Study Protocol for a Randomized Controlled Trial: Peer to Peer Group Problem Management Plus (PM+) for Adult Syrian Refugees in Turkey

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Study protocol

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Abstract

Background: A large proportion of Syrians have been exposed to potentially traumatic events, multiple losses, breakdown of supportive social networks and many of them have sought refuge in host countries where they also face post migration living difficulties such as discrimination or/and integration problems. These adversities may put Syrian refugees at high risk for common mental disorders. In response to this, the World Health Organization (WHO) developed a transdiagnostic scalable psychological intervention called Problem Management Plus (PM+) to reduce psychological distress among populations exposed to adversities. PM+ has been adapted for Syrian refugees and can be delivered by non-specialist peer lay persons in the community.

Methods: A randomized controlled trial (RCT) will be conducted with 380 Syrian refugees in Turkey. After providing informed consent, participants with high levels of psychological distress (scoring >15 on the Kessler-10 Psychological Distress Scale (K10)) and functional impairment (scoring >16 on the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0)) will be randomly assigned to Group PM+/Enhanced Care As Usual (Group PM+/E-CAU) (n = 190) or enhanced-care-as-usual (E-CAU) (n = 190). Outcome assessments will take place 1-week after the 5 th session (post assessment), 3 months after the 5 th session and 12 months after baseline assessment. The primary outcome is psychological distress as measured by the Hopkins Symptom Checklist (HSCL-25). Secondary outcomes include functional impairment, posttraumatic stress symptoms, self-identified problems, as well as health system and productivity costs. A process evaluation will be conducted to explore the feasibility, challenges and success of the intervention with 25 participants including participants, facilitators, policy makers and mental health professionals.

Discussion: The treatment manual of the Syrian-Arabic Group PM+ and training materials will be made available through the WHO once the effectiveness and cost-effectiveness of group PM+ has been established.

Keywords: Cognitive behavioural therapy, depression, anxiety, posttraumatic stress, refugee, mental health, group interventions, task shifting, trans-diagnostic

Background

The past eight years have resulted in a great increase of Syrian refugees with Syria becoming the principal contributor to refugees and asylum seekers worldwide [1]. A large proportion of Syrians have sought refuge in neighbouring countries such as Turkey, Jordan and Lebanon, while others have fled to Europe [2]. Turkey now hosts 3.6 million Syrian refugees, the largest number of Syrian refugees worldwide [1]. Syrians residing in Turkey are given the status of “under temporary protection” and not “refugee status” by the government of the Republic of Turkey. However, for simplicity, they will be called refugees throughout this paper.

Similar to other refugee populations, Syrian refugees may have been exposed to potentially traumatic events such as threats to life, injuries, or witnessing deaths during the war and their flight from conflict [3, 4]. They may face post-migration difficulties such as unemployment, social isolation, and discrimination after arriving in a host country [3]. Traumatic events and post-migration difficulties may make Syrian refugees more vulnerable to psychological distress and common mental disorders (anxiety, depression, posttraumatic stress disorder) [5–10]. Psychological distress and mental disorders among refugees may become more profound and may create considerable economic burden for the community if left untreated [11]. There are currently no evidence-based community-based mental health interventions available in Turkey which Syrian refugees can access, and which address their complex mental health needs. Moreover, Turkey lacks Arabic speaking specialized mental health care professionals who can deliver such treatments to Syrian refugees. In response to this treatment gap, we adapted a WHO psychological intervention called PM+ for Syrian refugees in Turkey.

Problem Management Plus (PM+) is a brief, scalable, transdiagnostic psychological intervention which has been developed as part of the mental health GAP (mhGAP) action programme [12]. PM+ addresses symptoms of depression, anxiety, PTSD and psychological distress through cognitive behavioural therapy strategies. Previous randomized controlled trials (RCT) have demonstrated the effectiveness of individually delivered PM+ in Kenya and in Pakistan, and Group PM+ in Pakistan in decreasing depression and anxiety symptoms [13–16]. In Turkey, PM+ is delivered by trained and supervised non-specialist peer refugees who have a minimum of 12 years of education. Using peer-Syrian providers as delivery agents overcomes language issues, which has been found to modify the effect on patient outcomes [17]. In Turkey, group PM+ is being used. Group counselling has been found to be as effective as individual face to face sessions [18]. Group sessions also reach more people at one point in time, while another advantage is that patients benefit from other group members' experiences and points of view[19].

