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

DELIVERABLE 5.3

PUBLIC VERSION

SCALING UP PSYCHOLOGICAL INTERVENTIONS WITH SYRIAN REFUGEES

STRENGTHS

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Project title: Fostering responsive mental health systems in the Syrian refugee crisis

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Table of contents

1. Executive summary

1.1. Introduction

Europe is facing its largest refugee protection crisis since the aftermath of World War II. According to the UNHCR (2022), by mid-2022, there was an unprecedented number of over 100 million people worldwide who had been forced to flee their homes because of persecution, conflict, violence, and other reasons. These numbers are expected to increase further due to the Iran and Afghanistan crises and the Ukraine war. Although most refugees are displaced internally or in neighboring countries, approximately 14% are resettled in high-income countries, posing an increasing challenge for those host countries to respond adequately. In Switzerland, there are currently more than 135.000 people with a refugee background, including refugees and asylum seekers (RAS), which is equivalent to the population of the city of Bern (State Secretariat for Migration, 2019) and around 75.000 Ukrainian refugees with a special resident status.
RAS are at a high risk of developing psychological disorders (Bogic, Njoku, & Priebe, 2015; Heeren et al., 2012; Maier, Schmidt, & Mueller, 2010; Morina, Akhtar, Barth, & Schnyder, 2018; Turrini et al., 2017), with evidence from Switzerland suggesting that 40-60% of RAS suffer a psychological disorder, such as depression or post-traumatic stress disorder (PTSD) (Heeren et al., 2012; Maier et al., 2010; Müller, Roose, Landis, & Gianola, 2018). The high prevalence of mental health problems in RAS is related to traumatic experiences before and during displacement (Johnson & Thompson, 2008; Mollica, McInnes, Pham, et al., 1998; Mollica, McInnes, Poole, & Tor, 1998; Steel et al., 2011), as well as to post-migration stressors in host countries (e.g., fear of deportation, unemployment, isolation, worries about family members back home) (Ben Farhat et al., 2018; Kiselev, Pfaltz, Schick, et al., 2020; Schick et al., 2016). In addition, the asylum process itself can foster mental health problems among RAS via such factors as lengthy asylum processes (Hainmueller, Hangartner, & Lawrence, 2016; Hvidtfeldt, Petersen, & Norredam, 2020) and employment bans (Marbach, Hainmueller, & Hangartner, 2018). Together, these post-migration living difficulties can have a more significant impact on mental health than previous trauma (Bogic et al., 2015; Miller & Rasmussen, 2010; Schick et al., 2016). These mental health problems lead to many adverse societal impacts for RAS, including the poorer mental health of their children (Bryant et al., 2018; Schick et al., 2013).

Despite the urgent need for psychological care, RAS in Switzerland are underdiagnosed and often do not receive adequate treatment (Maier et al., 2010; Müller et al., 2018). Socio-cultural barriers, including stigma, health illiteracy, or distrust, prevent the Swiss healthcare system from responding adequately to RAS' needs (Kiselev, Pfaltz, Haas, et al., 2020). Moreover, the availability of psychological care in specialised facilities is scarce and costs for interpreters are often not covered (Müller et al., 2018). This treatment gap in mental healthcare is especially problematic, considering that untreated mental health problems tend to become chronic. The latter, in turn, is likely to hinder integration and participation in Swiss society, which, given the predominantly young age of those affected, leads to a loss of productive years of life and highly individual, family, and societal long-term costs (Schick et al., 2016). Consequently, alternative mental health services need to be delivered in order to bridge this gap in mental healthcare. In response to this situation, the World Health Organization (WHO) developed a novel evidence-based low-intensity intervention, PM+, that can address this critical global issue (World Health Organization, 2016).

1.2. Key contributions

The STRENGTHS project has made significant contributions towards the adaptation of the PM+, its evaluation and future scaling in high-income countries, such as Switzerland.

1.3. Cultural adaptation of PM+

PM was developed by the WHO and UNSW to reduce psychological distress for people exposed to adversities. It has already been tested in several settings and populations, such as Pakistan and Kenya (Bryant et al., 2017; Rahman et al., 2016). Yet, before being used in a new setting, the materials and the intervention used in the current project were linguistically and culturally adapted to the needs of the Syrian refugee group and Swiss context by adapting the WHO adaptation process and within the framework of the DIME model (AMHRG, 2013). This cultural adaptation addressing the specific situation of Syrian refugees and asylum seekers in Switzerland was made in collaboration with the Danish Red Cross (see their report for final developments, which also includes our contribution).

1.4. Scientific outputs

Through the STRENGTHS project, we have contributed to significant knowledge generation in relation to the implementation, evaluation and scaling of PM+ in Switzerland; (i) 6 scientific publications published or under review, and another 3 in preparation; (ii) 11 students could finish their Master's Thesis, and 1 PhD and 1 MD were finished during the project time, 1 PhD is planned to be finished mid 2023; (iii) 1 new evaluation instrument to asses quality of trained helpers was tested and piloted for the first time in Syrians (EQUIP); (iv) 10 PM+ training videos in Arabic were co-developed and are being used in current and future trainings.

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8. Hemmo M, Akhtar A, Kohrt B, Pederson G, Alkamel AF, Martin-Soelch C, Schafer A, Bryant RA, Morina N. (*in preparation*). Validation of a competency rating scale for a low-intensity, psychological intervention with non-professional helpers in Switzerland.

9. Casanova L, Spaaij J, Fuhr D, Klein T, Roberts B, Schick M, Weilenmann S, Morina N (*in preparation*). Facilitators for the implementation of systematic mental health screenings for refugees in Switzerland: A qualitative study

2. Definitive RCT (phase 4)

2.1. Background and preparatory work

2.1.1. Description of context in which study took place

In Switzerland, STRENGTHS was funded by the Swiss Government, the SERI (State Secretariat for Education, Research and Innovation; under contract number 16.0205) since at the time of the application and approval by Horizon2020, Switzerland was not a full member of the H2020 scheme.

