School of Psychology, University of New South Wales

Study Information and Consent (Intervention)

STRENGTHS
Scaling-up psychological interventions with Syrian refugees

This study is organized by the University of New South Wales (UNSW) and International Medical Corps (IMC)

Dear Sir/Madam,

We are asking you if you would like to participate in a clinical trial. You have already taken part in the screening assessment and below you will find the trial described.

Detailed Information

1. Aims of the Study

There is an increased risk of multiple health problems for refugees, especially mental illnesses. These can arise from the events before, during, and after fleeing your home country. The World Health Organization (WHO) has developed a new program called ”Problem Management Plus (PM+)” for the treatment of mental distress. This intervention has already been tested abroad, but has not yet been tested in Jordan. With this study, we want to investigate whether the intervention is also effective in Jordan. In addition to the effect, we would like to examine the acceptance of the intervention, and clarify how this can be implemented in the local health system.

2. Participant Selection

You have already participated and completed the screening. The scores have shown that the level of your mental stress may be helped by the program. Therefore, you have qualified to be part of the target group for the main study. The selection criteria are identical to the screening. All persons who have came to Jodan from Syria since the beginning of the Syrian civil war (2011) and have an elevated level of stress, as measured during the screening questionnaires, can participate in the study. You must also be able to understand the consent form and not be younger than 18 years of age, as well as speak Arabic, to participoate in the program.

Persons who are suffering from acute severe mental disorders currently or during the next five weeks, while participating in the study, are not allowed to participate.

3. General Information

The most imporant things to know about the study are that:

- The study is conducted in Arabic inside of Azraq camp, Jordan
- The group PM+ techniques are an official WHO-developed and empirically-researched method for reducing stress-related symptoms
- The questionnaires used are standardized and scientifically validated. The screenings will take place between July-2018 and July-2020
- The study is a single-centred, single-blind, randomized – this means:
  - Single-centrered: the study is being carried out by employees of IMC on site in Azraq camp
  - Single blind: Employees who assist you in the surveys (before and immediately after the intervention, and at 3 and 12 months after the intervention) are not aware of whether you will receive treatment or not
  - Randomized: participants are randomized into the treatment group with group intervention or one without the intervention
- The participants are randomly assigned to one of the two groups: the intervention group or the control group. The assessors performing the screenings do not know who will be assigned and to which group
- Participants who are randomized into the group PM+ intervention will attend a 90-minute session for 5 weeks (once a week) and 4 surveys (before, immediately after the intervention, 3 months, and 12 months thereafter).
- If you have a child aged between 10 -16 years old, one of these children will be invited to complete a brief measure of their mental health on 4 occasions (before, immediately after the intervention, 3 months, and 12 months thereafter). Your child will not take part in the intervention but they will be assessed. If we assess your child and notice that your child requires urgent help, we will immediately refer them for assistance.
- The participants of the control group will only participate in 4 surveys. If you are assigned to the control roup, you will be instructed to contact a specialist if the condition worsens.
- Approximately 350 will be recruited to particpate in the study (in both groups)
- This survey and subsequent study will be conducted in accordance to the laws of the Hashemite Kingdom of Jordan. In addition, we adhere to all internationally recognized guidelines
- The study has been approved by the King Hussein Cancer Centre Institutional Review Board
- Further information for this study can also be found at the STRENGTHS website: https://strengths-project.eu/

4. What Will Happen

After you have received all the information about the study and all your questions have been answered to your satisfaction, you can sign the encolsed declaration of consent if you wish to particpate in the study.

After signing the consent form, you will complete several questionnaires on a table (as you did for the screening). The duration for completing the questionnaire is about 30-40 minutes.