The present RCT protocol is part of the larger Syrian Refugees Mental Health Care Systems (STRENGTHS; https://strengths-project.eu/) [20]. STRENGTHS aims to evaluate the effectiveness and cost-effectiveness of PM+, delivered in group, individual and e-format by conducting eight RCTs in countries neighbouring Syria as well as in European host countries. STRENGTHS also aim to scale-up the delivery and dissemination of PM+ for Syrian refugees in these countries. The PM+ group manual has been translated into Arabic and adapted for Syrian refugees, and this work will be presented elsewhere. The adaptation process was carried out according to the Bernal framework which consisted of the following steps: a) literal translation by an Arabic-speaking WHO translator, b) free listening and key informant interviews with Syrian refugees and mental health professionals in order to identify key mental health concepts and problems among Syrian refugees and c) cognitive testing of the translated manual [21, 22, 41].

Objective

The main objective of the present study is to evaluate the (cost-) effectiveness of the culturally adapted version of Group PM+ in adult Syrian refugees with elevated levels of psychological distress in Turkey.

Design And Setting

This study is a two-arm, single blind, RCT comparing Group PM+/E-CAU to E-CAU in 380 study participants (see the flowchart in Figure 1). It will be conducted in collaboration with the partner NGO (non-governmental organization) RASASA (Refugee and Asylum Seekers Assistance and Solidarity Association) in the Sultanbeyli district of Istanbul. Sultanbeyli district is an economically deprived area with more than 23,000 Syrians residing in overcrowded conditions in rented apartment blocks with high levels of poverty and unemployment [23]. RASASA works for the protection of refugees and provides them with psychosocial support in addition to legal assistance. Methods of recruitment include but are not limited to the distribution of various advertisements and documents such as brochures and short movies, in addition to social media. The study protocol has been reported in line with the Standard Protocol Items: Recommendations for Clinical Interventional Trials (SPIRIT) guidelines (Additional File 1). Figure 1 shows the study flow chart, and Figure 2 shows the SPIRIT figure.

- Figure 1 -

(study flow chart)

Participant Recruitment

Participant Inclusion Criteria

Participants must be adult (18 years or above) Syrians under temporary protection who are Arabic-speaking and residing in Turkey. The inclusion criteria include the following: (1) scoring greater than 16 on the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) for health and disability and (2) scoring greater than 15 on the Kessler-10 Psychological Distress Scale for psychological distress [24, 25].

Participant Exclusion Criteria

Participants will be excluded if they present with (1) an acute medical condition, (2) have an imminent risk of suicide, (3) have a severe mental disorder (e.g., psychotic disorders, substance-dependence), or (4) show severe cognitive impairment (e.g., severe intellectual disability or dementia). Participants excluded from the study will be referred for appropriate treatment and support. Participants found to be eligible will

be informed about their eligibility and will be invited to complete a baseline assessment before randomisation (-T1).

Informed Consent

Participants will be invited to the collaborating partners for screening. Participants who come to the interview will be informed about the study and provided with an Informed Consent (IC) form. Written or witnessed oral consent (for illiterate participants) is required before completing screening and baseline assessments.

Sample Size and Power Calculations

The VU University Medical Centre Department of Epidemiology and Biostatistics carried out the power calculations for this study. Based on previous studies with PM+ in Peshawar, Pakistan, and Nairobi, Kenya, we aim for a conservatively estimated small to medium Cohen's d effect size of 0.4 in the PM+ group at 3 months follow-up [13, 15]. Power calculations suggest a minimum sample size of 133 participants per group (power = 0.90, a = 0.05, two-sided). Considering an expected 30% attrition at 3 months follow-up, we aim to include a total number of 380 participants (190 in the Group PM+/E-CAU group and 190 in the E-CAU group).

Randomization

After baseline assessment, participants will be randomized on a 1:1 basis to either Group PM+/E-CAU (n=190) or to E-CAU (n=190) (T0). Randomisation will be done by an independent researcher using computerized software who is not involved in the intervention delivery, clinical supervision, assessments, or other aspects of the study.

