End report on process and outcomes of gPM+ implementation in Türkiye

DELIVERABLE 5.4

SCALING UP PSYCHOLOGICAL INTERVENTIONS WITH SYRIAN REFUGEES

STRENGTHS

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1. Executive summary

1.1. Introduction

By mid-2022, there were 103 million forcibly displaced people worldwide. 32.5 million of those are refugees and 6.8 million originate from the Syrian Arab Republic. After the conflict in Syria started in 2011, many Syrians sought refuge in neighbouring and European countries. Türkiye, the country that hosts the highest number of refugees worldwide, had given “under temporary protection” status to 3.5 million Syrians. Refugees are at higher risk to develop common mental health symptoms due to the potentially traumatic experiences they were exposed to during war, migration, and post-migration. This results in increased demands on the health systems of host countries, especially on mental health care services. However, the mental health service use by refugees is low due to factors such as the language barrier, lack of information on how to receive services, financial limitations, and mental health stigma.

The World Health Organization (WHO) developed a generation of scalable psychological interventions in response to the treatment gap. One of those interventions is Problem Management Plus (PM+). The group version of PM+ (gPM+) was also developed to deliver PM+ in groups of a maximum of twelve participants. gPM+ consists of 5 group sessions that are delivered in 5 consecutive weeks and each session takes around 120 minutes. The intervention aims to reduce the symptoms of depression, anxiety, post-traumatic stress disorder (PTSD), and related conditions, and hence, it is transdiagnostic. It also aims to teach participants techniques for them to manage their practical problems. PM+ can be delivered under supervision by peer facilitators who are non-specialized after receiving an 8-day training.

1.2. Key contributions

The STRENGTHS project has made significant contributions towards the development of gPM+, its evaluation, and future scaling-up.

1.2.1. Cultural Adaptation gPM+

Within the STRENGTHS project, we have worked closely with the Danish Red Cross (DRC) for the cultural adaptation of gPM+ and therefore contributed to the final available version of gPM+. The rapid qualitative assessment (RQA) process was managed by the DRC. The aims of the RQA were to (1) identify and explore problems that participants face from their perspective, (2) give insight into how symptoms of psychological distress are experienced and expressed, and (3) how people commonly seek assistance for these. DRC coordinated the process of cultural adaptation, and it included three phases of qualitative research following module one of the DIME manual, namely (1) Free list interviews (FL), (2) Key informant interviews (KI), (3) Focus groups discussions (FGD).

The research team from Türkiye conducted free listing interviews (N =24), key informant interviews (N = 14), and focus group interviews (N = 20). Each interview lasted between 30 to 60 minutes and was conducted in Arabic (for Arabic native speakers) between April and June 2017. The data collected from these interviews were submitted to DRC for further analysis and the results of the RQA were delivered in the Cultural Adaption Report prepared for WP3.

1.2.2. Testing and Implementation of gPM+

Through the STRENGTHS project, we were among the first to implement and test the effectiveness of the gPM+ in an urban community setting. It was also the first time that the gPM+ was being tested in Türkiye. Before the main trial, we conducted a randomized controlled pilot trial to test the feasibility and acceptability of gPM+ among Syrian refugees (n = 46) who were living in a community setting in Türkiye. To our knowledge, this was the first study using a brief psychological intervention delivered by peer refugees in Türkiye. Although we did not find significant differences between the intervention and control group due to the small sample size, our findings suggested that gPM+ delivered by non-specialist peer providers was an acceptable, feasible, and safe intervention for adult Syrian refugees in Türkiye with elevated levels of psychological distress. This pilot trial indicated that a fully powered randomized controlled trial may be conducted. Following the pilot trial, we conducted the main RCT in Türkiye (N = 368). We did not find a significant difference in the primary outcome measure between the intervention and control groups at the 3-month follow-up assessment. However, there was a significant difference between the two conditions in one of the secondary measures that assessed functional impairment at 3-month. The preliminary results of the process evaluation indicated that the gPM+ participants had a positive experience with the intervention. However, the professionals working with refugees suggest the use of gPM+ in combination with other services, such as interventions to foster sustainable livelihoods, due to the challenging conditions that the refugees live in. In combination, these findings set the stage for the future evaluation of gPM+ combined with other social interventions as a response to the various needs of refugees in Türkiye.

1.2.3. Scientific Outputs

Through the STRENGTHS project, we have contributed to significant knowledge generation in relation to the implementation, evaluation, and scaling of PM+; 2 scientific publications published, and another 2 in preparation. In addition, the two publications given below, the manuscript of the main RCT and the manuscript for the qualitative study we conducted to investigate the scalability of PM+ in Türkiye, in partnership with WP2 are being prepared.

Uygun, E., Ilkkursun, Z., Sijbrandij, M., Aker, A. T., Bryant, R., Cuijpers, P., ... & Acarturk, C. (2020). Protocol for a randomized controlled trial: peer-to-peer Group Problem Management Plus (PM+) for adult Syrian refugees in Turkey. *Trials, 21*(1), 1-9.

Fuhr, D. C., Acarturk, C., Uygun, E., McGrath, M., Ilkkursun, Z., Kaykha, S., ... & Roberts, B. (2020). Pathways towards scaling up problem management plus in Turkey: a theory of change workshop. *Conflict and Health, 14*(1), 1-9.

