Meta-analyses indicate that this approach can be effective [4]. The World Health Organization has developed one such program, Problem Management Plus (PM+) that is a 5-session program that adopts a transdiagnostic approach to reduce common mental disorders by teaching skills in arousal reduction, problem solving, behavioural activation, and accessing social support [5]. This program has been shown to be effective in large trials in both individual (PM+) and group (gPM+) formats in communities affected by adversity [6-8]. One of the major challenges for advancing the generalizability of gPM+ to populations most affected by prior trauma and ongoing adversity is to determine its effectiveness in refugee camp settings in which people have significant restrictions on their movements, choices, and capacity to exert control over their futures.

Central to the issue of global mental health is the psychological wellbeing of children. Although the efficacy of gPM+ and other task-shifting programs have been shown, there is a scarcity of effective programs that address the needs of children [9, 10]. This is a particularly an urgent issue for refugee children and youth, who represent more than half of refugees in the world today. Many reports indicate that refugee youth experience high rates of psychological distress. One possible means to improve the psychological wellbeing of refugee youth is by improving the psychological health of their parents or caregivers. There is evidence that refugees’ mental health is associated with the psychological status of their children, and it appears this association is partly attributed to their parenting behaviour, which in turn affects the psychological wellbeing of their children. For example, one population-based study found that refugees’ PTSD severity was associated with harsh parenting, which was in turn associated with worse psychological problems in their children [11]. This convergent evidence raises the possibility that reducing common mental disorders in refugees may improve their parenting behaviour, which may have a downstream beneficial effect on the psychological health of their children; this possibility is supported by meta-analysis indicating that psychotherapy for depressed mothers has beneficial effects of their children’s mental health [12].

To address the significant mental health needs of refugees, and particularly those in refugee camp settings, we conducted a randomised controlled trial (RCT) of gPM+ to adult Syrian refugees in a camp in Jordan and compared this program to enhanced usual care (EUC). This trial focused on refugees in a camp because of the limited evidence regarding scalable psychological programs for refugees in camps. Worldwide, approximately one-quarter of refugees reside in camps [13]. It is important to test the capacity of gPM+ in refugees who in camp settings because there can be specific stressors in refugee camps, as well as some limitations that may limit the extent to which refugees can use the skills taught in gPM+. For example, refugees in camps may have restricted movement, limited employment opportunities, and separation from family that can compound psychological difficulties and hamper the extent to which problem management strategies may be employed.
This WP successfully completed preparatory cultural adaptation [14], a pilot trial [15], and a randomised controlled trial of gPM+ comprising 410 refugees [16]. This study showed for the first time that gPM+ can effectively reduce depression in Syrian refugees 3 months after the intervention, although this benefit did not persist at 12 months [17]. Subsequent to this result, we have implemented gPM+ in Jordan by conducting training >100 providers in PM+ in order to facilitate national coverage of PM+ for refugees across Jordan.

This report describes the implementation of gPM+ in a Jordan refugee camp, and the follow-up implementation in Jordan community settings.
2. Definitive RCT (phase 3)

2.1. Overview of this report

This report includes a description of work done for two deliverables: D4.2 (End report on process and outcomes of PM+ implementation in Jordan communities (adults)) and D4.3 (Report describing process evaluation of PM+ scaling-up in refugee camp and community settlements in Jordan). Since these activities the activities are strongly intertwined, the two deliverables are combined in the current single report. This has been agreed upon by the EU project officer, dd. December 20, 2022. This is in line with the reports for the other project sites in WP4 (Lebanon), WP5 (the Netherlands, Turkey and Switzerland) and WP6 (online).

2.2. Background and preparatory work

This two-arm, single-blind RCT was conducted in Azraq Refugee Camp in Jordan. There are over 650,000 Syrian refugees registered with the UNHCR in Jordan, however the government estimates there are more than 1.4 million Syrians currently residing in Jordan. There are three refugee camps in Jordan which are home to more than 125,000 Syrians; Azraq is the second largest camp located in the desert near the city of Azraq with a population of 36,657 Syrians (as of June, 2020) of which 61% are children. Due to high levels of camp security, internet access is limited as is internal and external mobility. Additionally, there are finite employment opportunities. There are currently 8,660 caravans, housing up to a maximum of six family members, that are in use across four residential villages, two of which were used to recruit participants for this project. The study was conducted in collaboration with International Medical Corps (IMC) Jordan, who was the local implementer in Jordan.

Description of PM+

The gPM+ program followed the WHO group program [18]. The gPM+ intervention comprised 5 weekly 2 h group sessions (8-10 people per group that were gender-specific). Session 1 established group rules, psychoeducation, and a stress management strategy. Session 2 focused on problem-solving strategies. Session 3 provided instructions in behavioural activation. Session 4 focused on strategies in accessing social supports. Finally, Session 5 reviewed all strategies and addressed relapse prevention options. In addition, Sessions 2-4 reviewed progress on previously taught strategies. The focus in the group sessions were to teach the participants skills in managing the stressors faced in the camp, and group discussion was facilitated to encourage group members to provide input on problem-solving the common challenges that participants experienced on a daily basis.

Cultural adaptation of PM+

Prior to undertaking the trial and implementation of gPM+ in Jordan, it was important to ensure that the program was culturally appropriate. Undertaking the process of cultural adaptation ensures the appropriateness and acceptability of gPM+ with Syrian refugees in Jordan. We initially conducted a rapid qualitative assessment following the DIME model and comprised free list interviews, key informant interviews, and focus groups discussions [14]. Based on the results, a total of 82 changes were proposed across the intervention manual, training, supervision, and implementation protocols. On the basis of this work, changes were made that ranged from minor amendments in terminology to broader changes to how metaphors, stories, and illustrations are presented during the intervention. Additionally, two substantial adaptations were suggested: (1) the addition of a session designed to enhance family
engagement, and (2) the development of a male case study. These changes were incorporated prior to the implementation of the gPM+ intervention in Jordan.