There may be a chance that participants of the study are recruited from the same household creating a risk for contamination (if family members were to be allocated to receive different treatments, i.e. either group PM+ or E-CAU). To limit the likelihood of contamination participants from the same household will be assigned to the same intervention arm.

Group PM+

Problem Management Plus (PM+) is a brief, trans-diagnostic psychological intervention based on cognitive behavioural therapy (CBT) techniques and developed by the WHO [12, 26]. It consists of 5

sessions delivered in 5 consecutive weeks and aims to reduce symptoms of depression, anxiety, PTSD, and related conditions. Groups are separated by gender and gender-matched facilitators will lead groups consisting of 6 to 8 participants (T1). Sessions include evidence-based strategies of stress management, problem-solving, behavioural activation, and strengthening social support. PM+ is designed to be delivered by non-specialist helpers who receive an 8-day training in PM+. These Arabic speaking non-specialist helpers who are called facilitators are supervised by psychologists and psychiatrists that have participated in the PM+ training-of-trainers program. Supervision consists of weekly, face-to-face group supervisions and individual supervisions when needed.

Enhanced Usual Care

Syrians in Turkey have free access to mental health services in public hospitals and migrant health centres [27]. However, due to numerous barriers such as lack of knowledge on available mental health services or (self-)stigma, the use of mental health services is low among Syrian refugees [28, 40]. Usual care will be enhanced by providing study participants with a leaflet on publicly available mental health services in the area where they live.

Outcome Measures

All instruments will be administered by trained research staff blind to the allocation status of the participants at post-assessment (1 week after the 5^{th} PM+ session) (T1), 3 months after the 5^{th} session (T2) and 12 months after baseline (T3).

Primary Outcome Measure

The primary outcome measure of this study is the Hopkins Symptom Checklist (HSCL-25). This assesses anxiety and depression symptoms' levels at 3 months follow-up assessment [29]. It has 25 items that include two sub-scales for depression (13 items) and anxiety symptoms (10 items) and two items related to somatic symptoms. These items are scored on a 4-point Likert scale.

Secondary Outcome Measures

The secondary outcome measures are the (1) PTSD Checklist for DSM-5 (PCL-5) to assess the severity of posttraumatic stress reactions, (2) Psychological Outcomes Profiles (PSYCHLOPS) to assess self-identified problems, (3) Client Service Receipt Inventory (CSRI) to assess health service utilization and productivity impacts, and (4) WHODAS which is also part of the screening and which assesses functional

disability [30, 31]. In addition, perceived access to health services will be measured (see Figure 2). The PCL-5 has 20 items scored on a 0-4 scale adding up to a total severity score of 80, with higher scores indicating higher levels of symptomatology. The PSYCHLOPS consists of four questions on three domains: problems (2 questions), function (1 question), and wellbeing (1 question). Problem and function questions are asked in the form of free texts and the responses are scored on an ordinal six-point scale producing a maximum score of 20. The CSRI includes questions about resource use for health and social care services, informal care, and productivity as a result of functionality in people with mental disorders. The CSRI has been adapted for Syrians in Turkey to match Turkish health care services that are available to Syrians. Relevant unit costs will be attached to service utilisation to estimate changes in use of health services and health care costs, while Turkish minimum wage rates will be used to conservatively estimate changes in costs associated with both informal family care and lost productivity by the patient from work.

- Figure 2 -

(SPIRIT figure will take part here)

Other Measures

A self-constructed questionnaire will be used to assess lifetime trauma exposure. This questionnaire includes items from the Harvard Trauma Questionnaire (HTQ), and the Posttraumatic Diagnostic Scale (PDS), and asks questions on specific traumatic experiences of Syrian refugees. It has 28 items scored as 0 (no) or 1 (yes), ranging from 0 to 28 [32, 33].

The Post-Migration Living Difficulties Checklist (PMLDC) will be used to assess post-migration stressors. PMLDC has 17 items scored on a five-point scale, ranging from 0 to 4 (0= not a problem 4= very serious problem) (range 0-68). Items scored at least 2 (a moderately serious problem) are considered positive responses [34, 35].