Wen, K., McGrath, M., Acarturk, C., Ilkkursun, Z., Fuhr, D. C., Sondorp, E., ... & Roberts, B. (2020). Post-traumatic growth and its predictors among Syrian refugees in Istanbul: a mental health population survey. *Journal of migration and health, 1*, 100010.

McGrath, M., Acarturk, C., Roberts, B., Ilkkursun, Z., Sondorp, E., Sijbrandij, M., ... & Fuhr, D. C. (2020). Somatic distress among Syrian refugees in Istanbul, Turkey: A cross-sectional study. *Journal of Psychosomatic Research, 132*, 109993.

Barbui, C., Purgato, M., Abdulmalik, J., Acarturk, C., Eaton, J., Gastaldon, C., ... & Thornicroft, G. (2020). Efficacy of psychosocial interventions for mental health outcomes in low-income and middle-income countries: an umbrella review. *The Lancet Psychiatry, 7*(2), 162-172.

Acarturk, C., McGrath, M., Roberts, B., Ilkkursun, Z., Cuijpers, P., Sijbrandij, M., ... & Fuhr, D. C. (2021). Prevalence and predictors of common mental disorders among Syrian refugees in Istanbul, Turkey: a cross-sectional study. *Social psychiatry and psychiatric epidemiology, 56*(3), 475-484.

Drescher, A., Kiselev, N., Akhtar, A., Acarturk, C., Bryant, R. A., Ilkkursun, Z., ... & Morina, N. (2021). Problems after flight: understanding and comparing Syrians' perspectives in the Middle East and Europe. *BMC Public Health, 21*(1), 1-12.

Acarturk, C., Uygun, E., Ilkkursun, Z., Yurtbakan, T., Kurt, G., Adam-Troian, J., ... & Fuhr, D. C. (2022). Group problem management plus (PM+) to decrease psychological distress among Syrian refugees in Turkey: a pilot randomised controlled trial. *BMC psychiatry, 22*(1), 1-11.

2. Definitive RCT (phase 3)

2.1. Background and preparatory work

2.1.1. Description of context in which the study took place

The study was conducted in Türkiye, the country that hosts the highest number of refugees worldwide. In Türkiye more than 98% of Syrian refugees live in non-camp settings within the community which is associated with refugees experiencing various difficulties of living in a city such as financial challenges and lack of sufficient resources and services. The recruitment for the study was conducted in Sultanbeyli, a suburb of Istanbul that hosts more than 30.000 Syrian refugees. Sultanbeyli is located on the Anatolian side of Istanbul, and it became a hub and home to refugees during the last few years. It is reported by the municipality of Sultanbeyli that most people including refugees in the district live in crowded households due to financial limitations. The socioeconomic vulnerability level in Sultanbeyli is high and almost half of the households' income is monthly minimum wage or less. A survey study conducted within the STRENGTHS project also found that the access to mental health services of Syrian refugees in Sultanbeyli is low even though the need for such services is comparatively high.

The project was conducted in collaboration with the Refugee and Asylum Seekers Assistance and Solidarity Association (RASASA) in Türkiye, a non-governmental organisation (NGO) which provides health, psychosocial and legal support to Syrians in need since 2014. RASASA was a consortium member in the STRENGTHS project and supported the RCT during the recruitment and implementation phases of the trial.

Our main RCT started in August 2019. We recruited 369 participants in collaboration with RASASA until March 2020 when the COVID-19 pandemic struck Türkiye. Various protection measures were implemented by the Turkish government such as the use of masks, social distancing, curfews, lockdowns, and closure of offices and public places. Due to these measures, the gPM+ could not be offered to the participants since it was not possible to conduct face-to-face group sessions. The research team evaluated the potential implementation of online group sessions; however, this option was not implemented due to the limited technological resources of the participants and potential privacy issues due to crowded households. It was decided to put a temporary hold on the delivery of the group sessions. The implementation of the remaining group sessions was conducted between August 2020 and October 2020. The remaining assessments were conducted by phone. This means that a portion of the follow-up assessments was conducted during the pandemic, at times when Syrian refugees living in the cities of Türkiye were reporting having lost access to essential needs such as food and losing their source of income. The decision to terminate recruitment was given by the General Assembly since 369 participants were already recruited and recruiting the remaining 12 participants may have contaminated the results due to the impacts of COVID-19 on the mental health of the potential participants.

2.1.2. Description of gPM+

gPM+ consists of 5 sessions delivered in a group format over 5 consecutive weeks. It is an intervention based on four evidence-based techniques: 1) stress management (session 1), 2) problem management (session 2), 3) behavioural activation (session 3), and 4) accessing social support (session 4). The last session goes over all the techniques that were previously practised and prepares the participants for the future use of these techniques. The group sessions are delivered by facilitators who are non-specialist, peer refugees who received the 8-day Training of Facilitators (ToF). ToF trains potential facilitators on basic helping skills, group management skills, gPM+ techniques, the importance of supervision, privacy of the participants, security,

and self-care. In Türkiye, the trainees were evaluated at the end of the training and provided with a Facilitator Certificate if they were found to be eligible by the trainers. They delivered sessions under the weekly supervision of mental health specialists who were also trained as trainers in PM+. The gPM+ sessions were delivered by 2 facilitators per each group to 8-12 participants and each session took around 120 minutes.

2.1.3. Cultural adaptation of gPM+

2.1.3.1. **Procedures**

The cultural adaptation of the gPM+ process was managed by one of the STRENGTHS project partners, the Danish Red Cross (DRC) within Work Package 3 (WP3). For the cultural adaptation, RQA was conducted by the Turkish research team. DRC coordinated this process of qualitative research following module one of the DIME manual and the research team from Türkiye conducted three kinds of interviews which were free listing interviews, key informant interviews, and focus group interviews. Each interview lasted between 30 to 60 minutes and was conducted in Arabic by native-speaker research assistants between April and June 2017. The interviewers were split into groups according to gender for cultural reasons, where each group had 3 people of the same gender: one leading interviewer and two note-takers. The voice recordings were not allowed by the Turkish government, so each team took the responsibility of transferring the information in the forms to the computer system and translating it into English. The data was submitted to the DRC for further analysis.

2.1.3.2. **Data Collection**

Free Listing interviews (N = 24) were conducted in RASASA by a team of research assistants who took the training necessary for RQA interviews. The aim of these interviews was to identify the frequent problems of Syrians residing in Türkiye.

Key Informant interviews (N = 14) were conducted in the community centre of the Turkish Red Crescent in Sultanbeyli, the International Refugee Rights Association, and RASASA. Most of the names collected from FL interviews were Turkish names, mostly the names of the people working in different NGOs' departments. Some interviewees did not give any names but gave the name of organisations such as RASASA and The Turkish Red Crescent instead. For this reason, the research team started this process by visiting NGOs and community centers. These interviews were conducted with mental health workers (n = 7) including project managers and psychologists in which two of whom were Arabs and a health worker (n =1) who is an Arab doctor employed in RASASA, a policy worker (n = 1) who is working as an officer in the Immigration Authority, and stakeholders (n=5) including managers and officers of RASASA and a Syrian legal advisor.

Focus group interviews (N = 20) were conducted in RASASA. These interviews were conducted in two groups separated by gender (10 males and 10 females).

2.1.3.3. **Results**

Several problems were identified such as language, medical and mental health issues, and social issues at home via free listing interviews and focus group discussions. In addition, main recommendations were developed for the adaptation of gPM+ via these interviews. The results of the RQA and recommendations were prepared and reported by the DRC within "D3.1 Report on Cultural Adaptation".

The data from RQA were also analysed and reported in a publication that was written by the STRENGTHS consortium members including the research team from Türkiye:

Akhtar, A., Engels, M. H., Bawaneh, A., Bird, M., Bryant, R., Cuijpers, P., ... & STRENGTHS consortium. (2021). Cultural adaptation of a low-intensity group psychological intervention for Syrian refugees. Intervention, 19(1), 48.

2.1.4. Pilot randomized controlled trial

We conducted a pilot randomized controlled trial to evaluate the feasibility, acceptability, effectiveness, and cost-effectiveness of the gPM+ among adult Syrian refugees in Türkiye. Specifically, the main objectives of the pilot RCT were to (1) inform the definitive RCT on feasibility, safety, and delivery of the gPM+ in Türkiye, (2) identify issues around the training, supervision of PM+ and outcome measures, and (3) obtain estimates of drop-out. The pilot study was a two-arm, single-blind study. The included participants were randomized to either gPM+/Enhanced Care as Usual (ECA-U) or ECA-U only by an independent researcher with a 1:1 ratio.

The pilot RCT was implemented between September 2018 and February 2019 in Sultanbeyli, Istanbul. The screening phase took place in September. Potential participants (N=78) were screened in September 2018. All potential participants who are adult Arabic-speaking Syrians under temporary protection signed the informed consent form. These participants were assessed with the screening form which consists of Kessler Psychological Distress Scale (K-10), the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0), a form for thoughts of imminent suicide and, a form for impairments possibly due to severe mental, neurological or substance use disorders which were filled by the assessor. The potential participants who met the inclusion criteria by getting more than 15 on K-10, more than 16 on WHODAS 2.0, who did not have a plan to end their life in the near future, and with severe mental health and/or neurological impairment were included in the study.

The participants of the pilot study who meet the inclusion criteria (N=46) were recruited from these potential participants while the participants who did not were excluded (N=32). The included participants were assessed at three time points: (1) pre-intervention which was named the baseline assessment (T0), (2) post-intervention which was named the post-assessment (T1), and 3-month follow-up assessment (T2). After T2, a process evaluation was also conducted in which the acceptability of gPM+ was evaluated via semi-structured interviews with PM+ participants and stakeholders. Persons from different groups (N = 17; five gPM+ participants who completed all gPM+ sessions, five participants who dropped out, five family members of participants who completed gPM+, and two gPM+ facilitators) were interviewed for process evaluation.