Pilot randomized controlled trial

Prior to conducting the definitive trial, a pilot controlled trial was conducted in the Azraq Refugee Camp to identify areas for adaptation in preparation for the definitive trial [15]. A feasibility randomized controlled trial was conducted in Azraq refugee camp in Jordan that hosts Syrian refugees and will be the site for the definitive trial. Inclusion criteria were: (1) Syrian adults aged ≥ 18 years, (2) parent of a child aged 10-16 years, (3) experiencing psychological distress as defined by a score of ≥16 on the Kessler Distress Scale, and (4) ≥17 on the WHO Disability Assessment Schedule 2.0. Following baseline assessments, participants were randomized to receive gPM+ or enhanced treatment-as-usual. Post-assessments were conducted one week following the last gPM+ session. Primary outcomes were feasibility and acceptance of gPM+; symptoms of anxiety, depression, PTSD, prodromal psychosis, grief, and child’s self-reported psychological distress were also assessed. Of the 207 persons screened, 64 (31%) screened positive for psychological distress. Of the 35 randomized into the gPM+ intervention, 24 (69%) completed the intervention. No adverse events were reported throughout the trial. Children whose parents received gPM+ had greater reductions in internalizing and externalizing symptoms at posttreatment. 55 (86%) participants completed the post-assessment follow-up. These results demonstrate both the feasibility of conducting the trial in a camp and acceptance of the gPM+ intervention by Syrian refugees. Following the feasibility trial, both the implementation procedures and intervention were shown to be safe and culturally acceptable.

Ethics approval definitive RCT

The project was prospectively registered (Australian and New Zealand Clinical Trials Registry, no. 12619001386123), and ethically approved by the Institutional Review Board at the King Hussein Cancer Centre in Jordan and the University of New South Wales Human Research Ethics Committee.

Objectives and design

To address the significant mental health needs of refugees, and particularly those in refugee camp settings, we conducted a randomised controlled trial (RCT) of gPM+ to adult Syrian refugees in a camp in Jordan and compared this program to enhanced usual care (EUC). This trial focused on refugees in a camp because of the limited evidence regarding scalable psychological programs for refugees in camps. Worldwide, approximately one-quarter of refugees reside in camps [24]. It is important to test the capacity of gPM+ in refugees who in camp settings because there can be specific stressors in refugee camps, as well as some limitations that may limit the extent to which refugees can use the skills taught in gPM+. For example, refugees in camps may have restricted movement, limited employment opportunities, and separation from family that can compound psychological difficulties and hamper the extent to which problem management strategies may be employed. This trial also investigated the potential impact of gPM+ on refugees’ parenting behaviour, and also how this may benefit their children’s mental health. It was hypothesised that gPM+ would reduce anxiety and depression, disability, posttraumatic stress, personally identified problems, prolonged grief, prodromal psychotic symptoms, as well as improving parenting behaviours and children’s mental health, relative to EUC at the follow-up assessment.

To test these hypotheses, this two-arm, single-blind RCT was conducted in Azraq Refugee Camp in Jordan. Adult Syrian refugees were randomised to either gPM+ or Enhanced Usual Care, and were assessed at baseline, post-treatment, 3-month follow-up, and 12-month follow-up. The primary outcome timepoint was the 3-month follow-up.
2.3. Methods

Participants and procedures

Participants comprised refugees in Azraq Refugee Camp and inclusion criteria were: (a) aged ≥ 18 years, b) scores ≥16 on the Kessler Psychological Distress Scale (K10 [19]), (c) Arabic-speaking, (d) scores ≥17 on the WHO Disability Assessment Schedule 2.0 (WHODAS [20]) had a child or dependent living in the household aged 10-16 years. The K10 is a 10-item questionnaire that assesses psychological distress, with a range of 10-50; a cut-off of 16 has been shown to indicate psychological distress [21]. The K-10 has been validated in Syrian populations [22], and the recommended cut-off of 16 has been successfully used in refugee populations [23]. This measure was employed as a brief screener to permit rapid screening of refugees with psychological distress. The WHODAS is a 12-item questionnaire that assesses general functioning, with a possible total score of 48; following prior trials of gPM+ [6, 7], a cut-off of 17 was used to identify functional impairment. Exclusion criteria were: a) significant cognitive or neurological impairment, b) acute medical conditions, c) severe mental disorders (e.g. psychotic or substance-abuse disorders), and d) acute risk of suicide. Exclusion criteria were assessed by structured questions pertaining to each criterion described in the WHO PM+ manual [24]. Refugees meeting exclusion criteria were referred to specialised services in the camp. Recruitment was conducted by Arabic-speaking assessors through door-to-door screening of consecutive caravans; to reduce contamination of the interventions, only one adult per caravan was invited to participate in the study. It was considered that there would likely not be significant contamination between neighbouring caravans because socialization did not adhere to caravan proximity. The invitation was initially extended to the person who answered the door and if they declined, the offer was made to another adult living in the caravan. Informed consent involved two-steps: 1) consent to participate in the screening and 2) participants who screened positive were invited to provide their consent to participate in the trial. Participants completed a written consent form and those who were illiterate provided witnessed oral consent, in line with recommendations from WHO. Additionally, caregivers were asked to provide written consent for participation for one of their children whom the caregiver nominated between the ages of 10 and 16 years to be assessed; additionally, verbal assent was obtained from the child. Children were then approached to obtain assent to complete the Pediatric Symptoms Checklist (PSC-35) [25] during the pre- and post-assessments; children’s assent was not a requirement for participation of their caregiver.