If the validated Arabic version of the included measures are available, they [see measures] will be selected and tested through cognitive interviews with Arabic speaking adult Syrians. If the validated Arabic version of the measures are not available, these measures will be translated and back-translated according to the WHO guidelines [36].

Process Evaluation

We will explore the feasibility, challenges and success of the intervention through semi-structured interviews with facilitators, PM+ participants, policy makers and health professionals. From each

category five participants will be included. Interviews will take between 30-60 minutes and will start after ICs were obtained from the participants. Moreover, PM+ dose (i.e., number of sessions completed), treatment fidelity and quality will be assessed. Trained research assistants will be present during 10% of the sessions and will score treatment fidelity with a checklist listing PM+ elements given that audio recording of sessions is not allowed by the Turkish Immigration Authority (see in Ethics Approval) [37]. In addition, PM+ facilitators will be asked to fill in a fidelity checklist on the PM+ components immediately after completion of sessions [13].

Data Management

All data will be handled confidentially. Quantitative data will be either collected through pen and paper format or through tablets. The quantitative data and the identifying key (a list connecting names to numbers) will be kept in a separate, secure locked location at the Trauma Research Lab in Istanbul Sehir University (ISU). The data will be entered into a data-analytic computer program, without the identifying key.

Qualitative interviews will be saved separately from the participants' identifiers and will be transcribed and safely stored at the Trauma Research Lab in ISU. There will be no audio data because the Immigration Authority of Turkey does not give permission to take audio recordings in research studies with Syrian refugees (see in Ethics Approval).

Statistical Methods

Descriptive analyses will be carried out in SPSS and HLM analyses in Stata version 11.2. Across all analyses, two-tailed tests will be reported with $p < 0.05$. To estimate the effectiveness and cost-effectiveness of Group PM+, the following data analysis methods will be conducted. First, to examine whether there are differences between conditions t-tests (continuous variables) or chi-squared test (categorical variables) will be conducted at baseline to compare the two intervention arms (i.e. Group PM+/E-TAU vs. E-TUA) for normally distributed data; Mann-Whitney tests will be conducted for continuous non-normally distributed data.

Intent-to-treat (ITT) analyses including all randomized participants (N= 380), as well as treatment completers' (PP) analyses will be conducted. The primary outcomes of the trial will be the ITT analyses. A linear mixed model will be used for the primary endpoint analysis to estimate the intervention effect, which will have 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 will be derived from the mixed model. A covariate-adjusted mixed model for the primary endpoint

will also be performed by adding pre-specified covariates at baseline (gender, age, education, traumatic experiences, and post migration difficulties, etc.) into the above model. Qualitative data from the process evaluation will be analysed thematically following the framework approach [38]. Interview transcripts will be coded using Nvivo version 11 [39].

Economic Analyses

The economic analysis will be conducted from both a health system perspective broader perspective including productivity impacts in order to determine the difference in costs and outcomes in Group PM+/E-CAU, compared to E-CAU. Costs will be compared between arms using a regression model, controlling for baseline, and with bootstrapped confidence intervals using 10,000 resamples. Incremental cost-effectiveness ratios (ICERs) will be calculated comparing changes in mean costs and primary outcomes from both payer and societal perspectives between the two groups. Non-parametric bootstrapping analyses, using 10,000 resamples, will be performed to account for uncertainty and derive 95% confidence intervals around ICERs in order to generate cost-effectiveness planes. Cost-effectiveness acceptability curves (CEAC) will also be plotted to present the probability of the PM+/E-CAU intervention being cost-effective at various willingness-to-pay threshold levels.

Ethical Considerations

The study protocol received approval both from the Istanbul Sehir University Research Ethics Committee on April 12, 2017 (Protocol ID: 12/2017) and the Immigration Authority of the Republic of Turkey to conduct the study on March 29, 2017. This study will be conducted according to the principles of the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013). It will be in accordance with the International Conference on Harmonisation (ICH), the WHO Good Clinical Practice standards (GCP), and the Medical Research Involving Human Subjects Act (WMO).

Trial Management

The site principal investigator (PI) of the STRENGTHS Project is responsible for the management of the project in Turkey. Overall trial management is provided by the international PI and senior research and intervention staff who hold monthly telephone conferences and meet annually in a face to face consortium meetings. The STRENGTHS' Safety Board (SB) will monitor all ethical, legal and societal issues that arise within the STRENGTHS project.