At the end of the pilot trial, 75% of the gPM+ participants completed the intervention by attending 3 or more group sessions. The reasons provided by the participants for not attending the sessions were reasons such as sickness, lack of time, and no approval from their employer to attend sessions. 86% of the included participants attended the 3-month follow-up assessments, hence we found good retention rates. 13% of sessions were assessed using the gPM+ fidelity checklist and the results indicated that 80% of the core components of gPM+ were delivered well. In addition, no serious adverse events were reported in our study. The pilot trial was not powered enough to show significant differences in the primary and secondary outcomes between gPM+ and the E-CAU group at 3-month follow. However, the results of the process evaluation indicated that the culturally adapted version of gPM+ provided by non-specialist peer providers was acceptable to participants.

Our findings from the pilot trial suggested that gPM+ is an acceptable, feasible, and safe intervention for delivering Syrian refugees in Türkiye with elevated levels of psychological distress.

2.1.5. Ethics approval definitive RCT

Ethical approval to conduct the definitive RCT was obtained from the Ethics Committees of Istanbul Sehir University (Protocol ID: 12/2017), Koc University (Protocol ID: 2021.025.IRB3.006), and the Immigration Authority of the Republic of Türkiye.

2.1.6. Objectives and design

This two-arm, single-blind, individually randomized trial was conducted in Türkiye, with the objective to test the effectiveness and cost-effectiveness of gPM+ among adult Syrian refugees. We hypothesized that participation in gPM+ sessions would result in decreased depression and anxiety symptoms compared to the control condition (ECA-U only). Outcomes were assessed at baseline (T0), post-intervention (T2), 3-months follow-up (T2), and 12-month follow-up (T3), with the 3-months follow-up assessment as the primary time point for testing the effectiveness of gPM+. The trial was implemented by Koc University in collaboration with RASASA. The trial was prospectively registered at ClinicalTrials.gov on 21 May 2019 (NCT03960892). The trial protocol has been previously published (Uygun et al., 2020).

2.2. Methods

2.2.1. Sample

Participants were recruited for the trial through several recruitment strategies. We have collaborated with our partner RASASA for recruitment. The posters and brochures advertising the study were available for the beneficiaries of RASASA at all times located at different locations within their building. In addition, an advertisement video was shot previously that included information on (1) gPM+ including what and whom it is for, (2) problem types that PM+ can address, (3) what the sessions look like, and (4) how the program will be. This video was also presented to the beneficiaries of RASASA at the entrance of their building. Lastly, we have received referrals from the protection unit of RASASA.

The potential participants who provided written consent were included in the study if they were found to be eligible to participate. The inclusion criteria consisted of (a) being 18 years old or above, (b) having temporary protection status, (c) being an Arabic speaker, (d) having elevated levels of psychological stress (score > 15 on the Kessler-10 Psychological Distress Scale), and (e) having reduced psychosocial functioning determined by scoring higher than 16 on the WHO Disability Scale (WHODAS). The exclusion criteria consisted of having (a) an acute medical condition, (b) an imminent risk of suicide, (c) severe mental disorder (psychotic disorders or substance use dependence), or (d) severe cognitive impairment. The participants who were found to have an imminent risk of suicide were referred to the mental health service providers of RASASA through the protection officer. In the case of more than one person who is living in the same household meeting the eligibility criteria, only one of them was included in the study to prevent contamination in case they are randomized into different groups.

2.2.2. Randomization and masking

After their baseline assessments were completed, the included participants were randomly assigned to either gPM+/ECA-U or ECA-U only by an independent researcher following a 1:1 ratio. The outcome

assessors were masked to treatment condition allocation. At the end of each assessment, the assessors guessed the allocation of the participant, to assess to what degree masking was maintained.

2.2.3. Control Condition

gPM+ has been described above. The usual care available to Syrian refugees in Türkiye (free access to health services in primary health care centers and hospitals) was enhanced by providing all included participants with a leaflet that included information on available community mental health services that were delivered in Arabic at baseline assessment.

2.2.3. Trainings

Two main trainings were conducted by the research team before the start of the trial: (1) the training of the assessors, and (2) the training of the facilitators (ToF). For the training of the assessors, several Arabic-speaking research assistants were selected to conduct the assessments. The selection criteria of these assessors were (1) being fluent in Arabic, (2) being knowledgeable about the Arabic culture, and (3) having good communication skills in order to be able to conduct the assessment in an effective way. These potential assessors attended a two-day training. The training was given by the research team who followed the Assessor's Guide which was prepared by the research team by VUA. The first part of the training included the provision of information such as the basic helping skills, the objectives of the STRENGTHS project, the design of the trial, the importance of standardization and blinding, potential safety issues, and self-care. Different from the first part, the second part of the training was delivered in Arabic as well as in English in which Arabic-speaking research assistants reviewed the questions in the screening and the baseline assessment with the trainees and answered their questions.

The ToF was delivered on 1, 7, 9, 15, 18, 19, 20, and 27 of May before the pilot trial. Out of 21 potential facilitators who attended the training, a number of them were selected to take part in the definitive RCT as a facilitator.

2.3.4. Instruments

2.3.4.1. Primary Outcome

The primary outcome measure was The Hopkins Symptoms Checklist (HSCL-25) (Mollica et al., 1987). HSCL-25 consists of 25 items and is divided into three subscales which are depression symptoms (13 items), anxiety symptoms (10 items), and somatic symptoms (2 items). Each item was rated between 1 (not at all) and 4 (extremely) and higher scores indicated increased experience of symptoms by the respondent. The Arabic version of HSCL-25 was used in this study which was used in various previous studies (Al-Turkait et al., 2011, Fares et al., 2019).

2.3.4.2. Secondary Outcome

Five secondary outcomes were also completed by the study participants. Functional impairment was assessed with the WHO Disability Assessment Schedule (WHODAS) (Ustun et al., 2010). WHODAS consists of 12 items asking about the functionality. Each item was rated 1 and 5, with total scores ranging between 12 and 60. Higher scores increased functional impairment. Post-traumatic stress disorder symptoms were assessed with the PTSD Checklist for DSM-5 (PCL-5) (Weathers et al., 2013). PCL-5 consists of 20 items asking about the symptoms of traumatic stress such as intrusion and avoidance symptoms, negative mood and

cognitions, and alterations in arousal and reactivity. Each item was rated between 0 (not at all) and 4 (extremely) with total scores ranging between 0 and 80. Higher scores indicated increased symptoms of post-traumatic stress. The Arabic version of PCL-5 was used in various previous studies (Ibrahim et al., 2018). Self-identified problems were assessed with The Psychological Outcomes Profiles (PSYCHLOPS) scale (Ashworth et al., 2004). PSYCHOLOPS consists of four questions, and three domains (problems, functions, and well-being) and it assesses the change after the intervention. Participants were asked to answer open-ended questions about their self-identified problems and functional domains. The answers were scored between 0 (not at all) and 5 (severely). Higher scores indicated higher self-identified problems. Mental health service utilization and the cost of care were measured with CSRI schedule to calculate the economic impacts on service utilisation and productivity loss of intervention provision. This scale was developed for the study and translated according to the WHO guidelines by the STRENGTHS project's research team. Access to health care was also measured with a questionnaire that consisted of 23 items about the use of mental health services and the reasons for not using these services. This scale was developed for the study and translated according to the WHO guidelines again by the project research team.

2.3.4.3. Other Measures

The lifetime trauma exposure was measured with a questionnaire that was developed for the study by the STRENGTHS research team. This questionnaire included items from the Harvard Trauma Questionnaire (HTQ) and the Post-traumatic Diagnostic Scale (PDS). It had 28 items that asked about various traumatic events such as serious injury, being in a warzone, and being kidnapped and tortured. Each item was rated as either 0 (no) or 1 (yes) and the total score ranged between 0 and 28. Higher scores indicated a higher number of different traumatic events experienced by the participant. Post-migration stressors were assessed with The Post-Migration Living Difficulties Checklist (PMLD) (Silove et al., 1997). PMLD consists of 17 items about various stressors such as discrimination, communication difficulties, and difficulties obtaining financial assistance. Each item was rated between 0 (not a problem) and 4 (very serious problem) and the total score ranged between 0 and 68. Higher scores indicated increased post-migration problems experienced by the participants. The Arabic version of the scale was used in studies before (Schick et al., 2016).

2.3.4.4. Administration

All measures were selected and agreed upon by the STRENGTHS consortium. The assessments were conducted by the native Arabic speaker research assistants who were trained as described above.

2.2.5. Analyses

Descriptive analyses were carried out in Statistical Package for the Social Sciences (SPSS). Across all analyses, two-tailed tests were reported with a P value of less than 0.05. To estimate the effectiveness and cost-effectiveness of Group PM+, the following data analysis methods were conducted. First, to examine whether there are differences between conditions, t-tests (continuous variables) or chi-squared test (categorical variables) were conducted at baseline to compare the two intervention arms (i.e., Group PM+/E-CAU vs. E-CAU) for normally distributed data; Mann–Whitney tests were conducted for continuous non-normally distributed data.

Intention-to-treat (ITT) analyses, including all randomly assigned participants (N = 368) and treatment completers' (per protocol) analyses, were conducted. The primary outcomes of the trial were the ITT analyses. A linear mixed model was used for the primary endpoint analysis to estimate the intervention

effect, which has intervention as fixed effects, baseline measurement of primary endpoint as covariate, and participants as random effects.

The mean difference between the two treatment arms at each visit/time together with its 95% confidence interval was derived from the mixed model. A covariate-adjusted mixed model for the primary endpoint was performed by adding pre-specified covariates at baseline (gender, age, education, traumatic experiences, post-migration difficulties, etc.) into the above model. Missing data were treated as missing at random. No imputations of missing values were made, as multilevel models can deal with missing data.

2.3. Results

2.3.1. The flow of participants

The recruitment for the study started in August 2019 and the final 12-month follow-up assessment was conducted in October 2021. From 714 adult Syrian refugees who were screened, 368 (51.54%) met the eligibility criteria and were randomly assigned (1:1) to gPM+/ECA-U (n = 184) and ECA-U (n = 184). The retention rates were within the expected limits: 10.33% at post-assessment, 16.03% at 3-month follow-up, and 37.77% at 12-month follow-up. See Figure 1 for the full overview of participant recruitment, reasons for exclusion, and retention.

Sample characteristics are summarised in Table 1. The included participants were 69% female, and the average age was 37.21 (SD = 11.084). The most reported traumatic experience reported by the participants was “being a civilian in the war zone” (70.7%), followed by “having been in danger during the flight” (54.6%), and “lack of food/water” (53.3%) as summarised in Table 2. The results of PMLD also showed that 84% of our participants did not have enough money to buy food, pay the rent or buy necessary clothes while 81.5% experienced difficulties in obtaining financial assistance as summarised in Table 3. There were no meaningful differences in baseline demographic characteristics between gPM+/ECA-U and ECA-U groups.

Figure 1: CONSORT Flowchart

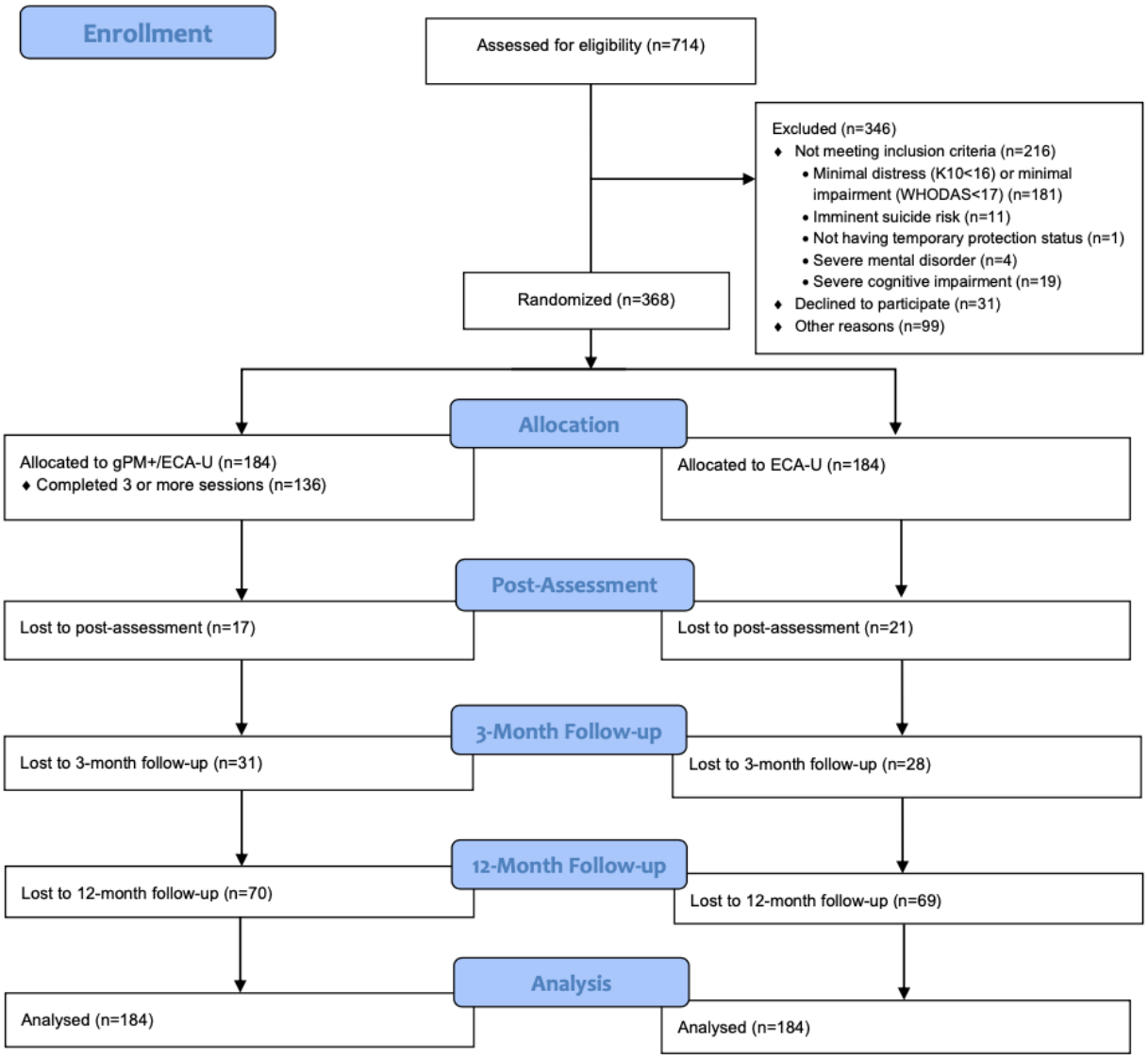

Table 1: Sample Characteristics

Characteristic	**%**
Female	69.0
Married	82.3
Basic education	65.2
Left Syria > 5 years	98.3
Probable Depression	47.3
Probable Anxiety	56.5

Probable PTSD	56.3

Table 2: Summary of Lifetime Trauma Exposure

Lifetime Trauma	**%**
Being a civilian in war zone	70.7
Having been in danger during the flight (sea, boat, border)	54.6
Lack of food/water	53.3
Brainwashing	2.7
Sexual assault (rape, attempted rape, made to perform any type of sexual act through force or threat of harm)	2.7
Other unwanted or uncomfortable sexual experience	2.7