Participants were randomly allocated (on a 1:1 ratio) to either a 5-week gPM+ intervention or EUC. Randomisation was conducted at the UNSW Australia by staff who were independent of the trial using computerized software that generated random number sequences. Allocation concealment was ensured by keeping the treatment assignments in sequentially numbered, opaque, sealed envelopes that informed the trial co-ordinator in Jordan on assignment to gPM+ or EUC. Masking participants and facilitators was not achieved because allocation to the respective condition was transparent. Assessors who identified participants, enrolled participants into the trial, and conducted all assessments were masked to treatment condition allocation. Assessors were located separately from the refugee camp, and at no point did they interact with group facilitators. At the commencement of each assessment assessors instructed participants to not inform them about their allocated condition.

Participants randomised to EUC received a visit to their caravan from IMC staff and given specific information about their services in the camp that could assist with the problems identified in the assessment. This information included organisations providing services for mental health problems, as well as health, parenting, and vocational training. Sessions were approximately 15 minutes in duration. If participants in EUC displayed severe psychiatric problems (e.g. psychosis or suicidality) during the feedback sessions that were not reported in the initial assessment that required immediate attention, they were referred to IMC mental health clinics in the camp for further intervention. If risk of harm was determined, participants were referred to the National Centre for Mental Health in Amman.
Measures

The primary outcome was the total score for anxiety and depression, respectively, measured with the Hopkins Symptom Checklist-25 (HSCL-25) [26]. The HSCL consists of 25 questions that are rated on a 4-point scale (1 = not at all, 4 = extremely), with higher total scores reflecting more severe anxiety and depression. The HSCL has been validated across many cultures, including in Arabic contexts [27]; recommended cut-offs for probable cases of anxiety and depression on the Arabic version of the HSCL relative to structured clinical interview is 2.0 and 2.1, respectively [27]. The internal consistency of the HSCL in the current sample was robust for the anxiety (0.79) and depression (0.84) scales, respectively.

Secondary outcomes were functional impairment, PTSD symptoms, personally identified problems, prolonged grief symptoms, prodromal psychotic symptoms, parenting behaviour, and children’s self-reported mental health. Functional impairment was assessed using the 12-item WHODAS 2.0, with each item scored of 4-point scale and higher scores indicating more severe disability. The WHODAS has good psychometric properties across many countries [20], and the internal consistency in the current study was 0.82. PTSD symptoms were measured using the PCL-5 [28], which is a 20-item checklist corresponding with the 20 DSM-5 PTSD symptoms. Items are rated on a 5-point scale, with higher scores indicating more severe PTSD. A validity study of Syrian and Iraqi refugees observed that a score of 23 is the optimal cut-off to indicate probable PTSD diagnosis [29]. Personally identified problems were assessed with the Psychological Outcome Profiles (PSYCHLOPS) [30], which address three domains (main problems experienced, 2 questions), functioning (1 question), and wellbeing (1 question). Each response is scored on a 6-point scale, with a possible total score of 20 on which higher scores indicate greater problem severity. The PSYCHLOPS has been validated repeatedly in global mental health [44, 45], and has been shown to be sensitive to change in prior PM+ and gPM+ trials [6-8]. Prolonged grief symptoms were assessed using the PG-13 [31], which is a 13-item self-report measure that indexes the core symptoms of prolonged grief disorder (PGD); in current study the internal consistency was 0.86. Eleven items are rated on a 5-point scale and two items on a 2-item scale, providing a possible total score of 57 with higher score reflecting more severe grief. Prodromal psychotic symptoms were assessed using the Prodromal Questionnaire-16 (PQ-B [32]). The PQ-B comprises 16 true or false items about early signs of psychosis, and ask about levels of distress experienced for the endorsed items on a 4-point scale, and higher scores indicate worse prodromal symptoms. Respondents who endorse ≥ 6 items are considered to be at risk for developing psychosis; the internal consistency was 0.82. Parenting behaviour was assessed using the Alabama Parenting Questionnaire-42 (APQ) [33]. The APQ measures five major parenting constructs: (i) involvement (10 items), (ii) poor supervision and monitoring (10 items), (iii) positive parenting (6 items), (iv) inconsistent discipline (6 items), and (v) corporal punishment (3 items). Each item is scored on a 5-point scale, with higher scores indicating greater strength of the relevant subscale. Psychological distress in children of participants were assessed using the youth-reported version of the Pediatric Symptoms Checklist (PSC), which been validated in 6-16 year olds [25]. The PSC comprises 35 items rated on a 3-point scale and yields a total score, as well as three subscale scores of attentional (5 items), internalizing (5 items), and externalizing (7 items) problems. Higher scores indicate more severe difficulties in the respective domain. Additionally, at baseline prior exposure to traumatic events was assessed using an adapted form of published Traumatic Events Checklists [34]; this 27-item dichotomously scored checklist provided a potential score of 27, with higher scores indicating greater exposure to traumatic events. Ongoing stressors were assessed at baseline using the 17-item Post-Migration Living Difficulties checklist [35], which assesses the extent to which post-migration challenges concern the respondent over the prior 12 months; items were rated on a 5-point scale, with items scores ≥ 2 (a moderately serious problem) were defined as the stressor being present, with higher scores indicating more ongoing stressors. This scale has previously been used in Arabic speaking refugees [36].
All assessments were conducted by Arabic speaking Jordanians, who received four days of training in research ethics, the assessment battery, and general interviewing techniques, and psychological first aid in order to allow them to manage any distressed participants during an assessment. Assessments were conducted on portable tablets to ensure that data could be reliably collected and uploaded. On the basis that a proportion of participants were inadequately literate in Arabic, assessors verbally administered the questions and assessors entered participants’ responses on the tablets.