Adverse Event Monitoring

All adverse events (AEs) and serious adverse events (SAEs) will be recorded through the web-based software, Castor Electronic Data Capture. SAEs will be reported to Istanbul Sehir University Research Ethics Committee within 15 days. SAEs that result in death or are life threatening will be reported within eight days. All AEs will be followed until they have abated, or until a stable situation has been reached.

Discussion

The present study reports the protocol of a RCT that evaluates the effectiveness and cost-effectiveness of the culturally adapted version of Group PM+ among adult Syrians residing in Turkey. PM+ is a 5-session long, transdiagnostic psychological intervention developed by the WHO and aims to decrease symptoms of psychological distress (depression, anxiety, and PTSD) and to improve psychosocial functioning.

This study builds on prior research that has demonstrated the effectiveness of PM+ in different settings in decreasing depression and anxiety symptoms [13, 15, 16]. However, PM+ has not been adapted for Syrian refugees who migrated to Europe and the Middle East after experiencing adversities in Syria, during and after migration. We hypothesise that training Arabic speakers in Group PM+ and providing peer to peer Group PM+ to refugees may be useful in overcoming the mental health treatment gap we are seeing in this population group. If proven to be effective, the adapted Group PM+ version will be disseminated by WHO and recommended for scaling up.

Declarations

Trial Status

The trial was registered at ClinicalTrials.gov on 21 May 2019 (identifier NCT03960892), and protocol version 4.2/201903. Recruitment of participants began on 3 August, 2019 and we are planning to finish it on June 2020.

Additional Files

Additional File 1: SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents.

Abbreviations

AE: Adverse Events; CBT: Cognitive Behavioural Therapy; CEAC: Cost-Effectiveness Acceptability Curves; CSRI: Client Service Receipt Inventory; E-CAU: Enhanced Care As Usual; GCP: Good Clinical Practice Standards; HLM: Hierarchical Linear Modelling; HSCL-25: Hopkins Checklist 25; HTQ: Harvard Trauma Questionnaire; IC: Informed Questionnaire; ICERs: Cost-Effectiveness Ratios; ICH: International Conference on Harmonisation; ISU: Istanbul Sehir University; ITT: Intent to Treat; K10: Kessler-10 Psychological Distress Scale; mhGAP: Mental Health Gap; NGO: Non-Governmental Organization; PCL-5: PTSD Checklist for DSM-5; PDS: Posttraumatic Diagnostic Scale; PI: Principal Investigator; PM+: Problem Management Plus; PMLDC: The Post-Migration Living Difficulties Checklist; PP: Per Protocol; PSYCHLOPS: Psychological Outcomes Profiles; RCT: Randomized Controlled Trial; SAE: Serious Adverse Events; SB: Safety Board; SPSS: Statistical Package for the Social Sciences; STRENGTHS: Syrian Refugees Mental Health Care Systems; VU: Vrije University; WHO: World Health Organization; WHODAS: World Health Organization Disability Assessment Schedule

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Authors' Contributions

EU, ZI, MS, RB, PC, DF, AG, JJ, DMD, NM, AP, BR, PV, and CA designed the trial and involved in drafting the study protocol for ethics review, and all authors were involved in drafting and commenting on the paper.

Ethics Approval

The Research Ethics Committee of Istanbul Sehir University approved the study protocol on 12 April 2017 (Protocol ID: 10/2017). The Directorate General for Migration Management of Turkey have approved the study protocol on 29 March 2017. Consent to participate in the trial will be obtained from every participant.

Consent for Publication

Not applicable.

