# Informed Consent Form for Trial

This Informed Consent Form is for Syrian refugees who reside in Istanbul, Turkey, for men and women whom we are inviting to participate in research on the feasibility of administering Group Problem Management Plus (PM+). The title of our research project is "STRENGTHS".

**Site principle investigator: Associate Professor Zeynep Ceren Acartürk, Istanbul Sehir University**

**Project Partner: Refugees and Asylum Seekers Assistance and Solidarity Association (RASASA)**

**Sponsor: EU, H2020**

**This Informed Consent Form has two parts:**

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

**You will be given a copy of the full Informed Consent Form**

**PART I: Information Sheet**

**Introduction**

We are a group of researchers from the Istanbul Sehir University (ISU). This study is being conducted in collaboration with the RASASA, a non-governmental organization located in Istanbul, Turkey, and supported by the European Union, H2020. We are studying the feasibility of a new support program for individuals with stress-related problems. This program is called "Problem Management Plus (PM+)".

A research assistant will conduct an interview with you and if your responses indicate that, you are probably distressed. Therefore, we will complete the interview with you to take part in the next part of our study. In this part, we will test the feasibility of the Group PM+ program in reducing these feelings of distress.

I may use some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the interviewer, service provider or other staff members involved in the project.

**Purpose of the research**

Emotional problems, such as feelings of extreme sadness and extreme anxiety are very common. These may affect the ability of people to carry out day to day tasks. Many people with such problems do not get effective help. In this research, we aim to find out whether a support program called "Problem Management Plus (PM+)" is useful and acceptable in reducing such problems.

PM+ consist of 5 group sessions of around 2-3 hours each. During these sessions, a service provider will listen to you and will discuss issues related to your emotions and feelings with you. You will also be given advice on ways you can address problems that cause distress. Research in other countries suggests that this program may reduce stress-related problems. We now want to find out whether it is useful and acceptable for the Syrian refugees who are living in Istanbul.

**Type of Research Intervention**

This research involves interviews about feelings and emotions. In addition, half of the participants will receive five Group PM+ sessions. The other half of the participants will be referred to their physician for additional support and will be offered Group PM+ at the end of the study, if still necessary.

**Participant selection**

We are inviting all adult participants visiting RASASA aged 18 and above, and who have found to be distressed through the first part of the interview to participate in this research.

**Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this association will continue and nothing will change. You may change your mind at any time and stop participating, even if you agreed earlier. If you stop, your responses will be destroyed.

**Procedures and Protocol**

**A. Unfamiliar Procedures**

This research involves a few procedures which may be unfamiliar to you.

*Random group assignment*

Because we do not know if Group PM+ is better than enhanced care as usual for reducing stress-related problems, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin. One group of participants will receive enhanced care as usual at this association, while the other group will receive enhanced care as usual along with Group PM+. The participants in the enhanced care as usual group will be offered Group PM+ at the end of the study at twelve months, if still necessary and if they wish to. This enables us to find out if Group PM+ is an improvement on enhanced care as usual.

*Outcome assessments*

The interviewers do not know whether you are receiving Group PM+ or enhanced care as usual until after the research has finished. We ask you not to tell the research assistant to which group you were assigned during the research. This is the best way we have for testing which of the two – Group PM+ or enhanced care as usual - has the best results, without being influenced by what we think or hope might happen.

**B. Description of the Process**

- If you agree to participate, then you will be interviewed again. The interviewer will ask you some additional questions on adverse events and reactions related to these events, and other difficulties concerning your health. This will take approximately 40 minutes.

- Finally, another research assistant will tell you to which group you are assigned: enhanced care as usual or Group PM+ along with enhanced care as usual. The group to which you are allocated is determined by chance (see *Random group assignment*). In case you are allocated to the Group PM+ group, the same research assistant will also inform you about intervention group that you will be in and for the time of the first Group PM+ session.

- During the next five weeks, the participants invited to take part in this research will receive five group PM+ sessions. If you are allocated to this group, during these sessions the service provider will listen to you and will discuss issues related to your emotions and feelings with you. You will also be given advice on ways you can address problems that cause distress. These sessions take 2-3 hours each. Participants in the enhanced care as usual group will be offered extra meetings with their physician, who will talk with them and provide support.