**Interventions (PM+ and Care as Usual) and trainings**

The gPM+ groups were conducted by two facilitators. The facilitators held a bachelor’s degree in social sciences or a related health discipline, were proficient in Arabic, but had no prior experience in delivering psychosocial programs. The facilitators received 8 days of training in the delivery of gPM+, as well as basic counselling and group facilitation skills. Following training, the gPM+ providers were required to complete two practice groups, as a lead facilitator and as a co-facilitator, under close supervision. In addition, a local supervisor (HAH) who worked within the camp provided weekly supervision throughout the trial. The local supervisor also received fortnightly supervision by a primary trainer of gPM+ in Sydney, Australia (KD) via Skype calls. To evaluate treatment fidelity, 20% of gPM+ sessions were attended by the supervisor, who used a checklist to ensure that all gPM+ components were delivered. Each strategy was checked by the supervisor as present/absent, and whether it was delivered satisfactorily or not. Fidelity checks via recording of sessions were not possible because of concerns from refugees that recorded information disclosed during sessions may be accessed by government or Syrian authorities and used against them or their families.

Participants randomised to EUC received a visit to their caravan from IMC staff and given specific information about their services in the camp that could assist with the problems identified in the assessment. This information included organisations providing services for mental health problems, as well as health, parenting, and vocational training. Sessions were approximately 15 minutes in duration. If participants in EUC displayed severe psychiatric problems (e.g. psychosis or suicidality) during the feedback sessions that were not reported in the initial assessment that required immediate attention, they were referred to IMC mental health clinics in the camp for further intervention. If risk of harm was determined, participants were referred to the National Centre for Mental Health in Amman.

**Analyses**

We based our power analysis on prior trials of gPM+ [10], and aimed for a medium Cohen’s $d$ effect size of 0.4 in the gPM+ group at 3 months follow-up (the primary outcome timepoint). Power calculations suggest a minimum sample size of 133 participants per group (power = 0.90, $\alpha = 0.05$, two-sided). Taking into account an expected 35% attrition at 3 months follow-up, we aim to include a total number of 410 participants (205 in gPM+ and 205 in EUC).

Analyses focused primarily on intent-to-treat analysis. Linear mixed models were used to study differential effects of each treatment condition because this method allows the number of observations to vary between participants. Further, this statistical approach handles missing data by including all available data and using maximum likelihood estimation methods which makes valid inferences under the assumption of data missing at random. Fixed (intervention, time of assessment) effects and their interactions were entered in the unstructured models, which provided an index of the relative effects of the treatments; time of assessment included baseline, posttreatment, and 3-month follow-up. Fixed effects parameters were tested with the Wald test ($t$-test, $p < .05$, two-sided) and 95% confidence intervals (no Bonferroni adjustment was made). Analyses focus on the primary (HSCL) and secondary (WHODAS, PCL, PSYCHLOPS, PG-13, PQB, APQ, and PSC scores) outcomes, with the main outcome point being the 3-month follow-up. Missing data were assumed to be random on the basis that participants completing the 3-month assessment and those who were missing did not differ in
terms of age, education level, trauma exposure, or primary outcome measures at baseline (S1 Table). Further, there were only 43 (10.5%) of cases in which there was no follow-up data on the primary outcome measures. To assess the robustness of this statistical approach, we conducted subsequent analyses including only participants who completed the 3-month follow-up. Further, in recognition of the variable impacts of prior traumatic experiences and ongoing stressors experienced by participants, analyses were repeated adjusting the models using baseline scores of the Traumatic Events Checklist and the Post-Migration Living Difficulties as covariates. To determine the effectiveness of the intervention on refugees with probable clinically significant problems, we also conducted sensitivity analyses focusing on refugees who presented with probable anxiety or depression on the HSCL (defined as mean item score ≥ 2 on anxiety or ≥ 2.1 on depression subscales). We also conducted non-planned analyses on the minimally important difference for outcomes by comparing the proportions of participants in each treatment arm showing changes of more than 0.5 SDs [37].

To explore the potential role of gPM+ on parenting and children’s mental health, an exploratory secondary mediation analysis was conducted by assessing the direct and indirect effects of intervention arm on change in Alabama Parenting Questionnaire subscale scores from baseline to 3-month follow-up, and change in PSC subscale scores. The proposed mediation model was examined using the PROCESS macro (Version 3.15; [38]) for SPSS (Version 27), PROCESS Model 4, with 5,000 bootstrapped samples. This model examined the relationship between intervention arm on changes in child mental health (PSC subscale scores), with changes in parenting behaviours (APQ subscale scores) as the mediators. All analyses were overseen by an independent statistician who was blind to treatment condition.

2.4. Results

Flow of participants

Participants were enrolled between October 14, 2019 and March 2, 2020, and the final follow-up assessments were conducted on July 6, 2020. There were 1,377 caravans approached, and this resulted in 624 refugees agreeing to be screened. There were 462 refugees meeting entry criteria, of whom 410 proceeded to randomization; 204 refugees were randomised to gPM+ and 206 to EUC. The primary outcome assessment at 3-months was conducted for 168 (82.4%) participants in gPM+ and 189 (91.7%) in EUC (see Figure 1). This level of attrition was within the projected 35% margin on which the power analysis was calculated. The attrition was much lower than we expected, possibly because of unfolding events in Syria that may have caused many refugees to be reluctant to return home. Interestingly, there was 10% greater attrition in the gPM+ arm than EUC at the 3-month follow-up, possibly reflecting fatigue in participating in the trial. No adverse events were attributable to the interventions or the trial.