Consent to Participate

Informed consent will be obtained from all study participants.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests

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Figures

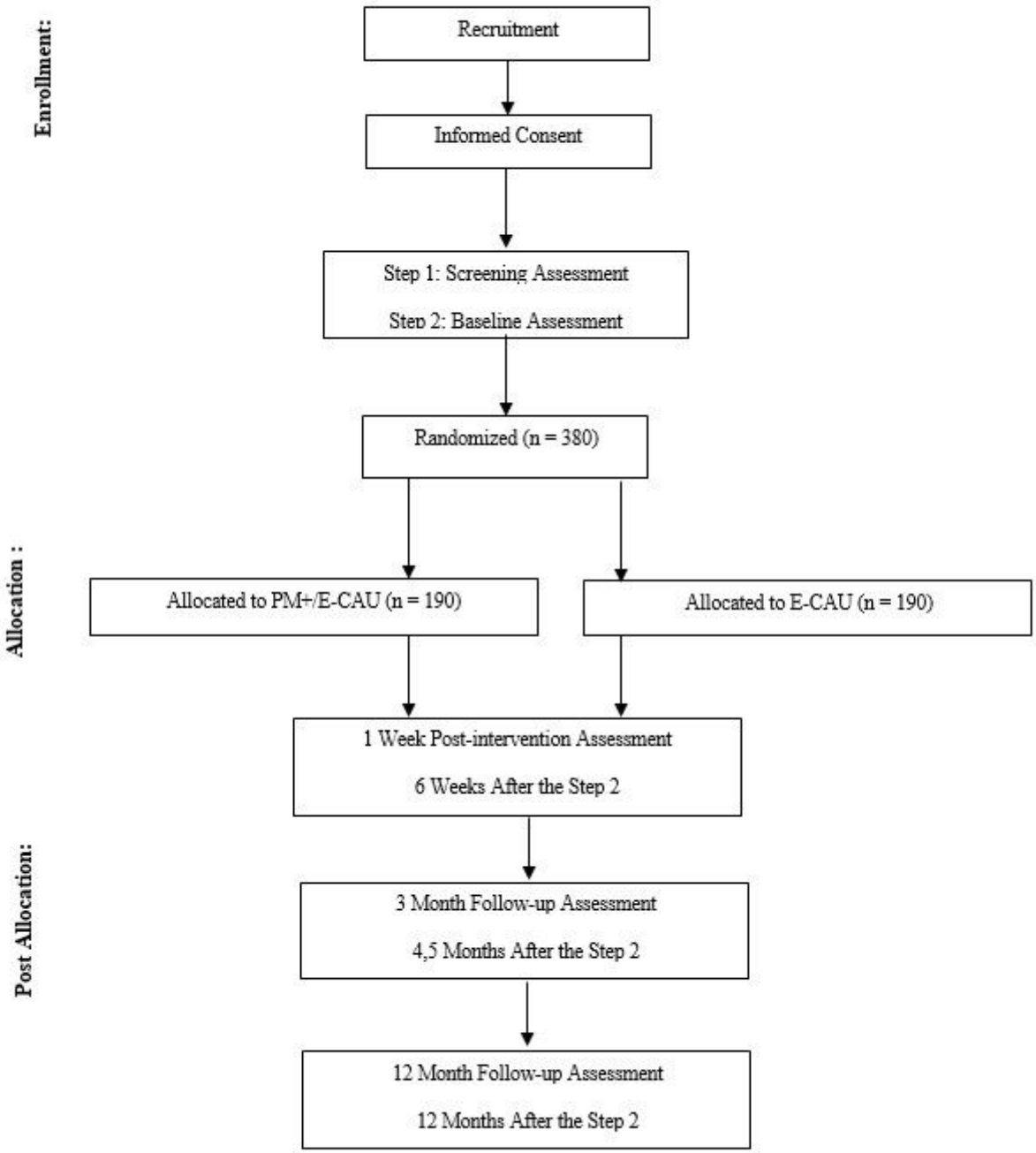

Figure 1

study flow chart

	STUDY PERIOD					
			Post-allocation			
TIMEPOINT	*Enrolment ($-t_1$)*	*Allocation (0)*	*Intervention (t_1)*	*Post-assessment (t_2)*	*3 Month Follow-up Assessment (t_3)*	*12 Month Follow-up Assessment (t_4)*
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Group PM+ & ECAU		X	X			
ECAU		X	X			
ASSESSMENTS:						
WHODAS 2.0	X			X	X	X
K10	X					
HSCL-25	X			X	X	X
PCL-5	X			X	X	X
PSYCHOLOPS	X			X	X	X
Trauma Experiences	X					X
PMLD	X				X	X
CSRI	X			X	X	X
Access to Health Care	X			X	X	X
Fidelity Checklist			X			

Figure 2

SPIRIT chart

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