STRENGTHS in Switzerland was carried out at the University of Zurich at the Outpatient Clinic for Victims of Torture and War, University Hospital Zurich. The study activities (e.g., outcome assessments, PM+ sessions etc.) were conducted in Zurich as well as at two collaborating outpatient clinics in Bern and St. Gallen.

In Switzerland, study participants were aimed to be recruited from the refugees who entered the country after the beginning of the Syrian Civil War (2011), particularly through a particular program. Since 2013, the Federal Council of Switzerland had taken various decisions to enable particularly vulnerable people direct and safe entry to Switzerland. As such they approved several resettlement programs. Among those in 2015 they agreed to participate in the relocation programme for a total of 40,000 persons in need of protection, together with the European Union, for Syrian refugees. But in fact, till spring 2019, only a total of 1,993 persons entered Switzerland under this programme. Thus, during the study period, only around 20,000 Syrians in total were living across the whole of Switzerland. Since half of those were minor and in addition, they were spread across the country, the eligible participants for the study were small. Thus, the study team decided to extend the inclusion to all Arabic-speaking people in Switzerland.
For further details regarding the context of the study see also barriers of recruitment.

2.1.2. Description of PM+

The low-intensity psychological intervention Problem Management Plus (PM+; Dawson et al. (2015) was originally developed by the WHO and UNSW to reduce psychological distress for people exposed to adversities. The intervention includes four core components: a) stress management, b) problem management, c) behavioural activation, and d) strengthening social support, and consists of five sessions. PM+ is a peer-based psychological intervention in which individuals without specific medical-therapeutic background are trained to become lay therapists (i.e., so-called «helpers»). Its peer-based approach overcomes socio-cultural and language barriers by having peers from the same cultural background deliver the intervention. This format enables PM+ to be cost-effective and readily scalable. PM+ has been proven to be an effective method for reducing mental health problems and improving the psychosocial functioning of people in crisis in various countries (Bryant et al., 2017; de Graaff et al., 2020; Rahman et al., 2016; Sangraula et al., 2020).

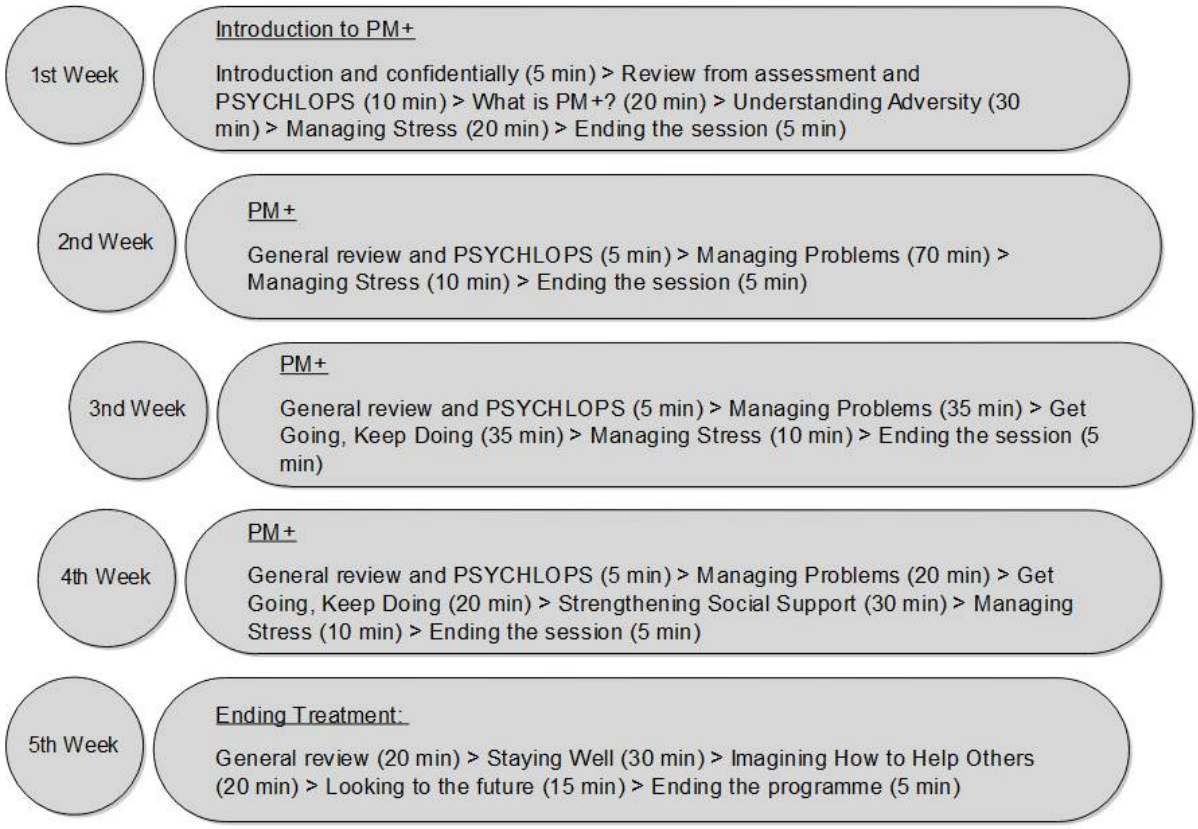


Figure 1. Five sessions of PM+ intervention

2.1.3. Control Intervention: Enhanced Treatment As Usual (ETAU)

The control group received enhanced treatment as usual (ETAU). ETAU means that the research team advised the participants to contact their doctor in case of physical or psychological problems. In addition, the research team handed out written information in Arabic (official brochure of the Federal Office of Public Health) about how the Swiss health system works. The doctor, usually a general practitioner who acts as a gatekeeper (an asylum seeker or refugee must first go to their assigned family doctor to access the health system), provides appropriate treatment.

2.1.4. Cultural adaptation of PM+

The cultural adaptation addressing the specific situation of Syrian refugees and asylum seekers, particularly in Switzerland, was done in collaboration with Danish Red Cross.

Results:
Several key challenges were identified regarding the specific situation of Syrian refugees and asylum seekers. The critical findings for Switzerland concerning problems and issues related to language, medical and mental health issues, social issues at home and residency issues. Additionally, problems specific to the Swiss site were identified. These other problems related to integration were very varied and less prominent. By order of magnitude:
Problems with integration pertain to discussions of how Syrian refugees should integrate and to what degree – if at all – they should assimilate. Several respondents also relate that Swiss culture and language (in this case, German as the canton included in STRENGTHS is German speaking) is more challenging to integrate

into than other European cultures. Asked what the consequences are for a person who cannot integrate well, a telling reply is:

They shut themselves off, maybe they'll look for other variants, maybe to go somewhere else, maybe a different Canton, where you think or hear they're better at integration into society. Where there might be more foreigners, where, yes, maybe they're looking for different variants. But when you don't have any hope and flexibility, then there'll probably be difficulties in the family, in the small society, the Syrian, the Arab, that won't appear positive. But I would, as an opportunity, I'd try, if I had the resources, if I'd make the decisions, I'd establish contact with as many Swiss as possible, who are open to such situations, who want to provide help, just that these foreigners, these Syrian, these refugees be more in contact with Swiss.

As for the recognition of education, the data stems entirely from a focus group discussion. In summary, participants experience that Switzerland does not recognise Syrian education at equal levels and asks people with degrees to retrain or offer lower equivalents of certificates than expected. This gives rise to much frustration:

I'm a 3rd-year law student and was among the most brilliant students in Syria. I come here and they bring [me] back to the 10th grade as if I'm a 15-year-old student. I see this as an insult to the Syrian diploma.

The topic of Pride and honour problems relates to the cultural significance of honour and pride for Syrians and how this clashes with the Swiss culture.
Living with uncertainty and the related loss of control of the future, which is both also connected to the issue of permits, pertain to the temporality of being a refugee. A comment from a respondent summarises the field of problems well:

"Then there's always a worry about the future, how does it go on, when will the war end, when am I able to go back, do I want to go back, where can I go back, what will expect me there? And those things are invisible and often not discussed. And, from a professional side, I often experience that we rather have blind spots, we're not aware of that while working, that there is something invisible. And then we overlook it. And when we overlook it, then on top of that there's the linguistic barrier and already the access is missing."

A few discussed that being a refugee reinforces pre-existing problems. One stated:

"But it's also like this, that these problems might have existed for a longer time and then just, under these circumstances, the flight in a foreign country, I'll experience them more strongly. And like this there are serious problems, which might be reinforced by this situation."

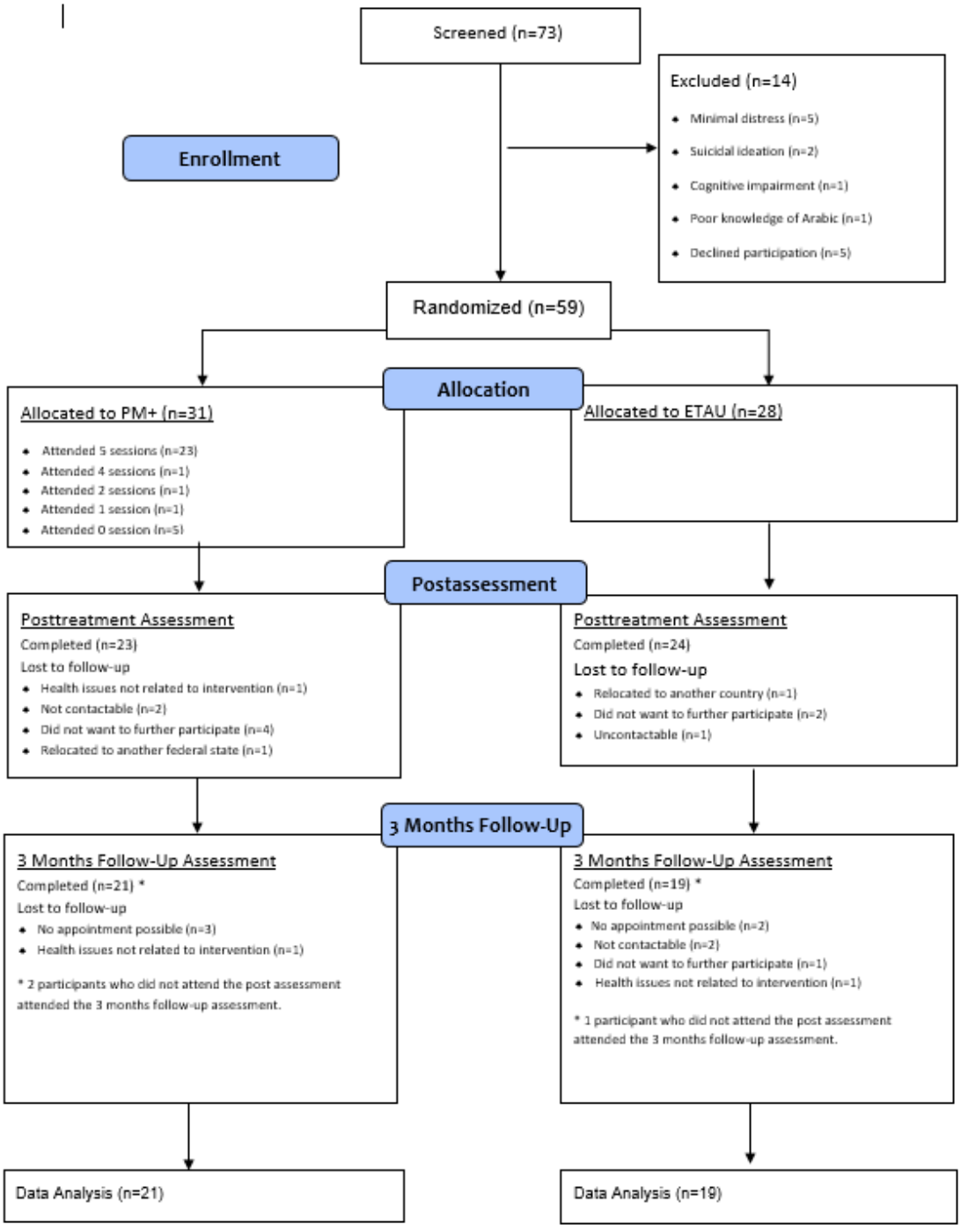
Based on the results, the cultural adaptation addressed this kind of problems and adapted the intervention to the target population's needs and situation.

2.1.5. Pilot randomized controlled trial

The pilot RCT was designed to test the feasibility and acceptability of individual PM+ among Syrian refugees in Switzerland and to assess the trial procedures in advance of a definite RCT. It was conducted between December 2018 and March 2020, and recruitment took place between December 2018 and November 2019. The study activities (e.g., outcome assessments, PM+ sessions etc.) were conducted at the Outpatient Clinic for Victims of Torture and War, University Hospital Zurich, and University of Zurich, as well as at two collaborating outpatient clinics in Bern and St. Gallen. To include a total number of N = 59 participants in the trial, 73 individuals were screened for eligibility. The participants were excluded due to the following reasons: low levels of distress (n=5), suicidal ideation (n=2), cognitive impairment (n=1), poor knowledge of Arabic (n=1), declined participation (n=5). Thus, 80.8 % of the individuals who completed the screening were

included in the trial. 40 of 59 participants stayed in the pilot RCT from baseline until the three-month follow-up assessment. The qualitative process evaluation was completed by February 2020. N=18 semi-structured interviews were conducted with different stakeholder groups (n=6 participants, n=5 assessors, n=5 helpers, n=2 mental health professionals working with refugees). The qualitative data were audio recorded and then transcribed verbatim. The Arabic interviews (conducted with participants of the interventional arm) were translated into English by a professional translator, and the rest of the interviews were transcribed in the interview language (English or German). The data was analysed thematically, combining an inductive and deductive approach.

Figure 2: *Flow diagram pilot RCT Switzerland*



A total of *N*=59 Syrian refugees were randomized into the PM+ (n=31) or the ETAU arm (n=28).

The sample included n=30 female and n=29 male participants. The CONSORT diagram of the study flow is presented in Figure 2.
Even though the recruitment focused mostly on three cities, interested individuals contacted the Swiss research team from all over Switzerland. Participants reported exposure to around 10 potentially traumatic events on average (*M*=10.10, *SD*=5.03). There were no significant differences in sociodemographic characteristics such as age or gender between the two arms. The study showed a retention rate of 67.8%. 40 of 59 participants stayed in the pilot RCT from baseline until the three-month follow-up assessment. There was no difference in retention between the intervention and control arms ($\chi 2(1)=0.00$, $p=.99$). On average, participants in the intervention arm attended four PM+ sessions (*M*=3.94, *SD*=1.97, range 0-5). 74.2 % of the participants attended all five sessions of PM+.

- The number of participants who attended all 5 sessions: 23
- The number of participants who attended only 4 sessions: 1
- The number of participants who attended only 3 sessions: 0
- The number of participants who attended only 2 sessions: 1
- The number of participants who attended only 1 session: 1
- The number of participants who did not attend any of the sessions: 5

All clinical outcomes improved on average over time (baseline – 3MFU) in both treatment arms and there were no severe adverse events which were related to the study intervention. During the pilot trial, there was one event that was classified as an SAE. This event was reported to the STRENGTHS safety board (SB). It was not found to be related to the trial or the intervention and therefore, no additional action was required.

The results of the qualitative interviews revealed that the pilot trial and the PM+ intervention were generally perceived as positive by the PM+ participants, helpers and assessors. All participants stated that they benefited from their participation. The analysis revealed four domains of subjective improvement: changes in behaviour, increased knowledge on how to deal with adversities, improvement of psychiatric symptoms and an increase in social interactions. Perceived barriers towards the study and the PM+ intervention were mental health stigma, distrust, lack of knowledge about mental health problems and a mismatch between the local health system and the perceived needs of Syrian refugees and asylum seekers. In addition, participants and staff members pointed out some modifications to the program concerning the upcoming randomized controlled trial (e.g., regarding recruitment) or the broader implementation of the program in Switzerland (e.g., regarding its content, its structure or its setting).

2.1.6. Ethics approval definitive RCT

The RCT protocol was submitted to the Ethics Committee of the Canton Zurich on 30th June 2017. The approval was granted on 8th September 2017 (BASEC 2017-01175).
Amendments were submitted to the Ethics Committee of the Canton of Zurich on 30th November 2018 (approved on 14th December 2018), on the 12th of February 2020 (approved on the 24th of February 2020), on the 16th of July 2020 (approved on the 28th of July 2020), on the 21st of December 2020 (approved on the 7th of January 2021) and on the 14th of July 2022 (approved on the 09th of August 2022).