The mean age of participants was 40.03 years (SD 6.95), most were female (300 [70.2%] females, 110 [29.8%] males) and the mean time since leaving their home in Syria was 5.89 years (SD 1.67; range: 1-9 years). The demographic characteristics were not significantly different between the two treatment arms. Notably, the participants reported common exposure to potentially traumatic events, including danger during fleeing from Syria (84.6%), direct exposure to war (69.3%), accidents (66.3%), disasters (31.7%), serious injury (23.9%), forced separation from family (21.5%), and murder of someone close to them (11.7%) (see table 2). In terms of current stressors, many refugees reported poverty (90.2%), poor work conditions (83.4%), loneliness (70.2%), worry for family in Syria (77.3%), and poor healthcare (67.1%). The sample included 267 (65.1%) with probable depression, 321 (78.3%) with probable anxiety disorder, and 138 refugees (61.5%) who reported probable PTSD.
The 12-month assessment was conducted for 307 participants (74.9%) participants. There were more participants retained in the EUC condition (164, 79.6%) than gPM+ (143, 70.1%), $\chi^2 = 4.9$, $p = .03$. Participants who did and did not complete the 12-month assessment did not differ on any baseline characteristics (with a Bonferroni-adjusted $\alpha = .002$), however those who dropped out had marginally higher depression and PTSD scores than those who were retained.
Figure 1. Participant Flowchart

624 Refugees screened for eligibility via casework visits

- Excluded (n = 162)
  - Minimal distress (n = 161)
  - Suicide risk (n = 1)

462 eligible for participation

- Declined treatment (n = 52)
  - Refusal (n = 26)
  - Not currently in camp (n = 11)
  - Husband refused participation (n = 8)
  - Returned to Syria (n = 4)
  - Health reasons (n = 3)
  - Moved villages (n = 2)

Randomization (n = 410)

- Allocated to gPM+ (n = 204)
  - Received 0 sessions (n = 3)
  - Received 1 session (n = 5)
  - Received 2 sessions (n = 16)
  - Received 3 sessions (n = 32)
  - Received 4 sessions (n = 60)
  - Received 5 sessions (n = 82)
  - Dropped out during gPM+ (n = 20)
    - Refused to continue gPM+ (n = 15)
    - Husband refused participation (n = 2)

- Allocated to EUC (n = 206)

Completed 6-week assessment (n = 174)

- Refusal (n = 4)
- Not currently in camp (n = 4)
- Moved villages (n = 1)
- Legal issues (n = 1)

Completed 3-month follow-up (n = 168)

- Refusal (n = 5)
- Not currently in camp (n = 3)
- Moved villages (n = 2)
- Legal issues (n = 1)

Included in intent-to-treat analyses (n = 204)

Completed 6-week assessment (n = 193)

- No lozenges residing in camp (n = 6)
- Refusal (n = 5)
- Returned to Syria (n = 1)
- Unable to be contacted (n = 1)

Completed 3-month follow-up (n = 189)

- Refusal (n = 10)
- Returned to Syria (n = 4)
- Husband refused participation (n = 1)
- Medical reasons (n = 1)
- Unable to be contacted (n = 1)

Included in intent-to-treat analyses (n = 206)

Results main outcomes
The mean number of gPM+ sessions attended was 3.96 (SD 1.14), with 180 (88%) participants attending at least three sessions. Twenty-three gPM+ sessions were observed throughout the study to evaluate the intervention fidelity, 22 (95.7%) of which were assessed to be satisfactory. Two-thirds (126; 66.7%) of refugees in EUC reported consulting a health professional in the camp during the period of the trial; more than half of these consultations were to the camp medical officers (58.2%).

In terms of primary outcomes, at the 3-month follow-up assessment the gPM+ had a greater reduction in HSCL-Depression scores than those in the EUC group (adjusted mean difference 3.69, 95% CI 1.90 to 5.48; p<.001; effect size, 0.40) (see Table X). There were more participants in the gPM+ arm (102; 50.0%) relative to EUC (89; 43.2%) achieving a minimally important difference in depression between baseline and follow-up (χ² = 6.67, p=.03) (S2 Table). There was no difference between treatment arms in change in anxiety levels (adjusted mean difference -0.56, 95% CI -2.09 to 0.96; p=.47; effect size, -0.03) at the 3-month follow-up.

Table X. Summary statistics and results from mixed model analysis of primary and secondary outcomes
Results secondary outcomes

In terms of secondary outcomes, at 3-months participants in the gPM+ condition had greater reductions in scores than EUC on the PSYCHLOPS (adjusted mean difference 0.88, 95% CI 0.07 to 1.69; p=.03), and the APQ discipline subscale (adjusted mean difference 1.54, 95% CI 1.03 to 2.05; p=.001). There were more participants in the gPM+ arm relative to EUC achieving a minimally important difference between baseline and 3-month follow-up for WHODAS (gPM+ 76.2%, EUC 66.1%; χ² = 10.2, p=.001). There were no significant differences at 3-months in changes of PTSD (adjusted mean difference -0.68, 95% CI -4.01 to 2.66; p=0.69), disability (adjusted mean difference -1.21, 95% CI -2.80 to 0.37; p=.13), grief (adjusted mean difference -0.29, 95% CI -3.14 to 2.55; p=.84), prodromal symptoms (adjusted mean difference -0.53, 95% CI -1.18 to 0.12; p=.11), parental involvement (adjusted mean difference 0.14, 95% CI -2.06 to 2.34; p=.90), parental supervision (adjusted mean difference 0.15, 95% CI -0.91 to 1.99; p=.79) positive parenting (adjusted mean difference -0.15, 95% CI -1.30 to 0.99; p=.79), parental punishment (adjusted mean difference -0.26, 95% CI -0.80 to 0.27; p=.34), children’s attentional problems (adjusted mean difference -0.24, 95% CI -0.81 to 0.33; p=.41), children’s internalizing problems (adjusted mean difference 0.03, 95% CI -0.37 to 0.42; p=.89), or children’s externalizing problems (adjusted mean difference 0.16, 95% CI -0.23 to 0.56; p=.41).