Table 3: Summary of Post-Migration Living Difficulties

Living Difficulties	**%**
Not enough money to buy food, pay the rent or buy necessary clothes	84.0
Difficulties obtaining financial assistance	81.5
Difficulties in learning the Turkish language	70.1
Conflicts with social workers/other authorities	10.9
Not being recognized as a refugee	9.5

2.3.2. Results

The included participants randomly assigned to the treatment group were divided over 17 gPM+ groups. The groups were separated by gender, and gender-matched facilitators will lead groups. There were 12 female groups and 5 male groups. Overall, 136 out of 184 participants attended 3 or more sessions and the dropout rate was 26.09%. There was a noticeable difference between the drop-out rates of female and male

participants being 19.55% for females and 43.14% for males. 12% of all sessions were observed for intervention fidelity and it was reported that 78% of the gPM+ components were delivered well. The results on the effectiveness of gPM+ will be available for publication to a wider public upon acceptance of the scientific paper in a peer-reviewed international journal.

2.4. Conclusion

2.4.1. Summary of findings

The research study conducted in Türkiye among adult Syrian refugees consisted of five stages which were (1) the cultural adaptation of gPM+, (2) the pilot RCT, (3) the process evaluation of the pilot RCT, (4) the definitive RCT and (5) the process evaluation of the definitive RCT. For the first stage of the research, overall, 58 participants were involved in the RQAs for the cultural adaptation of gPM+. The most mentioned problems by adult Syrian refugee participants resettled in Türkiye were economic problems, social problems, and psychological problems. The cause of these various kinds of problems was suggested to be post-migration living difficulties, such as cost of living and lack of resources, by key informants who were working with refugees at the time of interviews. The results of these interviews were then used for the adaptation of gPM+ materials by DRC and the detailed results were reported in "D3.1 Report on Cultural Adaptation". The RQAs were also conducted in a camp setting in Jordan among adult Syrian refugees since the gPM+ would also be implemented in Jordan within the STRENGTHS project. Although the main problems that were identified through the interviews conducted in both settings were similar, the results pointed out the additional difficulties of living in an urban setting such as accessing services and discrimination by the host community for the refugees living in Türkiye (Akhtar et al., 2021). It is also important to mention that these interviews were conducted prior to the COVID-19 pandemic and therefore, the impact of the pandemic on refugees and the potential challenges occurring due to this impact were not identified through these interviews. The results of the definitive RCTs conducted in Türkiye and Jordan may be evaluated in the future while considering the differences between the two settings and the impact of the COVID-19 pandemic.

After the cultural adaptation of the gPM+ materials, the aim of the pilot RCT was to investigate the feasibility and acceptability of gPM+ among adult Syrian refugees living in Sultanbeyli, Istanbul. Although the pilot RCT was not powered to show an effect, the results of the process evaluation indicated that the culturally adapted gPM+ was found to be acceptable by participants assigned to the intervention arm. Their perspectives on gPM+ content were generally positive and they stated that receiving the intervention was beneficial. The facilitators also reported that gPM+ was feasible for delivery and the results of fidelity assessments and attrition from the trial rates were in support of this finding. Challenges to attending the sessions such as child-care responsibilities and barriers to delivery such as difficulty in managing a group were also reported by the interviewees. To conclude, gPM+ was found to be a feasible, acceptable, and safe intervention to be delivered by non-specialist peer-refugee providers for adult Syrian refugees in Sultanbeyli. To our knowledge, this was the first study in Türkiye in which a psychological intervention was delivered by peer refugees and the results indicated that non-specialist peer refugees can be trained to deliver such interventions. These findings have supported the further investigation of the effectiveness of gPM+ among Syrian refugees in Türkiye via a definitive RCT.

The recruitment for the definitive RCT started in August 2019 and the last 12-month follow-up assessment was conducted in October 2021. Out of the 714 potential participants who were screened for eligibility, 368 adult Syrian refugees were included in the study and were randomly assigned to either gPM+/ECA-U (n = 184) or ECA-U only (n = 184) conditions. Overall, 17 gPM+ groups were formed and the rate of attrition from the trial was 26.09%. The results of the definitive trial are expected to be published in 2023.

2.4.2. Barriers to recruitment

The main challenge regarding the recruitment for both pilot RCT and definitive RCT processes was the recruitment of male participants. Potential male participants reported to our field coordinator and research assistants that they were not available to participate in the study due to their work schedules. They shared that they were working 6 days a week and had to or preferred to spend time on other things such as their family on a single day that they were not working. Therefore, we ended up recruiting more female participants than male participants in the definitive RCT. In addition, the dropout rate of our male participants was higher than our female participants among those who were assigned to the intervention group.

2.4.3. Limitations

The main limitation of the pilot RCT was that it was not powered to show an effect on the outcome measures although that was not the main aim of the study. There were a number of limitations of the definitive RCT. First and foremost, the study was under process when the COVID-19 pandemic struck Türkiye. Due to the pandemic restrictions, the delivery of the sessions was put on hold for 5 months and 15% of the intervention group received gPM+ during the pandemic when the restrictions were lower but still existed. The group sessions during the pandemic were conducted when all participants and facilitators wore masks, were careful about social distancing and applied other various measures which meant that the physical conditions of the group sessions were different compared to the groups that were conducted before the pandemic. This may have impacted their experience with gPM+. In addition, all the assessments after the pandemic were conducted over the phone, not face-to-face as before. This may have also impacted the responses they provided since we were not able to assess the privacy conditions of the participants that they were in during phone assessments.

3. Process evaluation (qualitative research)

3.1. Method

The process evaluation was conducted to understand the experience of participants, their challenges with the intervention and facilitators, and barriers to intervention. These evaluations are recommended to understand the process and inform future studies and implementations of the intervention.

3.1.1. Design

This qualitative study was a part of a larger RCT described above. A sample of gPM+ participants and their relatives were interviewed in addition to gPM+ facilitators and key stakeholders in RASASA. A total of 23 interviews were conducted. Ethical approval is mentioned above.

3.1.2. Setting

The study was conducted in Istanbul, Türkiye. The gPM+ participants were from the Sultanbeyli district of Istanbul, and the conditions of the setting are described above (2.1.1.).

3.1.3. Participants

As described above, the definitive RCT involved adult Syrian refugees who were identified as having elevated levels of psychological distress (K10>15) and impaired functioning (WHODAS>16). A sample of participants from the definitive RCT was selected through purposive sampling to ensure a heterogeneous sample in terms of demographic characteristics such as gender and age. All gPM+ participants included in the interviews (n=5 gPM+ completers, n=5 gPM+ drop-outs) and their relatives (n=%5) were living in Sultanbeyli. In addition, gPM+ facilitators who provided sessions within the study (n=4) and key stakeholders (n=4) who were informed about the implementation were also interviewed.

3.1.4. Procedure

Consent to take part in the qualitative interviews was sought and received from all participants. The interviews were conducted in Arabic for gPM+ participants and their relatives. The interviews with facilitators were conducted in English while the interviews with key stakeholders were conducted in Turkish. All interviews were conducted by research assistants who were trained in conducting qualitative interviews. The topic guide which includes the guidelines and questions of these semi-structured interviews were developed within the STRENGTHS project by researchers. Due to COVID-19 protection measures, all interviews were conducted either via phone or video conferencing and were recorded. Interviews were on average 30-50 minutes.

3.1.5. Analysis

The 4 English interviews were transcribed verbatim while the remaining 19 interviews were conducted in Arabic and Turkish and were translated into English. The translation tasks were conducted by research assistants. Data analysis was conducted according to the framework analysis (Gale et al.,2013). The coding

framework that was developed and used for the process evaluation of the pilot study was also used in this study with a deductive coding approach. However, to not to miss any emerging issues that were not considered before, using an inductive coding approach was also aimed.

3.2. Results

3.2.1. The Experience of gPM+

In general, the preliminary results of the qualitative study showed that gPM+ was perceived as acceptable. The participants reported that they found gPM+'s content beneficial and especially the "problem solving" strategy delivered in the second group session was perceived positively.

3.2.2. Barriers and facilitators

When potential barriers were questioned, participants mentioned practical challenges such as taking time off from work or leaving children to be able to attend the sessions. The duration of the program including the travel time was another reported barrier.

The participants who dropped out of the program provided reasons as mentioned above, in addition to the stress of sharing and listening to personal problems within a group. Although it should be mentioned that some participants found being in a group to be an advantage of the intervention. Participants reported that receiving intervention in their mother tongue was another advantage, and they also reported that they had a positive view of the facilitators.

3.2.3. Delivery of gPM+

The facilitators who provided gPM+ during the implementation process of the definitive RCT reported that they had a positive experience in general and were able to build rapport with the participants. When barriers and facilitators to skill development were questioned, the facilitators highlighted the importance of group management. The formation of groups according to their common problems and similar backgrounds of the participants was recommended for an impactful implementation.

3.2.4. Integration and scaling-up of gPM+

The key stakeholders who were either involved or were informed about the implementation of gPM+ in Sultanbeyli were in support of the delivery of the intervention in other care services such as community health care centers. However, they pointed out the importance of other basic needs of refugees such as having sufficient food for their family or finding a job. They recommended the integration of gPM+ with other social interventions to be able to address various needs within the same program or unit.

3.3. Discussion and conclusion

This study investigated the acceptability and feasibility of the gPM+ implementation. Overall, the results showed that the intervention was acceptable, and the participants had a positive view of the content. Although the group format was perceived to be a positive aspect of the intervention, there were a few challenges such as singular participants having difficulty attending at a time that was determined according to the availability of all participants. In addition, while sharing or listening in a group format may be a challenge for the participants, group management was a challenge for the facilitators if the problems or the demographic characteristics of the participants were not common. Although the intervention was perceived to be acceptable by participants, the integration of gPM+ with other interventions was recommended by key stakeholders.

When these results are interpreted in combination with the results of the definitive RCT, which will be available for publication, it may be suggested that the culturally adapted gPM+ may be delivered integrated with other interventions that target the improvement of basic needs which would create a holistic approach to supporting persons of concern.

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