2.1.7. Objectives and design

The aim of the definitive RCT was to test the effectiveness of the PM+ intervention in Switzerland. Therefore, N=54 Arabic-speaking refugees were randomized on a 1:1 basis into either the intervention arm or the control arm. Participants were assessed at baseline, post assessment, as well as three and twelve months after the intervention.

The definite RCT was registered online on clinicaltrials.gov (https://www.clinicaltrials.gov/ct2/show/NCT04574466). The data were collected from March 2020 until December 2022.

2.2. Methods

2.2.1. Participants and procedures

The sample consisted of Arabic-speaking refugees and asylum seekers experiencing elevated levels of psychological distress. Inclusion criteria were: 1) Arabic-speaking refugees who arrived in Switzerland after the outbreak of the Syrian civil war in 2011, 2) 18 years or older, 3) elevated psychological distress (Kessler Screening Scale for Psychological Distress (K 10) > 15) (Kessler et al., 2002), and 4) impaired psychosocial functioning (WHO Disability Assessment Schedule (WHODAS 2.0 > 16) (Üstün, Kostanjsek, Chatterji, & Rehm, 2010). Exclusion criteria were: a) severe cognitive impairment, b) severe mental disorders (e.g., psychosis), c) the acute risk of suicide, d) being under guardianship, and e) the inability to follow the study procedures.

Participants were recruited from refugee and asylum seeker centres, community settings and through local stakeholders in the Arab community. The recruitment process involved posting information about the study on social media (in Arabic and German), distributing leaflets and informing the community about the study at social events. To counteract the effect of the COVID-19 pandemic on the recruitment, a more active recruitment style was performed (i.e., contacting medical professionals working with refugees in different Swiss cantons, paid Facebook ads, a TV feature on a migrant media network, etc.).

Interested individuals were asked to contact the research team to be informed about the project and the study procedures in Arabic. If they fulfilled the inclusion criteria 1) and 2) and were interested in participating in the study, they completed an online screening in order to assess their level of psychological distress and psychological functioning (inclusion criteria 4–5). Participants unable to do the online screening (e.g., due to lower-literacy) were invited to the study site to complete the assessment with assistance of the RA. Electronic informed consent was obtained prior to screening.

If inclusion criteria were met, participants were invited to a briefing regarding the study procedures, including randomized allocation to one of the treatment arms. After signing a second informed consent form for participation in the study, a baseline assessment was conducted. Baseline and follow-up assessments were conducted in Arabic using the tablet-assisted screening software MAPSS (Morina et al., 2017), except for the CSRI (Client Service Receipt Inventory) on resource use administered as a paper-and-pencil standardized interview by the outcome assessors. The data were transferred and stored on the electronic data capture system SecuTrial® managed by the Clinical Trials Centre Zurich. After baseline assessment, participants were randomized to either the intervention arm (PM+) or the Enhanced Treatment as Usual (ETAU) arm. The randomization was performed by an independent RA not involved in the study by tossing a coin. Couples were randomized into the same treatment arm to minimize dropout rates or a bias due to contamination.

Randomization was performed on a 1:1 basis by an independent research assistant not involved in the assessments. To minimize the risk of an information transfer or a high dropout rate, couples were randomized into the same condition.

One week after the fifth PM+ session (intervention arm) or seven to eight weeks after the baseline assessments (ETAU arm), the RA invited participants to a post-assessment. A three-month follow-up assessment (3MFU) was scheduled around twelve weeks after the post-assessment, and a twelve-month follow-up assessment (12MFU) was scheduled approximately one year after the post-assessment. Each

participant received a shopping voucher worth CHF 20 (approximately $20) after the post-assessment, the three months follow-up assessment and the twelve months follow-up assessment. Participants also received a certificate for their participation after completion of the three months outcome assessment.

2.2.2. Measure

Primary outcome

The primary outcome were symptoms of depression and anxiety measured with the Hopkins Symptom Checklist (HSCL-25) (Derogatis, Lipman, Rickels, Uhlenhuth, & Covi, 1974). The questionnaire consists of 25 items (range = 1–4), 15 items measuring depression (e.g., 'Crying easily') and 10 items assessing anxiety (e.g., 'Suddenly scared for no reason'), with higher scores indicating more severe depression and anxiety, respectively. The HSCL-25 is a transcultural validated tool and has been employed previously in research with Arabic-speaking refugees (Lavik, Hauff, Solberg, & Laake, 1999; Schick et al., 2016). We used cut-off scores of ≥ 2.0 for symptomatic anxiety and of ≥ 2.1 for symptomatic depression based on other studies with similar study populations (Fuhr et al., 2020; Mahfoud, Kobeissi, Peters, Araya, & Ghantous, 2013). The internal consistency in this study was $\alpha = 0.89$ for the anxiety subscale and $\alpha = 0.88$ for the depression subscale at baseline.

Secondary outcome

Secondary outcomes were:
a) symptoms of posttraumatic stress disorder (PTSD) measured with the PCL-5 (Blevins, Weathers, Davis, Witte, & Domino, 2015), a 20 item-measure rated on a 5-point scale and summed up to a total score, with a higher score indicating more pronounced symptom severity ($\alpha= 0.92$ at baseline). We used cut-off score of ≥ 33 for symptomatic PTSD, based on similar trials with conflict-affected populations (Bovin et al., 2016; Fuhr et al., 2020).

b) psychological and functional impairment measured with the WHODAS 2.0 (Üstün et al., 2010). The WHODAS 2.0 is a 15-item measure developed by the WHO. The first 12 questions assess health and disability and are rated on a scale from 1 to 5 and summed up, with higher scores indicating more severe functional impairment. The last three items refer to the loss of (work-related) days. Cronbach's alpha at baseline was $\alpha= 0.71$.

Other outcomes

Other outcomes of interest were:

1) The Psychological Outcomes Profiles (PSYCHLOPS) scale is a patient-generated outcome measure, serving as an indicator of change in response to therapy (Ashworth et al., 2004).

2) Previous exposure to traumatic events was assessed using the 27-item Traumatic Events (TE) – a combination of two standardized questionnaires, namely the Posttraumatic Diagnostic Scale (Foa, Cashman, Jaycox, & Perry, 1997) and the Harvard Trauma Questionnaire (Mollica et al., 1992). Items were rated on a dichotomous scale (yes / no) and summed up to a total score.

3) Post-migration stressors were assessed using a version of the Post-Migration Living Difficulties Checklist (PMLDC) (Silove, Sinnerbrink, Field, Manicavasagar, & Steel, 1997; Steel, Silove, Bird, McGorry, & Mohan, 1999). The measure has previously been adapted to the Swiss context (Schick et al., 2016). It consists of 17 items (e.g., 'Worries about family back home') which are rated on a scale from 0 ('Was not a

problem/did not happen') to 4 ('A very serious problem'). The PMLDC has frequently been employed in research with refugee populations (Nickerson et al., 2015; Schick et al., 2018; Schick et al., 2016).

4) Somatization and somatic symptoms will be assessed using the Patient Health Questionnaire-15 (PHQ-15) (Kroenke, Spitzer, & Williams, 2002). The 15 item-questionnaire is rated on a scale from 0 to 3 and summed up to a total score with a higher score indicating more pronounced symptom severity.

5) The Immigration Policy Lab (IPL) Integration Index is a pragmatic and multidimensional measure of immigrant integration. The 12-item short form (IPL-12) captures six dimensions of integration: psychological, economic, political, social, linguistic, and navigational. The measure can be used across countries, over time, and across different immigrant groups and can be administered through short questionnaires available in different modes. The performance of this measure has been evaluated through four surveys (Harder et al., 2018).

6) General self-efficacy will be assessed with a short version (GSE-6) of the General Self-Efficacy Scale (Schwarzer & Jerusalem, 1995). The items are rated on a 4-point Likert scale with higher scores indicating higher levels of general self-efficacy. The measure has been validated across different cultures (Luszczynska, Scholz, & Schwarzer, 2005) and has been used with refugee populations before (Morina, Bryant, et al., 2018).

7) The participants' knowledge, perceptions and attitudes towards mental health will be assessed with a set of selected questions drawn from various questionnaires (MAKS, Evans-Lacko et al. (2010); RIBS, Evans-Lacko et al. (2011); CAMI; Taylor and Dear (1981)). This set has been put together by Rathod et al. (2016) and has previously been used to measure attitudes towards mental health in Syrian refugees (Fuhr et al., 2020).

8) The impact of the COVID-19 pandemic on the participants' (mental) health, their financial situation, their need of resources etc. will be assessed with selected questions designed by the research team.

9) The nine-item Reducing Tension Checklist (RTC) assesses the extent to which the participants perceive that they use specific strategies, which are trained during the intervention.

2.2.3. Interventions (PM+ and Enhanced Care as Usual (ETAU)) and trainings

Problem Management Plus (PM+)

Participants allocated to the intervention arm received five 90-minute sessions of PM+. The sessions took place once a week in Zurich, Bern or St. Gallen, depending on the residence of the participants. Session 1 included an introduction to PM+, psychoeducational elements and stress management techniques. Session 2 was about problem solving strategies and in session 3 and 4 participants learned strategies to enhance behavioural activation and social support. In all sessions, elements from the previous sessions were reviewed and consolidated. The 5th session concluded with a general review of the programme and relapse prevention. The material and the intervention were linguistically and culturally adapted to the needs of Syrian refugees (Akhtar et al., 2021; Bird et al., 2017).

ETAU

Participants randomized to ETAU were given a booklet explaining the Swiss health care system in Arabic (Bundesamt für Gesundheit & Staatssekretariat für Migration, 2017). In addition, participants were

instructed to contact their general practitioner if they required further mental health assistance. In addition, they could contact the research team at any time.

Trainings

Thirteen non-specialist 'helpers' and eight lay outcome assessors were recruited. All helpers and outcome assessors were Syrians (mostly refugees themselves) and fluent in Arabic and German or English. All of them had a diploma of higher education. Helpers participated in an eight-day training course conducted by one PM+ master trainer and one PM+ trainer, both Arabic speaking, and the research team in line with WHO training criteria. The training focused on basic counselling skills, delivering the strategies of PM+, as well as an adapted Good Clinical Practice (GCP) course and an introduction to Psychological First Aid (PFA). Before the intervention, each helper administered at least one practice case under supervision to become familiar with the intervention and all of its procedures. All helpers received continuous supervision (at the beginning on a weekly basis and later approximately once per month) by an experienced Arabic speaking clinical psychologist/psychotherapist and PM+ master trainer with extensive knowledge of the PM+ intervention. Helpers' fidelity was assessed using the EQUIP competency rating scale (Pedersen et al., 2021). For this purpose, the helper and a mock-patient simulated typical PM+ sessions in standardized form for a total of 75 minutes, focusing on the key elements of the intervention. A PM+ master trainer evaluated the helpers' performances on a 4-point scale. The items were divided into two categories: 1. 15 items included those competencies necessary for psychological interviewing and rapport building (e.g., non-verbal communication & active listening; demonstration of empathy, warmth & genuineness, etc.); 2. Ten items represent the technical competencies needed to apply the core strategies of PM+ properly. All helpers have been identified as sufficiently competent. Furthermore, the results provided a differentiated insight on the helpers' competencies and gave indications on which competency areas can be improved in the ongoing supervisions (Hemmo et al., 2021).

Outcome assessors completed a three-day training which focused on administering the clinical assessment tools, general interviewing techniques, GCP and responding to participants' distress, including Psychological First Aid (PFA). This training was conducted by the research team and the PM+ master trainer. Outcome assessors received continuous supervision by the members of the research team and the PM+ master trainer.

Helpers and outcome assessors did not know each other, and outcome assessors were blinded to the allocated treatment arm of the participants to minimize bias.

2.2.4. Analyses

All analyses were performed with SPSS, version 25. Descriptive statistics of sociodemographic and clinical outcomes were calculated with mean (M), standard deviation (SD) and / or percentages (%). To estimate the difference in change from baseline to the follow up assessments, linear mixed model analyses were used. We tested for the effect of group (PM+ vs. ETAU), time (baseline, post assessment, 3 months follow-up) and the group x time interaction on the outcome variables. We performed post-hoc comparisons of time points within each group as well as between group comparisons at different time points based on estimated marginal means.

2.2.5. Preliminary Results

The results of the definite RCT will be submitted for publication to a peer-reviewed journal in 2023.

The results remain confidential upon publication.

2.3. Summary of results and conclusion

The results of the definite RCT remain confidential upon publication.

2.4. Barriers to recruitment

Already at the beginning of the pilot RCT, the recruitment process was slow. After four months of recruitment, less than 15% of the anticipated study sample had been included. Thus, in April 2019 a focus group discussion on recruitment and associated problems with different stakeholders was held (former participants, key informants in the Syrian community etc.). The main findings which emerged from this exercise were that a) many Syrians did not know about the programme, that b) there was a lack of trust towards the research team, and that c) the programme and the information material were framed in a way that was not appealing to potential participants. They described the material as 'too academic' and mentioned that it contained the terms 'psychiatry' or 'mental disorders' which were considered as stigmatizing. Moreover, we learned that although individuals were interested in participating, some have not had the (financial) resources to do so as they would not be able to cover the cost of transport. Another important finding was that many Syrian refugees seemed to be occupied with immediate practical problems (e.g., finding work or housing). Therefore, they prioritized finding a job or an apartment over reaching out for psychological support.
After integrating these results into the recruitment strategy (e.g., by asking key informants in the Syrian community to promote the study or by redesigning our information material to make it more appealing and less stigmatizing to potential participants) we were able to increase the number of screening interviews for the pilot RCT.

The recruitment for the definite RCT assessing the (cost-) effectiveness of individual PM+ in Switzerland started in February 2020. In mid-March, Switzerland went into a nationwide lockdown due to the COVID-19 pandemic. Consequently, all research projects at the University Hospital Zurich, which involved direct contact with participants, had to be paused.
In July 2020, an amendment to extend the inclusion criteria to all Arabic-speaking refugees who have entered Switzerland after 2011 was approved by the local ethics committee (and by the EU, see AMD2).

The reasons for the extension of the inclusion criteria were manifold: the recruitment process in the pilot RCT had already been challenging, as the number of Syrian refugees who have resettled in Switzerland is relatively low compared to countries like Germany, Lebanon, or Jordan. Thus, enlarging the target group to all Arabic-speaking refugees might increase the feasibility of achieving the required sample size for the definitive RCT. In addition, during the pilot RCT, the research team often experienced a reluctance from social workers or staff at asylum centres to select only Syrian refugees for referral to the trial from their centre. Moreover, enlarging the target group to a broader sample may also facilitate later scaling-up of the PM+ intervention because the results of the definitive RCT will yield better generalisability to other refugee populations.

After the recruitment was on hold for six months, it was resumed in August 2020 and has been ongoing until February 2022. Since then, however, recruitment has been hampered due to the ongoing COVID-19 pandemic and related measures by the government. Many recruitment strategies that had originally been planned for the RCT could not be implemented, and participants were reluctant to travel due to fear of contracting COVID-19. Thus, the option to conduct online interventional sessions and follow-up assessments was introduced in February 2021 (an amendment was submitted to the local ethics committee accordingly).

Until June 2021, the following recruitment strategies had been used to increase inclusion:

- Enhancement of word-of-mouth recommendations (asking participants if they would want to recommend participating in the study and send them flyers to hand out to their friends and family)
- Presenting the project to organizations working with refugees, mental health institutions, government officials
- Contacting NGOs and other organisations related to refugee care
- Contacting local authorities who are responsible for refugee care
- Contacting language schools that teach German to refugees (e-mails, personal contacts)
- Contacting psychotherapist networks that offer therapy to refugees or promote it
- Social media (Facebook, Instagram) (posts are always in German AND Arabic)
- Creating own advertisement videos (German/Arabic) and disseminating them on Facebook, Instagram, our own website
- Being mentioned regularly in newsletters of religious institutions, organisations working with refugees, etc.
- Speaking about the STRENGTHS project with different NGOs
- Creating own website (Strengths-project.ch)

Due to the nationwide COVID-19 restrictions, many of the recruitment strategies originally planned (e.g., engagement of roadshows, presenting the project at various events, etc.) could not be implemented.

To counteract the slow recruitment process, a more active style was performed. The following recruitment strategies had been planned for June 2021 – end of recruitment in February 2022:

- Contacting medical professionals working with refugees in different Swiss cantons
- Creating new flyers and posters and sending/giving them to different institutions (community centers, libraries, universities, Arabic supermarkets, restaurants, mosques, churches, etc.)
- Paid Facebook ads (advertising texts via Facebook and Instagram targeting Arabic-speaking individuals)
- TV feature on the migrant media network
- Interview with PI in an Arabic newspaper
- Contacting participants from similar trials by our research group
- Cooperation with other researchers conducting trials with refugees
- Presenting the STRENGTHS project in various federal refugee centres
- Expanding reach by recruiting in other German-speaking cantons
- Increase the workload of the Arabic-speaking recruiter
- Re-engagement of roadshows (these were not possible due to COVID-19 restrictions for the past months)
- Contact participants from the pilot trial

However, even though additional recruitment strategies had been carried out, we were unable to reach the target study population of *N*= 184. After 24 months of recruiting, only approx. 30 % of the required sample size had been reached. The final sample was *N*=54.

2.5. Limitations

The results of the definite RCT remain confidential upon publication.

2.6. Recommendations for further scaling up

Based on results from STRENGTHS regarding the feasibility and acceptability of PM+ in the Swiss context in the Syrian refugees and discussions with the Swiss Government, we were able to get funding for a full

scaling-up of PM+ in a project called SPIRIT *("Scaling-up Psychological Interventions in Refugees In SwiTzerland")*. A nation-wide implementation of low-intensity interventions such as PM+ has been also strongly recommended by national evaluations of RAS' mental health (Müller et al., 2018) and a recent qualitative study (Spaaij et al., under review) with over 20 stakeholders conducted by our research group to unburden existing psychiatric structures.

Due to the experiences and knowledge gained in the STRENGTHS project we were able to secure additional funding and launch further projects supporting the scale-up of PM+ in Switzerland:

Within the framework of our most recent implementation project, SPIRIT, we are planning to scale up PM+ for RAS in Switzerland to improve their mental health and provide them with adequate access to mental healthcare. To achieve these goals, we will train 150-200 helpers to deliver PM+ to more than 8.000 RAS who suffer from psychological distress in Switzerland until the end of 2024. Within the framework of SPIRIT, PM+ will be delivered in 11 different languages, besides existing ones, there will be additionally PM+ language versions translated and adapted to the local context, such as Tamil, German, and Pashtu. Those PM+ versions will then be made accessible to everyone. SPIRIT aims at establishing PM+ as the foundation of a stepped care model and at building local networks within the healthcare system. SPIRIT is a collaborative project with regional, national and international partners such as the State Secretary for Migration, the Federal Office of Public Health, the Swiss Red Cross (federal and several cantonal levels), Network Support for Torture Victims, WHO Collaborating Centre at the Vrije Universiteit Amsterdam, The London School of Hygiene & Tropical Medicine, and the co-developers of PM+ from the University of New South Wales who have extensive experience with the research and treatment of RAS.
The project SPIRIT is funded by Health Promotion Switzerland ("Gesundheitsförderung Schweiz"), the State Secretary of Migration, and various integration Cantonal Authorities, thus making the project itself more sustainable and integrated into current structures.
In addition, we were able to get a significant funding of CHF 2.8 million from the Swiss National Science Foundation to explore further and investigate the effects of PM+ by using the SPIRIT Network. The research project BRIGHT ("Boosting Refugee Integration throuGh psycHological inTervention") makes significant advances in the quest to answer several questions by using cutting-edge methods across complementary disciplines. BRIGHT's aims are three-fold. First, we will design and administer the first large-scale representative survey among refugees and asylum seekers in Switzerland to describe this population in terms of mental health and integration problems, assess their correlation, and identify the predictors thereof. Second, we will adapt, pilot, and evaluate the low-intensity and scalable psychological intervention called "Problem Management Plus" (PM+). In addition to its 5 original sessions in which beneficiaries learn different stress and problem management skills, we will provide 3 booster sessions and a digital support program. We will evaluate this augmented PM+ using a stepped wedge randomised-controlled trial in 1.240 refugees and asylum seekers across Switzerland to provide evidence on i) its effectiveness to reduce mental distress, ii) potential underlying mechanisms contributing to its mental health benefits, and iii) adherence among recipients. Third, we aim to elucidate how mental health benefits of PM+ can result in social, political, economic, and navigational dimensions of integration of refugees and asylum seekers into Swiss society.
In BRIGHT many of the STRENGTHS partners are involved (VU Amsterdam, UNSW, UNHCR), but also extended with others, such as the Leading Center of Swiss Economic Institute or the Policy Immigration Lab from the Swiss Federal Institute of Technology Zurich or other Swiss Universities.
Finally, in partnership with several STRENGHTS project partners we were able to get approval by the WHO to use the EASE intervention in Switzerland. This is as an expansion of the ongoing SPIRIT project, where our team, has begun an implementation initiative, in terms of capacity building, to provide the EASE intervention to young Ukrainian adolescents and their caregivers in the Cantons of Zurich, Basel, and Thurgau. As part of this initiative, we have brought in an EASE trainer who has led the EASE program in several contexts to conduct a training, with a subsequent three trainings planned in the immediate future. The current intervention has begun on November 1, 2022, and as part of the implementation initiative, together with the Project Partner, the Clinic of Child and Adolescent Psychiatry and Psychotherapy (CAPS) of the Psychiatric University Hospital (PUK) of the University of Zurich, the School Psychologists and the Swiss Red Cross Zurich,

we aim to reach at least 100 adolescents and their caregivers in Canton of Zurich, with the other regions (Canton Thurgau and Basel) to begin enrollment in early 2023.

3. Process evaluation (qualitative research)

The process evaluation aimed at identifying factors influencing a potential scale-up of PM+ in Switzerland and to provide information on how to guide an implementation process.

A manuscript on the results of the process evaluation has been submitted for publication in the journal “BMC Health Services Research” on 13 October 2022 and is currently under review. The results of the process evaluation remain confidential upon publication.

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