The sensitivity analysis that focused only on participants that were retained at the 3-month follow-up did not change any of the results observed in linear mixed models analyses (S3 Table). Results of the covariate-adjusted analysis were consistent with those in the primary linear mixed model analysis; this indicated that degree of trauma exposure and ongoing stressors did not significantly impact results (S4 Table); the effect size for the depression outcome was higher after controlling for these factors relative to the initial analysis (0.90 vs 0.40). The analysis that focused only on participants with probable anxiety or depressive disorder indicated that the same results were observed as with the primary analyses; specifically, gPM+ resulted in greater reductions in depression, personally identified problems, and disciplinary parenting relative to EUC (S5 Table).

Regarding primary outcomes, at the 12-month assessment there were no significant differences between gPM+ and EUC on either HSCL-Depression (adjusted mean difference -1.0, 95% CI -3.2 to 1.3; p = .39; effect size, 0.11) or HSCL-Anxiety (adjusted mean difference -1.7, 95% CI -4.8 to -1.3; p = 0.06; effect size, 0.27) scores (Table 3). It should be noted that although there were no significant differences between these conditions, participants in EUC tended to have greater reductions at 12 months relative
to gPM+, and especially in terms of anxiety. There were no differences between the two treatment arms at 12-months on any of the secondary outcomes, with the exception that participants in gPM+ reported more improved negative parenting relative to those in EUC (adjusted mean difference -2.0, 95% CI -3.7 to -0.3; p = 0.02; effect size, 0.41).

Exploratory analyses and other findings

The mediation analysis indicated significant indirect paths between receiving gPM+ and greater reductions in the children’s reported attentional (β = 0.11, SE .07; 95% CI .003, .27) and internalising (β = 0.08, SE .05; 95% CI .003, .19) problems were mediated through reductions in caregivers’ disciplinary (Fig 2 and S1 Fig). These patterns suggest that gPM+ was associated with improvements in children’s attentional and internalising problems when there was an increase in consistent disciplinary behaviours in caregivers.

2.5. Conclusion

Summary of findings

This trial tested the effectiveness of the WHO gPM+ intervention in Syrian refugees who were living in a secure refugee camp, and who had fled the war in Syria in recent years and reported psychological distress. The major findings were that gPM+ significantly reduced depression and disability in refugees, and also reduced disciplinary parenting behaviour. The intervention did not demonstrate reductions in anxiety, PTSD, grief, prodromal symptoms, or child mental health problems. Notably, the benefits of gPM+ did not appear to persist 12 months after the program.

A novel finding was that gPM+ reduced maladaptive disciplinary parenting behaviour in refugees. Although only an exploratory analysis was conducted with participants who completed the 3-month follow-up, we observed that gPM+ was associated with reduced attentional and internalizing problems in refugees’ children via the caregivers’ reduced disciplinary behaviour. This accords with evidence from parenting programs that reducing maladaptive discipline can have positive impacts on children’s mental health. This is an important finding because, although tentative at this stage, it suggests that brief behavioural programs aimed at refugees can have an indirect benefit on their children by reducing maladaptive parenting practices.

In terms of the process evaluation, three core issues were identified. Emotional and psychological distress was mentioned as one of the three core problems facing Syrians. Distress in refugees in Jordan centered on uncertainties around their future and difficulties meeting basic needs. Living in a camp setting appears to coincide with increased reporting of social support, with those in urban settings reporting more difficulties in forming social relationships. Syrians living in camp settings are likely to enjoy easier access to services as NGOs are based directly in the camp and camp management is responsible for ensuring that necessary services are provided. This appears to be reflected in the findings as those living in camps reported utilizing structured activities as a source of coping such as engagements in informal education, recreational activities and sports. Despite the potential ease of access to services that was reportedly found within the camp setting, harsh living conditions were noted as a significant source of distress. Similarly, for those living in urban settings, primary problems identified in Jordan were economic and work-related issues. Further, the abuse of women and children was named as a primary concern amongst respondents.
Barriers to recruitment

The trial in the camp had no significant barriers to recruitment. This success can be attributed to the fact that this study recruited participants from a secure camp in which all inhabitants were Syrian refugees. We retained 87% of the sample at the primary 3-month follow-up, which is also a very high rate of retention. This again can be attributed to the fact that this population is not mobile because they live in the camp.

Limitations

Limitations of the project included use of some measures that have not been culturally validated. Whereas the HSCL, WHODAS, and PCL have been validated in Arabic populations, other measures used in this trial were not culturally adapted for this population. This lack of proper adaptation may result in use of linguistically inappropriate idioms, failure to measure the intended constructs in Syrian refugees, and also the adapted measures may not possess optimal psychometric properties. We also note that provision of weekly group contact was not matched across conditions, and there was a preponderance of females in the study. Participation of males in psychological trials is much-needed in global mental health, however they are typically difficult to recruit into programs. Concerted efforts are needed in future research and implementation programs to recruit more men to psychosocial programs. We were also not able to obtain objective documentation regarding the services provided by health workers in the camp to EUC participants. Prescription of psychotropic medication is common practice yet this information could not be detailed. Further, there is stigma regarding consulting a psychologist or mental health professional in this setting, and so there may be under-reporting or poor attendance to these services; many refugees may consult physicians instead of mental health professionals. Although we retained 87.1% of the sample at follow-up, and secondary analyses indicated this did not impact our findings, we recognize that the drop-outs from gPM+ and the follow-up assessments are a limitation. Finally, we do not have data to validate the efficacy of the masking of assessors, such as by having assessors guess the participants’ allocated condition. Having this information may provide stronger evidence that masking was successfully achieved.

Recommendations for further scaling up

There has been significant interest in gPM+ since this trial in Jordan. To respond to this, a concerted effort has been initiated to train more providers in delivery of PM+. This has involved training of trainers, as well as training of facilitators. The training of trainers is a significant step forward because it promotes local capacity in Jordan to train other providers. To date, over 100 PM+ facilitators have been trained in PM+, and 20 trainers have been trained. Importantly, these trainers have conducted over 50 facilitators, which reflects our success in embedding ongoing capacity in Jordanian agencies to foster sustainable capacity to roll out PM+ in Jordan. We have taken the strategy of collaborating with a national humanitarian agency, the Institute for Family Health because it is the most trusted humanitarian organisation in Jordan, is part of the respected King Hussein Foundation, and provides psychosocial services throughout Jordan. Since the Syrian war, it has provided services to many 1,000’s of Syrian refugees. In collaboration with the Institute for Family Health, in September 2022 we conducted a launch meeting of the PM+ training in Amman that was attended by many of the local agencies, and importantly by the Jordanian Ministry of Health. This strategy has established a platform for ongoing training and scaling up of PM+ in Jordan. We have recommended to the Institute for Family Health, the Ministry of Health, and other agencies that personnel in all agencies should be initially trained as PM+ facilitators, and that those who are more proficient be trained as PM+ trainers who can conduct further training within each agency. This strategy will ensure that many agencies, as well as government providers, will have sufficient capacity of PM+ trainers and facilitators to enable sustainable scale-up of PM+. Importantly, this approach will minimise risks posed by attrition of staff.
It should also be noted that the process evaluation indicated significant challenges for the potential implementation of a low-intensity psychological intervention focused on problem-solving strategies. Finding gainful employment free from exploitation and preventing domestic violence are often not problems that can be easily solved. The creators of gPM+ acknowledged the array of adversities faced by conflict-affected populations and utilize the term ‘management’ to signify teaching to skills to deal with stress arising from stressors rather than solution of stressors themselves; this is important in contexts with unemployment or lack of housing is a reality that is not readily solved. Similarly, certain realities exist in the camp setting because of restricted movement and limited access to communication.

Despite the challenges of implementing psychological interventions in settings that are characterised by adversity, the combined findings from the quantitative and qualitative studies in this project suggest that gPM+ is an evidence-supported intervention that has much potential in Jordan for Syrian refugees. When delivered by non-specialist peers in group settings it is highly acceptable and at least at 3 months after the intervention there are benefits in reduced depression and improvements in parenting skills. The observation that the benefits did not persist at 12 months is perhaps not surprising given the ongoing stressors that the refugees in the camp were facing, and this may suggest that further input is needed in terms of booster sessions to promote ongoing use of the strategies learnt during the gPM+ sessions.
3. Process evaluation (qualitative research)

Background

Whilst gPM+ has been validated for use in Pakistan and Nepal, its applicability to the Jordan context has not been explored prior to this project. Further, it has not been validated for people in a refugee camp context who have fled a war. Rapid Qualitative Assessments (RQAs) were conducted to gain a thorough understanding of the needs and cultural nuances of Syrian refugees, to inform the cultural adaptation of the intervention protocol for these settings. The RQA utilized the Design, Implementation, Monitoring and Evaluation (DIME) model. The process was implemented by the mental health and psychosocial support teams at International Medical Corps (IMC) Jordan country office. The International Federation of the Red Cross and Red Crescent Societies (IFRC) Reference Centre for Psychosocial Support based at Danish Red Cross led the implementation of this process.

Method

In accordance with the DIME model, the RQA was conducted using three-phases of qualitative data collection: (a) free list interviews, (b) key informant interviews, and (c) focus groups discussions (FGD). All three phases were conducted in Jordan by native Arabic speakers. Data was collected over a three-week period in two refugee camps (Zataari and Azraq). All participants were adult Syrian refugees (≥18 years old) living in Jordan in camp or community locations.

Consent was solicited by reading aloud the consent form and asking respondents to sign or mark their agreement on the form. All participants were informed that their answers will remain confidential and that no identifying information would be collected. Participants had the right to withdraw from the interview or group discussion at any time with no negative consequences. The interview tools were developed in English and then translated to Arabic and back-translated. Fourteen staff were trained over the course of two-days. The 14 trainees were Jordanian IMC staff working in the field of mental health and psychosocial support who were native Arabic speakers and fluent in English. The training familiarized staff with the various interview proformas as well as covered communication skills, interviewing techniques and referral pathways. During the training, trainees were instructed to check the accuracy of the translation against the meaning of each question being asked. Trainees were invited to provide feedback on any changes to the questions needed to ensure cultural appropriateness and acceptance. The training provided information about PM+, communication skills, qualitative interviewing techniques, RQA methods, and the study procedures.