The surveys are:

Name in the Study	Name of the Questionnaire	Purpose of the Questionnaire
HSCL-25	Hopkins Symptom Checklist	Measurement of Mental Stress
PCL-5	Posttraumatic Stress Disorder Checklist	Recording the symptoms of post-traumatic stress disorder
PSYCHLOPS	Psychological Outcomes Profiles	Monitoring the dynamics of the therapy session
PTE	Potentially Traumatic Events	Survey of experienced stress
PMLDC	Post-Migration Living Difficulties Checklist	Survey of life difficulties after migration
CSRI	Client Service Receipt Inventory	Cost-effectiveness analysis of mental health care systems
PSC	Pediatric Symptom Checklist	Mental health of your child

PQ 16	Brief Prodromal Questionnaire	Screen the risk of Psychosis
PGS	Prolonged Grief Disorder	Screen the difficulties of the Loss experience

Regardless of the results of this survey, you will be randomly assigned to either the intervention group or the control group by an independent body that is not involved in the research project.

If you are assigned to the control group, you will be informed on the next visit. You will be invited for a repeat survey using the same questionnaire listed above in 6 to 7 weeks, and then at 3 and 12 months. If your mental state changes in the course of this time, you can contact the nearest medical provider.

If you are assigned to the intervention group, you will be assigned a group facilitater who will schedule five sessions with you and up to nine others. These sessions are scheduled for the next five consecutive weeks – one session a week Each session lasts 90 minutes each. During these sessions you will be taught various techniques for stress management, behavioural activation, strengthening of social support, etc., which form the basic concept of PM+. After completing the treatment, you will be invited to resubmit the same questionnaires listed above, as well as at 3 and 12 months later.

If you are assigned to the intervention group or the control group, we will invite one child of your's between the ages of 10 - 16 to complete one questionnaire at the same times that you are assessed,

5. Benefits

Participating in the study and being assigned to the PM+ group sessions may reduce the stress-related symptoms. These findings can also be very useful for other people who have similar symptoms. If you are placed in the control group, you will not have any personal benefits from participating in the study.

6. Rights

Your participation is voluntarily. If you do not want to join, or want to later withdraw your participation, you do not need to justify it. Medical treatment and support is not bound to participation and is guaranteed regardless of your decision.

You are always welcome to ask questions about participating in the study. Please contact the person named at the end of this information.

7. Obligations

As a participant it is necessary that you:

- Adhere to the necessary requirements and requirements of the study through the test plan;
- Inform your examiner or group facilitator about the course of the symptoms, and report any new symtoms, new complaints, and changes in your current condition (even after the end of the study/termination);
- Inform your examiner or group facilitator about the simultaneous treatments and therapies with other organizations or doctors, or if you are taking medications

8. Risks and burdens for participants

In principle, the study does not involve any risks. However, dealing with one's own feelings and emotions can temporarily increase the psychological burden. It may also be difficult for you to talk about it. If this is the case, please talk to your group facilitator. Referrals to specialized staff is also available in such situations.

Should your condition deteriorate massively during the intervention, appropriate steps will be taken to ensure you receive the necessary treatment. However, this is an extremely unlikely scenario.

For women who can get pregnant

A possible pregnancy plays no role in the screening process. Pregnancy is not considered a contraindication nor is there any affect on the unborn child. However, we kindly ask you to inform your contact person if you may be pregnant – pregnancy may change one's mood and influence the results. We would like to that this into consideration for our evaluations.

9. Other treatment options

You do not have to participate in this study. If you do not want to participate but want treatment, you should contact the nearest medical provider.

10. Results from the survey

The responsible person from the research team will inform you after the survey about the findings that may affect the benefit of the study or your safety and thus your consent to participate in the study. Will will receive this information verbally or in writing.

11. Confidentiality of data and samples

Your personal and medical data will be collected for this study. Only the principle investigator Prof. Dr. Richard Bryant and his program manager, Mr. Aemal Akhtar, are allowed to see your unencrypted data solely for the purposes of the study. Both are subject to secrecy. When collecting data for study purposes, the data in encrypted. Encryption means that any reference data you could be used to identify you (name, data of birth) is deleted and replaced with a idenfication key. Therefore, those people who do not know the identification key cannot draw any conclusions about you. The key list always remains in the posession of the University of New South Wales, and at program managers office, in a locked cabinet. All persons who have access to your data are also subject to secrecy. All data protection requirements will be met and we will not make your name public in a publication or on the internet. As a participant, you have the right to access your data at any time.