- At the second assessment, seven weeks after the first, all participants will again be asked questions, which are similar to the first assessment. This assessment will take approximately 60 minutes.

- At the final assessment, four months and twelve months after the first, all participants will again be asked questions similar to the first assessment. These assessments takes approximately 60 minutes. If you were in the enhanced usual care group, you will be offered Group PM+ at this point if you still experience significant distress.

**Risks**

We do not expect that Group PM+ will have any negative effects. However, it is possible that talking about your feelings and emotions will make you more stressed, fearful or tense for a little while. Talking about your feelings or emotional topics may be difficult for some people, and cause emotional upset in some. You may always skip any questions which make you feel uncomfortable. If you become upset, you will be able to speak with an appropriate member of the clinical staff. Our research assistant and Group PM+ staff are trained in helping you to cope with such feelings.

**Benefits**

We expect that the program might be helpful to people experiencing distress. If the study shows that Group PM+ is helpful, then additional service providers in your area will be trained to deliver Group PM+ so that other people who experience stress-related problems may benefit from it.

**Reimbursements**

No compensation will be offered for participating in this study. However, any costs you incur due to the study, will be paid by us.

**Confidentiality**

We and any researchers working on this study ensure privacy and confidentiality for all study-related data, documents, and findings. It is possible that if others in the community are aware that you are participating, they may ask you questions. But we will not be sharing the identity of who is participating in the research and of persons accompanying them. However, for your safety, I will inform the supervisor immediately if I will realize that there is a risk to your life.

All information collected about you will be kept strictly confidential. The results of all assessments and tests will never be linked to yourself. Any information about you will have a number on it instead of your name. Data will be stored in a document on a computer at Istanbul Sehir University that can only be opened by the researcher. Only group results will be reported that cannot be linked to yourself to protect confidentiality. No one else except Dr. Acartürk and the research team will have

access to the information documented during your interview. The interviews will be destroyed after five years.

**Sharing the Results**

The knowledge that we gain during this research will be shared with you through community meetings before it is made widely available to the public. Nothing that identifies you will be shared at these meetings or at any point during this study, and we will not tell anybody that you have contributed to this research. Small meetings in the community to share research findings will be announced. After these meetings, we will publish what we have learnt so that other interested people may learn from this research.

The research team is allowed to transfer the encrypted data to other research teams in Turkey and abroad including the other partners of the project. It can be analyzed and stored by them and. The decoding key stays by the parent organization which is ISU. Only Zeynep Ceren Acartürk and the research team have an access to the decoding key. All partners adhere to EU regulations as in Turkey.

**Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so. Refusing to participate will not affect your treatment at this association in any way. You will still have all the benefits that you would otherwise have at this association. You may also stop participating in the research at any time you choose without losing any of your rights here.

**Who to Contact**

If you or your accompanying person have questions now you can ask me. We will also give you the name and phone number of a study team member to contact if you have questions later. This person is: ……., Phone no: ……..

This proposal has been reviewed and approved by the Ethics Committee of the Istanbul Sehir University, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the research, contact ……, Ph.No: ……. Of note, this proposal has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is supporting the study.

**PART II: Certificate of Consent**

***Literate participant:***

**I have read and understood the above information, or it has been read to me. I have had the opportunity to ask questions, and any questions that I have asked have been answered to my satisfaction. I consent voluntarily be a participant in this research.**

**Print Name of Participant_____**

**Signature of Participant _____**

**Date _____**

**Day/month/year**

***Illiterate participant:***

**I have witnessed the accurate reading of the consent form to the participant, and the participant has had the opportunity to ask questions and these have been answered to the participant's satisfaction. I confirm that the individual has given consent freely.**

**Print Name of Witness_____**

**Signature of Witness _____**

**Date _____**

**Day/month/year**

***Statement by the researcher/person taking consent***

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the purpose and process of the study.**

**I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this informed consent form has been provided to the participant.**

**Print Name of Researcher/person taking the consent_____**

**Signature of Researcher /person taking the consent_____**

**Date _____**

**Day/month/year**