Free list interviews (FL) utilized a structured format to provide an overview of a given topic. The FL aimed to identify problems faced by the Syrian population in both countries, and coping strategies commonly employed at both the individual and community levels. The primary question asked was: “What are all the problems that affect Syrian refugees living in Jordan?”. Respondents were also asked to list all the important daily tasks and activities Syrian refugees regularly do to care for themselves, their families and their community. Data collected was segregated for men, women, and children to identify unique coping skills of these populations. In Jordan, children were also interviewed as part of this step.

The purpose of the key informant interviews (KII) were to gather in depth information about the problems and coping strategies mentioned during the FL interviews. KII participants were identified from the FL interview respondents and included Syrian refugee community members, mental health care service providers and mental health policy makers. Psychosocial problems identified during FL interviews were explored in a semi-structured way. Priority was given to problems frequently mentioned or that were not
already well understood during the FL exercise. KIIs were conducted in a proximate, private, and comfortable location decided based on convenience to the participant.

The KIIs focused on the following aspects of the three most commonly noted mental health and psychosocial wellbeing related problems selected from the FL exercise:

- A. The characteristics and symptoms of the problem;
- B. The perceived causes;
- C. The effects on those having the problems, and on others close to them;
- D. Coping methods predominantly implemented by the Syrian refugee community to address such problems;
- E. Help-seeking behaviors and potential deterrents or barriers to help-seeking.

Focus group discussions (FGD) built on information gathered during FL and KIIs. The FGD were designed to focus on coping strategies employed by Syrian refugees in Jordan, help-seeking behavior and the gathering of initial impressions of PM+. FGD were segregated by gender and facilitator gender was matched accordingly. Eight FGDs were conducted across two camps and two urban locations. FGD were facilitated by one interviewer who was paired with a note taker. Participants were asked direct questions about the suitability of PM+, along with adaptation considerations, such as: “Would people prefer a group-based or individual intervention?” and “Who could be good providers of peer support?”

Cognitive interviews and focus groups were conducted to determine appropriateness of language. Participants were asked to comment on text and illustrations, relevance, and acceptability. The Bernal framework of language, persons, metaphors, content, concepts, goals, methods, and context was used. Following completion of the cognitive interviews an adaptation workshop was held with key stakeholders to review the results elicited from the RQA and the cognitive interviews.

**Results**

Overall, there were 103 participants in the RQA. There were 27 participants (14 male, 13 female) in the free-list interviews, 24 (14 male, 10 female) in the key informant interviews, and 52 in the focus groups (four groups of males and four of females).

The three most prominent problems identified in Jordan were (1) emotional and psychological distress, (2) abuse of women and children, and (3) work related problems. Work problems were primarily related to working conditions, financial aspects, and work-status. Working conditions for both Syrians in the community and residing in the camp were very long hours, in harsh conditions (e.g. working in fields for 12+ hours a day), as well as children working. These working conditions gave rise to distress related to their disdain with the renumeration. Additionally, many Syrians in both community and camp settings did not have legal working permits which allowed for exploitation from employers. Violence against women and children were reportedly caused by: (1) widowed women being subjected to abuse, (2) gender norms violated as women needing to work to support the family, and (3) children needing to work to assist family financial situation. Lastly, psychological and emotional distress was caused by uncertainty of the future, inability to secure even the most basic human needs, and harsh living conditions. In the urban communities, levels of psychological distress were reported at higher rates, as were difficulties in forming social relationships. Living conditions were significantly more challenging in camp locations relative to urban sites.

Information was also gathered on the activities that Syrian refugees currently do to help manage such problems. In camps, emphasis was placed on engagement in informal education opportunities, recreational activities and sports. For Syrians in urban settings, coping activities centered on volunteer work, family gatherings, and solitary activities (e.g. watching television). Older persons were perceived to be especially vulnerable in Jordan, as they were said to prioritize the needs of other family members, over their own needs for healthcare. This means they generally do not access necessary treatments for the management
of chronic conditions, and this places them at risk of poor health outcomes. Interestingly though, older persons were reportedly highly respected and may be suitable as PM+ facilitators. Group discussion amongst community members was viewed as normal to support wellbeing. In Jordan, preference was given to a group version of PM+ by both key informants and FGD participants. However, participants did note that if highly personal information is to be divulged which may not be relevant to the full group the individual version would be preferable.

Overall, the RQA in Jordan found interesting differences between camp locations, and urban settings in terms of the problems faced, and coping strategies employed, by the Syrian refugee community. The implementation of a group-program appeared to be culturally consistent, and a preferred method of delivery as reported by respondents. Older persons within the community were seen as well-suited facilitators of such a program due to their unique position as being trusted and well-respected members of the Syrian refugee community.

The PM+ intervention was discussed in both the key-informant interviews and FGDs. The possibility of implementing the intervention was primarily met with positive feedback from respondents. The majority of participants noted that the intervention would be helpful in widening the reach of MHPSS services to reach as many community members as possible; this would be the primary benefit to providing services in a group format as opposed to the individual format. Key-informants also believed that PM+ could be well integrated into primary health services for both local population and refugee populations, and that it would be possible to scale-up the intervention and provide services throughout Jordan in the way of primary health centers. Most respondents (male and female) indicated that they would prefer to attend a group version of the PM+ intervention. There were a number of participants who indicated that there was a need for individual formats as well and would prefer to attend the individual PM+ due to the perceived sensitivity of issues that may be discussed in the sessions.

There were some concerns related to psychological interventions, including PM+, in group formats. Mainly, how would such an intervention be able to support persons with practical problems such as job seeking. Some respondents believed that such an intervention alone without more tangible support for income generation and job seeking would not be sufficient to manage the complex problems faced by Syrian refugees in Jordan. Additionally, accessibility was frequently mentioned as a challenge if PM+ was going to be implemented in urban settings due to transportation and accessibility barriers.
4. Publications


5. References