The data is stored on site into a database for research purposes.

The data can be sent encrypted to other research groups at home and abroad, examined for this project and kept for 7 years. The key list remains in the possession of only the two persons mentioned above. The sponsor is responsible for ensuring that the same standards are observed abroad as in Jordan.

This survey may be reviewed by the responsible ethics committee or by the institution that initated the study. To ensure appropriate controls, the project manager may need to disclose your personal and medical data. All persons must maintain absolute confidentiality.

12. Withdrawal

You can stop at any time and withdraw from the surey if you wish. The data collected until then will be deleted.

13. Compensation for participants

You will be provided with a Sympolic present each time you complete an assessment. That is, if you do all 4 assessments then you will receive 4 gifts.

14. Liability

The institution (sponsor) that initiated the study and is responsible for its performance is responsible for any damage that you may suffer in connection with the research that is being tested. The conditions and procedure are regulated by law. If you have suffered damage, please contact the research team.

15. Financing the Study

The study is funded by the National Health and Medical Research Council (NHMRC).

16. Contact Person (s)

If you have any questions, uncertainties, or emergencies that arise during or after the trial, you can contact us here:

Studies: Aemal Akhtar & Manar Awwad
und e-mail: a.akhtar@unsw.edu.au
Manar E-mail: mawwad@internationalmedicalcorps.org

Informed Consent (Intervention)

Written declaration of consent to participate in the study
Please read this form carefully. Please ask if you do not understand or want to know something. Participating requires your written consent.

Study Number (after submission):	
Title of the Study (Scientific and Lay language)):	Scaling-up psychological interventions with Syrian refugees Testing a psychological intervention among Syrian Refugees
Responsible Institution (Sponsor with address):	Prof. Dr. Richard Bryant School of Psychology University of New South Wales Sydney, NSW, Australia 2052
Place of Implementation:	Jordan
Responsible investigator at the Study Location: Name and first name in block letters:	MR. AKHTAR AEMAL
Participant/Participants: Name and first name in block letters: Date of Birth:	☐ Female ☐ Male

- I have been informed verbally and in writing by the underssigned investigator about the purpose, the course of the screening for the implementation of PM+ about possible advantages and disadvantages as well as about possible risks.
- I voluntarily participate in this study and accept the content of the written information provided. I had plenty of time to make my decision.
- I have been asked questions related to participating in this screening. I keep the written information and receive a copy of my written consent.
- I will be informed in the case of survey results or incidental findings that directly affect my health. If I do not want that, I will inform my examiner.
- I know that my health-related and personal data can only be passed on in encrypted form for research purposes and abroad for this survey
- I agree that if I continue to be treated outside the trial centre, the investigator may contact the treating physicians to obtain the relevant post-treatment data for the survey.
- I can withdraw from the survey participation at any time and without giving reasons. My further medical treatment is always guaranteed regardless of the survey participation. The data and samples collected until the resignation will be deleted.

- The liability insurance of the institution is payable for any damage. I am aware that insurance covers any damage caused by the study.
- I am aware that the obligations stated in the participant information must be adhered to. In the interest of my health, the investigator can exclude me from the study at any time.

Place and date:	Participant Signature:

Confirmation by the investigator or a test person trained by him:
I hereby certify that I have explained to this participant the nature, significance, and scope of the survey. I declare that I will fulfull all obligations arising from this survey in accordance with applicable law. If, at any time during the course of the survey, I am aware of any issues that may affect the participant's willingness to participate in the survey, I will promptly inform you.

Place and date:	Name and First Name of the examiner in block letters: Signature of the investigator/examiner: