TEMPLATES OF INFORMED CONSENT FORMS AND INFORMATION SHEETS

DELIVERABLE 9.1
DELIVERABLE 9.9

SCALING UP PSYCHOLOGICAL INTERVENTIONS WITH SYRIAN REFUGEES
STRENGTHS

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About this document

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Project acronym: STRENGTHS (**S**yrian **RE**fu**G**ees Me**NT**al Heal**TH** Care **S**ystems)

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STRENGTHS Templates of Informed Consent Forms and Information Sheets

This document provides templates of the Informed Consent Forms and Information Sheets used in STRENGTHS, as approved by the authoritative ethic review committees.
An overview of the informed consent procedures and authoritative ethic review committees is provided in Deliverable 9.7.

Note that the Informed Consent Forms and Information Sheets may differ across study sites due to local regulations and requirements imposed by the authoritative ethic review committees across the participating countries.

The following Informed Consent Forms and Information Sheets used in STRENGTHS are provided in this document:

Workpackage and STRENGTHS partners	**Ethics Review Committee**
WP1: Management and Overall Coordination	NA (no primary data collection)
WP2: Health Systems Evaluation; Study 1 (rapid health system assessments)	
London School of Hygiene and Tropical Medicine (LSHTM)	Ethics approval submitted to London School of Hygiene and Tropical Medicine, approval received September 14 2017.
International Medical Corps (IMC)	Ministry of Health, Jordan, approval June 11, 2017
War Child Holland (WCH)	St Joseph University, Beirut, Lebanon
Vrije Universiteit Amsterdam (VUA)	Waiver from VU Medical Center Medical Ethics Committee (dd. April 20, 2017).
İstanbul Sehir Universitesi (ISU)	Approval from ISU Research Ethics Committee (dd. April 12, 2017), The Immigration Authority of Turkey (dd. March 29, 2017)
Universität Zürich (UZH)	No objection waiver by Ethics Committee of Canton Zurich KEK-ZH REQ-2017-00404 (dd. June 02, 2017).
Freie Universität Berlin (FUB)	Ethics committee of the Department of Education and Psychology at Freie Universität Berlin (dd. June 12, 2017).
WP2: Health Systems Evaluation; Study 2 (surveys)	
London School of Hygiene and Tropical Medicine (LSHTM)	Overall ethics approval London School of Hygiene and Tropical Medicine received September 14 2017. Local ethics approval received from Istanbul Sehir Universityby ISU Research Ethics Committee (dd. April 12, 2017) in Turkey and under review at Leipzig university (outcome expected early October 2017).

İstanbul Sehir Universitesi (ISU)	ISU Research Ethics Committee (dd. June 22, 2017)
Leipzig University	Ethics Committee of Leipzig University, approval expected early October 2017
WP3: Adaptation	
Danish Red Cross (DRC)	Waiver from Region Hovedstaden- Center for Sundhed, De Videnskabsetiske Komiteer, (dd. June 28, 2917)
International Medical Corps (IMC)	Ministry of Health, Jordan, approval June 11, 2017
War Child Holland (WCH)	St Joseph University, Beirut, Lebanon (approved dd March 24, 2017)
Vrije Universiteit Amsterdam (VUA)	No objection waiver from VU Medical Center Medical Ethics Committee (dd. April 20, 2017).
İstanbul Sehir Universitesi (ISU)	Research Ethics Committee (dd. April 12, 2017), The Immigration Authority of Turkey (dd. March 29, 2017).
Universität Zürich (UZH)	No objection waiver by Ethics Committee of Canton Zurich KEK-ZH REQ-2017-00404 (dd. June 02, 2017).
Freie Universitaet Berlin (FUB)	Ethics committee of the Department of Education and Psychology at Freie Universität Berlin (dd. June 12, 2017).
WP4: Refugee Settlement and Camp Implementation; Study 1 (Jordan)	
University of New South Wales (UNSW)	UNSW Human Research Ethics Committee (HREC), dd. July 27, 2017
WP4: Refugee Settlement and Camp Implementation; Study 2 (Lebanon)	
War Child Holland (WCH)	Approved by the Ethics Review Committee of St Joseph University, Beirut, Lebanon on September 25, 2017
WP5: Community Implementation; Study 1 (The Netherlands)	
VU University Amsterdam (VUA)	VU Medical Center Medical Ethics Committee, approval dd. September 6, 2017
WP5: Community Implementation; Study 2 (Turkey)	
İstanbul Sehir Universitesi (ISU)	ISU Research Ethics Committee (dd. April 12, 2017), The Immigration Authority of Turkey (dd. March 29, 2017).
WP5: Community Implementation; Study 3 (Switzerland)	
Universität Zürich (UZH)	Ethics Committee of Canton Zurich [BASEC-Nr.: 2017-01175]), dd. September 08, 2017.
WP6: Online Implementation; Study 1 (Germany), 2 (Egypt) and 3 (Sweden)	

Freie Universitaet Berlin (FUB)	Ethics committee of the Department of Education and Psychology at Freie Universität Berlin (approved dd. August 16, 2017).
WP7: Economic and Implementation Evaluation	NA (no primary data collection)
WP8: Synthesis and Dissemination	NA (no primary data collection)

WP2: Health Systems Evaluation; study 1 (rapid health system assessments)

London School of Hygiene and Tropical Medicine (LSHTM)

Information sheets for semi-structured interviews

Separate information sheets will be used for each type of stakeholder group as found below (i.e. Syrian refugees using MHPSS services, family members of Syrian refugees receiving MHPSS, providers of MHPSS, and key informants).

Separate information sheets will be used for each type of stakeholder group as found below (i.e. Syrian refugees using MHPSS services, family members of Syrian refugees receiving MHPSS, providers of MHPSS, and key informants).

London School of Hygiene and Tropical Medicine
Information Sheet for Service Users (Syrian refugees)

Study title: "Access to mental health and psychosocial support services for Syrian refugees in [insert name of country]"

This information sheet provides an overview about a research study which you have been asked to participate in. Please take time to read the following information and ask the interviewer if there is anything that is not clear to you. This research is being conducted by [add name of local partner] and the London School of Hygiene and Tropical Medicine.

What is the purpose of this study?
The purpose of this study is to investigate the health system in country [insert name of country] and how it serves the needs of Syrian refugees requiring psychosocial care [insert appropriate/locally accepted term for psychosocial].

What will happen to me if I take part?
If you take part in our study, you will be interviewed for about 1 hour at a time and location of convenience to you. You will be asked to describe the MHPSS [insert appropriate/locally accepted term for MHPSS] you received and your experiences with it. We are especially interested to learn about how you accessed those services, your satisfaction with the care you received and its quality. The interview will be recorded using a digital recorder. This is to help us remember everything that you have told us. The information you provide to the research assistant will not be disclosed to anyone else.

Do you have to take part?
No. Participation is completely voluntary. It is your choice to participate in this study or not. If you choose to participate, you retain the right to refuse answers to any questions that you do not feel comfortable with. Also, you retain the right to withdraw from this study at any point during the interview. Refusal to participate will have no negative effect on the health care you receive, and will not limit any other rights for you or your family.

What are the possible benefits of taking part?
If you decide to take part, you will be contributing to our understanding of what needs to be done to improve psychosocial support services [insert appropriate/locally accepted term for psychosocial] for refugees in [insert name of country].

What are the possible disadvantages?
You might find discussing some details of your use of psychosocial support services [insert appropriate/locally accepted term for psychosocial] with someone who you do not know upsetting. 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 clinical staff. Our researchers and staff are trained in dealing with these situations and emotional disturbances, and will help you to cope with such feelings. The following local organisation can also be contacted should you need further help and support [add name and contact details of local MHPSS support].

Confidentiality

All information collected about you will be kept strictly confidential. Please note, that we and any researchers working on this study ensure privacy and confidentiality for all study-related data, documents, and findings. Participant-related data will be labelled by a code rather than by using your name or by using any other personal identifiers of you. Audio files will be securely stored and password protected at [name of partner institution] and LSHTM for the duration of the study and no one but the researchers will be able to access them. The study results will be reported in a way that ensures complete confidentiality to the fullest extent possible.

What will happen to the findings of the study?
We will use the findings of the study to try and improve psychosocial support systems [insert appropriate/locally accepted term for psychosocial] in [insert name of country]. Results from the study (including quotations from the interviews) may be published in scientific journals or reports, without the use of any information that could identify individual persons or families.

Who has approved the study?
This study has been reviewed and approved by a scientific committee in [insert name of university and local partner organisation] and the London School of Hygiene & Tropical Medicine in the United Kingdom.

Who should I contact for further information?
If you would like to receive more information regarding our study, or if you would like to discuss your rights regarding participation in this study please contact [insert name of staff + address + telephone number at partner site].

London School of Hygiene and Tropical Medicine
Information Sheet for Family Members of Service Users

Study title: "Access to mental health and psychosocial support services for Syrian refugees in [insert name of country]"

This information sheet provides an overview about a research study which you have been asked to participate in. This research is being conducted by [add name of local partner] and the London School of Hygiene and Tropical Medicine. Please take time to read the following information and ask the interviewer if there is anything that is not clear to you.

What is the purpose of this study?

The purpose of this study is to investigate the health system in country [insert name of country] and how it serves the needs of Syrian refugees requiring psychosocial care [insert appropriate/locally accepted term for psychosocial].

What will happen to me if I take part?

If you take part in our study, you will be interviewed for about 1 hour at a time and location of convenience to you. You will be asked to describe the MHPSS [insert appropriate/locally accepted term for MHPSS] your family member received and his/her experiences with it. We would like to learn about his/her satisfaction with the care which was received and its quality. We are especially interested to learn about your viewpoints and how the provision of care affected family life. The interview will be recorded using a digital recorder. This is to help us remember everything that you have told us. The information you provide to the research assistant will not be disclosed to anyone else.

Do you have to take part?

No. Participation is completely voluntary. It is your choice to participate in this study or not. If you choose to participate, you retain the right to refuse answers to any questions that you do not feel comfortable with. Also, you retain the right to withdraw from this study at any point during the interview. Refusal to participate will have no negative effect on the health care you receive, and will not limit any other rights for you or your family.

What are the possible benefits of taking part?

If you decide to take part, you will be contributing to our understanding of what needs to be done to improve psychosocial support services [insert appropriate/locally accepted term for psychosocial] for refugees in [insert name of country].

What are the possible disadvantages?

You might find discussing some details of your family member's use of psychosocial support services [insert appropriate/locally accepted term for psychosocial] with someone who you do not know upsetting. 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 clinical staff. Our researchers and staff are trained in dealing with these situations and emotional disturbances, and will help you to cope with such feelings. The following local organisation can also be contacted should you need further help and support [add name and contact details of local MHPSS support].

Confidentiality

All information collected about you will be kept strictly confidential. Please note, that we and any researchers working on this study ensure privacy and confidentiality for all study-related data,

documents, and findings. The results of all assessments will never be linked to yourself. Participant-related data will be labelled by a code rather than by using your name or by using any other personal identifiers of you. Audio files will be securely stored and password protected at [name of partner institution] and LSHTM for the duration of the study and no one but the researchers will be able to access them. The study results will be reported in a way that ensures complete confidentiality to the fullest extent possible.

What will happen to the findings of the study?
We will use the findings of the study to try and improve psychosocial support systems [insert appropriate/locally accepted term for psychosocial] in [insert name of country]. Results from the study (including quotations from the interviews) may be published in scientific journals or reports, without the use of any information that could identify individual persons or families.

Who has approved the study?
This study has been reviewed and approved by a scientific committee in [insert name of university and local partner organisation] and the London School of Hygiene & Tropical Medicine in the United Kingdom.

Who should I contact for further information?
If you would like to receive more information regarding our study, or if you would like to discuss your rights regarding participation in this study please contact [insert name of staff + address + telephone number at partner site]. Should you require any help or advice on your emotional and mental well-being, this can be obtained from [add local support advice contact details].

London School of Hygiene and Tropical Medicine
Information Sheet for Service Providers

Study title: "Access to mental health and psychosocial support services for Syrian refugees in [insert name of country]"

This information sheet provides an overview about a research study which you have been asked to participate in. This research is being conducted by [add name of local partner] and the London School of Hygiene and Tropical Medicine. Please take time to read the following information and ask the interviewer if there is anything that is not clear to you.

What is the purpose of this study?
The purpose of this study is to investigate the health system in country [insert name of country] and how it serves the needs of Syrian refugees requiring psychosocial care.

What will happen to me if I take part?
If you take part in our study, you will be interviewed for about 1 hour at a time and location of convenience to you. We are interested in your work, and your work with refugees requiring MHPSS. You will be asked to describe the mental health system in your country and the type of mental health services Syrian refugees receive. We are especially interested to learn about how refugees access those services, and potential problems associated with it. We would also like to learn more about the mental health professionals providing care to Syrian refugees and about potential linkages with other providers. The interview will be recorded using a digital recorder. This is to help us remember everything that you have told us. The information you provide to the research assistant will not be disclosed to anyone else.

Do you have to take part?
No. Participation is completely voluntary. It is your choice to participate in this study or not. If you choose to participate, you retain the right to refuse answers to any questions that you do not feel comfortable with. Also, you retain the right to withdraw from this study at any point during the interview. Refusal to participate will have no negative effect you.

What are the possible benefits of taking part?
If you decide to take part, you will be contributing to our understanding of what needs to be done to improve psychosocial support services for refugees in [insert name of country].

What are the possible disadvantages?
You might feel uncomfortable to discuss details about your work with someone who you do not know. You may always skip questions which make you feel uncomfortable.

Confidentiality
All information collected about you will be kept strictly confidential. Please note, that we and any researchers working on this study ensure privacy and confidentiality for all study-related data, documents, and findings. Participant-related data will be labelled by a code rather than by using your name or by using any other personal identifiers of you. Audio files will be securely stored and password protected at [name of partner institution] and LSHTM for the duration of the study and no one but the

researchers will be able to access them. The study results will be reported in a way that ensures complete confidentiality to the fullest extent possible.

What will happen to the findings of the study?
We will use the findings of the study to try and improve psycho-social support systems in [insert name of country]. Results from the study (including quotations from the interviews) may be published in scientific journals or reports, without the use of any information that could identify individual persons or families.

Who has approved the study?
This study has been reviewed and approved by a scientific committee in [insert name of university and local partner organisation] and the London School of Hygiene & Tropical Medicine in the United Kingdom.

Who should I contact for further information?
If you would like to receive more information regarding our study, or if you would like to discuss your rights regarding participation in this study please contact [insert name of staff + address + telephone number at partner site].

London School of Hygiene and Tropical Medicine
Information Sheet for Key Informants

Study title: "Access to mental health and psychosocial support services for Syrian refugees in [insert name of country]"

This information sheet provides an overview about a research study which you have been asked to participate in. This research is being conducted by [add name of local partner] and the London School of Hygiene and Tropical Medicine. Please take time to read the following information and ask the interviewer if there is anything that is not clear to you.

What is the purpose of this study?
The purpose of this study is to investigate the health system in country [insert name of country] and how it serves the needs of Syrian refugees requiring psychosocial care.

What will happen to me if I take part?
If you take part in our study, you will be interviewed for about 1 hour at a time and location of convenience to you. We are interested in the mental health system of your country and the type of mental health services Syrian refugees receive. You will be asked to describe the services which are available to refugees, its organisation, and the financing of mental health and psychosocial support services for Syrian refugees. We would also like to learn more about the mental health professionals providing care to Syrian refugees and about potential linkages with other providers. The interview will be recorded using a digital recorder. This is to help us remember everything that you have told us. The information you provide to the research assistant will not be disclosed to anyone else.

Do you have to take part?
No. Participation is completely voluntary. It is your choice to participate in this study or not. If you choose to participate, you retain the right to refuse answers to any questions that you do not feel comfortable with. Also, you retain the right to withdraw from this study at any point during the interview. Refusal to participate will have no negative effect you.

What are the possible benefits of taking part?
If you decide to take part, you will be contributing to our understanding of what needs to be done to improve psychosocial support services for refugees in [insert name of country].

What are the possible disadvantages?
You might feel uncomfortable to discuss details about your work with someone who you do not know. You may always skip questions which make you feel uncomfortable.

Confidentiality
All information collected about you will be kept strictly confidential. Please note, that we and any researchers working on this study ensure privacy and confidentiality for all study-related data, documents, and findings. Participant-related data will be labelled by a code rather than by using your name or by using any other personal identifiers of you. Audio files will be securely stored and password protected at [name of partner institution] and LSHTM or the duration of the study and no one but the

researchers will be able to access them. The study results will be reported in a way that ensures complete confidentiality to the fullest extent possible.

What will happen to the findings of the study?
We will use the findings of the study to try and improve psycho-social support systems in [insert name of country]. Results from the study (including quotations from the interviews) may be published in scientific journals or reports, without the use of any information that could identify individual persons or families.

Who has approved the study?
This study has been reviewed and approved by a scientific committee in [insert name of university and local partner organisation] and the London School of Hygiene & Tropical Medicine in the United Kingdom.

Who should I contact for further information?
If you would like to receive more information regarding our study, or if you would like to discuss your rights regarding participation in this study please contact [insert name of staff + address + telephone number at partner site].

Consent form for semi-structured interviews

[main local research contact information to be added here]

Study title: "Access to mental health and psychosocial support services for Syrian refugees in [insert name of country]"

Thank you for considering taking part in this research. This research is being conducted by [add name of local partner] and the London School of Hygiene and Tropical Medicine. If you have any questions arising from the information sheet or explanation given to you, please ask the research assistant before you decide whether to sign this form or not.

	Please tick if you agree
1. I have read the information sheet concerning this study [and/or have understood the verbal explanation] and have received a copy of it for me to keep. I fully understand what will be required of me to take part in the study.	**2.**
• I understand that I may withdraw from this study without giving a reason at any point in time. There will be no effect, positive or negative, on me or my household if I decide to withdraw from this study.	
• Results from the study (including quotations from my interview) may be published in scientific journals or reports, without the use of any information that could identify me.	
• I consent to my interview being audio recorded.	

I agree to take part in this study

Signature: …….. Date: ……../……../…….. [dd/mm/yyyy]

Signature of impartial witness (if participant illiterate): ……..
Date: ……../……../…….. [dd/mm/yyyy]

Statement by the researcher/person taking consent
I have made sure that the participant understands the purpose and process of the study. I confirm that the participant was given the opportunity to ask questions, and that all of 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 that 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: _____

Print position of researcher/person taking the consent: _____

Signature of researcher/person taking the consent: Date (Day/month/year):

_____ _____

International Medical Corps (IMC)

Interviews Phase 1 (All Interviews) – Jordan

Consent form

Interview ID: ____ Date: ____ Interviewer: ____

Project Introduction

International Medical Corps (IMC) is an international humanitarian organization that has been working in Jordan for the past seven years. IMC provides a range of support to Syrian refugees and vulnerable Jordanians, including the provision of healthcare. A core part of IMC programming involves supporting Syrian refugees' wellbeing through psychosocial support and mental health services.

Problem Management Plus (PM+) is a 5 session group-based program for communities affected by difficult conditions, that was developed by the World Health Organization (WHO). The aim is to support persons in distress to cope with common challenges faced by the community. IMC is hoping to implement PM+ in Jordan to support members of the Syrian refugee community. First, IMC wants to learn more about the common challenges faced by the Syrian refugee community.

To learn about the common challenges facing the Syrian refugee community, IMC is conducting individual interviews and focus group discussions to try and hear from as many people as possible who are knowledgeable about the topic. We want to know about common problems faced by the Syrian refugee community as a whole,
and also how people in the community cope with such problems.

Free Listing and Key Informant Interviews

This interview will take approximately one hour. I will ask you some questions, and you have the right to choose not to participate at any time, or to refuse to answer any question. You can leave any time before completing the interview without any problems.

Focus Group Discussions

This focus group discussion may take approximately 2 hours. The aim is to have a discussion which captures a variety of perspectives on problems faced by the Syrian community as well as gathers information on coping and how best to address such issues. You have the right to withdraw from the focus group at any time with no negative consequences.

We cannot offer any compensation or benefits for your participation in this assessment. Your decision whether or not you participate, will have no impact on the provision of any support or

services you receive now, or may access in the future. We assure you that your answers will be confidential and will not be accessed by anyone except the researchers involved in the study. Please tick which part the respondent is participating in:

- ☐ Free Listing Interview
- ☐ Key Informant Interview
- ☐ Focus Group Discussion

Signature Date

_____

War Child Holland (WCH)

1. Consent form for Caregivers of Children that participate in the Free Listing Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to the caregiver of the participant prior to the Free Listing interview. If the caregivers and the child then agree to participate, you must gather all the relevant signatures (including child's assent) at the end of this form. Also mark the date on the appropriate lines.
Note: Please be aware that the consent form for caregivers that participate is separate from this consent form.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Free Listing Interview for young adolescents: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

Purpose of the Study
Your child is being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the problems affecting children and adolescents in this community and also about the tasks and activities that children and adolescents normally do. By learning about the problems and normal activities of children and adolescent we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite your child to participate.

Procedures
To obtain this information we are talking to children between 10 and 14 years old, who live here and know about the situation of children and adolescents in your community. This is why we selected your child to participate. If you agree your child to be in this study I will ask your child some questions about the problems affecting children and adolescents in this community, and the tasks and activities that children and adolescents normally do in this community.

Risks and Discomfort
Each interview will take about 60 minutes. It is possible that your child may not like some questions or that some questions may upset him/her. Your child may refuse to answer these questions, or any questions, if he/she wishes. He/she may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the mental health of the children and adolescents in this area. However, there may be no direct benefit to your child personally. If the location of interviewing is not at school, transportation to and from the interview will be provided by War Child Holland.

Confidentiality

During the interview I will write down the information your child tells me. This is the information we will use for our study. The record of this information will not include anything that can be used to identify your child. I will also record your child's name and address, but this will be stored separately from the record, and will be stored in a locked cabinet in the research coordinator's office. The Research coordinator will have the key. Only the research team will be able to see this information.

Nothing that your child tells us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that your child or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness

If you, or your child decides at any time during the study, to no longer wish to participate, you or your child can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact

The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX]. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

_____

If you are interested in having your child participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent for your child to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree my child to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Parent or Caregiver:

_____ _____ _____

Signature of Parent or Caregiver Date Time

_____

Name

_____

Name (-s) of eligible child or children

_____ _____ _____

Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:

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

Print Name of Witness_____

Signature of Witness _____

Thumb print of Parent or Caregiver

_____

Parent or Guardian Name

_____

Name of eligible child

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or read out the information sheet to the caregiver of the potential participant, and to the best of my ability made sure that the caregiver understands the purpose and process of the study. I confirm that the caregiver was given an opportunity to ask questions about the study, and all the questions asked by the caregiver 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

Child Assent To Participate

"*The interview will take no longer than 1 hour. You are free to say that you do not want to participate. And, once we start, if you don't want to continue, you can tell me and we will stop. If there is any question you don't want to answer, you don't need to- we can skip that question.*

The things we talk about will stay confidential- that means, we will write a report on the answers of ALL respondents in this community, but we won't use your name in this report, or tell anyone you took part. The only time we would tell anyone about something you tell us, would be if we had a concern for your safety, and in that case we would need to share that information with someone, in order to keep you safe.

Do you agree to take part?"

I, _____, agree to participate in the Research Study Conducted by War Child Holland in my community, in order to improve programs that assist children and adolescents in communities like my community. I understand that participation means that I will take part of a Free Listing Interview of 60 minutes, and that I will be asked to answer questions around the situation in my community.

_____

Child may sign name here

or

give verbal assent now, witnessed by his/her parent or caregiver or a trusted/known person to the child

_____

_____

Witness Signature Relationship to Child

2. Consent form for Caregivers that participate in the Free Listing Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to the participant prior to the Free Listing interview. If the caregiver agrees to participate, you must gather all the relevant signatures at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Free Listing Interview for caregivers of young adolescents: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

You are being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the problems affecting children and adolescents in this community and also about the tasks and activities that children and adolescents normally do. By learning about the problems and normal activities of children and adolescent we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite you to participate.

Procedures
To obtain this information we like to talk to you, to know more about the situation of children and adolescents in the community. This is why we selected you to participate. If you agree to be in this study we will ask you some questions about the problems affecting children and adolescents in this community, and the tasks and activities that children and adolescents normally do in this community.

Risks and Discomfort
Each interview will take about 60 minutes. It is possible that you may not like some questions or that some questions may upset you. You may refuse to answer these questions, or any questions, if you wish. You may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the health of the children and adolescents in this area. However, there may be no direct benefit to you personally. If the location of interviewing is not at home or school, transportation to and from the interview will be provided by War Child Holland.

Confidentiality
During the interview I will write down the information you tell me. This is the information we will use for our study. The record of this information will not include anything that can be used to identify you. I will also record your name and address, but this will be stored separately from the record, and will be stored in a locked cabinet in the research coordinator's office. The

Research coordinator will have the key. Only the research team will be able to see this information.
Nothing that you tell us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that you or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness
If you decide at any time during the study, to no longer wish to participate, you can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact
The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX].. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

If you are interested to participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Participant:

_____ _____ _____
Signature of participant Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:

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 participants satisfaction. I confirm that the individual has given consent freely.

Print Name of Witness_____

Signature of Witness _____

Thumb print of Participant

_____
Participant Name

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or 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

3. Consent form for Caregivers of Children that participate in the Key Informant Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to caregiver of the participant prior to the Key informant interview. If the caregivers and the child then agrees to participate, you must gather all the relevant signatures (including child's assent) at the end of this form. Also mark the date on the appropriate lines.
Note: Please be aware that the consent form for caregivers and other Key informants that participate is separate from this consent form.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Key Informant Interview for young adolescents: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

Purpose of the Study
Your child is being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and input on the way how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area. By learning more about this we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite your child to participate.

Procedures
To obtain this information we are talking to children between 10 and 14 years old, who live here and know about the situation of children and adolescents in your community. This is why we selected your child to participate. If you agree your child to be in this study I will ask your child some questions about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area.

Risks and Discomfort
Each interview will take about 60-90 minutes. It is possible that your child may not like some questions or that some questions may upset him/her. Your child may refuse to answer these questions, or any questions, if he/she wishes. He/she may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the mental health of the children and adolescents in this area. However, there may be no direct benefit to your child personally. If the location of interviewing is not at school, transportation to and from the interview will be provided by War Child Holland.

Confidentiality

When the interview starts, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.

Nothing that your child tells us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that your child or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness

If you, or your child decides at any time during the study, to no longer wish to participate, you or your child can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact

The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX]. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

_____

If you are interested in having your child participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent for your child to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree my child to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Parent or Caregiver:

_____ _____ _____

Signature of Parent or Caregiver Date Time

_____

Name

_____

Name (-s) of eligible child or children

_____ _____ _____

Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:

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

Print Name of Witness_____

Signature of Witness _____

Thumb print of Parent or Caregiver

_____

Parent or Guardian Name

_____

Name of eligible child

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or read out the information sheet to the caregiver of the potential participant, and to the best of my ability made sure that the caregiver understands the purpose and process of the study. I confirm that the caregiver was given an opportunity to ask questions about the study, and all the questions asked by the caregiver 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

Child Assent To Participate

"*The interview will take no longer than 1,5 hour. You are free to say that you do not want to participate. And, once we start, if you don't want to continue, you can tell me and we will stop. If there is any question you don't want to answer, you don't need to- we can skip that question.*
When the interview starts, everything will be recorded by the interviewer with an audio device, but we will make sure that this device is stored in a locked space, so that only the research team can reach it.
The things we talk about will stay confidential- that means, we will write a report on the answers of ALL respondents in this community, but we won't use your name in this report, or tell anyone you took part. The only time we would tell anyone about something you tell us, would be if we had a concern for your safety, and in that case we would need to share that information with someone, in order to keep you safe.
Do you agree to take part?"

I, _____, agree to participate in the Research Study Conducted by War Child Holland in my community, in order to improve programs that assist children and adolescents in communities like my community. I understand that participation means that I will take part of an Key Informant Interview of 60-90 minutes, and that I will be asked to answer questions around the situation in my community.

_____
Child may sign name here
or
give verbal assent now, witnessed by his/her parent or caregiver or a trusted/known person to the child

_____
_____
Witness Signature Relationship to Child

4. Consent form for Caregivers that participate in the Key Informant Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to the participant prior to the Key Informant Interview. If the caregiver agrees to participate, you must gather all the relevant signatures at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Key Informant Interview for caregivers of young adolescents: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

You are being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and input on the way how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area. . By learning more about this we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite you to participate.

Procedures
To obtain this information we like to talk to you, to know more about the situation of children and adolescents in the community. This is why we selected you to participate. If you agree to be in this study we will ask you some questions about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area.

Risks and Discomfort
Each interview will take about 60-90 minutes. It is possible that you may not like some questions or that some questions may upset you. You may refuse to answer these questions, or any questions, if you wish. You may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the health of the children and adolescents in this area. However, there may be no direct benefit to you personally. If the location of interviewing is not at home or school, transportation to and from the interview will be provided by War Child Holland.

Confidentiality

When the interview starts, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.
Nothing that you tell us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that you or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness
If you decide at any time during the study, to no longer wish to participate, you can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact
The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX]. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

If you are interested to participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Participant:

_____ _____ _____
Signature of participant Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:

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 _____

Thumb print of Participant

_____

Participant Name

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or 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

5. Consent form for Community members that participate in the Key Informant Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to the participant prior to the Key Informant Interview. If the Community Member agrees to participate, you must gather all the relevant signatures at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Key Informant Interview for community members: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

You are being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and input on the way how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area. You have been selected for this study, because some community members have indicated you as knowledgeable about these topic. By learning more about this we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite you to participate.

Procedures
To obtain this information we like to talk to you, to know more about the situation of children and adolescents in the community. This is why we selected you to participate. If you agree to be in this study we will ask you some questions about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area.

Risks and Discomfort
Each interview will take about 60-90 minutes. It is possible that you may not like some questions or that some questions may upset you. You may refuse to answer these questions, or any questions, if you wish. You may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the health of the children and adolescents in this area. However, there may be no direct benefit to you personally. If the location of interviewing is not at your home, transportation to and from the interview will be provided by War Child Holland.

Confidentiality

When the interview starts, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.

Nothing that you tell us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that you or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness

If you decide at any time during the study, to no longer wish to participate, you can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact

The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX].. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

If you are interested to participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Participant:

_____ _____ _____

Signature of participant Date Time

_____ _____ _____

Signature of Person Obtaining Consent Date Time

For 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 _____

Thumb print of Participant

_____

Participant Name

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or 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

6. Consent form for (Mental) Health Care Service providers that participate in the Key Informant Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to the participant prior to the Key Informant Interview. If the (mental) health care service provider/coordinator agrees to participate, you must gather all the relevant signatures at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Key Informant Interview for health care providers: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

You are being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the services provided in this area related to Mental Health and Psychosocial Support for children and adolescent between the age of 10-14. We would also like to receive input on how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area. By learning more about this we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite you to participate.

Procedures
To obtain this information we like to talk to you, to know more about the situation of children and adolescents in the community. This is why we selected you to participate. If you agree to be in this study we will ask you some questions about the services provided in this area related to Mental Health and Psychosocial Support for children and adolescent between the age of 10-14 and your ideas on how the Helping Young Adolescent Cope Intervention of War Child can be best delivered to respond to the mental health needs of children and adolescents in this area.

Risks and Discomfort
Each interview will take about 60-90 minutes. It is possible that you may not like some questions. You may refuse to answer these questions, or any questions, if you wish. You may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the health of the children and adolescents in this area. However, there may be no direct benefit to you personally. If the location of interviewing is not at your place of work, transportation to and from the interview will be provided by War Child Holland.

Confidentiality

When the interview starts, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.
Nothing that you tell us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that you or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness
If you decide at any time during the study, to no longer wish to participate, you can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact
The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX]. . In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

_____

If you are interested to participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent to participate. You will be given a copy of this Consent Form after it has been signe

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Participant:

_____ _____ _____
Signature of participant Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

For 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 _____

Thumb print of Participant

_____

Participant Name

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or 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

7. Consent form for Caregivers of Children that participate in the Focus Groups Discussion as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to caregiver of the participant prior to the Focus Group Discussion. If the caregivers and the child then agrees to participate, you must gather all the relevant signatures (including child's assent) at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Focus Group Discussion for young adolescents: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

Purpose of the Study
Your child is being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the tasks and activities that children and adolescents normally do. By learning more about this we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite your child to participate.

Procedures
To obtain this information we are talking to children between 10 and 14 years old, who live here and know about the situation of children and adolescents in your community. This is why we selected your child to participate. If you agree your child to be in this study I will ask your child some questions about the tasks and activities that children and adolescent normally do in this community.

Risks and Discomfort
Each interview will take about 60 minutes. It is possible that your child may not like some questions or that some questions may upset him/her. Your child may refuse to answer these questions, or any questions, if he/she wishes. He/she may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the mental health of the children and adolescents in this area. However, there may be no direct benefit to your child personally. If the location of interviewing is not at school or the community center, transportation to and from the interview will be provided by War Child Holland.

Confidentiality
When the interview start, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.
Nothing that your child tells us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that your child

or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness
If you, or your child decides at any time during the study, to no longer wish to participate, you or your child can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact
The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX].. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

_____

If you are interested in having your child participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent for your child to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree my child to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Parent or Caregiver:

_____ _____ _____
Signature of Parent or Caregiver Date Time

_____
Name

_____
Name (-s) of eligible child or children

_____ _____ _____
Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:

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

Print Name of Witness_____

Signature of Witness _____

Thumb print of Parent or Caregiver

_____

Parent or Guardian Name

_____

Name of eligible child

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or read out the information sheet to the caregiver of the potential participant, and to the best of my ability made sure that the caregiver understands the purpose and process of the study. I confirm that the caregiver was given an opportunity to ask questions about the study, and all the questions asked by the caregiver 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

Child Assent To Participate

The interview will take no longer than 1 hour. You are free to say that you do not want to participate. And, once we start, if you don't want to continue, you can tell me and we will stop. If there is any question you don't want to answer, you don't need to- we can skip that question.

When the interview starts, everything will be recorded by the interviewer with an audio device, but we will make sure that this device is stored in a locked space, so that only the research team can reach it.

The things we talk about will stay confidential- that means, we will write a report on the answers of ALL respondents in this community, but we won't use your name in this report, or tell anyone you took part. The only time we would tell anyone about something you tell us, would be if we had a concern for your safety, and in that case we would need to share that information with someone, in order to keep you safe.

Do you agree to take part?

I, _____, agree to participate in the Research Study Conducted by War Child Holland in my community, in order to improve programs that assist children and adolescents in communities like my community. I understand that participation means that I will take part of an Focus group discussion of 30-60 minutes, and that I will be asked to answer questions around the situation in my community.

_____

Child may sign name here

or

give verbal assent now, witnessed by his/her parent or caregiver or a trusted/known person to the child

_____

_____

Witness Signature Relationship to Child

Deelnemersinformatie voor deelname aan onderzoek

Key-informant interviews Syrische vluchtelingen

'Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes'

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt. Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksproject STRENGTHS. STRENGTHS is een samenwerking tussen verschillende internationale organisaties en universiteiten. De VU Amsterdam voert het onderzoek in Nederland uit naar de problemen van Syrische vluchtelingen in Nederland.

De London School of Hygiene and Tropical Medicine en het Deense Rode Kruis zijn onze partners in STRENGTHS en coördineren dit onderzoek. Om deze reden zullen wij de informatie uit dit interview delen met deze twee partners. Wij zullen geen persoonsgegevens zoals namen en telefoonnummers overhandigen aan de London School of Hygiene and Tropical Medicine of aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie. In deze publicatie zullen geen naar personen herleidbare gegevens worden beschreven.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, wordt u gevraagd naar problemen die Syrische vluchtelingen in Nederland ervaren. We zullen u geen vragen over uzelf of over een specifiek ander persoon vragen. De vragen gaan over

Syrische vluchtelingen in Nederland in het algemeen. Dit interview zal maximaal één uur duren.

3. Mogelijke voor- en nadelen

Met uw deelname kunnen wij meer leren over de problemen en situatie van Syrische vluchtelingen in Nederland. We zullen deze informatie gebruiken om programma's voor de Syrische vluchtelingengemeenschap in Nederland te verbeteren. U ontvangt een tegoedbon van Euro 10,00 voor uw deelname aan het interview.

Naar ons weten zijn er geen risico's bij deelname aan deze studie. Het kan echter zijn dat u sommige vragen onprettig vindt. U doet vrijwillig mee en bent niet verplicht de vragen te beantwoorden. U mag tijdens het onderzoek stoppen.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam, sekse, leeftijd, opleidingsniveau en functie/beroep. Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet 'gecodeerd'. Uw naam wordt dan niet meer gebruikt. Het interview wordt opgenomen op audio. Op de audio opname zullen geen namen worden genoemd. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw persoonsgegevens (naam, sekse, leeftijd, opleidingsniveau en functie/beroep).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens

Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan

om onderzoek naar Syrische vluchtelingen in Nederland. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu (website nog in ontwikkeling). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens

mw. Anne de Graaff (onderzoeker)
T: +31(0)205983833
E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)
E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer

Key-informant interviews Syrische vluchtelingen

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek.

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

□ Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Indien analfabeet

Vingerafdruk:

Naam getuige:

Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Deelnemersinformatie voor deelname aan onderzoek

Focus groep interviews Syrische vluchtelingen

'Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes'

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt. Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksconsortium STRENGTHS. In STRENGTHS doen we onder andere onderzoek naar de effectiviteit van een psychologische behandeling, Problem Management Plus (PM+), bij Syrische vluchtelingen. Op basis van eerder onderzoek naar PM+ verwachten wij dat deze behandeling effectief zal zijn in het verminderen van psychische klachten bij Syrische vluchtelingen. De VU Amsterdam doet onderzoek naar PM+ bij Syrische vluchtelingen in Nederland.

Het doel van de huidige studie is om het onderzoekconsortium STRENGTHS te informeren over eventuele (culturele) aanpassingen aan de PM+ behandelmethode om het zo beter te laten aansluiten bij het Arabische taalgebruik en de Syrische cultuur. Hiervoor benaderen wij Syrische vluchtelingen in Nederland.

De London School of Hygiene and Tropical Medicine en het Deense Rode Kruis zijn onze partners in STRENGTHS en coördineren dit onderzoek. Om deze reden zullen wij de informatie uit dit interview delen met deze twee partners. Wij zullen geen persoonsgegevens zoals namen en telefoonnummers overhandigen aan de London School of Hygiene and Tropical Medicine of aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie. In deze publicatie zullen geen naar personen herleidbare gegevens worden beschreven.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, wordt u gevraagd naar dagelijkse activiteiten van mannen en vrouwen in de Syrische vluchtelingengemeenschap in Nederland. Tevens wordt u gevraagd naar uw mening over de implementatie van PM+. Het interview is een groepsgesprek met zes tot acht personen. Dit groepsgesprek zal ongeveer één uur tot maximaal anderhalf uur duren.

3. Mogelijke voor- en nadelen

Met uw deelname draagt u bij aan het verbeteren van een psychologische behandeling voor Syrische vluchtelingen in Nederland. U heeft zelf geen voordeel van meedoen aan dit onderzoek.

Naar ons weten zijn er geen risico's bij deelname aan deze studie. Gezien de aard van focus groep discussies, kunnen wij echter niet garanderen dat vertrouwelijkheid gewaarborgd wordt. Wij vragen alle deelnemers van de focus groep de privacy van andere deelnemers te respecteren en wat er gezegd wordt niet met derden te bespreken. Wij laten iedere deelnemer een geheimhoudingsverklaring tekenen.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam, sekse, leeftijd, opleidingsniveau en culturele achtergrond. Elke deelnemer krijgt een code die wordt gebruikt om aan te duiden wie wat heeft gezegd in het groepsgesprek ('coderen'). Uw naam wordt dan niet meer gebruikt. Het groepsgesprek wordt opgenomen op audio. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw

persoonsgegevens (naam, sekse, leeftijd, opleidingsniveau en culturele achtergrond).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens
Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan om onderzoek naar de behandeling van PM+. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu (website nog in ontwikkeling). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u een onkostenvergoeding van Euro 15,00 en reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens

mw. Anne de Graaff (onderzoeker)
T: +31(0)205983833
E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)
E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer

Focus groep interviews Syrische vluchtelingen

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek.

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

□ Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist.

□ Ik zal de antwoorden van andere deelnemers vertrouwelijk behandelen.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Indien analfabeet

Vingerafdruk:

Naam getuige:

Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Interviews Phase 1 (Health Care Providers) - The Netherlands

Deelnemersinformatie voor deelname aan onderzoek
Key informant interviews behandelaren (G)GZ

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt. Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksconsortium STRENGTHS. In STRENGTHS doen we onder andere onderzoek naar de effectiviteit van een psychologische behandeling, Problem Management Plus (PM+), bij getrainde Syrische vluchtelingen. Op basis van eerder onderzoek naar PM+ verwachten wij dat deze behandeling effectief zal zijn in het verminderen van psychische klachten bij Syrische vluchtelingen. De VU Amsterdam is verantwoordelijk voor het onderzoek naar PM+ bij Syrische vluchtelingen in Nederland.

De huidige studie heeft twee doelen:

- Doel 1: Het in kaart brengen van de geestelijke gezondheidszorg voor Syrische vluchtelingen in Nederland.
- Doel 2: Het onderzoeksconsortium STRENGTHS informeren over eventuele aanpassingen aan het PM+ behandelprotocol.

Hiervoor benaderen wij behandelaren werkzaam binnen de GGZ om hun ervaringen en kennis over hun werk met ons te delen.

De London School of Hygiene and Tropical Medicine en het Deense Rode Kruis zijn onze partners in STRENGTHS en coördineren dit onderzoek. Om deze reden zullen wij de informatie uit dit interview delen met deze twee partners. Wij zullen geen persoonsgegevens zoals namen en telefoonnummers overhandigen aan de London School of Hygiene and Tropical Medicine of aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld

verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, wordt u gevraagd naar uw ervaringen in de (vluchtelingen)zorg en over uw ideeën over de moeilijkheden en mogelijkheden bij het implementeren van een behandeling zoals PM+. Het interview is een individueel gesprek en zal ongeveer één uur duren.

3. Mogelijke voor- en nadelen

Met uw deelname draagt u bij aan het verbeteren van een psychologische behandeling voor Syrische vluchtelingen in Nederland. U heeft zelf geen voordeel van meedoen aan dit onderzoek. Naar ons weten zijn er geen risico's bij deelname aan deze studie.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam en functie/beroep. Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet 'gecodeerd'. Uw naam wordt dan niet meer gebruikt. Het interview wordt opgenomen op audio. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw persoonsgegevens (naam en functie/beroep).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens

Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan

om onderzoek naar de behandeling van PM+. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu (website nog in ontwikkeling). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens

mw. Anne de Graaff (onderzoeker)
T: +31(0)205983833
E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)
E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer
Key-informant interviews behandelaren

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek
- Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Naam interviewer:

Handtekening: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Interviews Phase 1 (Policy Makers) - The Nethlerands

Deelnemersinformatie voor deelname aan onderzoek

Key-informant interviews beleidsmakers

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt. Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksconsortium STRENGTHS. In STRENGTHS doen we onder andere onderzoek naar de effectiviteit van een psychologische behandeling, Problem Management Plus (PM+), bij getrainde Syrische vluchtelingen. Op basis van eerder onderzoek naar PM+ verwachten wij dat deze behandeling effectief zal zijn in het verminderen van psychische klachten bij Syrische vluchtelingen. De VU Amsterdam is verantwoordelijk voor het onderzoek naar PM+ bij Syrische vluchtelingen in Nederland.

De huidige studie heeft twee doelen:

- Doel 1: Het in kaart brengen van de geestelijke gezondheidszorg voor Syrische vluchtelingen in Nederland.
- Doel 2: Het onderzoeksconsortium STRENGTHS informeren over eventuele aanpassingen aan de implementatie van PM+.

Hiervoor benaderen wij beleidsmakers om hun ervaringen en kennis over hun werk met ons te delen.

De London School of Hygiene and Tropical Medicine en het Deense Rode Kruis zijn onze partners in STRENGTHS en coördineren dit onderzoek. Om deze reden zullen wij de informatie uit dit interview delen met deze twee partners. Wij zullen geen persoonsgegevens zoals namen en telefoonnummers overhandigen aan de London School of Hygiene and Tropical Medicine of aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, wordt u gevraagd naar uw ervaringen in de (vluchtelingen)zorg en over uw ideeën over de moeilijkheden en mogelijkheden bij het implementeren van een behandeling zoals PM+. Het interview is een individueel gesprek en zal ongeveer één uur duren.

3. Mogelijke voor- en nadelen

Met uw deelname draagt u bij aan het verbeteren van een psychologische behandeling voor Syrische vluchtelingen in Nederland. U heeft zelf geen voordeel van meedoen aan dit onderzoek. Naar ons weten zijn er geen risico's bij deelname aan deze studie.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam en functie/beroep. Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet 'gecodeerd'. Uw naam wordt dan niet meer gebruikt. Het interview wordt opgenomen op audio. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw persoonsgegevens (naam en functie/beroep).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens

Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan om onderzoek naar de behandeling van PM+. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord

gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu (website nog in ontwikkeling). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens

mw. Anne de Graaff (onderzoeker)
T: +31(0)205983833
E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)
E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer
Key-informant interviews beleidsmakers

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek
- Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Naam interviewer:

Handtekening: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Istanbul Sehir Universitesi (ISU)

Interviews Phase 1 (Syrian Refugees – Key Informants and Focus Group) – Turkey

Consent Form

Gender _____ Age _____ Education level _____ Cultural background _____
Interviewer _____ Date __-__-__ Interview ID: FL___

Introducing the project:
PM+ is a low-intensity, psychological intervention for communities in adversity. We are planning to implement PM+ as a peer-refugee delivered intervention for Syrian refugees in Turkey. Arabic speaking psychologists in Turkey will train Syrian refugees, so they can provide the 5-session treatment to Syrian refugees in distress.

Information on the Key Informant interviews:
We conducted interviews with a few Syrian refugees residing in Turkey about the problems that they come across in this country. We asked them to share the names of the people who might have knowledge on these problems and your name was one of the names that they shared with us. The purpose of this interview is to gather in depth information about the problems selected from the data of these interviews.
This interview will take about one hour and we will ask you a couple of questions. You have the right to refuse to participate or answer any questions, or withdraw at any time, without any adverse consequences.
We assure that the answers you will give to our questions and your names will be kept confidential so that the information provided cannot be linked back to you and only people involved in the study will see the interview text.

Name:
Signature:

Universität Zürich (UZH)

Information and consent for Phase 1 given orally.

Freie Universitaet Berlin (FUB)

Interviews Phase 1 (Syrian Refugees – Key Informant Interviews) – Germany/Sweden/Egypt

Participant Information
- Key Informant Interviews with Syrian refugees -

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by the Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

1. Purpose of the study

This research is part of the STRENGTHS research project. STRENGTHS is a collaboration between several international organizations and universities. Freie Universität Berlin conducts research on problems of Syrian refugees and the usage of digital technologies among Syrian refugees in [Germany/Sweden/Egypt]. You were chosen to be interviewed because other people in the Syrian refugee community told us that you would be a good person to ask about one or both of these topics. The information you give us will be used to develop and improve a program that helps Syrian refugees with problems and difficult life circumstances.

2. Content of the interview

We would like to ask you about problems that Syrian refugees in your community in [Germany/Sweden/Egypt] experience. After presenting you a concept version of the PM+ app, we would like to ask for your opinion on the app.
There will be an individual interview conducted by two interviewers. We will not ask questions about yourself or about any specific other person. The questions will be about Syrian refugees in your community in [Germany/Sweden/Egypt in general.
The interview will take approximately one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

3. Possible advantages and disadvantages

With your participation, we will learn more about problems in the Syrian refugee community in [Germany/Sweden/Egypt]. We will use this information to improve the PM+ app for the Syrian refugees in [Germany/Sweden/Egypt. Furthermore, you will receive 10€ for your participation.
To our knowledge, there are no risks associated with participation. However, it is possible that a question makes you feel uncomfortable. Therefore, you are not obliged to answer any questions and

you may stop the interview at any time.

4. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

5. Usage and storage of your data

The study protocol requires that we collect the following personal information: name, sex, age, education and profession.
Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data. The interview will not be recorded on audio.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGTHS project and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study. If you sign the consent form, you agree to the collection, storage and processing of your personal data (name, sex, age, education and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant.

6. Compensation for participation

You will receive 10€ for participation in the study.

7. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Informed Consent Form
- Key Informant Interviews with Syrian refugees -

ID: _____

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

please read the following statements regarding your participation in the study.

1) I have read the information letter. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate.
2) I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions.
3) I agree that my data will be collected and used in the ways described in the information letter. I give permission to store these data for 10 years.
4) I want to participate in this study.

Please mark the following statements with a cross, if you agree.

□ I give permission to approach me after this survey again for a follow-up study.

□ I want to be informed about the results of this study.

Name of participant:

Signature: Date:
____/____/____

Name of witness:

Signature of witness: Date:
____/____/____

Interviews Phase 1 (Syrian Refugees- Focus Group)- Germany/Sweden/Egypt

Participant Information
- Focus Group Discussions with Syrian refugees -

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by the Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

3. Purpose of the study

This research is part of the STRENGHTS research project. In this project we conduct research on the effectiveness of a psychological treatment for Syrian refugees, called Problem Management Plus (PM+). Based on previous research on PM+, we expect that this treatment will be effective in reducing psychological symptoms in Syrian refugees. At Freie Universität Berlin we will develop a digital version of PM+ that will be accessible in the form of a smartphone app for Syrian refugees in [Germany/Sweden/Egypt].

The aim of this study is to gather information that will be used to create the PM+ app in a way that is most suitable for the needs of Syrian refugees in [Germany/Sweden/Egypt]. For this reason, we have approached you as a member of the Syrian refugee community in [Germany/Sweden/Egypt].

4. Content of the Focus Group

We would like to ask you about daily activities of men and women in the Syrian refugee community in [Germany/Sweden/Egypt]. After presenting you a concept version of the PM+ app, we would like to ask for your opinion on the app. You will also be asked for your ideas on how to provide the app to the Syrian refugee community here in [Germany/Sweden/Egypt].
The interview will be conducted in a group of 6 to 8 people and with two interviewers. You will not be asked questions about yourself or about any specific other person. The questions will be about Syrian refugees in your community in [Germany/Sweden/Egypt in general. The group discussion will take approximately one hour to one and a half hours.
If you are not available in person, the interview can also be conducted as a conference call via an online audio/video messaging service.

5. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of psychological care for Syrian refugees in [Germany/Sweden/Egypt]. We will use this information to improve the PM+ app for Syrian refugees in [Germany/Sweden/Egypt. Furthermore, you will receive 10€ for your participation.
To our knowledge, there are no risks associated with participation. Given the nature of focus group

discussions, we cannot guarantee confidentiality. However, all participants will be asked to respect the privacy other participants and not to discuss the contents of the group discussion with others. Each participant will also sign a confidentiality agreement.

6. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

7. Usage and storage of your data

The study protocol requires that we collect the following personal information: name, sex, age, education and profession.
Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data. The interview will not be recorded on audio.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and Danish Red Cross are our partners in the STRENGHTS project and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study. If you sign the consent form, you agree to the collection, storage and processing of your personal data (name, sex, age, education and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGHTS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant.

8. Compensation for participation

You will receive 10€ for participation in the study.

9. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Informed Consent Form
- Focus Group Discussions with Syrian refugees -

ID: _____

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

please read the following statements regarding your participation in the study.

10. I have read the information letter. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate.
11. I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions.
12. I agree that my data will be collected and used in the ways described in the information letter. I give permission to store these data for 10 years.
13. I want to participate in this study.

Please mark the following statements with a cross, if you agree.

□ I give permission to approach me after this survey again for a follow-up study.
□ I want to be informed about the results of this study.
□ I will treat the contents of the discussion as confidential.

Name of participant:

Signature: Date:
____/____/____

Name of witness:

Signature of witness: Date:
____/____/____

Interviews Phase 1 (Health Care Providers- Key Informany Interviews)- Germany/Sweden/Egypt

Participant Information
- Key Informant Interviews with mental health care providers -

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

14. Purpose of the study

This research is part of the STRENGTHS research consortium. In the STRENGTHS program we will investigate the effectiveness of a psychological intervention for common mental health and psychosocial problems in Syrian Refugees. The intervention is called Problem Management Plus (PM+) and it was developed by the World Health Organization (WHO). Based on previous research on PM+, we expect that this treatment will be effective in reducing psychological symptoms in Syrian refugees. The Freie Universität Berlin is responsible for the development and evaluation of a digital version of PM+ for Syrian refugees in [Germany/Sweden/Egypt]. To this end, we will provide PM+ in the form of a smartphone app to Syrian refugees in [Germany/Sweden/Egypt].

The present study has three objectives:

a) Mapping of mental health care for Syrian refugees in [Germany/Sweden/Egypt].
b) Gathering information that will inform adjustments to the PM+ treatment protocol.
c) Gathering information that will inform the conceptualization and development of the PM+ app.

For this reason, we approach mental care providers to share their experiences and their knowledge from their professional work with us.

15. Content of the interview

We would like to ask you about your experiences with (refugee) care and about your ideas on problems and opportunities for the implementation of the smartphone version of PM+ for Syrian refugees in [Germany/Sweden/Egypt]. There will be an individual interview conducted by two interviewers. The interview will take approximately one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

16. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of psychological care for Syrian refugees in [Germany/Sweden/Egypt]. Apart from that, you will have no personal benefit from

participating in this study. To our knowledge, there are not risks associated with participation.

17. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

18. Usage and storage of your data

The study protocol requires that we collect the following personal information: name and profession. Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data. The interview will not be recorded on audio.

All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.

The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGTHS consortium and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.

The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study.

If you sign the consent form, you agree to the collection, storage and processing of your personal data (name and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.

This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant. However, the website will contain a summary of the results.

19. Compensation for participation

You will receive compensation for travel expenses.

20. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Informed Consent Form
- Key Informant Interviews with mental health care providers -

ID: _____

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

please read the following statements regarding your participation in the study.

21. I have read the information letter. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate.
22. I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions.
23. I agree that my data will be collected and used in the ways described in the information letter. I give permission to store these data for 10 years.
24. I want to participate in this study.

Please mark the following statements with a cross, if you agree.

□ I give permission to approach me after this survey again for a follow-up study.

□ I want to be informed about the results of this study.

Name of participant:

Signature: Date:
____/____/____

Interviews Phase 1 (Policy Makers- Key Informant Interviews)- Germany/Sweden/Egypt

Participant Information
- Key Informant Interviews with policy makers -

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

25. Purpose of the study

This research is part of the STRENGTHS research consortium. In the STRENGTHS program we will investigate the effectiveness of a psychological intervention for common mental health and psychosocial problems in Syrian Refugees. The intervention is called Problem Management Plus (PM+) and it was developed by the World Health Organization (WHO). Based on previous research on PM+, we expect that this treatment will be effective in reducing psychological symptoms in Syrian refugees. The Freie Universität Berlin is responsible for the development and evaluation of a digital version of PM+ for Syrian refugees in [Germany/Sweden/Egypt]. To this end, we will provide PM+ in the form of a smartphone app to Syrian refugees in [Germany/Sweden/Egypt].

The present study has three objectives:

d) Mapping of mental health care for Syrian refugees in [Germany/Sweden/Egypt].
e) Gathering information that will inform adjustments to the PM+ treatment protocol.
f) Gathering information that will inform the conceptualization and development of the PM+ app.

For this reason, we approach policy makers to share their experiences and their knowledge from their professional work with us.

26. Content of the interview

We would like to ask you about your experiences with (refugee) care and about your ideas on problems and opportunities for the implementation of the smartphone version of PM+ for Syrian refugees in [Germany/Sweden/Egypt]. There will be an individual interview conducted by two interviewers. The interview will take approximately one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

27. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of psychological care for Syrian refugees in [Germany/Sweden/Egypt]. Apart from that, you will have no personal benefit from

participating in this study. To our knowledge, there are not risks associated with participation.

28. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

29. Usage and storage of your data

The study protocol requires that we collect the following personal information: name and profession. Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data. The interview will not be recorded on audio.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGTHS consortium and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study.
If you sign the consent form, you agree to the collection, storage and processing of your personal data (name and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant. However, the website will contain a summary of the results.

30. Compensation for participation

You will not receive compensation.

31. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Informed Consent Form
- Key Informant Interviews with policy makers -

ID: _____

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

please read the following statements regarding your participation in the study.

32. I have read the information letter. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate.
33. I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions.
34. I agree that my data will be collected and used in the ways described in the information letter. I give permission to store these data for 10 years.
35. I want to participate in this study.

Please mark the following statements with a cross, if you agree.
□ I give permission to approach me after this survey again for a follow-up study.
□ I want to be informed about the results of this study.

Name of participant:

Signature: Date:
____/____/____

WP2: Health Systems Evaluation; study 2 (surveys)

Ek I: Bilgilendirme ve Onam Formları

Study title: "Access to mental health and psychosocial support services for Syrian refugees in Turkey"
Site principle investigator: Dr. Zeynep Ceren Acartürk, Istanbul Sehir University
Project Partner: Refugees and Asylum Seekers Assistance and Solidarity Association (RASASA)
Sponsor: EU, H2020

This sheet provides information on a study which you have been asked to participate in.

Who is doing this research and who has approved it?
We are from the Mülteciler ve Sığınmacılar Yardımlaşma ve Dayanışma Derneği, İstanbul Şehir University and London School of Hygiene and tropical Medicine. *[to add: 'This study has been approved by the Ethics Committees of Istanbul Sehir University and the London School of Hygiene and Tropical Medicine]*.

What is the purpose of this study?
We are undertaking a survey of Syrian refugees living here in Istanbul which seeks to increase understanding on their mental health and their access to health services here in Istanbul.

How was I selected?
You were randomly selected to participate in this survey using the registration list of Syrian refugees in Istanbul.

What does the study involve?
We would like to ask you some questions on aspects of your health such as your overall mental health and access to health care services. The interview will be held in a private space here in the community centre of RASASA. It will take approximately 45 minutes.

Right to refuse or withdraw:
Your participation is completely voluntary so you should feel completely free to refuse to participate, to stop the interview at any time, or to not answer questions you do not feel comfortable with. If you do withdraw there will be no effect, positive or negative, on you or your household.

What are the risks and benefits?
The study does not give any benefits for you or other people in the household. The information will be used to try and help improve mental health services in the future.

The study asks questions no your feelings and mental health. If you feel upset or distressed with these questions you can stop at any time and you do not have to continue. This sheet also contains information on sources of help and support if needed [Mülteciler ve Sığınmacılar Yardımlaşma ve Dayanışma Derneği , + 90 216 564 45 45; İstanbul Şehir University +90 444 40 34 (9353)].

Will it be confidential?
The interview will be held in a private space, and all the answers you provide are confidential and anonymous. We will not write down any names on the questionnaires so answers cannot be connected to individual persons. We will keep all the forms securely stored and they will not be shared with anyone outside of the research team. You may be contacted again by the research team but this will only be as part of our process to monitor the quality of the survey.

Further information:
If you have any questions on this study in the future you can contact us on the details at the top of this sheet. Thank you for your kind help.

Survey Participant Consent Form

Study title: "Access to mental health and psychosocial support services for Syrian refugees in Turkey"

Literate Participant:

I have read the information sheet concerning this study [or have understood the verbal explanation of it] and I have a copy of it for me to keep, and I understand what will be required of me to take part in the study.

I understand that at any time I may withdraw from this study without giving a reason, and that if I do withdraw there will be no effect, positive or negative, on me or my household.

My questions concerning this study have been answered by ……..
[name of investigator performing interview]

I agree to take part in this study

Name/ Surname:…….

Signature: …….. Date: …...../…...../….....
[dd/mm/yyyy]

Signature of investigator: …… Date: …...../…...../….....
[dd/mm/yyyy]

Illiterate Participant:
I have witnessed the accurate reading of the information sheet concerning this study to the participant, and the participant has had the opportunity to ask questions and these have been answered to the participants satisfaction. I confirm that the individual has given consent freely.
I confirm that the participant understands what will be required of him/her to take part in the study, that at any time he/she may withdraw from this study without giving a reason, and that if he/she does withdraw there will be no effect, positive or negative, on me or my household.

Thumb print of participant 

Print Name of Witness_____
Signature of Witness _____
Date _____
Day/month/year

Statement by the investigator 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

Leipzig University- Survey in Leipzig, Germany

Survey Respondent Information Sheet

Study title: "A survey on access to mental health and psychosocial support services for Syrian refugees in Germany"

This sheet provides information on a study which you have been asked to participate in.

Who is doing this research and who has approved it?
We are from Leipzig University and the London School of Hygiene and Tropical Medicine. *This study has been approved by the Ethics Committees of the London School of Hygiene and Tropical Medicine and [to be added: Leipzig* University *and local authorities].*

What is the purpose of this study?
We are undertaking a survey of Syrian refugees and asylum seekers living here in Leipzig which seeks to increase understanding on their mental health and their access to health services in Leipzig.

How was I selected?
You were randomly selected to participate in this survey using the registration list of Syrian refugees and asylum seekers in Leipzig.

What does the study involve?
We would like to ask you some questions on aspects of your health such as your overall mental health and access to health care services. The interview will be held in a private space chosen by you. It will take approximately 45 minutes.

Right to refuse or withdraw:
Your participation is completely voluntary so you should feel completely free to refuse to participate, to stop the interview at any time, or to not answer questions you do not feel comfortable with. If you do withdraw there will be no effect, positive or negative, on you or your household.

What are the risks and benefits?
The study does not give any benefits for you or other people in the household. The information will be used to try and help improve mental health services in the future.

The study asks questions no your feelings and mental health. If you feel upset or distressed with these questions you can stop at any time and you do not have to continue. This sheet also contains information on sources of help and support if needed [to be added].

Will it be confidential?
The interview will be held in a private space, and all the answers you provide are confidential and anonymous. We will not write down any names on the questionnaires so answers cannot be connected to individual persons. We will keep all the forms securely stored and they will not be shared with anyone outside of the research team. You may be contacted again by the research team but this will only be as part of our process to monitor the quality of the survey.

Further information:

If you have any questions on this study in the future you can contact us on the details at the top of this sheet. Should you require any help or advice on your emotional and mental well-being, this can be obtained from [add local advice contact details]
Thank you for your kind help.

Leipzig University- Survey in Leipzig, Germany

Survey Respondent Consent Form

Study title: "A survey on access to mental health and psychosocial support services for Syrian refugees in Germany"

I have read the information sheet concerning this study [or have understood the verbal explanation of it] and I have a copy of it for me to keep, and I understand what will be required of me to take part in the study.

I understand that at any time I may withdraw from this study without giving a reason, and that if I do withdraw there will be no effect, positive or negative, on me or my household.

My questions concerning this study have been answered by ……..
[name of investigator performing interview]

I agree to take part in this study

Name/ Surname:……..

Signature: …….. Date: ……../……../……..
[dd/mm/yyyy]

Signature of investigator: …… Date: ……../……../……..
[dd/mm/yyyy]

WP3: Adaptation

Danish Red Cross (DRC)

Cognitive Interviews – Turkey

Consent Form

Date __-__-__
Gender _____ Age _____ Education level _____ Cultural background _____

Introducing the project:
PM+ is a low-intensity, psychological intervention for communities in adversity. We are planning to implement PM+ as a peer-refugee delivered intervention for Syrian refugees in Turkey. Arabic speaking psychologists in Turkey will train Syrian refugees, so they can provide the 5-session treatment to Syrian refugees in distress.

Information on the Free List (FL) interviews:
The purpose of this interview is to ask the individuals from the target community about some of the points in the manual, which will be used during the psychological support intervention sessions and to take their opinions on the intervention.
This interview will take about 4-5 hours and we will ask you a couple of questions. You have the right to refuse to participate or answer any questions, or withdraw at any time, without any adverse consequences.
We assure that the answers you will give to our questions and your names will be kept confidential so that the information provided cannot be linked back to you and only people involved in the study will see the interview text.

Name:
Signature:

Deelnemersinformatie voor deelname aan onderzoek

Key informant interviews behandelaren (G)GZ

'Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes'

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam en het Deense Rode Kruis. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt.
Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksconsortium STRENGTHS. In STRENGTHS doen we onder andere onderzoek naar de effectiviteit van een psychologische behandeling, Problem Management Plus (PM+), bij getrainde Syrische vluchtelingen. Op basis van eerder onderzoek naar PM+ verwachten wij dat deze behandeling effectief zal zijn in het verminderen van psychische klachten bij Syrische vluchtelingen. De VU Amsterdam is verantwoordelijk voor het onderzoek naar PM+ bij Syrische vluchtelingen in Nederland.

De huidige studie heeft twee doelen:

- Doel 1: Het in kaart brengen van de geestelijke gezondheidszorg voor Syrische vluchtelingen in Nederland.
- Doel 2: Het onderzoeksconsortium STRENGTHS informeren over eventuele aanpassingen aan het PM+ behandelprotocol.

Hiervoor benaderen wij behandelaren werkzaam binnen de GGZ om hun ervaringen en kennis over hun werk met ons te delen.

Het Deense Rode Kruis is onze partner in STRENGTHS en coördineert dit onderzoek. Om deze reden zullen wij de informatie uit dit interview met het Deense Rode Kruis delen. Wij zullen geen persoonsgegevens zoals namen en

telefoonnummers overhandigen aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, zullen we met u het PM+ behandelprotocol doorspreken en u vragen naar eventuele aanpassingen en suggesties. Het interview is een individueel gesprek en zal ongeveer […] uur duren.

3. Mogelijke voor- en nadelen

Met uw deelname draagt u bij aan het verbeteren van een psychologische behandeling voor Syrische vluchtelingen in Nederland. U krijgt een vergoeding voor deelname ([€…] voucher). Naar ons weten zijn er geen risico's bij deelname aan deze studie.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam en functie/beroep. Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet 'gecodeerd'. Uw naam wordt dan niet meer gebruikt.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw persoonsgegevens (naam en functie/beroep).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens

Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan om onderzoek naar de behandeling van PM+. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord

gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu. Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens

mw. Anne de Graaff (onderzoeker)
T: +31(0)205983833
E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)
E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer
Key-informant interviews behandelaren

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Naam interviewer:

Handtekening: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Deelnemersinformatie voor deelname aan onderzoek
Focus groep interviews Syrische vluchtelingen

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt.
Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksconsortium STRENGTHS. In STRENGTHS doen we onder andere onderzoek naar de effectiviteit van een psychologische behandeling, Problem Management Plus (PM+), bij Syrische vluchtelingen. Op basis van eerder onderzoek naar PM+ verwachten wij dat deze behandeling effectief zal zijn in het verminderen van psychische klachten bij Syrische vluchtelingen. De VU Amsterdam doet onderzoek naar PM+ bij Syrische vluchtelingen in Nederland.

Het doel van de huidige studie is om het onderzoekconsortium STRENGTHS te informeren over eventuele (culturele) aanpassingen aan de PM+ behandelmethode om het zo beter te laten aansluiten bij het Arabische taalgebruik en de Syrische cultuur. Hiervoor benaderen wij Syrische vluchtelingen in Nederland.

Het Deense Rode Kruis is onze partner in STRENGTHS en coördineert dit onderzoek. Om deze reden zullen wij de informatie uit dit interview delen met deze twee partners. Wij zullen geen persoonsgegevens zoals namen en telefoonnummers overhandigen aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie. In deze publicatie zullen geen naar personen herleidbare gegevens worden beschreven.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, wordt u gevraagd naar dagelijkse activiteiten van mannen en vrouwen in de Syrische vluchtelingengemeenschap in Nederland. Tevens wordt u gevraagd naar uw mening over de implementatie van PM+. Het interview is een groepsgesprek met zes tot acht personen. Dit groepsgesprek zal ongeveer [X] uur duren.

3. Mogelijke voor- en nadelen

Met uw deelname draagt u bij aan het verbeteren van een psychologische behandeling voor Syrische vluchtelingen in Nederland. U heeft zelf geen voordeel van meedoen aan dit onderzoek.

Naar ons weten zijn er geen risico's bij deelname aan deze studie. Gezien de aard van focus groep discussies, kunnen wij echter niet garanderen dat vertrouwelijkheid gewaarborgd wordt. Wij vragen alle deelnemers van de focus groep de privacy van andere deelnemers te respecteren en wat er gezegd wordt niet met derden te bespreken. Wij laten iedere deelnemer een geheimhoudingsverklaring tekenen.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam, sekse, leeftijd, opleidingsniveau en culturele achtergrond. Elke deelnemer krijgt een code die wordt gebruikt om aan te duiden wie wat heeft gezegd in het groepsgesprek ('coderen'). Uw naam wordt dan niet meer gebruikt.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw persoonsgegevens (naam, sekse, leeftijd, opleidingsniveau en culturele achtergrond).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens

Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan om onderzoek naar de behandeling van PM+. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu (website nog in ontwikkeling). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u een onkostenvergoeding van Euro […] en reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens

mw. Anne de Graaff (onderzoeker)
T: +31(0)205983833
E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)
E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer

Focus groep interviews Syrische vluchtelingen

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek.

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

□ Ik zal de antwoorden van andere deelnemers vertrouwelijk behandelen.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Indien analfabeet

Vingerafdruk: ☐

Naam getuige:

Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

International Medical Corps (IMC)

Interviews Phase 1 (All Interviews) – Jordan

Consent form

Interview ID: ____ Date: ____ Interviewer: ____

Project Introduction

International Medical Corps (IMC) is an international humanitarian organization that has been working in Jordan for the past seven years. IMC provides a range of support to Syrian refugees and vulnerable Jordanians, including the provision of healthcare. A core part of IMC programming involves supporting Syrian refugees' wellbeing through psychosocial support and mental health services.

Problem Management Plus (PM+) is a 5 session group-based program for communities affected by difficult conditions, that was developed by the World Health Organization (WHO). The aim is to support persons in distress to cope with common challenges faced by the community. IMC is hoping to implement PM+ in Jordan to support members of the Syrian refugee community. First, IMC wants to learn more about the common challenges faced by the Syrian refugee community.

To learn about the common challenges facing the Syrian refugee community, IMC is conducting individual interviews and focus group discussions to try and hear from as many people as possible who are knowledgeable about the topic. We want to know about common problems faced by the Syrian refugee community as a whole,
and also how people in the community cope with such problems.

Free Listing and Key Informant Interviews

This interview will take approximately one hour. I will ask you some questions, and you have the right to choose not to participate at any time, or to refuse to answer any question. You can leave any time before completing the interview without any problems.

Focus Group Discussions

This focus group discussion may take approximately 2 hours. The aim is to have a discussion which captures a variety of perspectives on problems faced by the Syrian community as well as gathers information on coping and how best to address such issues. You have the right to withdraw from the focus group at any time with no negative consequences.

We cannot offer any compensation or benefits for your participation in this assessment. Your

decision whether or not you participate, will have no impact on the provision of any support or services you receive now, or may access in the future. We assure you that your answers will be confidential and will not be accessed by anyone except the researchers involved in the study. Please tick which part the respondent is participating in:

- ☐ Free Listing Interview
- ☐ Key Informant Interview
- ☐ Focus Group Discussion

Signature Date

_____

War Child Holland (WCH)

1. Consent form for Caregivers of Children that participate in the Free Listing Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to the caregiver of the participant prior to the Free Listing interview. If the caregivers and the child then agree to participate, you must gather all the relevant signatures (including child's assent) at the end of this form. Also mark the date on the appropriate lines.
Note: Please be aware that the consent form for caregivers that participate is separate from this consent form.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Free Listing Interview for young adolescents: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

Purpose of the Study
Your child is being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the problems affecting children and adolescents in this community and also about the tasks and activities that children and adolescents normally do. By learning about the problems and normal activities of children and adolescent we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite your child to participate.

Procedures
To obtain this information we are talking to children between 10 and 14 years old, who live here and know about the situation of children and adolescents in your community. This is why we selected your child to participate. If you agree your child to be in this study I will ask your child some questions about the problems affecting children and adolescents in this community, and the tasks and activities that children and adolescents normally do in this community.

Risks and Discomfort
Each interview will take about 60 minutes. It is possible that your child may not like some questions or that some questions may upset him/her. Your child may refuse to answer these questions, or any questions, if he/she wishes. He/she may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the mental health of the children and adolescents in this area. However, there may be no direct benefit to your child personally. If the location of interviewing is not at school, transportation to and from the interview will be provided by War Child Holland.

Confidentiality
During the interview I will write down the information your child tells me. This is the

information we will use for our study. The record of this information will not include anything that can be used to identify your child. I will also record your child's name and address, but this will be stored separately from the record, and will be stored in a locked cabinet in the research coordinator's office. The Research coordinator will have the key. Only the research team will be able to see this information.
Nothing that your child tells us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that your child or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness
If you, or your child decides at any time during the study, to no longer wish to participate, you or your child can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact
The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX]. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

_____

If you are interested in having your child participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent for your child to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree my child to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Parent or Caregiver:

_____ _____ _____
Signature of Parent or Caregiver Date Time

_____
Name

_____
Name (-s) of eligible child or children

_____ _____ _____
Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:

I have witnessed the accurate reading of the consent form to the caregiver of the participant, and the

caregiver has had the opportunity to ask questions and these have been answered to the caregiver's satisfaction. I confirm that the individual has given consent freely.
Print Name of Witness_____

Signature of Witness _____

Thumb print of Parent or Caregiver

_____

Parent or Guardian Name

_____

Name of eligible child

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately provided or read out the information sheet to the caregiver of the potential participant, and to the best of my ability made sure that the caregiver understands the purpose and process of the study. I confirm that the caregiver was given an opportunity to ask questions about the study, and all the questions asked by the caregiver 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

Child Assent To Participate
"*The interview will take no longer than 1 hour. You are free to say that you do not want to participate. And, once we start, if you don't want to continue, you can tell me and we will stop. If there is any question you don't want to answer, you don't need to- we can skip that question.*
The things we talk about will stay confidential- that means, we will write a report on the answers of ALL respondents in this community, but we won't use your name in this report, or tell anyone you took part. The only time we would tell anyone about something you tell us, would be if we had a concern for your safety, and in that case we would need to share that information with someone, in order to keep you safe.
Do you agree to take part?"

I, _____, agree to participate in the Research Study Conducted by War Child Holland in my community, in order to improve programs that assist children and adolescents in communities like my community. I understand that participation means that I will take part of a Free Listing Interview of 60 minutes, and that I will be asked to answer questions around the situation in my community.

_____

Child may sign name here

or

give verbal assent now, witnessed by his/her parent or caregiver or a trusted/known person to the child

_____

_____

Witness Signature Relationship to Child

2. Consent form for Caregivers that participate in the Free Listing Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to the participant prior to the Free Listing interview. If the caregiver agrees to participate, you must gather all the relevant signatures at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Free Listing Interview for caregivers of young adolescents: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

You are being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the problems affecting children and adolescents in this community and also about the tasks and activities that children and adolescents normally do. By learning about the problems and normal activities of children and adolescent we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite you to participate.

Procedures
To obtain this information we like to talk to you, to know more about the situation of children and adolescents in the community. This is why we selected you to participate. If you agree to be in this study we will ask you some questions about the problems affecting children and adolescents in this community, and the tasks and activities that children and adolescents normally do in this community.

Risks and Discomfort
Each interview will take about 60 minutes. It is possible that you may not like some questions or that some questions may upset you. You may refuse to answer these questions, or any questions, if you wish. You may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the health of the children and adolescents in this area. However, there may be no direct benefit to you personally. If the location of interviewing is not at home or school, transportation to and from the interview will be provided by War Child Holland.

Confidentiality
During the interview I will write down the information you tell me. This is the information we will use for our study. The record of this information will not include anything that can be used to identify you. I will also record your name and address, but this will be stored separately from the record, and will be stored in a locked cabinet in the research coordinator's office. The Research coordinator will have the key. Only the research team will be able to see this

information.
Nothing that you tell us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that you or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness
If you decide at any time during the study, to no longer wish to participate, you can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact
The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX].. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

If you are interested to participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Participant:

_____ _____ _____
Signature of participant Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:

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 participants satisfaction. I confirm that the individual has given consent freely.

Print Name of Witness_____

Signature of Witness _____

Thumb print of Participant

_____
Participant Name

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or 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

3. Consent form for Caregivers of Children that participate in the Key Informant Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to caregiver of the participant prior to the Key informant interview. If the caregivers and the child then agrees to participate, you must gather all the relevant signatures (including child's assent) at the end of this form. Also mark the date on the appropriate lines.
Note: Please be aware that the consent form for caregivers and other Key informants that participate is separate from this consent form.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Key Informant Interview for young adolescents: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

Purpose of the Study
Your child is being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and input on the way how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area. By learning more about this we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite your child to participate.

Procedures
To obtain this information we are talking to children between 10 and 14 years old, who live here and know about the situation of children and adolescents in your community. This is why we selected your child to participate. If you agree your child to be in this study I will ask your child some questions about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area.

Risks and Discomfort
Each interview will take about 60-90 minutes. It is possible that your child may not like some questions or that some questions may upset him/her. Your child may refuse to answer these questions, or any questions, if he/she wishes. He/she may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the mental health of the children and adolescents in this area. However, there may be no direct benefit to your child personally. If the location of interviewing is not at school, transportation to and from the interview will be provided by War Child Holland.

Confidentiality

When the interview starts, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.

Nothing that your child tells us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that your child or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness

If you, or your child decides at any time during the study, to no longer wish to participate, you or your child can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact

The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX]. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

_____

If you are interested in having your child participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent for your child to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree my child to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Parent or Caregiver:

_____ _____ _____

Signature of Parent or Caregiver Date Time

_____

Name

_____

Name (-s) of eligible child or children

_____ _____ _____

Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:

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

Print Name of Witness_____

Signature of Witness _____

Thumb print of Parent or Caregiver

_____

Parent or Guardian Name

_____

Name of eligible child

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or read out the information sheet to the caregiver of the potential participant, and to the best of my ability made sure that the caregiver understands the purpose and process of the study. I confirm that the caregiver was given an opportunity to ask questions about the study, and all the questions asked by the caregiver 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

Child Assent To Participate

"*The interview will take no longer than 1,5 hour. You are free to say that you do not want to participate. And, once we start, if you don't want to continue, you can tell me and we will stop. If there is any question you don't want to answer, you don't need to- we can skip that question.*
When the interview starts, everything will be recorded by the interviewer with an audio device, but we will make sure that this device is stored in a locked space, so that only the research team can reach it.
The things we talk about will stay confidential- that means, we will write a report on the answers of ALL respondents in this community, but we won't use your name in this report, or tell anyone you took part. The only time we would tell anyone about something you tell us, would be if we had a concern for your safety, and in that case we would need to share that information with someone, in order to keep you safe.
Do you agree to take part?"

I, _____, agree to participate in the Research Study Conducted by War Child Holland in my community, in order to improve programs that assist children and adolescents in communities like my community. I understand that participation means that I will take part of an Key Informant Interview of 60-90 minutes, and that I will be asked to answer questions around the situation in my community.

_____
Child may sign name here
or
give verbal assent now, witnessed by his/her parent or caregiver or a trusted/known person to the child

_____
_____
Witness Signature Relationship to Child

4. Consent form for Caregivers that participate in the Key Informant Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to the participant prior to the Key Informant Interview. If the caregiver agrees to participate, you must gather all the relevant signatures at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Key Informant Interview for caregivers of young adolescents: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

You are being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and input on the way how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area. . By learning more about this we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite you to participate.

Procedures
To obtain this information we like to talk to you, to know more about the situation of children and adolescents in the community. This is why we selected you to participate. If you agree to be in this study we will ask you some questions about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area.

Risks and Discomfort
Each interview will take about 60-90 minutes. It is possible that you may not like some questions or that some questions may upset you. You may refuse to answer these questions, or any questions, if you wish. You may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the health of the children and adolescents in this area. However, there may be no direct benefit to you personally. If the location of interviewing is not at home or school, transportation to and from the interview will be provided by War Child Holland.

Confidentiality

When the interview starts, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.
Nothing that you tell us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that you or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness
If you decide at any time during the study, to no longer wish to participate, you can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact
The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX]. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

If you are interested to participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Participant:

_____ _____ _____
Signature of participant Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:

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 _____

Thumb print of Participant

_____

Participant Name

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or 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

5. Consent form for Community members that participate in the Key Informant Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to the participant prior to the Key Informant Interview. If the Community Member agrees to participate, you must gather all the relevant signatures at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Key Informant Interview for community members: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

You are being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and input on the way how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area. You have been selected for this study, because some community members have indicated you as knowledgeable about these topic. By learning more about this we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite you to participate.

Procedures
To obtain this information we like to talk to you, to know more about the situation of children and adolescents in the community. This is why we selected you to participate. If you agree to be in this study we will ask you some questions about the problems affecting children and adolescents in this community, the causes of these problems, the current services provided to respond to these problems and how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area.

Risks and Discomfort
Each interview will take about 60-90 minutes. It is possible that you may not like some questions or that some questions may upset you. You may refuse to answer these questions, or any questions, if you wish. You may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the health of the children and adolescents in this area. However, there may be no direct benefit to you personally. If the location of interviewing is not at your home, transportation to and from the interview will be provided by War Child Holland.

Confidentiality

When the interview starts, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.

Nothing that you tell us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that you or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness

If you decide at any time during the study, to no longer wish to participate, you can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact

The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX].. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

If you are interested to participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Participant:

_____ _____ _____

Signature of participant Date Time

_____ _____ _____

Signature of Person Obtaining Consent Date Time

For 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 _____

Thumb print of Participant

_____

Participant Name

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or 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

6. Consent form for (Mental) Health Care Service providers that participate in the Key Informant Interviews as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to the participant prior to the Key Informant Interview. If the (mental) health care service provider/coordinator agrees to participate, you must gather all the relevant signatures at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Key Informant Interview for health care providers: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

You are being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the services provided in this area related to Mental Health and Psychosocial Support for children and adolescent between the age of 10-14. We would also like to receive input on how the Helping Young Adolescent Cope Intervention of War Child can be delivered to respond to the mental health needs of children and adolescents in this area. By learning more about this we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite you to participate.

Procedures
To obtain this information we like to talk to you, to know more about the situation of children and adolescents in the community. This is why we selected you to participate. If you agree to be in this study we will ask you some questions about the services provided in this area related to Mental Health and Psychosocial Support for children and adolescent between the age of 10-14 and your ideas on how the Helping Young Adolescent Cope Intervention of War Child can be best delivered to respond to the mental health needs of children and adolescents in this area.

Risks and Discomfort
Each interview will take about 60-90 minutes. It is possible that you may not like some questions. You may refuse to answer these questions, or any questions, if you wish. You may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the health of the children and adolescents in this area. However, there may be no direct benefit to you personally. If the location of interviewing is not at your place of work, transportation to and from the interview will be provided by War Child Holland.

Confidentiality

When the interview starts, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.

Nothing that you tell us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that you or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness

If you decide at any time during the study, to no longer wish to participate, you can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact

The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX]. . In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

_____

If you are interested to participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent to participate. You will be given a copy of this Consent Form after it has been signe

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Participant:

_____ _____ _____

Signature of participant Date Time

_____ _____ _____

Signature of Person Obtaining Consent Date Time

For 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 _____

Thumb print of Participant

_____
Participant Name

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or 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

7. Consent form for Caregivers of Children that participate in the Focus Groups Discussion as part of the Rapid Qualitative Assessment

Instructions for the Interviewer
The following sections below are to be read by or to caregiver of the participant prior to the Focus Group Discussion. If the caregivers and the child then agrees to participate, you must gather all the relevant signatures (including child's assent) at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Focus Group Discussion for young adolescents: The *Helping Young Adolescents Cope* study

Conducted by **War Child Holland**

Purpose of the Study
Your child is being asked to be part of this research study. This research is being done by War Child Holland. We want to find out about the tasks and activities that children and adolescents normally do. By learning more about this we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite your child to participate.

Procedures
To obtain this information we are talking to children between 10 and 14 years old, who live here and know about the situation of children and adolescents in your community. This is why we selected your child to participate. If you agree your child to be in this study I will ask your child some questions about the tasks and activities that children and adolescent normally do in this community.

Risks and Discomfort
Each interview will take about 60 minutes. It is possible that your child may not like some questions or that some questions may upset him/her. Your child may refuse to answer these questions, or any questions, if he/she wishes. He/she may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the mental health of the children and adolescents in this area. However, there may be no direct benefit to your child personally. If the location of interviewing is not at school or the community center, transportation to and from the interview will be provided by War Child Holland.

Confidentiality
When the interview start, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.
Nothing that your child tells us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that your child

or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness
If you, or your child decides at any time during the study, to no longer wish to participate, you or your child can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact
The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX].. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

_____

If you are interested in having your child participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent for your child to participate. You will be given a copy of this Consent Form after it has been signed.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree my child to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

For literate Parent or Caregiver:

_____ _____ _____
Signature of Parent or Caregiver Date Time

_____
Name

_____
Name (-s) of eligible child or children

_____ _____ _____
Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:
I have witnessed the accurate reading of the consent form to the caregiver of the participant, and the caregiver has had the opportunity to ask questions and these have been answered to the caregiver's satisfaction. I confirm that the individual has given consent freely.
Print Name of Witness_____

Signature of Witness _____

Thumb print of Parent or Caregiver

_____

Parent or Guardian Name

_____

Name of eligible child

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or read out the information sheet to the caregiver of the potential participant, and to the best of my ability made sure that the caregiver understands the purpose and process of the study. I confirm that the caregiver was given an opportunity to ask questions about the study, and all the questions asked by the caregiver 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

8. Cognitive Interviews (Syrian Refugees-Young Adolescents)

Instructions for the Interviewer
The following sections below are to be read by or to the caregiver of the participant prior to the Cognitive interview. If the caregivers and the child then agree to participate, you must gather all the relevant signatures (including child's assent) at the end of this form. Also mark the date on the appropriate lines.
Note: Please be aware that the consent form for caregivers that participate is separate from this consent form.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Cognitive Interview for young adolescents: The *Early Adolescent Skills for Emotions* study

Conducted by **War Child Holland**

Purpose of the Study
Your child is being asked to be part of this research study. This research is being done by War Child Holland. We want to understand how children, in the community, understand storybooks and pictures and react to its content, which are extracted from an intervention we developed to help children, aged 10 to 14 years old, with high level of distress and ensure that the content of this interventions is culturally acceptable and is relevant to the target population.
. By learning about the children and adolescent's understanding, we hope to design better programs to assist children and adolescents in your community that are showing signs of distress. We would like to invite your child to participate.

Procedures
To obtain this information we are talking to children between 10 and 14 years old, who live here. This is why we selected your child to participate. If you agree your child to be in this study I will ask your child some questions about their understanding of storybooks and pictures, extracted from an intervention we developed..

Risks and Discomfort
The interview will take about 60 minutes. It is possible that your child may not like some questions or that some questions may upset him/her. Your child may refuse to answer these questions, or any questions, if he/she wishes. He/she may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the mental health of the children and adolescents in this area. However, there may be no direct benefit to your child personally. If the location of interviewing is not at school, transportation to and from the interview will be provided by War Child Holland.

Confidentiality
When the interview start, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research

coordinator will have the key. The audio fragment will be transcribed, and all information that can identify your child will be removed. This transcript will be stored on a password protected laptop and is only available to the core research team.
Nothing that your child tells us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that your child or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness
If you, or your child decides at any time during the study, to no longer wish to participate, you or your child can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact
The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone +961 (0) 1 801725. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

_____
____
If you are interested in having your child participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent for your child to participate. You will be given a copy of this Consent Form after it has been signed.
STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree my child to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."
For literate Parent or Caregiver:

_____ _____ _____
Signature of Parent or Caregiver Date Time

_____
Name

_____
Name (-s) of eligible child or children

_____ _____ _____
Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:

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

Print Name of Witness_____

Signature of Witness _____

Thumb print of Parent or Caregiver

_____

Parent or Guardian Name

_____

Name of eligible child

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or read out the information sheet to the caregiver of the potential participant, and to the best of my ability made sure that the caregiver understands the purpose and process of the study. I confirm that the caregiver was given an opportunity to ask questions about the study, and all the questions asked by the caregiver 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

Child Assent To Participate

"*The interview will take no longer than 1 hour. You are free to say that you do not want to participate. And, once we start, if you don't want to continue, you can tell me and we will stop. If there is any question you don't want to answer, you don't need to- we can skip that question.*

The things we talk about will stay confidential- that means, we will write a report on the answers of ALL respondents in this community, but we won't use your name in this report, or tell anyone you took part. The only time we would tell anyone about something you tell us, would be if we had a concern for your safety, and in that case we would need to share that information with someone, in order to keep you safe. Do you agree to take part?"

I, _____, agree to participate in the Research Study Conducted by War Child Holland in my community, in order to improve programs that assist children and adolescents in communities like my community. I understand that participation means that I will take part of a Cognitive Interview of 60 minutes, and that I will be asked to answer questions related to my understanding of stories and pictures.

_____

Child may sign name here

or

give verbal assent now, witnessed by his/her parent or caregiver or a trusted/known person to the child

_____ _____

Witness Signature Relationship to Child

9. Cognitive Interviews (Syrian Refugees-Caregivers of Young Adolescents)

Instructions for the Interviewer
The following sections below are to be read by or to the participant prior to the Cognitive interview. If the caregiver agrees to participate, you must gather all the relevant signatures at the end of this form. Also mark the date on the appropriate lines.

Please complete this form after you have read and/or listened to an explanation of the study.
Title of Study:
Cognitive Interview for caregivers of young adolescents: The *Early Adolescent Skills for Emotions* study

Conducted by **War Child Holland**

You are being asked to be part of this research study. This research is being done by War Child Holland. We want to understand how parents/caregiver, in the community, understand pictures and activities that we will go through together and how they react to its content. These are extracted from an intervention we developed to help children, aged 10 to 14 years old, with high level of distress and ensure that the content of this interventions is culturally acceptable and is relevant to the target population.

. By learning about the children and adolescent's understanding, we hope to design better programs to assist children and adolescents in your community that are showing signs of distress.

Procedures
If you agree to be in this study, we would like to go through these activities and pictures extracted from the manual with parents from the community. This is why we selected you to participate.

Risks and Discomfort
Each interview will take about 60 minutes. It is possible that you may not like some questions or that some questions may upset you. You may refuse to answer these questions, or any questions, if you wish. You may stop the interview at any time.

Benefits
This information will help War Child Holland to provide better programs to improve the health of the children and adolescents in this area. However, there may be no direct benefit to you personally. If the location of interviewing is not at home or school, transportation to and from the interview will be provided by War Child Holland.

Confidentiality
When the interview start, everything will be recorded by the interviewer with an audio device. This device will be stored in a locked cabinet in the research coordinator's office. The research coordinator will have the key. The audio fragment will be transcribed, and all information that can identify you will be removed. This transcript will be stored on a password protected laptop and is

only available to the core research team.
Nothing that you tell us will be shared with anyone outside the research team. We will not allow anyone else to find out who gave a particular answer unless we think that you or someone else might be in danger. In that case, we cannot keep that information private and we will take steps to make sure that all people involved are kept safe. Every effort will be made to protect the confidentiality of this information as far as is legally possible.

Voluntariness
If you decide at any time during the study, to no longer wish to participate, you can notify the interviewer or anyone from the research team at any time and withdraw from the study without giving any reason, and without any negative consequence.

Whom to Contact
The Research coordinator is in charge of the study and can be contacted through the War Child Holland office in Beirut, telephone [XXXXX].. In the future if you have any questions or suggestions about the study, you should also contact the Research Coordinator.

If you are interested to participate in the study, please read through the following statement. If you have any questions arising from the explanation already given to you, please ask me or anyone else from the research team before you decide to give your consent to participate. You will be given a copy of this Consent Form after it has been signed.
STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."
For literate Participant:

_____ _____ _____
Signature of participant Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

For Illiterate Parent or Caregiver:
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 participants satisfaction. I confirm that the individual has given consent freely.
Print Name of Witness_____

Signature of Witness _____

Thumb print of Participant

_____
Participant Name

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately provided or 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

Deelnemersinformatie voor deelname aan onderzoek

Free list interviews Syrische vluchtelingen

'Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes'

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt. Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksproject STRENGTHS. STRENGTHS is een samenwerking tussen verschillende internationale organisaties en universiteiten. De VU Amsterdam voert het onderzoek in Nederland uit naar de problemen van Syrische vluchtelingen in Nederland.

Het Deense Rode Kruis is de coördinator van dit onderzoek. Om deze reden zullen wij de (geanonimiseerde) informatie uit dit interview delen met het Deense Rode Kruis. Wij zullen geen persoonsgegevens zoals namen en telefoonnummers overhandigen aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie. In deze publicatie zullen geen naar personen herleidbare gegevens worden beschreven.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, wordt u gevraagd naar problemen die Syrische vluchtelingen in Nederland ervaren en naar dagelijkse activiteiten van mannen en vrouwen in de Syrische vluchtelingengemeenschap in Nederland. We zullen u geen vragen over uzelf of over een specifiek ander persoon vragen. De vragen gaan over

Syrische vluchtelingen in Nederland in het algemeen. Dit interview zal ongeveer 30 tot 60 minuten duren.

3. Mogelijke voor- en nadelen

Met uw deelname kunnen wij meer leren over de problemen en situatie van Syrische vluchtelingen in Nederland. We zullen deze informatie gebruiken om programma's voor de Syrische vluchtelingengemeenschap in Nederland te verbeteren.

Naar ons weten zijn er geen risico's bij deelname aan deze studie. Het kan echter zijn dat u sommige vragen onprettig vindt. U doet vrijwillig mee en bent niet verplicht de vragen te beantwoorden. U mag tijdens het onderzoek stoppen.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam, sekse, leeftijd, opleidingsniveau en culturele achtergrond. Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet 'gecodeerd'. Uw naam wordt dan niet meer gebruikt.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw persoonsgegevens (naam, sekse, leeftijd, opleidingsniveau en culturele achtergrond).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens

Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan om onderzoek naar Syrische vluchtelingen in Nederland. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu (website nog in ontwikkeling). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens

mw. Anne de Graaff (onderzoeker)

T: +31(0)205983833

E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)

E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer

Free list interviews Syrische vluchtelingen

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek.

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Indien analfabeet

Vingerafdruk:

Naam getuige:

Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Deelnemersinformatie voor deelname aan onderzoek

Key-informant interviews Syrische vluchtelingen

'Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes'

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt.
Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksproject STRENGTHS. STRENGTHS is een samenwerking tussen verschillende internationale organisaties en universiteiten. De VU Amsterdam voert het onderzoek in Nederland uit naar de problemen van Syrische vluchtelingen in Nederland.

De London School of Hygiene and Tropical Medicine en het Deense Rode Kruis zijn onze partners in STRENGTHS en coördineren dit onderzoek. Om deze reden zullen wij de informatie uit dit interview delen met deze twee partners. Wij zullen geen persoonsgegevens zoals namen en telefoonnummers overhandigen aan de London School of Hygiene and Tropical Medicine of aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie. In deze publicatie zullen geen naar personen herleidbare gegevens worden beschreven.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, wordt u gevraagd naar problemen die Syrische vluchtelingen in Nederland ervaren. We zullen u geen vragen over uzelf of over een specifiek ander persoon vragen. De vragen gaan over Syrische vluchtelingen in Nederland in het algemeen. Dit interview zal maximaal één uur duren.

3. Mogelijke voor- en nadelen

Met uw deelname kunnen wij meer leren over de problemen en situatie van Syrische vluchtelingen in Nederland. We zullen deze informatie gebruiken om programma's voor de Syrische vluchtelingengemeenschap in Nederland te verbeteren. U ontvangt een tegoedbon van Euro 10,00 voor uw deelname aan het interview.

Naar ons weten zijn er geen risico's bij deelname aan deze studie. Het kan echter zijn dat u sommige vragen onprettig vindt. U doet vrijwillig mee en bent niet verplicht de vragen te beantwoorden. U mag tijdens het onderzoek stoppen.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam, sekse, leeftijd, opleidingsniveau en functie/beroep. Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet 'gecodeerd'. Uw naam wordt dan niet meer gebruikt. Het interview wordt opgenomen op audio. Op de audio opname zullen geen namen worden genoemd. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw persoonsgegevens (naam, sekse, leeftijd, opleidingsniveau en functie/beroep).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens

Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan om onderzoek naar Syrische vluchtelingen in Nederland. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu (website nog in ontwikkeling). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens

mw. Anne de Graaff (onderzoeker)

T: +31(0)205983833

E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)

E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer

Key-informant interviews Syrische vluchtelingen

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek.

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

□ Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Indien analfabeet

Vingerafdruk:

Naam getuige:

Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende

toestemmingsformulier.

Deelnemersinformatie voor deelname aan onderzoek

Focus groep interviews Syrische vluchtelingen

'Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes'

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt. Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksconsortium STRENGTHS. In STRENGTHS doen we onder andere onderzoek naar de effectiviteit van een psychologische behandeling, Problem Management Plus (PM+), bij Syrische vluchtelingen. Op basis van eerder onderzoek naar PM+ verwachten wij dat deze behandeling effectief zal zijn in het verminderen van psychische klachten bij Syrische vluchtelingen. De VU Amsterdam doet onderzoek naar PM+ bij Syrische vluchtelingen in Nederland.

Het doel van de huidige studie is om het onderzoekconsortium STRENGTHS te informeren over eventuele (culturele) aanpassingen aan de PM+ behandelmethode om het zo beter te laten aansluiten bij het Arabische taalgebruik en de Syrische cultuur. Hiervoor benaderen wij Syrische vluchtelingen in Nederland.

De London School of Hygiene and Tropical Medicine en het Deense Rode Kruis zijn onze partners in STRENGTHS en coördineren dit onderzoek. Om deze reden zullen wij de informatie uit dit interview delen met deze twee partners. Wij zullen geen persoonsgegevens zoals namen en telefoonnummers overhandigen aan de London School of Hygiene and Tropical Medicine of aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie. In deze publicatie zullen geen naar personen herleidbare gegevens worden beschreven.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, wordt u gevraagd naar dagelijkse activiteiten van mannen en vrouwen in de Syrische vluchtelingengemeenschap in Nederland. Tevens wordt u gevraagd naar uw mening over de implementatie van PM+. Het interview is een groepsgesprek met zes tot acht personen. Dit groepsgesprek zal ongeveer één uur tot maximaal anderhalf uur duren.

3. Mogelijke voor- en nadelen

Met uw deelname draagt u bij aan het verbeteren van een psychologische behandeling voor Syrische vluchtelingen in Nederland. U heeft zelf geen voordeel van meedoen aan dit onderzoek.

Naar ons weten zijn er geen risico's bij deelname aan deze studie. Gezien de aard van focus groep discussies, kunnen wij echter niet garanderen dat vertrouwelijkheid gewaarborgd wordt. Wij vragen alle deelnemers van de focus groep de privacy van andere deelnemers te respecteren en wat er gezegd wordt niet met derden te bespreken. Wij laten iedere deelnemer een geheimhoudingsverklaring tekenen.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam, sekse, leeftijd, opleidingsniveau en culturele achtergrond. Elke deelnemer krijgt een code die wordt gebruikt om aan te duiden wie wat heeft gezegd in het groepsgesprek ('coderen'). Uw naam wordt dan niet meer gebruikt. Het groepsgesprek wordt opgenomen op audio. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw

persoonsgegevens (naam, sekse, leeftijd, opleidingsniveau en culturele achtergrond).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens
Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan om onderzoek naar de behandeling van PM+. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu (website nog in ontwikkeling). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u een onkostenvergoeding van Euro 15,00 en reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens

mw. Anne de Graaff (onderzoeker)
T: +31(0)205983833
E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)
E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer

Focus groep interviews Syrische vluchtelingen

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek.

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

□ Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist.

□ Ik zal de antwoorden van andere deelnemers vertrouwelijk behandelen.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Indien analfabeet
Vingerafdruk:

Naam getuige:

Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Deelnemersinformatie voor deelname aan onderzoek

Key informant interviews behandelaren (G)GZ

'Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes'

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt. Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksconsortium STRENGTHS. In STRENGTHS doen we onder andere onderzoek naar de effectiviteit van een psychologische behandeling, Problem Management Plus (PM+), bij getrainde Syrische vluchtelingen. Op basis van eerder onderzoek naar PM+ verwachten wij dat deze behandeling effectief zal zijn in het verminderen van psychische klachten bij Syrische vluchtelingen. De VU Amsterdam is verantwoordelijk voor het onderzoek naar PM+ bij Syrische vluchtelingen in Nederland.

De huidige studie heeft twee doelen:

- Doel 1: Het in kaart brengen van de geestelijke gezondheidszorg voor Syrische vluchtelingen in Nederland.
- Doel 2: Het onderzoeksconsortium STRENGTHS informeren over eventuele aanpassingen aan het PM+ behandelprotocol.

Hiervoor benaderen wij behandelaren werkzaam binnen de GGZ om hun ervaringen en kennis over hun werk met ons te delen.

De London School of Hygiene and Tropical Medicine en het Deense Rode Kruis zijn onze partners in STRENGTHS en coördineren dit onderzoek. Om deze reden zullen wij de informatie uit dit interview delen met deze twee partners. Wij zullen geen persoonsgegevens zoals namen en telefoonnummers overhandigen aan de London School

of Hygiene and Tropical Medicine of aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, wordt u gevraagd naar uw ervaringen in de (vluchtelingen)zorg en over uw ideeën over de moeilijkheden en mogelijkheden bij het implementeren van een behandeling zoals PM+. Het interview is een individueel gesprek en zal ongeveer één uur duren.

3. Mogelijke voor- en nadelen

Met uw deelname draagt u bij aan het verbeteren van een psychologische behandeling voor Syrische vluchtelingen in Nederland. U heeft zelf geen voordeel van meedoen aan dit onderzoek. Naar ons weten zijn er geen risico's bij deelname aan deze studie.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam en functie/beroep. Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet 'gecodeerd'. Uw naam wordt dan niet meer gebruikt. Het interview wordt opgenomen op audio. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw persoonsgegevens (naam en functie/beroep).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens

Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan om onderzoek naar de behandeling van PM+. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu (website nog in ontwikkeling). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens

mw. Anne de Graaff (onderzoeker)

T: +31(0)205983833

E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)

E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer

Key-informant interviews behandelaren

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek
- Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Naam interviewer:

Handtekening: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Deelnemersinformatie voor deelname aan onderzoek

Key-informant interviews beleidsmakers

'Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes'

Inleiding

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Dit onderzoek wordt uitgevoerd door de VU Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt. Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

Dit onderzoek is onderdeel van het onderzoeksconsortium STRENGTHS. In STRENGTHS doen we onder andere onderzoek naar de effectiviteit van een psychologische behandeling, Problem Management Plus (PM+), bij getrainde Syrische vluchtelingen. Op basis van eerder onderzoek naar PM+ verwachten wij dat deze behandeling effectief zal zijn in het verminderen van psychische klachten bij Syrische vluchtelingen. De VU Amsterdam is verantwoordelijk voor het onderzoek naar PM+ bij Syrische vluchtelingen in Nederland.

De huidige studie heeft twee doelen:

- Doel 1: Het in kaart brengen van de geestelijke gezondheidszorg voor Syrische vluchtelingen in Nederland.
- Doel 2: Het onderzoeksconsortium STRENGTHS informeren over eventuele aanpassingen aan de implementatie van PM+.

Hiervoor benaderen wij beleidsmakers om hun ervaringen en kennis over hun werk met ons te delen.

De London School of Hygiene and Tropical Medicine en het Deense Rode Kruis zijn onze partners in STRENGTHS en coördineren dit onderzoek. Om deze reden zullen wij de informatie uit dit interview delen met deze twee partners. Wij zullen geen persoonsgegevens zoals namen en telefoonnummers overhandigen aan de London School of Hygiene and Tropical Medicine of aan het Deense Rode Kruis. Alle informatie wordt anoniem en versleuteld

verzonden. Daarnaast willen wij de informatie gebruiken voor een wetenschappelijke publicatie.

2. Wat meedoen inhoudt

Wanneer u mee doet aan deze studie, wordt u gevraagd naar uw ervaringen in de (vluchtelingen)zorg en over uw ideeën over de moeilijkheden en mogelijkheden bij het implementeren van een behandeling zoals PM+. Het interview is een individueel gesprek en zal ongeveer één uur duren.

3. Mogelijke voor- en nadelen

Met uw deelname draagt u bij aan het verbeteren van een psychologische behandeling voor Syrische vluchtelingen in Nederland. U heeft zelf geen voordeel van meedoen aan dit onderzoek. Naar ons weten zijn er geen risico's bij deelname aan deze studie.

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat wij de volgende gegevens van u verzamelen: naam en functie/beroep. Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet 'gecodeerd'. Uw naam wordt dan niet meer gebruikt. Het interview wordt opgenomen op audio. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de partners in STRENGTHS niet naar u te herleiden. Indien u wilt, zullen wij u op de hoogte stellen van de uitkomsten van het onderzoek.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw persoonsgegevens (naam en functie/beroep).
De onderzoeker bewaart uw gegevens vijf jaar. Daarna worden de persoonsgegevens vernietigd.

Later gebruik gegevens

Wij willen uw gegevens graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan

om onderzoek naar de behandeling van PM+. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken. Uw gegevens worden dan vernietigd.

Dit onderzoek staat ook beschreven op de website van STRENGTHS: www.strengths-project.eu (website nog in ontwikkeling). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen.

6. Vergoeding voor meedoen

Voor het meedoen aan dit onderzoek ontvangt u reiskostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met mw. Anne de Graaff (onderzoeker).

Contactgegevens
mw. Anne de Graaff (onderzoeker)
T: +31(0)205983833
E: a.m.de.graaff@vu.nl

mw. Marit Sijbrandij (hoofdonderzoeker)
E: e.m.sijbrandij@vu.nl

Dank voor uw aandacht.

Toestemmingsformulier deelnemer

Key-informant interviews beleidsmakers

‘Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes’

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog vijf jaar na dit onderzoek te bewaren.
- Ik wil meedoen aan dit onderzoek
- Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist

□ Ik geef toestemming dat mijn (geanonimiseerde) gegevens mogelijk later nog voor ander onderzoek zal worden gebruikt, zoals in de informatiebrief staat.

□ Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

□ Ik wil op de hoogte worden gebracht van de resultaten.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Naam interviewer:

Handtekening: Datum : __ / __ / __

Ik verklaar dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De deelnemer krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Consent Form

Gender _____ Age _____ Education level _____ Cultural background _____
Interviewer _____ Date __-__-__ Interview ID: FL___

Introducing the project:
PM+ is a low-intensity, psychological intervention for communities in adversity. We are planning to implement PM+ as a peer-refugee delivered intervention for Syrian refugees in Turkey. Arabic speaking psychologists in Turkey will train Syrian refugees, so they can provide the 5-session treatment to Syrian refugees in distress.

Information on the Key Informant interviews:
We conducted interviews with a few Syrian refugees residing in Turkey about the problems that they come across in this country. We asked them to share the names of the people who might have knowledge on these problems and your name was one of the names that they shared with us. The purpose of this interview is to gather in depth information about the problems selected from the data of these interviews.
This interview will take about one hour and we will ask you a couple of questions. You have the right to refuse to participate or answer any questions, or withdraw at any time, without any adverse consequences.
We assure that the answers you will give to our questions and your names will be kept confidential so that the information provided cannot be linked back to you and only people involved in the study will see the interview text.

Name:
Signature:

Interviews Phase 1 (Syrian Refugees – Free List Interviews) – Turkey

Consent Form

Gender _____ Age _____ Education level _____ Cultural background _____
Interviewer _____ Date __-__-__ Interview ID: FL___

Introducing the project:
PM+ is a low-intensity, psychological intervention for communities in adversity. We are planning to implement PM+ as a peer-refugee delivered intervention for Syrian refugees in Turkey. Arabic speaking psychologists in Turkey will train Syrian refugees, so they can provide the 5-session treatment to Syrian refugees in distress.

Information on the Free List (FL) interviews:
The purpose of the Free List interviews is to ask individuals from a target community about the problems of that community (asking about the community rather than the individual seeks to capture problems applicable to everyone).
This interview will take about one hour and we will ask you a couple of questions. You have the right to refuse to participate or answer any questions, or withdraw at any time, without any adverse consequences.
We assure that the answers you will give to our questions and your names will be kept confidential so that the information provided cannot be linked back to you and only people involved in the study will see the interview text.

Name:
Signature:

UniversitätsSpital Zürich

Universität Zürich (UZH)

Information and consent Phase 1 given orally.

Participant Information
- Free List Interviews with Syrian refugees -

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by the Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

36. Purpose of the study

This research is part of the STRENGTHS research project. STRENGTHS is a collaboration between several international organizations and universities. Freie Universität Berlin conducts research on problems of Syrian refugees and on the usage of digital technologies among Syrian refugees in [Germany/Sweden/Egypt]. You were chosen to be interviewed as a member of the Syrian refugee community.
The information you give us will be used to develop and improve a program that helps Syrian refugees with problems and difficult life circumstances.

37. Content of the interview

We would like to ask you about problems and daily activities of men and women in the community of Syrian refugees in [Germany/Sweden/Egypt]. Furthermore, we would like to ask you about the usage of digital technologies among Syrian refugees in your community. There will be an individual interview conducted by two interviewers. We will not ask questions about yourself or about any specific other person. The questions will be about Syrian refugees in your community in [Germany/Sweden/Egypt in general.
The interview will take between 30 minutes to one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

38. Possible advantages and disadvantages

With your participation, we will learn more about problems of Syrian refugees and the usage of digital technologies among Syrian refugees in [Germany/Sweden/Egypt]. We will use this information to improve digital programs for the Syrian refugees in [Germany/Sweden/Egypt. Furthermore, you will receive 10€ for your participation.
To our knowledge, there are no risks associated with participation. However, it is possible that a question makes you feel uncomfortable. Therefore, you are not obliged to answer any questions and you may stop the interview at any time.

39. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

40. Usage and storage of your data

The study protocol requires that we collect the following personal information: name, sex, age, education and profession.
Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data. The interview will not be recorded on audio.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGTHS project and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study. If you sign the consent form, you agree to the collection, storage and processing of your personal data (name, sex, age, education and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website: www.strengths-project.eu. This website does not contain any information that will allow to identify you as a participant.

41. Compensation for participation

You will receive 10€ for participation in the study.

42. Do you have any questions?

For questions please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Informed Consent Form

- Free List Interviews with Syrian refugees -

ID: _____

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

please read the following statements regarding your participation in the study.

43. I have read the information letter. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate.
44. I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions.
45. I agree that my data will be collected and used in the ways described in the information letter. I give permission to store these data for 10 years.
46. I want to participate in this study.

Please mark the following statements with a cross, if you agree.
□ I give permission to approach me after this survey again for a follow-up study.
□ I want to be informed about the results of this study.

Name of participant:

Signature: Date:
____/____/____

Name of witness:

Signature of witness: Date:
____/____/____

Interviews Phase 1 (Syrian Refugees-Key Informant Interviews) – Germany/Sweden/Egypt

Participant Information
- Key Informant Interviews with Syrian refugees -

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by the Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

47. Purpose of the study

This research is part of the STRENGTHS research project. STRENGTHS is a collaboration between several international organizations and universities. Freie Universität Berlin conducts research on problems of Syrian refugees and the usage of digital technologies among Syrian refugees in [Germany/Sweden/Egypt]. You were chosen to be interviewed because other people in the Syrian refugee community told us that you would be a good person to ask about one or both of these topics. The information you give us will be used to develop and improve a program that helps Syrian refugees with problems and difficult life circumstances.

48. Content of the interview

We would like to ask you about problems that Syrian refugees in your community in [Germany/Sweden/Egypt] experience. After presenting you a concept version of the PM+ app, we would like to ask for your opinion on the app.
There will be an individual interview conducted by two interviewers. We will not ask questions about yourself or about any specific other person. The questions will be about Syrian refugees in your community in [Germany/Sweden/Egypt in general.
The interview will take approximately one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

49. Possible advantages and disadvantages

With your participation, we will learn more about problems in the Syrian refugee community in [Germany/Sweden/Egypt]. We will use this information to improve the PM+ app for the Syrian refugees in [Germany/Sweden/Egypt. Furthermore, you will receive 10€ for your participation.
To our knowledge, there are no risks associated with participation. However, it is possible that a question makes you feel uncomfortable. Therefore, you are not obliged to answer any questions and you may stop the interview at any time.

50. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

51. Usage and storage of your data

The study protocol requires that we collect the following personal information: name, sex, age, education and profession.
Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data. The interview will not be recorded on audio.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGTHS project and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study. If you sign the consent form, you agree to the collection, storage and processing of your personal data (name, sex, age, education and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant.

52. Compensation for participation

You will receive 10€ for participation in the study.

53. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Informed Consent Form
- Key Informant Interviews with Syrian refugees -

ID: _____

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

please read the following statements regarding your participation in the study.

54. I have read the information letter. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate.
55. I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions.
56. I agree that my data will be collected and used in the ways described in the information letter. I give permission to store these data for 10 years.
57. I want to participate in this study.

Please mark the following statements with a cross, if you agree.
□ I give permission to approach me after this survey again for a follow-up study.
□ I want to be informed about the results of this study.

Name of participant:

Signature: Date:
____/____/____

Name of witness:

Signature of witness: Date:
____/____/____

Participant Information
- Focus Group Discussions with Syrian refugees -

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by the Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

58. Purpose of the study

This research is part of the STRENGHTS research project. In this project we conduct research on the effectiveness of a psychological treatment for Syrian refugees, called Problem Management Plus (PM+). Based on previous research on PM+, we expect that this treatment will be effective in reducing psychological symptoms in Syrian refugees. At Freie Universität Berlin we will develop a digital version of PM+ that will be accessible in the form of a smartphone app for Syrian refugees in [Germany/Sweden/Egypt].

The aim of this study is to gather information that will be used to create the PM+ app in a way that is most suitable for the needs of Syrian refugees in [Germany/Sweden/Egypt]. For this reason, we have approached you as a member of the Syrian refugee community in [Germany/Sweden/Egypt].

59. Content of the Focus Group

We would like to ask you about daily activities of men and women in the Syrian refugee community in [Germany/Sweden/Egypt]. After presenting you a concept version of the PM+ app, we would like to ask for your opinion on the app. You will also be asked for your ideas on how to provide the app to the Syrian refugee community here in [Germany/Sweden/Egypt].
The interview will be conducted in a group of 6 to 8 people and with two interviewers. You will not be asked questions about yourself or about any specific other person. The questions will be about Syrian refugees in your community in [Germany/Sweden/Egypt in general. The group discussion will take approximately one hour to one and a half hours.
If you are not available in person, the interview can also be conducted as a conference call via an online audio/video messaging service.

60. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of psychological care for Syrian refugees in [Germany/Sweden/Egypt]. We will use this information to improve the PM+ app for Syrian refugees in [Germany/Sweden/Egypt. Furthermore, you will receive 10€ for your participation.
To our knowledge, there are no risks associated with participation. Given the nature of focus group

discussions, we cannot guarantee confidentiality. However, all participants will be asked to respect the privacy other participants and not to discuss the contents of the group discussion with others. Each participant will also sign a confidentiality agreement.

61. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

62. Usage and storage of your data

The study protocol requires that we collect the following personal information: name, sex, age, education and profession.
Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data. The interview will not be recorded on audio.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and Danish Red Cross are our partners in the STRENGHTS project and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study. If you sign the consent form, you agree to the collection, storage and processing of your personal data (name, sex, age, education and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGHTS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant.

63. Compensation for participation

You will receive 10€ for participation in the study.

64. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Informed Consent Form
- Focus Group Discussions with Syrian refugees -

ID: _____

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

please read the following statements regarding your participation in the study.

65. I have read the information letter. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate.
66. I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions.
67. I agree that my data will be collected and used in the ways described in the information letter. I give permission to store these data for 10 years.
68. I want to participate in this study.

Please mark the following statements with a cross, if you agree.
□ I give permission to approach me after this survey again for a follow-up study.
□ I want to be informed about the results of this study.
□ I will treat the contents of the discussion as confidential.

Name of participant:

Signature: Date:
____/____/____

Name of witness:

Signature of witness: Date:
____/____/____

Interviews Phase 1 (Health Care Providers- Key Informany Interviews) – Germany/Sweden/Egypt

Participant Information
- Key Informant Interviews with mental health care providers -

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

69. Purpose of the study

This research is part of the STRENGTHS research consortium. In the STRENGTHS program we will investigate the effectiveness of a psychological intervention for common mental health and psychosocial problems in Syrian Refugees. The intervention is called Problem Management Plus (PM+) and it was developed by the World Health Organization (WHO). Based on previous research on PM+, we expect that this treatment will be effective in reducing psychological symptoms in Syrian refugees. The Freie Universität Berlin is responsible for the development and evaluation of a digital version of PM+ for Syrian refugees in [Germany/Sweden/Egypt]. To this end, we will provide PM+ in the form of a smartphone app to Syrian refugees in [Germany/Sweden/Egypt].

The present study has three objectives:

g) Mapping of mental health care for Syrian refugees in [Germany/Sweden/Egypt].
h) Gathering information that will inform adjustments to the PM+ treatment protocol.
i) Gathering information that will inform the conceptualization and development of the PM+ app.

For this reason, we approach mental care providers to share their experiences and their knowledge from their professional work with us.

70. Content of the interview

We would like to ask you about your experiences with (refugee) care and about your ideas on problems and opportunities for the implementation of the smartphone version of PM+ for Syrian refugees in [Germany/Sweden/Egypt]. There will be an individual interview conducted by two interviewers. The interview will take approximately one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

71. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of psychological care for Syrian refugees in [Germany/Sweden/Egypt]. Apart from that, you will have no personal benefit from

participating in this study. To our knowledge, there are not risks associated with participation.

72. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

73. Usage and storage of your data

The study protocol requires that we collect the following personal information: name and profession. Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data. The interview will not be recorded on audio.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGTHS consortium and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study.
If you sign the consent form, you agree to the collection, storage and processing of your personal data (name and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant. However, the website will contain a summary of the results.

74. Compensation for participation

You will receive compensation for travel expenses.

75. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Informed Consent Form
- Key Informant Interviews with mental health care providers -

ID: _____

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

please read the following statements regarding your participation in the study.

76. I have read the information letter. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate.
77. I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions.
78. I agree that my data will be collected and used in the ways described in the information letter. I give permission to store these data for 10 years.
79. I want to participate in this study.

Please mark the following statements with a cross, if you agree.
□ I give permission to approach me after this survey again for a follow-up study.
□ I want to be informed about the results of this study.

Name of participant:

Signature: Date:
____/____/____

Interviews Phase 1 (Policy Makers – Key Informant Interviews) – Germany/Sweden/Egypt

Participant Information
- Key Informant Interviews with policy makers -

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

80. Purpose of the study

This research is part of the STRENGTHS research consortium. In the STRENGTHS program we will investigate the effectiveness of a psychological intervention for common mental health and psychosocial problems in Syrian Refugees. The intervention is called Problem Management Plus (PM+) and it was developed by the World Health Organization (WHO). Based on previous research on PM+, we expect that this treatment will be effective in reducing psychological symptoms in Syrian refugees. The Freie Universität Berlin is responsible for the development and evaluation of a digital version of PM+ for Syrian refugees in [Germany/Sweden/Egypt]. To this end, we will provide PM+ in the form of a smartphone app to Syrian refugees in [Germany/Sweden/Egypt].

The present study has three objectives:

j) Mapping of mental health care for Syrian refugees in [Germany/Sweden/Egypt].
k) Gathering information that will inform adjustments to the PM+ treatment protocol.
l) Gathering information that will inform the conceptualization and development of the PM+ app.

For this reason, we approach policy makers to share their experiences and their knowledge from their professional work with us.

81. Content of the interview

We would like to ask you about your experiences with (refugee) care and about your ideas on problems and opportunities for the implementation of the smartphone version of PM+ for Syrian refugees in [Germany/Sweden/Egypt]. There will be an individual interview conducted by two interviewers. The interview will take approximately one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

82. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of psychological care for Syrian refugees in [Germany/Sweden/Egypt]. Apart from that, you will have no personal benefit from

participating in this study. To our knowledge, there are not risks associated with participation.

83. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

84. Usage and storage of your data

The study protocol requires that we collect the following personal information: name and profession. Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data. The interview will not be recorded on audio.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGTHS consortium and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study.
If you sign the consent form, you agree to the collection, storage and processing of your personal data (name and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant. However, the website will contain a summary of the results.

85. Compensation for participation

You will not receive compensation.

86. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Informed Consent Form
- Key Informant Interviews with policy makers -

ID: _____

"Cultural and digital adaptation of the low-intensity Problem Management Plus (PM+) program"

Dear Madam or Sir,

please read the following statements regarding your participation in the study.

87. I have read the information letter. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate.
88. I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions.
89. I agree that my data will be collected and used in the ways described in the information letter. I give permission to store these data for 10 years.
90. I want to participate in this study.

Please mark the following statements with a cross, if you agree.
□ I give permission to approach me after this survey again for a follow-up study.
□ I want to be informed about the results of this study.

Name of participant:

Signature: Date:
____/____/____

WP4: Refugee Settlement and Camp Implementation; Study 1 (Jordan)

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Improving Mental Health of Syrian Refugees in Jordan: Screening Phase

Professor Richard Bryant

1. What is the research study about?
This is an invitation for you and your child in your care to take part in this research project, which is called 'Improving Mental Health of Syrian Refugees in Jordan'.

2. Who is conducting this research?
The study is being carried out by the following researchers: Professor Richard Bryant at the University of New South Wales in Sydney, Australia, in partnership with the The Noor Al Hussein Foundation here in Jordan. The project is funded by Australia's National Health and Medical Research Council.

3. **Inclusion/Exclusion Criteria**
To participate in this project you need to be an Arabic-speaking Syrian adult refugee woman who is experiencing distress with difficulties in coping, and you have a child between the ages of 10-16 years. You will not be included in the study if you have an acute medical condition, are at immediate risk of suicide or of being harmed by someone, or have a severe mental disorder or cannot understand our instructions. We will find out if you meet these conditions by asking you to complete several questionnaires about your mood and situation.

4. Do I have to take part in this research study?
Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully;
- Sign and return the consent form if you decide to participate in the study;
- Take a copy of this form with you to keep.

5. What does participation in this research require, and are there any risks involved?
If you decide to take part in the research study, we will ask you questions about your mood to see if you are eligible for the study. This will only take about 10 minutes. If you are eligible, I will then give you more information about the study and you can then decide on whether you want to take part. At this time we are only giving a brief assessment to see if you are eligible for the study. *We do not expect there are any risks in this program.* If you are very distressed at any time, Noor Al Hussein will offer referral to services near your home for counselling or crisis assistance.

6. What are the possible benefits to participation?
We hope to use information we get from this research study to help Syrians overcome their psychological challenges more effectively. We will not be reimbursing you for doing this survey.

7. What will happen to information about me?
By signing the consent form you consent to the research team collecting and using information about your child for the research study. We will keep the data for 7 years. We will store information about your child in a way that their identify is anonymous and in an electronic file secured in files at Noor Al Hussein and UNSW Sydney. The information about your child will only be used for data analysis about their psychological health over time.

Researchers at UNSW are required to store their any aggregated data in the UNSW data repository, this is a system called ResData. Once the aggregated data is deposited into this repository it will be retained in this system permanently. It will, however, be retained in a format where your identity will not be known.

Your information will only be used for data analysis of the study's outcomes. Your data will be stored in an electronic file in a way that your personal identify is unknown, and it is stored in a secure server at UNSW Sydney.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a compliant about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the **UNSW Privacy Management Plan**.

8. How and when will I find out what the results of the research study are?
The research team intend to publish and/ report the results of the research study in a variety of ways. All information published will be done in a way that will not identify you. If you would like to receive a copy of the results you can let the research team know by email or telephone call. We will only use these details to send you the results of the research. The results will also be made available via Noor Al Hussein's website [http://www.nooralhusseinfoundation.org/index.php].

9. What if I want to withdraw from the research study?
If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or Noor Al Hussein.

If you decide to leave the research study, the researchers will not collect additional information from you. Any identifiable information about you will be withdrawn from the research project. The research team will destroy any information about you that was collected during your participation in the study.

10. What should I do if I have further questions about my involvement in the research study?
The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

Name	Maha Ghatasheh	[INSERT full name]
Position	Development Unit Director	[INSERT position title]
Telephone	962 65344190	[INSERT work telephone number. Please do not use personal mobile numbers]
Email	M.ghatasheh@ifh-jo.org	[INSERT work email address. Please use only UNSW email addresses]

Support Services Contact Details
If at any stage during the study you become distressed or require additional support from someone not involved in the research please call:

Name/Organisation	International Medical Corps	[INSERT name/organisation]
Position	Psychosocial Coordinator	[INSERT position title]
Telephone	798516131	[INSERT work telephone number]
Email	abawaneh@internationalmedicalcorps.org	[INSERT work email address]

What if I have a complaint or any concerns about the research study?
If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC17520

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ *[Recordings]* I understand that the research team will audio/video record the interviews; I agree to be recorded for this purpose.
- ☐ *[Collection of Biospecimens]* I understand that the research team will collect *[INSERT type of speciment to be collected];* I provide my consent for this to happen.
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.
- ☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- ☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;
  Name: _____

  Address: _____

  Email Address: _____

- ☐ I understand that I will be given a signed copy of this document to keep;

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

- ☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

[+]An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, *[other participating organisation[s] or other professional(s)]*. In withdrawing my consent I would like any information which I have provided for the purpose of this research study withdrawn. *[I understand that the information collected about me during my participation in the focus group cannot be withdrawn given the nature of the focus group]*.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Professor Richard Bryant
Email:	r.bryant@unsw.edu.au
Phone:	61-405375874
Postal Address:	School of Psychology, UNSW Sydney, NSW, 2052, Australia

11.

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ *[Recordings]* I understand that the research team will audio/video record the interviews; I agree to be recorded for this purpose.
- ☐ *[Collection of Biospecimens]* I understand that the research team will collect *[INSERT type of speciment to be collected];* I provide my consent for this to happen.
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.
- ☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- ☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;

  Name: _____

  Address: _____

  Email Address: _____

- ☐ I understand that I will be given a signed copy of this document to keep;

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

- ☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

[+]An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, *[other participating organisation[s] or other professional(s)]*. In withdrawing my consent I would like any information which I have provided for the purpose of this research study withdrawn. *[I understand that the information collected about me during my participation in the focus group cannot be withdrawn given the nature of the focus group]*.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	**12.** Professor Richard Bryant
Email:	**13.** r.bryant@unsw.edu.au
Phone:	**14.** 61-405375874
Postal Address:	**15.** School of Psychology, UNSW Sydney, NSW, 2052, Australia

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Improving Mental Health of Syrian Refugees in Jordan: Screening Phase

Professor Richard Bryant

91. What is the research study about?

This is an invitation for you and your child in your care to take part in this research project, which is called 'Improving Mental Health of Syrian Refugees in Jordan'.

92. Who is conducting this research?

The study is being carried out by the following researchers: Professor Richard Bryant at the University of New South Wales in Sydney, Australia, in partnership with the The Noor Al Hussein Foundation here in Jordan. The project is funded by Australia's National Health and Medical Research Council.

1. Inclusion/Exclusion Criteria

To participate in this project you need to be an Arabic-speaking Syrian adult refugee woman who is experiencing distress with difficulties in coping, and you have a child between the ages of 10-16 years. You will not be included in the study if you have an acute medical condition, are at immediate risk of suicide or of being harmed by someone, or have a severe mental disorder or cannot understand our instructions. We will find out if you meet these conditions by asking you a series of questions.

93.

94. Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

95. If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully;
- Sign and return the consent form if you decide to participate in the study;
- Take a copy of this form with you to keep.

96. What does participation in this research require, and are there any risks involved?

If you decide to take part in the research study, we will ask you questions about your mood and your situation to see if you are eligible for the study. If you are eligible, you will then be asked further questions and then be allocated to receive either 5 sessions of group skills training or you will be offered referral to services that can provide assistance. All participants will be asked questions about mood again after 6 weeks, 3 months, and 12 months, which will occur in your home or somewhere else convenient if you prefer that. We also wish to assess one of your children at each assessment, which will involve your child answering a brief series of questions about their mood – this takes about 7 minutes. Children will not take part in the group sessions. You will be reimbursed $JD3 for each time you are assessed. If you are allocated to receive the 5 sessions of skills training (called Problem Management Plus; PM+), you will be asked to attend the Noor Al Hussein clinic for 5 weekly 3-hour sessions (including breaks), in which you will join in a group of 6-8 Syrian women to learn skills on managing stress. We do not expect there are any risks in this program. If you are very distressed at any time, Noor Al Hussein will offer referral to services near your home for counselling

or crisis assistance. If you are allocated to the other condition, you and your child will also be assessed soon, and again after 6 weeks, 3 months, and 12 months (and you will receive $JD3 for each time you are assessed). You will also be referred to a local service conducted or recommended by Noor Al Hussein that can assist with your needs. In either condition, your child will not be referred to another service unless there is an urgent need to do so.

If you decide to take part in the research study, we will also ask you to complete some questionnaires on tablet. The questionnaire will ask you questions about your mood. It should take approximately 45-60 minutes to complete. We don't expect this questionnaire to cause any harm or discomfort, however if you experience feelings of distress as a result of participation in this study you can let the research team know and they will provide you with assistance. As well, there are services available from the list below.

97. What are the possible benefits to participation?

We hope to use information we get from this research study to help Syrians overcome their psychological challenges more effectively.

98. What will happen to information about me?

By signing the consent form you consent to the research team collecting and using information about your child for the research study. We will keep the data for 7 years. We will store information about your child in a way that their identify is anonymous and in an electronic file secured in files at Noor Al Hussein and UNSW Sydney. The information about your child will only be used for data analysis about their psychological health over time.

Researchers at UNSW are required to store their any aggregated data in the UNSW data repository, this is a system called ResData. Once the aggregated data is deposited into this repository it will be retained in this system permanently. It will, however, be retained in a format where your identity will not be known.

Your information will only be used for data analysis of the study's outcomes. Your data will be stored in an electronic file in a way that your personal identify is unknown, and it is stored in a secure server at UNSW Sydney.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a compliant about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the **UNSW Privacy Management Plan**.

99. How and when will I find out what the results of the research study are?

The research team intend to publish and/ report the results of the research study in a variety of ways. All information published will be done in a way that will not identify you. If you would like to receive a copy of the results you can let the research team know by email or telephone call. We will only use these details to send you the results of the research. The results will also be made available via Noor Al Hussein's website [http://www.nooralhusseinfoundation.org/index.php].

100. What if I want to withdraw from the research study?

101. If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or Noor Al Hussein.

If you decide to leave the research study, the researchers will not collect additional information from you. Any identifiable information about you will be withdrawn from the research project. The research team will destroy any information about you that was collected during your participation in the study.

102. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

Name	Maha Ghatasheh	[INSERT full name]
Position	Development Unit Director	[INSERT position title]
Telephone	962 65344190	[INSERT work telephone number. Please do not use personal mobile numbers]
Email	M.ghatasheh@ifh-jo.org	[INSERT work email address. Please use only UNSW email addresses]

Support Services Contact Details

If at any stage during the study you become distressed during the sessions, Noor Al Hussein has trained counsellors who will be immediately available to assist you. Additionally, if you require additional support from someone not involved in the research you can contact:

Name/Organisation			International Medical Corps	[INSERT name/organisation]
Position			Psychosocial Coordinator	[INSERT position title]
Telephone			798516131	[INSERT work telephone number]
Email			abawaneh@internationalmedicalcorps.org	[INSERT work email address]

16. What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au

17. HC Reference Number	**18.** HC17520

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.
- ☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- ☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;
  Name: _____

  Address: _____

  Email Address: _____

- ☐ I understand that I will be given a signed copy of this document to keep;

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

- ☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

[+]An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales of Noor Al Hussein In withdrawing my consent I would like any information which I have provided for the purpose of this research study withdrawn.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	**19.** Professor Richard Bryant
Email:	**20.** r.bryant@unsw.edu.au
Phone:	**21.** 61-405375874
Postal Address:	**22.** School of Psychology, UNSW Sydney, NSW, 2052, Australia

WP4: Refugee Settlement and Camp Implementation; Study 2 (Lebanon)

War Child Holland (WCH)

Informed consent and Assent Forms Screening Phase 2 and 4

Information Sheet

Introduction

Hello! My name is …… and along with me are ……. We have come from War Child Holland and live in the North of Lebanon as well.

We are a group of researchers and we are doing a program that is call Early Adolescents Skills for Emotions, so it's called EASE, which aims to reduce distress and improve wellbeing for young adolescents that are experiencing some difficulties with their thoughts and feelings at the moment. War Child Holland, along with other partners, is conducting a research programme to see whether it is helpful for young adolescents in this community and how we may be able to improve the programme to better help others in Lebanon and other countries in the region. This research programme will take place in several locations in Tripoli and Akkar.

You most likely have got in contact with use via one of the following two options:

- You have attended one of War Child's awareness and outreach activities.
- Your child is taking part in our War Child Holland education program -'Back to the Future'

I will now explain a bit more. I am going to ask you if you give permission for your child to take part in a brief interview with our research team. We will ask them some questions to see whether they are likely to benefit from the programme we are trialling. You and your child can decide if your child will participate in this test. I may use some words that you may 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, my colleagues/friends here, the principal, or the ministry staff.

You can take time to decide whether or not you will agree to your child participating in the research. Before you decide, you can talk to anyone you feel comfortable with about the research such as a friend or family member.

Research ID:

INFORMATION SHEET AND CONSENT FORM FOR PARENTS OF CHILDREN TO BE PART OF SCREENING

To be read by Research Assistants

Research assistants –

Please stop to ask the questions throughout and tick the box, or ask parents to tick the boxes to indicate their agreement. If a parent does not agree to any of the sections below, please thank the parent for their time and discontinue the consent interview.

As you listen to the information, I'm going to stop to ask for you to agree, please signal your agreement to me/ tick the appropriate box.

If you are interested in having your child participate in this interview, I will ask you to sign or provide a thumbprint at the end.

If you have any questions, there will be time for you to ask them of me, or my colleagues.

_____

1. What is the purpose of the research activity?

- Emotional problems, like feelings of sadness, anxiety and stress are very common, especially when young adolescents have left their home due to violence or other problems. Many young adolescents with emotional problems do not get the help they need.
- We have developed a program to help young adolescents between 10-14 in dealing with their emotional problems.
- This program is only meant for children with higher levels of distress and emotional problems. The interview with your child will help us to see if your child has any emotional problems and if he/she finds it difficult to cope with them. This will let us know whether your child might benefit from taking part in our programme

- ***Question to check understanding:*** *Do you know why we are asking your child to take part of this test?*

I understand and agree to this ☐ ☐

2. What will the research involve?

- If you agree for your child to take part in this interview, we will ask your child questions about him/herself, their emotions and how they deal with difficult emotions.
- The test will take no more than 30 minutes. The interviewer will sit down with your child in a comfortable place. If you child does not wish to answer any question during the interview, he/she may say so and the interviewer will move on to the next question.
- After the interview, it may be that the answers to the questions show that your child is not experiencing the kinds of emotional problems that this programme is designed to help with. If this is the case, your child will not take part in the programme. But, we will provide some feedback on the results to you and your child and we will provide some information for you on how young adolescents can deal with difficult emotions.
- If we find from the interveiw that our programme might be suitable for your child, we will invite you and your child to take part in the research study.
- If your child is in the study, they will be randomly allocated to one of our two programmes. This means you and your child will receive either:
  - the Early Adolescents Skills for Emotions programme, called EASE. It involves 7 group sessions for adolescents, each 90 minutes, and 3 group sessions for parents, each 120 minutes. Strategies for managing distress will be covered with both adolescents and their parents, as we know how essential parents are in helping their children benefit from programmes like this.

OR

One session with a trained facilitator to provide some information on self-care strategies and referral options in your area. You will also be invited for this session.
The programme that you and your child will receive will be chosen randomly- like flipping a coin. No one will be able to choose which programme you and your child take part in. You will be informed about which group your child is assigned to within one week.

I understand and agree to this  ☐ ☐

3. Does my child have to participate?

- It is your choice whether you and your child participate for this test.
- You may choose today for your child to be involved in the research part. If you agree for them to be involved, you may still change your mind and withdraw them at any time.
- Deciding not to take part will not have any negative impact on your family
- During any research activities, if your child does not want to continue then they can stop at any time and they don't have to give a reason.
- If you do decide to withdraw your child, we ask that you contact the PI (contact information provided below) or the offices of XX (contact information provided below).
- ***Questions to check understanding:*** *Do you know that you and your child do not have to take part in this research project, if you or your child do not wish to? Do you have any questions?*

I understand and agree to this  ☐ ☐

4. Will my and my child's results be confidential?

- You and your child's details and answers to the test will be kept confidential- only members of our team will have access to you and your child's name and details.
- The only time we would have to disclose these to anyone would be if we were required to by law, because of a safety issue.
- The information we collect, will be kept securely.
- We will use a code to link to your child's results, rather than use their name.

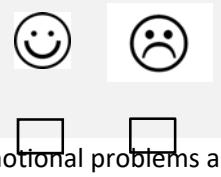
I understand and agree to this ☐ ☐

5. Will there be any risks to myself or my child?

- We do not expect that the test for the EASE programme will have any negative effects.
- However, it is possible that responding to questions 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
- If you or your child find any of the interview questions too personal, uncomfortable or difficult to answer you do not have to answer them. Your child does not have to give us any reason for

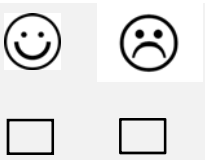
not answering any question, or for not completing the test.

- If you or your child become upset at any time during the study, you and your child will be able to speak with an appropriate member of the research team. If you or our staff become seriously concerned about your or your child's mental wellbeing, we will assist you to other care.

I understand and agree to this 

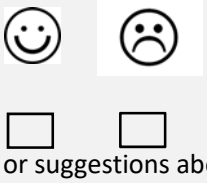
6. What are the benefits to my child?

- If we find from the interview that your child has difficulties with emotional problems and we think that our programmes will be right for you child, he/she may be invited to take part in the research study and receive one of the programmes.
- If we find from the interview that the programme is not right for you, we will provide you with information about how to deal with the kind of emotional problems your child has.
- You and your child will not receive compensation (i.e. money or any material goods) for taking part in this study.

I understand and agree to this 

7. How will the results be used?

- The knowledge that we gain during this test will be shared with you and your child and we will let you know if the programme will be suitable for your child.
- We may publish what we have learnt from everyone who did the interview, so that other interested people may learn from this research. Your identity will never be revealed.

I understand and agree to this 

8. Whom Do I Call If I Have Questions or Problems?

For questions about the study, or if you have problems, concerns, questions or suggestions about the research, contact the Principle Investigator (contact information provided below).

+31 6 48431702

I understand and agree to this 

I have understood and agree to all of the above and consent to my child participating

_____ _____

Parent or Guardian Signature Date

_____

Parent or Guardian Name

_____

Name (-s) of eligible child or children

_____ _____

Signature of Research Assistant Obtaining Consent Date

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 participants satisfaction. I confirm that the individual has given consent freely.

Thumb print of participant

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

Assent form for screening

Child Assent To Participate

Hello! My name is ……. and along with me are …….. We have come from War Child Holland and live in the North of Lebanon as well.

We are finding out how we best can help young adolescents between 10-14, so adolescents from your age, that have difficulties with their emotions. Our research is called Early Adolescents Skills for Emotions, also called EASE. We want to test the effects of a new programme to help young adolescents who are having some difficulties with their thoughts and feelings. Today, we would like to ask you some questions about your thoughts and feelings, to see if we think that this programme might be helpful for you.

We are asking you because, or you are already part of the Back to the Future program from War Child Holland, or we have met you or your caregivers during an event in your community.

If you agree, we will ask you some questions about how you are feeling. The interview will take about 30 minutes. The interviewer will sit down with you in a comfortable place. If you do not wish to answer any question during the test, you may say so and the interviewer will move on to the next question.

If after the interview, we think that the programmes might be helpful for you, you will be invited take part in the research study, and you may receive the programme.

[Check:] Do you understand it so far?

You don't have to take part in this interview if you don't want to. And if you agree to do it, but then change your mind, we can stop and that's not a problem. If there is a question that you don't want to answer, you can tell me and we can skip it. If you do not feel comfortable you can always stop the test.

Everything that we talk about will be confidential. I will share it with my team, but they will only see the information without your name on it. The only time we would tell anyone about something you tell us, would be if we had a concern for your safety, and in that case we would need to share that information with someone, in order to keep you safe.

Do you have any questions?

Do you agree to take part?

_____

Child may sign name here

or

give verbal assent now, witnessed by his/her parent or guardian or a trusted/known person to the child

Witness Signature Relationship to Child

Informed Consent and Assent Forms Trial Phase 2 and 4

Information Sheet

Introduction

Hello! My name is …… and along with me are …….. We have come from War Child Holland and live in the North of Lebanon as well.

The World Health Organization has developed a programme called Early Adolescents Skills for Emotions, so it's called EASE, which aims to reduce distress and improve wellbeing for young adolescents that are experiencing some difficulties with their thoughts and feelings at the moment. War Child Holland, along with other partners, is conducting a research programme to see whether it is helpful for young adolescents in this community and how we may be able to improve the programme to better help others in Lebanon and other countries in the region. This research programme will take place in several locations in Tripoli and Akkar.

Your child recently had an interview with a member of the research team, which identified them as someone who may benefit from the programme.

If your child takes part in this study, they will either receive the Early Adolescents Skills for Emotions programme, or your child and you will receive a session with a trained facilitator to provide some information on self-care strategies and referral options in your area.

I will now explain a bit more. I may use some words that you may 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, my colleagues/friends here.

You can take time to decide whether or not you will agree to your child participating in the research. Before you decide, you can talk to anyone you feel comfortable with about the research such as a friend or family member.

Research ID:

INFORMATION SHEET AND CONSENT FORM FOR PARENTS OF CHILDREN IN EASE INTERVENTION STUDY

To be read by Research Assistants

Research assistants –

Please stop to ask the questions throughout and tick the box, or ask parents to tick the boxes to indicate their agreement. If a parent does not agree to any of the sections below, please thank the parent for their time and discontinue the consent interview.

As you listen to the information, I'm going to stop to ask for you to agree, please signal your agreement to me/ tick the appropriate box.

If you are interested in having you and your child participate in the study, I will ask you to sign or provide

a thumbprint at the end.

If you have any questions, there will be time for you to ask them of me, or my colleagues.

_____

1. What is the purpose of the research activity?

- Emotional problems, like feelings of sadness, anxiety and stress are very common, especially when young adolescents have left their home due to violence or other problems. Many young adolescents with emotional problems do not get the help they need.
- We have developed a program to help young adolescents between 10-14 in dealing with their emotional problems.
- Your child recently had an interview with a member of the research team which identified your child as someone who may benefit from the programme we have designed. We believe that the programme may help your child to manage with the emotional problems. We would like to see through this research whether it does help young adolescents in North of Lebanon, and how we may be able to improve the programme to better help other people.
- ***Question to check understanding:*** *Do you know why we are asking your child to take part in this research?*
-


I understand and agree to this ☐ ☐

2. What will the research involve?

- If you agree for your child to take part in the study, your child will receive either:
  - The Early Adolescents Skills for Emotions programme, called EASE. It involves 7 group sessions for adolescents, each 90 minutes, and 3 group sessions for parents, each 120 minutes. Strategies for managing distress will be covered with both adolescents and their parents, as we know how essential parents are in helping their children benefit from programmes like this.

23.

24. OR

25.

  - One session with a trained facilitator to provide some information on self-care strategies and referral options in your area. You will also be invited for this session.
- The programme that you and your child will receive will be chosen randomly- like flipping a coin. No one will be able to choose which programme you and your child take part in. You will be informed about which group your child is assigned to within one week.
- You and your child will be asked to complete some questionnaire with a researcher at 4 times, over a period of 6 to 7 months [+ 12 months for full RCT]. These will include you will be asked some more questions about different kinds of emotional problems. This activity will take approximately 1 hour each time.
- You or your child may also be asked to take part in a group or individual interview at the end of the programme, so that we can learn more about their experiences in the programme. This will be held in a private place with trained researchers, and will take no longer than 1 hour. This

interview will be audio-recorded. You or your child do not have to participate in this interview if you do not want to and you do not have to decide this right now.

I understand and agree to this 

3. Does my child have to participate?

- It is your choice whether you and your child participate in this study.
- You may choose today for your child to be involved in the research part. If you agree for them to be involved, you may still change your mind and withdraw them at any time.
- Deciding not to take part will not have any negative impact on your family
- During any research activities, if your child does not want to continue then they can stop at any time and they don't have to give a reason.
- If you do decide to withdraw your child, we ask that you contact the PI (contact information provided below) or the offices of XX (contact information provided below).
- ***Questions to check understanding:*** *Do you know that you and your child do not have to take part in this research project, if you or your child do not wish to? Do you have any questions?*

I understand and agree to this 

4. Will our results be confidential?

- You and your child's details and answers to the activities will be kept confidential- only members of our team will have access to you and your child's name and details.
- The only time we would have to disclose these to anyone would be if we were required to by law, because of a safety issue.
- The information we collect, will be kept securely.
- We will use a code to link to your child's results, rather than use their name.
- Everyone in the programme group workshops will be asked to maintain confidentiality of other participants.

I understand and agree to this 

5. Will there be any risks to myself or my child?

- We do not expect that the EASE programme 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. If you or your child find any of the programme workshop activities too uncomfortable, you do not have to take part in them. You do not have to give us any reason for not taking part.
- If you or your child find any of the interview questions too personal, uncomfortable or difficult to answer you do not have to answer them. You do not have to give us any reason for not

answering any question, or for not completing the interviews.

- If you or your child become upset at any time during the study, you and your child will be able to speak with an appropriate member of the research team. If you or our staff become seriously concerned about your or your child's mental wellbeing, we will provide you with support to access available services in your area. .

I understand and agree to this 

6. What are the benefits to my child?

- We expect that both programmes might be helpful for young adolescents experiencing emotional problems. However it may be that you and your child do not experience any direct benefits.
- This research will help us to learn more about the best ways to help young adolescents with emotional problems, so in this way , there will be benefits to children in Lebanon and other countries in the future
- You and your child will not receive compensation (i.e. money or any material goods) for taking part in this study.
- You will receive a small reimbursement for your time and transportation costs for coming towards the interviews that will be taken before and three times after both programmes.

I understand and agree to this 

7. How will the results be used?

- Small meetings in the communities to share research findings will be announced.
- We will write reports on the research and the results so that other interested people may learn from it.
- Nothing that identifies you or your child will be shared at these meetings or at any point during this study, and we will not tell anybody that you or your child have contributed to this research.
- The results will be kept for at least 7 years after the activity is completed.
- At that time the information will be destroyed or information identifying you or your child will be removed from such results.

I understand and agree to this 

8. Whom Do I Call If I Have Questions or Problems?

For questions about the study, or if you have problems, concerns, questions or suggestions about the research, contact the Principle Investigator (contact information provided below).

+31 6 48431702

I understand and agree to this ☐ ☐

I have understood and agree to all of the above and consent to my child participating

_____ _____

Parent or Guardian Signature Date

_____

Parent or Guardian Name

_____

Name (-s) of eligible child or children

_____ _____

Signature of Research Assistant Obtaining Consent Date

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 participants satisfaction. I confirm that the individual has given consent freely.

Thumb print of participant ☐

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

Assent form for participation Phase 2-4

Child Assent To Participate

Hello! My name is …… and along with me are …….. We have come from War Child Holland and live in the North of Lebanon as well.

We are finding out how we best can help young adolescents between 10-14, so adolescents from your age, that have difficulties with their emotions. Our research is called Early Adolescents Skills for Emotions, also called EASE. We want to test the effects of a new programme to help young adolescents who are having some difficulties with their thoughts and feelings.

You have recently had an interview with a member of the research team, and we think that joining one of these programs will be helpful for you as well.

If you agree, you will receive:

- a session with a trained facilitator to provide some information and strategies on how you can help yourself and which other organisation could help you in this area. Your parents will also be invited for this session.

26. OR

- you will go to 7 group sessions for adolescents, one each week that will take 90 minutes. You parents will be invited for 3 group sessions for parents, each 120 minutes. In these sessions we will talk about strategies on how you can handle your emotions and distress.

The programme that you will receive, will be chosen randomly- like flipping a coin. No one will be able to choose which programme he/she will take part in.

If you agree to take part in this EASE study, I will ask you some questions about yourself, your family and how you feel about yourself. The questions will take about an hour, and we will take breaks whenever we need to. Within one week after the questions, we will tell you to which of the programmes you will be assigned and when the actual programmes start. After the programme and also 3 months later we will invite you again to answer some more questions.

[Check:] Do you understand it so far?

You don't have to take part if you don't want to. And if you agree to do it, but then change your mind, we can stop and that's not a problem. If there is a question that you don't want to answer, you can tell me and we can skip it. If you do not feel comfortable during the sessions of both programmes, you can always stop.

Everything that we talk about will be. I will share it with my team, but they will only see the information without your name on it. The only time we would tell anyone about something you tell us, would be if we had a concern for your safety, and in that case we would need to share that information with someone, in order to keep you safe. If you agree to take part, you might be asked to be part of a group discussion later on, or a discussion on your own.

Do you have any questions?

Do you agree to take part?

_____

Child may sign name here

or

give verbal assent now, witnessed by his/her parent or guardian or a trusted/known person to the child

Witness Signature Relationship to Child

Information Sheet

Introduction

Hello! My name is …… and along with me are …….. We have come from War Child Holland and live in the North of Lebanon as well.

We are a group of Researchers and we are now evaluating the program, that you have been part of, called EASE, which aims to reduce distress and improve wellbeing for young adolescents that are experiencing some difficulties with their thoughts and feelings at the moment. We are evaluating whether it is helpful for young adolescents in this community and how we may be able to improve the programme to better help others in Lebanon and other countries in the region. This research programme will take place in several locations in Tripoli and Akkar.

I will now explain a bit more. I am going to ask you if we may ask you or your child some additional questions about the EASE intervention. You (and/or your child) can decide if you or your child will participate in this interview. I may use some words that you may 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, my colleagues/friends here, the principal, or the ministry staff.

You can take time to decide whether or not you will agree to you or your child participating in this additional part of the research. Before you decide, you can talk to anyone you feel comfortable with about the research such as a friend or family member.

Research ID:

INFORMATION SHEET AND CONSENT FORM FOR PARENTS OF CHILDREN TO BE PART OF SCREENING

To be read by Research Assistants

Research assistants –

Please stop to ask the questions throughout and tick the box, or ask parents to tick the boxes to indicate their agreement. If a parent does not agree to any of the sections below, please thank the parent for their time and discontinue the consent interview.

As you listen to the information, I'm going to stop to ask for you to agree, please signal your agreement to me/ tick the appropriate box.

If you are interested in having you and/or your child participate in this interview, I will ask you to sign or provide a thumbprint at the end.

If you have any questions, there will be time for you to ask them of me, or my colleagues.

_____

1. What is the purpose of the research activity?

- As you know, we are developing a programme to help young adolescents here in dealing with their emotional problems. We have delivered the programme to a group of young adolescents and their caregivers in North Lebanon.
- Now that you know more about our programme, we believe that you can help us by telling us your thoughts about the programme, both good and bad. We would like you to be honest about the programme, in order to help us to improve it.
- ***Question to check understanding:*** *Do you know why we are asking you /your child to take part of this interview?*


I understand and agree to this ☐ ☐

2. What will the research involve?

- If you agree for you / your child to take part in this interview, we will ask you/ your child questions about the EASE program.
- The interview will take about 60 minutes. The interviewer will sit down with your child in a comfortable place. If you / your child does not wish to answer any question during the test, you/he/she may say so and the interviewer will move on to the next question.
- You are being invited to take part in this research because you have had experience with the programme in some way and your experience can help us to make the programme better.

I understand and agree to this


☐ ☐

3. Do I/ Does my child have to participate?

- It is your choice whether you / your child participate for this interview.
- You may change your mind and withdraw them at any time.
- Deciding not to take part will not have any negative impact on you / your family
- During any research activities, if you / your child does not want to continue then you / they can stop at any time and you / they don't have to give a reason.
- (only for caregivers): If you do decide to withdraw your child, we ask that you contact the PI (contact information provided below) or the offices of XX (contact information provided below).
- ***Questions to check understanding:*** *Do you know that you / your child do not have to take part in this research project, if you / your child do not wish to? Do you have any questions?*

I understand and agree to this


☐ ☐

4. Will my and my child's results be confidential?

- Your / your child's details and answers to the interview will be kept confidential- only members of our team will have access to you and your child's name and details.
- The only time we would have to disclose these to anyone would be if we were required to by

law, because of a safety issue.

- The information we collect, will be kept securely.
- We will use a code to link to your / your child's results, rather than use your / their name.

I understand and agree to this ☐ ☐

5. Will there be any risks to myself or my child?

- If you/ your child find(s) any of the questions too personal, uncomfortable or difficult to answer you/ you child do/does not have to answer them.
- You/your child do not have to give us any reason for not answering any question, or for not completing the interview. If you/your chid become(s) very upset from talking about your/their experience of the programme, you/he/she will be able to speak to a member of staff who will support you/your child

I understand and agree to this 

6. What are the benefits to my child?

- There may not be any benefits to you from completing this interview, but your participation is likely to help us to develop a more useful programme to help local people in managing emotional problems.
- You will receive a small reimbursement for your time and transportation costs for coming towards the interviews that will be taken before and two times after both programmes.

I understand and agree to this 

7. How will the results be used?

- Small meetings in the communities to share research findings will be announced.
- We will write reports on the research and the results so that other interested people may learn from it.
- Nothing that identifies you or your child will be shared at these meetings or at any point during this study, and we will not tell anybody that you or your child have contributed to this research.
- The results will be kept for at least 7 years after the activity is completed.

I understand and agree to this 

8. Whom Do I Call If I Have Questions or Problems?

For questions about the study, or if you have problems, concerns, questions or suggestions about the research, contact the Principle Investigator (contact information provided below).

+31 6 48431702

I understand and agree to this ☐ ☐

I have understood and agree to all of the above and consent to my child participating

_____ _____

Parent or Guardian Signature Date

_____

Parent or Guardian Name

_____

Name (-s) of eligible child or children

_____ _____

Signature of Research Assistant Obtaining Consent Date

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 participants satisfaction. I confirm that the individual has given consent freely.

Thumb print of participant ☐

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

Assent form for Evaluation Interview

Child Assent To Participate

Hello! My name is …… and along with me are ……. We have come from War Child Holland and live in the North of Lebanon as well.

As you might know, we are finding out how we how we best can help young adolescents between 10-14, so adolescents from your age, that have difficulties with their emotions. That is the reason that we would like to learn more from your experience with the EASE intervention you have been involved in so far.

If you will join the interview, we will ask you some questions about how you experienced the EASE intervention. The interview will take about 60 minutes. The interviewer will sit down with you in a comfortable place. If you do not wish to answer any question during the test, you may say so and the

interviewer will move on to the next question.

[Check:] Do you understand it so far?

You don't have to take part in this test if you don't want to. And if you agree to do it, but then change your mind, we can stop and that's not a problem. If there is a question that you don't want to answer, you can tell me and we can skip it. If you do not feel comfortable you can always stop the test.

Everything that we talk about will be confidential – this means that nothing that you say will be shared with your mother, father, school, or community. I will share it with my team, but they will only see the information without your name on it. The only time we would tell anyone about something you tell us, would be if we had a concern for your safety, and in that case we would need to share that information with someone, in order to keep you safe.

Do you have any questions?

Do you agree to take part?

_____

Child may sign name here

or

give verbal assent now, witnessed by his/her parent or guardian or a trusted/known person to the child

Witness Signature Relationship to Child

WP5: Community Implementation; Study 1 (The Netherlands)

Informatie over het STRENGTHS onderzoek

Nederlandse titel:
Implementatie van Problem Management Plus bij Syrische vluchtelingen

Geachte heer/mevrouw,

Wij vragen u om mee te doen aan een onderzoek naar de haalbaarheid en toepasbaarheid van Problem Management Plus (PM+), een hulpprogramma voor psychische klachten als somberheid, stress en angst.

Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt ook de onafhankelijk deskundige, die aan het eind van deze brief genoemd wordt, om aanvullende informatie vragen. U kunt er ook over praten met uw partner, vrienden of familie (zie bijlage C).

1. Algemene informatie

Dit onderzoek is opgezet door de Vrije Universiteit (VU) Amsterdam en wordt uitgevoerd door onderzoekers van de VU. De medisch ethische toetsingscommissie VUmc heeft dit onderzoek goedgekeurd. Algemene informatie over de toetsing van onderzoek vindt u in de brochure 'Medisch-wetenschappelijk onderzoek' (zie bijlage C).

2. Doel en achtergrond van het onderzoek

Somberheid, stress en angst zijn veelvoorkomende psychische klachten bij Syrische vluchtelingen. Deze klachten kunnen zijn ontstaan naar aanleiding van schokkende ervaringen in Syrië of in de periode na het vertrek uit Syrië. Psychische klachten kunnen veel leed veroorzaken en leiden tot belemmeringen in het uitvoeren van dagelijkse activiteiten.

Het doel van het onderzoek is om uit te zoeken of een nieuw programma, genaamd "Problem Management Plus (PM+)", veelvoorkomende psychische klachten, zoals angst en somberheid, bij Syrische vluchtelingen vermindert. Het PM+ programma is ontwikkeld door de Wereldgezondheidsorganisatie (WHO).

Eerder onderzoek naar PM+ wijst uit dat het programma effectief is in het verminderen van psychische klachten. Met dit onderzoek willen we uitzoeken of het ook bruikbaar is voor Syrische vluchtelingen in Nederland.

3. Wat meedoen inhoudt

Voor dit onderzoek nodigen wij Syrische vluchtelingen uit die 18 jaar of ouder zijn.

Meedoen aan dit onderzoek betekent dat u over een periode van vijf maanden een aantal afspraken heeft. Het gaat dan om het PM+ programma en het invullen van vragenlijsten.

Screenings-vragen

Eerst bepalen we of u kunt meedoen. Een interviewer stelt u daarom eerst een aantal vragen over psychische klachten, zoals somberheid en angst, over uw algemeen functioneren, en over achtergrondgegevens zoals leeftijd en geslacht. De screenings-vragen zullen in totaal 20 minuten van uw tijd kosten. Wanneer uit deze vragen blijkt dat u enkele klachten ervaart zoals somberheid en angst, en problemen in uw algemeen functioneren, kunt u mee doen aan ons onderzoek.

Hieronder leggen we uit wat het onderzoek verder inhoudt.

Het PM+ programma

Het PM+ programma is een korte behandeling van in totaal vijf sessies die uitgevoerd wordt door getrainde, niet-professionele, Syrische hulpverleners. Een PM+ gesprek is in het Arabisch en duurt 90 minuten. U zult met de PM+ behandelaar over uw klachten praten. Tijdens het PM+ programma krijgt u uitleg over uw klachten en zult u oefeningen doen om stress reacties te verminderen. De PM+ behandelaar zal bijvoorbeeld ademhalingsoefeningen met u doen. U krijgt tips over hoe u in het dagelijks leven met de klachten om kunt gaan. In de PM+ gesprekken wordt gebruik gemaakt van technieken gebaseerd op cognitieve gedragstherapie. Cognitieve gedragstherapie is bewezen effectief voor het verminderen psychische klachten, zoals somberheid en angst.

Vragenlijsten

Bij deelnemers aan het onderzoek worden in totaal drie keer vragenlijsten over psychische klachten, zoals somberheid, angst en posttraumatische stress afgenomen. Dit zijn andere vragenlijsten dan de screenings-vragen. Ook krijgt u vragen over mogelijke ingrijpende gebeurtenissen die u heeft meegemaakt, uw algemeen lichamelijk functioneren en gebruik van de gezondheidszorg. Het afnemen van de vragenlijsten duurt ongeveer één tot anderhalf uur per keer.

Procedure

Na het invullen van de vragenlijsten wordt u in de PM+ groep of in de controlegroep ingedeeld. De indeling wordt door loting bepaald (willekeurig), vergelijkbaar met het opgooien van een munt. De helft

van de deelnemers krijgt vijf weken lang, één keer per week, het individuele PM+ programma. De andere helft van de deelnemers krijgt het PM+ programma niet (de controlegroep). Wel krijgt de controlegroep, evenals de PM+ groep, de gebruikelijke zorg.

Wanneer u in de PM+ groep wordt ingedeeld, krijgt u vijf PM+ gesprekken van ieder 90 minuten. U zult dan één op één met een Syrische PM+ behandelaar praten over uw klachten en krijgt advies over hoe u met uw klachten om kunt gaan.

De deelnemers in de PM+ groep en de controlegroep worden nog twee keer uitgenodigd voor het afnemen van vragenlijsten. Deze vinden zeven weken en drie maanden later plaats.

De onderzoeker weet niet of u wordt ingeloot in de PM+ groep of in de controlegroep. Dit is nodig om te voorkomen dat deze kennis de resultaten van het onderzoek kan beïnvloeden. Wij willen u daarom vragen de onderzoeker niet te vertellen in welke groep u ben ingedeeld.

4. Wat wordt er van u verwacht

Om het onderzoek goed te laten verlopen, is het belangrijk dat u op de afgesproken tijden komt.

Verder is het belangrijk dat u contact opneemt met de onderzoeker:

- Als u in een ziekenhuis wordt opgenomen of behandeld.
- Als u plotseling gezondheidsklachten krijgt.
- Als u niet meer wilt meedoen aan het onderzoek.
- Als uw contactgegevens wijzigen.

5. Mogelijke voor- en nadelen

Het is belangrijk dat u de mogelijke voor- en nadelen goed afweegt voordat u besluit mee te doen.

Voordelen:
Problem Management Plus (PM+) kan uw psychische klachten verminderen, maar zeker is dat niet. Als u in de controle groep komt, heeft u zelf geen voordeel van meedoen aan dit onderzoek. Uw deelname kan wel bijdragen aan meer kennis over de werking van kortdurende psychologische programma's voor Syrische vluchtelingen, zoals PM+, op het verminderen van veelvoorkomende psychische klachten.

Nadelen:
Een mogelijk nadeel is dat u tijdelijk meer spanning of angst ervaart doordat u wordt gevraagd over uw gevoelens te praten. Praten over gevoelens of emoties kan voor sommige mensen moeilijk zijn. U mag altijd vragen overslaan wanneer u dit prettiger vindt.

Wanneer u wordt ingeloot in de PM+ groep, is het mogelijk dat u tijdelijk meer spanning of angst

gedurende de PM+ gesprekken ervaart. De PM+ behandelaren zijn getraind in het omgaan met gevoelens van spanning en angst. Er is ook altijd een ervaren medewerker van de GGZ instelling i-Psy beschikbaar die ondersteuning kan verlenen en eventueel kan helpen in het bieden van meer specialistische zorg of u gericht kan verwijzen.

Deelname aan het onderzoek betekent ook dat u tijd kwijt bent voor de afname van vragenlijsten, en voor de PM+ groep, aan het volgen van de PM+ gesprekken.

6. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Als u niet wilt meedoen, kunt u contact opnemen met uw huisarts voor de gebruikelijke zorg voor uw psychische klachten. De onderzoeker kan u meer vertellen over de behandelingsmogelijkheden die er zijn en de voor- en nadelen daarvan.

Als u wel meedoet, kunt u zich altijd bedenken en toch stoppen, ook tijdens het onderzoek. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker.
De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

Als er nieuwe informatie over het onderzoek is die belangrijk voor u is, laat de onderzoeker dit aan u weten. U wordt dan gevraagd of u blijft meedoen.

7. Einde van het onderzoek

Uw deelname aan het onderzoek stopt als:

- U bij de screenings-vragen aangeeft geen psychische klachten, zoals depressie of angst, of geen dagelijkse beperkingen ervaart;
- Er na de screenings-vragen in totaal drie keer een set aan vragenlijsten zijn afgenomen;
- U zelf kiest om te stoppen;
- De onderzoeker het beter voor u vindt om te stoppen;
- De VU, de overheid of de beoordelende medisch ethische toetsingscommissie, besluit om het onderzoek te stoppen.

Het hele onderzoek is afgelopen als alle deelnemers klaar zijn.

Na het verwerken van alle gegevens informeert de onderzoeker u over de belangrijkste uitkomsten van het onderzoek. Dit gebeurt ongeveer twee jaar na uw deelname.

8. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat er medische en persoonsgegevens van u worden verzameld en gebruikt. Elke deelnemer krijgt een code die op de gegevens komt te staan. Uw naam en andere

persoonsgegevens worden weggelaten.

Uw gegevens
Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers op de VU weten welke code u heeft. De sleutel voor de code blijft bij de onderzoeker. Ook in rapporten over het onderzoek wordt alleen die code gebruikt, en worden alleen resultaten over de hele groep beschreven, die niet terug te zijn herleiden naar individuele deelnemers.

Sommige mensen mogen uw medische en persoonsgegevens inzien. Dit is om te controleren of het onderzoek goed en betrouwbaar uitgevoerd is. Algemene informatie hierover vindt u in de brochure 'Medisch-wetenschappelijk onderzoek'. Mensen die uw gegevens mogen inzien zijn het VU onderzoeksteam, de veiligheidscommissie die het onderzoek in de gaten houdt, een controleur van het Amsterdam Public Health Institute en de Inspectie voor de Gezondheidszorg. Zij houden uw gegevens geheim. Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw medische en persoonsgegevens.

De VU onderzoeker bewaart uw gegevens (geen persoonsgegevens) 15 jaar.

Benadering voor vervolgonderzoek
Mogelijk willen wij u in de toekomst nog benaderen voor vervolgonderzoek om te kijken hoe het u vergaat. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken.

Dit onderzoek staat ook in een overzicht van medisch-wetenschappelijke onderzoeken, namelijk in het Nederlands Trial Register (http://www.trialregister.nl/trialreg/index.asp). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen. U vindt dit onderzoek onder [studie aanduiding].

9. Verzekering voor deelnemers
Voor iedereen die meedoet aan dit onderzoek is een verzekering afgesloten. De verzekering dekt schade door het onderzoek. Niet alle schade is gedekt. In **bijlage B** vindt u meer informatie over de verzekering. Daar staat ook aan wie u schade kunt melden.

10. Vergoeding voor meedoen
Meedoen aan het PM+ programma kost u niets. U wordt niet betaald voor het meedoen aan dit onderzoek. Wel krijgt u een vergoeding wanneer u reiskosten maakt voor het afnemen van de vragenlijsten.

11. Heeft u vragen?

Bij vragen kunt u contact opnemen met het VU onderzoeksteam. Voor onafhankelijk advies over meedoen aan dit onderzoek kunt u terecht bij de onafhankelijke deskundige (Prof. dr. M. Huibers). Hij weet veel over het onderzoek, maar heeft niets te maken met dit onderzoek.
Bij klachten kunt u het beste terecht bij de klachtenfunctionaris (Prof. dr. A. van Straten). Alle gegevens vindt u in **bijlage A**: Contactgegevens.

12. Ondertekening toestemmingsformulier

Wanneer u voldoende bedenktijd heeft gehad (minimaal één week), wordt u gevraagd te beslissen over deelname aan dit onderzoek. Indien u toestemming geeft, zullen wij u vragen deze op de bijbehorende toestemmingsverklaring schriftelijk te bevestigen. Door uw schriftelijke toestemming geeft u aan dat u de informatie heeft begrepen en instemt met deelname aan het onderzoek.
Het handtekeningenblad wordt door de onderzoeker bewaard. U krijgt een kopie of een tweede exemplaar van deze toestemmingsverklaring.

Dank voor uw aandacht.

13. Bijlagen bij deze informatie

A. Contactgegevens
B. Informatie over de verzekering
C. Toestemmingsformulier
D. Brochure ‘Medisch-wetenschappelijk onderzoek. Algemene informatie voor de proefpersoon’ (versie Maart 2017)

Bijlage A: Contactgegevens

Onderzoekers VU Amsterdam:
Mw. Anne de Graaff, a.m.de.graaff@vu.nl / 020-5983833
Bereikbaar: maandag t/m vrijdag tussen 09.00-17.00 uur

Mw. Dr. Marit Sijbrandij, e.m.sijbrandij@vu.nl

Lokale hoofdonderzoeker i-psy: Mw. Yvette van Son, y.vanson@i-psy.nl / 088-3589200

Onafhankelijk deskundige: Dhr. Prof. dr. M. Huibers, m.j.h.huibers@vu.nl

Klachtenfunctionaris: Mw. prof. dr. Annemieke van Straten, a.van.straten@vu.nl

Bijlage B: informatie over de verzekering

Voor iedereen die meedoet aan dit onderzoek, heeft de Vrije Universiteit Amsterdam een verzekering

afgesloten. De verzekering dekt schade door deelname aan het onderzoek. Dit geldt voor schade tijdens het onderzoek of binnen vier jaar na het einde ervan. Schade moet u binnen die vier jaar aan de verzekeraar hebben gemeld.

De verzekering dekt niet alle schade. Onderaan deze tekst staat in het kort welke schade niet wordt gedekt.
Deze bepalingen staan in het Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen. Dit besluit staat op www.ccmo.nl, de website van de Centrale Commissie Mensgebonden Onderzoek (zie 'Bibliotheek' en dan 'Wet- en regelgeving').

Bij schade kunt u direct contact leggen met de verzekeraar .

De verzekeraar van het onderzoek is:
Naam: CNA Insurance Company Ltd.
Adres: Strawisnkylaan 703, 1077 XX Amsterdam
Telefoonnummer: 020-5737270

De verzekering biedt een dekking van € 650.000 per deelnemer, maximaal € 5.000.000 voor het hele onderzoek, en € 7.500.000 per jaar voor alle onderzoeken tezamen.

De verzekering dekt de volgende schade **niet**:
- Schade door een risico waarover u in de schriftelijke informatie bent ingelicht. Dit geldt niet als het risico zich ernstiger voordoet dan was voorzien of als het risico heel onwaarschijnlijk was;
- Schade aan uw gezondheid die ook zou zijn ontstaan als u niet aan het onderzoek had meegedaan;
- Schade door het niet (volledig) opvolgen van aanwijzingen of instructies;
- Schade aan uw nakomelingen, als gevolg van een negatief effect van het onderzoek op u of uw nakomelingen;
- schade door een bestaande behandelmethode bij onderzoek naar bestaande behandelmethoden.

Bijlage C: Toestemmingsformulier deelnemer

STRENGTHS: Implementatie van Problem Management Plus bij Syrische vluchtelingen

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee

te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.

- Ik weet dat sommige mensen mijn gegevens kunnen inzien. Die mensen staan vermeld in deze informatiebrief.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan (zie ook sectie 4).
- Ik geef toestemming om mijn gegevens op de onderzoekslocatie nog 15 jaar na dit onderzoek te bewaren.

- Ik geef □ **wel**
  □ **geen**
  toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek.
- Ik wil meedoen aan dit onderzoek.

Naam deelnemer:
Handtekening: Datum : __ / __ / __

Indien deelnemer analfabeet
Naam getuige:
Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):
Handtekening: Datum: __ / __ / __

De proefpersoon krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Informatie over het STRENGTHS onderzoek

Nederlandse titel:
Implementatie van Problem Management Plus bij Syrische vluchtelingen

Geachte heer/mevrouw,

Wij vragen u om mee te doen aan een onderzoek naar de haalbaarheid en effectiviteit van Problem Management Plus (PM+), een hulpprogramma voor psychische klachten als somberheid, stress en angst.

Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt ook de onafhankelijk deskundige, die aan het eind van deze brief genoemd wordt, om aanvullende informatie vragen. U kunt er ook over praten met uw partner, vrienden of familie (zie bijlage C).

1. Algemene informatie

Dit onderzoek is opgezet door de Vrije Universiteit (VU) Amsterdam en wordt uitgevoerd door onderzoekers van de VU. De medisch ethische toetsingscommissie VUmc heeft dit onderzoek goedgekeurd. Algemene informatie over de toetsing van onderzoek vindt u in de brochure ‘Medisch-wetenschappelijk onderzoek’ (zie bijlage C).

2. Doel en achtergrond van het onderzoek

Somberheid, stress en angst zijn veelvoorkomende psychische klachten bij Syrische vluchtelingen. Deze klachten kunnen zijn ontstaan naar aanleiding van schokkende ervaringen in Syrië of in de periode na het vertrek uit Syrië. Psychische klachten kunnen veel leed veroorzaken en leiden tot belemmeringen in het uitvoeren van dagelijkse activiteiten.

Het doel van het onderzoek is om uit te zoeken of een nieuw programma, genaamd “Problem Management Plus (PM+)”, veelvoorkomende psychische klachten, zoals angst en somberheid, bij Syrische vluchtelingen vermindert. Het PM+ programma is ontwikkeld door de Wereldgezondheidsorganisatie (WHO).

Eerder onderzoek naar PM+ wijst uit dat het programma effectief is in het verminderen van psychische klachten. Met dit onderzoek willen we uitzoeken of het ook bruikbaar is voor Syrische vluchtelingen in Nederland.

3. Wat meedoen inhoudt

Voor dit onderzoek nodigen wij Syrische vluchtelingen uit die 18 jaar of ouder zijn.

Meedoen aan dit onderzoek betekent dat u over een periode van 12 maanden een aantal afspraken heeft. Het gaat dan om het PM+ programma en het invullen van vragenlijsten.

Screenings-vragen

Eerst bepalen we of u kunt meedoen. Een interviewer stelt u daarom eerst een aantal vragen over psychische klachten, zoals somberheid en angst, over uw algemeen functioneren, en over achtergrondgegevens zoals leeftijd en geslacht. De screenings-vragen zullen in totaal 20 minuten van uw tijd kosten. Wanneer uit deze vragen blijkt dat u enkele klachten ervaart zoals somberheid en angst, en problemen in uw algemeen functioneren, kunt u mee doen aan ons onderzoek.

Hieronder leggen we uit wat het onderzoek verder inhoudt.

Het PM+ programma

Het PM+ programma is een korte behandeling van in totaal vijf sessies die uitgevoerd wordt door getrainde, niet-professionele, Syrische hulpverleners. Een PM+ gesprek is in het Arabisch en duurt 90 minuten. U zult met de PM+ behandelaar over uw klachten praten. Tijdens het PM+ programma krijgt u uitleg over uw klachten en zult u oefeningen doen om stress reacties te verminderen. De PM+ behandelaar zal bijvoorbeeld ademhalingsoefeningen met u doen. U krijgt tips over hoe u in het dagelijks leven met de klachten om kunt gaan. In de PM+ gesprekken wordt gebruik gemaakt van technieken gebaseerd op cognitieve gedragstherapie. Cognitieve gedragstherapie is bewezen effectief voor het verminderen psychische klachten, zoals somberheid en angst.

Vragenlijsten

Bij deelnemers aan het onderzoek worden in totaal vier keer vragenlijsten over psychische klachten, zoals somberheid, angst en posttraumatische stress afgenomen. Dit zijn andere vragenlijsten dan de screenings-vragen. Ook krijgt u vragen over mogelijke ingrijpende gebeurtenissen die u heeft meegemaakt, uw algemeen lichamelijk functioneren en gebruik van de gezondheidszorg. Het afnemen van de vragenlijsten duurt ongeveer één tot anderhalf uur per keer.

Procedure

Na het invullen van de vragenlijsten wordt u in de PM+ groep of in de controlegroep ingedeeld. De indeling wordt door loting bepaald (willekeurig), vergelijkbaar met het opgooien van een munt. De helft van de deelnemers krijgt vijf weken lang, één keer per week, het individuele PM+ programma. De andere helft van de deelnemers krijgt het PM+ programma niet (de controlegroep). Wel krijgt de controlegroep, evenals de PM+ groep, de gebruikelijke zorg.

Wanneer u in de PM+ groep wordt ingedeeld, krijgt u vijf PM+ gesprekken van ieder 90 minuten. U zult dan één op één met een Syrische PM+ behandelaar praten over uw klachten en krijgt advies over hoe u met uw klachten om kunt gaan.

De deelnemers in de PM+ groep en de controlegroep worden nog drie keer uitgenodigd voor het afnemen van vragenlijsten. Deze vinden zeven weken, drie maanden en 12 maanden later plaats.

De onderzoeker weet niet of u wordt ingeloot in de PM+ groep of in de controlegroep. Dit is nodig om te voorkomen dat deze kennis de resultaten van het onderzoek kan beïnvloeden. Wij willen u daarom vragen de onderzoeker niet te vertellen in welke groep u ben ingedeeld.

4. Wat wordt er van u verwacht

Om het onderzoek goed te laten verlopen, is het belangrijk dat u op de afgesproken tijden komt.

Verder is het belangrijk dat u contact opneemt met de onderzoeker:

- Als u in een ziekenhuis wordt opgenomen of behandeld.
- Als u plotseling gezondheidsklachten krijgt.
- Als u niet meer wilt meedoen aan het onderzoek.
- Als uw contactgegevens wijzigen.

5. Mogelijke voor- en nadelen

Het is belangrijk dat u de mogelijke voor- en nadelen goed afweegt voordat u besluit mee te doen.

Voordelen:
Problem Management Plus (PM+) kan uw psychische klachten verminderen, maar zeker is dat niet. Als u in de controle groep komt, heeft u zelf geen voordeel van meedoen aan dit onderzoek. Uw deelname kan wel bijdragen aan meer kennis over de werking van kortdurende psychologische programma's voor Syrische vluchtelingen, zoals PM+, op het verminderen van veelvoorkomende psychische klachten.

Nadelen:
Een mogelijk nadeel is dat u tijdelijk meer spanning of angst ervaart doordat u wordt gevraagd over uw gevoelens te praten. Praten over gevoelens of emoties kan voor sommige mensen moeilijk zijn. U mag altijd vragen overslaan wanneer u dit prettiger vindt.

Wanneer u wordt ingeloot in de PM+ groep, is het mogelijk dat u tijdelijk meer spanning of angst gedurende de PM+ gesprekken ervaart. De PM+ behandelaren zijn getraind in het omgaan met gevoelens van spanning en angst. Er is ook altijd een ervaren medewerker van de GGZ instelling i-Psy beschikbaar die ondersteuning kan verlenen en eventueel kan helpen in het bieden van meer

specialistische zorg of u gericht kan verwijzen.

Deelname aan het onderzoek betekent ook dat u tijd kwijt bent voor de afname van vragenlijsten, en voor de PM+ groep, aan het volgen van de PM+ gesprekken.

6. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Als u niet wilt meedoen, kunt u contact opnemen met uw huisarts voor de gebruikelijke zorg voor uw psychische klachten. De onderzoeker kan u meer vertellen over de behandelingsmogelijkheden die er zijn en de voor- en nadelen daarvan.

Als u wel meedoet, kunt u zich altijd bedenken en toch stoppen, ook tijdens het onderzoek. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker.
De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

Als er nieuwe informatie over het onderzoek is die belangrijk voor u is, laat de onderzoeker dit aan u weten. U wordt dan gevraagd of u blijft meedoen.

7. Einde van het onderzoek

Uw deelname aan het onderzoek stopt als:

- U bij de screenings-vragen aangeeft geen psychische klachten, zoals depressie of angst, of geen dagelijkse beperkingen ervaart;
- Er na de screenings-vragen in totaal vier keer een set aan vragenlijsten zijn afgenomen;
- U zelf kiest om te stoppen;
- De onderzoeker het beter voor u vindt om te stoppen;
- De VU, de overheid of de beoordelende medisch ethische toetsingscommissie, besluit om het onderzoek te stoppen.

Het hele onderzoek is afgelopen als alle deelnemers klaar zijn.

Na het verwerken van alle gegevens informeert de onderzoeker u over de belangrijkste uitkomsten van het onderzoek. Dit gebeurt ongeveer twee jaar na uw deelname.

8. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat er medische en persoonsgegevens van u worden verzameld en gebruikt. Elke deelnemer krijgt een code die op de gegevens komt te staan. Uw naam en andere persoonsgegevens worden weggelaten.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers op de VU weten welke code u heeft. De sleutel voor de code blijft bij de onderzoeker. Ook in rapporten over het onderzoek wordt alleen die code gebruikt, en worden alleen resultaten over de hele groep beschreven, die niet terug te zijn herleiden naar individuele deelnemers.

Sommige mensen mogen uw medische en persoonsgegevens inzien. Dit is om te controleren of het onderzoek goed en betrouwbaar uitgevoerd is. Algemene informatie hierover vindt u in de brochure 'Medisch-wetenschappelijk onderzoek'. Mensen die uw gegevens mogen inzien zijn het VU onderzoeksteam, de veiligheidscommissie die het onderzoek in de gaten houdt, een controleur van het Amsterdam Public Health Institute en de Inspectie voor de Gezondheidszorg. Zij houden uw gegevens geheim. Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw medische en persoonsgegevens.

De VU onderzoeker bewaart uw gegevens (geen persoonsgegevens) 15 jaar.

Benadering voor vervolgonderzoek
Mogelijk willen wij u in de toekomst nog benaderen voor vervolgonderzoek om te kijken hoe het u vergaat. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken.

Dit onderzoek staat ook in een overzicht van medisch-wetenschappelijke onderzoeken, namelijk in het Nederlands Trial Register (http://www.trialregister.nl/trialreg/index.asp). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen. U vindt dit onderzoek onder [studie aanduiding].

9. Verzekering voor deelnemers

Voor iedereen die meedoet aan dit onderzoek is een verzekering afgesloten. De verzekering dekt schade door het onderzoek. Niet alle schade is gedekt. In **bijlage B** vindt u meer informatie over de verzekering. Daar staat ook aan wie u schade kunt melden.

10. Vergoeding voor meedoen

Meedoen aan het PM+ programma kost u niets. U wordt niet betaald voor het meedoen aan dit onderzoek. Wel krijgt u een vergoeding wanneer u reiskosten maakt voor het afnemen van de vragenlijsten.

11. Heeft u vragen?

Bij vragen kunt u contact opnemen met het VU onderzoeksteam. Voor onafhankelijk advies over meedoen aan dit onderzoek kunt u terecht bij de onafhankelijke deskundige (Prof. dr. M. Huibers). Hij weet veel over het onderzoek, maar heeft niets te maken met dit onderzoek.

Bij klachten kunt u het beste terecht bij de klachtenfunctionaris (Prof. dr. A. van Straten). Alle gegevens vindt u in **bijlage A**: Contactgegevens.

12. Ondertekening toestemmingsformulier

Wanneer u voldoende bedenktijd heeft gehad (minimaal één week), wordt u gevraagd te beslissen over deelname aan dit onderzoek. Indien u toestemming geeft, zullen wij u vragen deze op de bijbehorende toestemmingsverklaring schriftelijk te bevestigen. Door uw schriftelijke toestemming geeft u aan dat u de informatie heeft begrepen en instemt met deelname aan het onderzoek.
Het handtekeningenblad wordt door de onderzoeker bewaard. U krijgt een kopie of een tweede exemplaar van deze toestemmingsverklaring.

Dank voor uw aandacht.

13. Bijlagen bij deze informatie

A. Contactgegevens
B. Informatie over de verzekering
C. Toestemmingsformulier
D. Brochure 'Medisch-wetenschappelijk onderzoek. Algemene informatie voor de proefpersoon' (versie Maart 2017)

Bijlage A: Contactgegevens

Onderzoekers VU Amsterdam:
Mw. Anne de Graaff, a.m.de.graaff@vu.nl / 020-5983833
Bereikbaar: maandag t/m vrijdag tussen 09.00-17.00 uur

Mw. Dr. Marit Sijbrandij, e.m.sijbrandij@vu.nl

Lokale hoofdonderzoeker i-psy: Mw. Yvette van Son, y.vanson@i-psy.nl / 088-3589200

Onafhankelijk deskundige: Dhr. Prof. dr. M. Huibers, m.j.h.huibers@vu.nl

Klachtenfunctionaris: Mw. prof. dr. Annemieke van Straten, a.van.straten@vu.nl

Bijlage B: informatie over de verzekering

Voor iedereen die meedoet aan dit onderzoek, heeft de Vrije Universiteit Amsterdam een verzekering afgesloten. De verzekering dekt schade door deelname aan het onderzoek. Dit geldt voor schade tijdens het onderzoek of binnen vier jaar na het einde ervan. Schade moet u binnen die vier jaar aan de

verzekeraar hebben gemeld.

De verzekering dekt niet alle schade. Onderaan deze tekst staat in het kort welke schade niet wordt gedekt.
Deze bepalingen staan in het Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen. Dit besluit staat op www.ccmo.nl, de website van de Centrale Commissie Mensgebonden Onderzoek (zie 'Bibliotheek' en dan 'Wet- en regelgeving').

Bij schade kunt u direct contact leggen met de verzekeraar .

De verzekeraar van het onderzoek is:
Naam: CNA Insurance Company Ltd.
Adres: Strawisnkylaan 703, 1077 XX Amsterdam
Telefoonnummer: 020-5737270

De verzekering biedt een dekking van € 650.000 per deelnemer, maximaal € 5.000.000 voor het hele onderzoek, en € 7.500.000 per jaar voor alle onderzoeken tezamen.

De verzekering dekt de volgende schade **niet**:
- Schade door een risico waarover u in de schriftelijke informatie bent ingelicht. Dit geldt niet als het risico zich ernstiger voordoet dan was voorzien of als het risico heel onwaarschijnlijk was;
- Schade aan uw gezondheid die ook zou zijn ontstaan als u niet aan het onderzoek had meegedaan;
- Schade door het niet (volledig) opvolgen van aanwijzingen of instructies;
- Schade aan uw nakomelingen, als gevolg van een negatief effect van het onderzoek op u of uw nakomelingen;
- schade door een bestaande behandelmethode bij onderzoek naar bestaande behandelmethoden.

Bijlage C: Toestemmingsformulier deelnemer

STRENGTHS: Implementatie van Problem Management Plus bij Syrische vluchtelingen

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik weet dat sommige mensen mijn gegevens kunnen inzien. Die mensen staan vermeld in deze

informatiebrief.

- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan (zie ook sectie 4).
- Ik geef toestemming om mijn gegevens op de onderzoekslocatie nog 15 jaar na dit onderzoek te bewaren.

- Ik geef □ **wel**
  □ **geen**
  toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek.
- Ik wil meedoen aan dit onderzoek.

Naam deelnemer:
Handtekening: Datum : __ / __ / __

Indien deelnemer analfabeet
Naam getuige:
Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):
Handtekening: Datum: __ / __ / __

De proefpersoon krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Informatie over het STRENGTHS onderzoek: audio opnames PM+ gesprekken

Nederlandse titel:
Implementatie van Problem Management Plus bij Syrische vluchtelingen

Geachte heer/mevrouw,

U doet mee aan het STRENGTHS onderzoek en u bent ingedeeld in de PM+ groep. In de aankomende weken zult u vijf keer een PM+ gesprek met een Syrische hulpverlener voeren. Wij willen u vragen of wij deze gesprekken mogen opnemen op audio (geen video). Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft.

Waarom willen wij de gesprekken opnemen?
Tijdens het PM+ programma krijgt u uitleg over uw klachten en zult u oefeningen doen om stress reacties te verminderen. Wij gebruiken de audio-opnames zodat de onderzoeker en de supervisor deze kunnen naluisteren. Zo kunnen zij nagaan of het PM+ programma op de juiste manier wordt uitgevoerd.

Bewaren van de opnames
Uw persoonsgegevens (zoals uw naam) zullen niet op de audio-opname komen. Elke deelnemer heeft een code die we zullen gebruiken voor de audio-opnames. Alleen de onderzoekers op de VU weten welke code u heeft. Nadat het STRENGTHS onderzoek is afgelopen, zullen wij de opnames vernietigen.

Hieronder kunt u aangeven of u akkoord gaat met het opnemen van de gesprekken. U kunt deze toestemming altijd weer intrekken.

Toestemming
- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen dat ik toch niet meer wil dat de PM+ gesprekken worden opgenomen. Daarvoor hoef ik geen reden te geven.

Ik geef □ **wel**
□ **geen**

toestemming om de PM+ gesprekken op te nemen op audio.

Naam deelnemer:
Handtekening: Datum : __ / __ / __

Indien deelnemer analfabeet
Naam getuige:
Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Naam onderzoeker (of diens vertegenwoordiger):
Handtekening: Datum: __ / __ / __

De proefpersoon krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Informed Consent Forms Phase 3 and 5 (i-Psy staff members, PM+ providers, PM+ participants and significant others)

Informatie over het STRENGTHS onderzoek

Nederlandse titel:
Implementatie van Problem Management Plus bij Syrische vluchtelingen

Geachte heer/mevrouw,

U bent als supervisor of medewerker van i-Psy betrokken bij een onderzoek naar de effectiviteit van het PM+ programma. In deze brief willen wij u vragen om mee te doen aan een interview om het PM+ programma te evalueren.

Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Voordat u beslist of u wilt meedoen aan dit interview, krijgt u uitleg over wat het interview inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt ook de onafhankelijk deskundige, die aan het eind van deze brief genoemd wordt, om aanvullende informatie vragen. Verdere informatie over meedoen aan zo'n onderzoek staat in de bijgevoegde brochure 'Medisch-wetenschappelijk onderzoek'.

103. Algemene informatie

Dit onderzoek is opgezet door de Vrije Universiteit (VU) Amsterdam en wordt uitgevoerd door onderzoekers van de VU. De medisch ethische toetsingscommissie VUmc heeft dit onderzoek goedgekeurd. Algemene informatie over de toetsing van onderzoek vindt u in de brochure 'Medisch-wetenschappelijk onderzoek'.

104. Achtergrond en doel van het onderzoek

Somberheid, stress en angst zijn veelvoorkomende psychische klachten bij Syrische vluchtelingen. Deze klachten kunnen zijn ontstaan naar aanleiding van schokkende ervaringen in Syrië of in de periode na het vertrek uit Syrië. Psychische klachten kunnen veel leed veroorzaken en leiden tot belemmeringen in het uitvoeren van dagelijkse activiteiten.

Het doel van het STRENGTHS onderzoek is om uit te zoeken of "Problem Management Plus (PM+)" veelvoorkomende psychische klachten, zoals angst en somberheid, bij Syrische vluchtelingen vermindert. Het PM+ programma is ontwikkeld door de Wereldgezondheidsorganisatie (WHO). Eerder onderzoek naar PM+ wijst uit dat het programma effectief is in het verminderen van psychische klachten. Met dit onderzoek willen we uitzoeken of het ook bruikbaar is voor Syrische vluchtelingen in Nederland.

Het doel van dit interview is om uit te zoeken wat de goede kanten zijn aan het PM+ programma, wat er verbeterd zou kunnen worden en welke stappen we moeten ondernemen om het programma beschikbaar te maken voor andere Syrische vluchtelingen met psychische klachten.

105. Wat meedoen inhoudt

U kunt ons helpen door, als betrokkene bij het PM+ onderzoek, uw mening over het PM+ programma met ons te delen. We zullen u niet vragen informatie met ons te delen die persoonlijk of vertrouwelijk is. Dit interview zal ongeveer 30 tot 60 minuten duren.

106. Mogelijke voor- en nadelen

Het is belangrijk dat u de mogelijke voor- en nadelen goed afweegt voordat u besluit mee te doen.

U heeft zelf geen voordeel van meedoen aan dit interview. Uw deelname kan wel bijdragen aan meer kennis over het PM+ programma. We zullen deze informatie gebruiken om het PM+ programma te verbeteren en beschikbaar te maken voor andere Syrische vluchtelingen met psychische klachten.

Het kan zijn dat u sommige vragen onprettig vindt. U doet vrijwillig mee en bent niet verplicht de vragen te beantwoorden. U mag tijdens het onderzoek stoppen.

107. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Als u wel meedoet, kunt u zich altijd bedenken en toch stoppen, ook tijdens het onderzoek. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker.
De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

108. Gebruik en bewaren van uw gegevens

Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet ‘gecodeerd’. Uw naam wordt dan niet meer gebruikt. Het interview wordt opgenomen op audio. Op de audio opname zullen geen namen worden genoemd. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De sleutel voor de code blijft bij de onderzoeker. Ook in rapporten over het onderzoek wordt alleen die code gebruikt.

Sommige mensen mogen uw medische en persoonsgegevens inzien. Dit is om te controleren of het onderzoek goed en betrouwbaar uitgevoerd is. Algemene informatie hierover vindt u in de brochure ‘Medisch-wetenschappelijk onderzoek’. Mensen die uw gegevens kunnen inzien zijn het VU

onderzoeksteam, de veiligheidscommissie die het onderzoek in de gaten houdt, een controleur van het Amsterdam Public Health Institute en de Inspectie voor de Gezondheidszorg. Zij houden uw gegevens geheim. Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw medische en persoonsgegevens.

De VU onderzoeker bewaart uw gegevens (geen persoonsgegevens) 15 jaar.

Benadering voor vervolgonderzoek
Mogelijk willen wij u in de toekomst nog benaderen voor vervolgonderzoek naar het PM+ programma. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken.

Dit onderzoek staat ook in een overzicht van medisch-wetenschappelijke onderzoeken, namelijk in het Nederlands Trial Register (http://www.trialregister.nl/trialreg/index.asp). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen. U vindt dit onderzoek onder [studie aanduiding].

109. Vergoeding voor meedoen

Meedoen aan het interview kost u niets. U wordt niet betaald voor uw deelname, maar u krijgt wel een vergoeding voor de reiskosten naar het interview.

110. Heeft u vragen?

Bij vragen kunt u contact opnemen met het VU onderzoeksteam. Voor onafhankelijk advies over meedoen aan dit onderzoek kunt u terecht bij de onafhankelijke deskundige (Prof. dr. M. Huibers). Hij weet veel over het onderzoek, maar heeft niets te maken met dit onderzoek. Bij klachten kunt u het beste terecht bij de klachtenfunctionaris (Prof. dr. A. van Straten). Alle gegevens vindt u in **bijlage A**: Contactgegevens.

111. Ondertekening toestemmingsformulier

Wanneer u voldoende bedenktijd heeft gehad, wordt u gevraagd te beslissen over deelname aan dit onderzoek. Indien u toestemming geeft, zullen wij u vragen deze op de bijbehorende toestemmingsverklaring schriftelijk te bevestigen. Door uw schriftelijke toestemming geeft u aan dat u de informatie heeft begrepen en instemt met deelname aan het onderzoek.
Het handtekeningenblad wordt de onderzoeker bewaard. U krijgt een kopie of een tweede exemplaar van deze toestemmingsverklaring.

Dank voor uw aandacht.

112. Bijlagen bij deze informatie

A. Contactgegevens

B. Toestemmingsformulier
C. Brochure ‘Medisch-wetenschappelijk onderzoek. Algemene informatie voor de proefpersoon’ (versie Maart 2017)

Bijlage A: Contactgegevens

Onderzoekers VU Amsterdam:
Mw. Anne de Graaff, a.m.de.graaff@vu.nl / 020-5983833
Bereikbaar: maandag t/m vrijdag tussen 09.00-17.00 uur

Mw. Dr. Marit Sijbrandij, e.m.sijbrandij@vu.nl

Lokale hoofdonderzoeker i-psy: Mw. Yvette van Son, y.vanson@i-psy.nl / 088-3589200

Onafhankelijk deskundige: Dhr. Prof. dr. M. Huibers, m.j.h.huibers@vu.nl

Klachtenfunctionaris: Mw. prof. dr. Annemieke van Straten, a.van.straten@vu.nl

Bijlage B: Toestemmingsformulier deelnemer

STRENGTHS: Implementatie van Problem Management Plus bij Syrische vluchtelingen

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik weet dat sommige mensen mijn gegevens kunnen inzien. Die mensen staan vermeld in deze informatiebrief.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan.
- Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist
- Ik geef toestemming om mijn gegevens op de onderzoekslocatie nog 15 jaar na dit onderzoek te bewaren.

- Ik geef □ **wel**
  □ **geen**

toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek.

- Ik wil meedoen aan dit onderzoek.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Ik verklaar dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):

Handtekening: Datum: __ / __ / __

De proefpersoon krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Informatie over het STRENGTHS onderzoek

Nederlandse titel:
Implementatie van Problem Management Plus bij Syrische vluchtelingen

Geachte heer/mevrouw,

U doet als PM+ behandelaar mee aan een onderzoek naar de effectiviteit van het PM+ programma. In deze brief willen wij u vragen om mee te doen aan een interview om het PM+ programma te evalueren.

Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Voordat u beslist of u wilt meedoen aan dit interview, krijgt u uitleg over wat het interview inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt ook de onafhankelijk deskundige, die aan het eind van deze brief genoemd wordt, om aanvullende informatie vragen. Verdere informatie over meedoen aan zo'n onderzoek staat in de bijgevoegde brochure 'Medisch-wetenschappelijk onderzoek'.

113. Algemene informatie

Dit onderzoek is opgezet door de Vrije Universiteit (VU) Amsterdam en wordt uitgevoerd door onderzoekers van de VU. De medisch ethische toetsingscommissie VUmc heeft dit onderzoek goedgekeurd. Algemene informatie over de toetsing van onderzoek vindt u in de brochure 'Medisch-wetenschappelijk onderzoek'.

114. Achtergrond en doel van het onderzoek

Somberheid, stress en angst zijn veelvoorkomende psychische klachten bij Syrische vluchtelingen. Deze klachten kunnen zijn ontstaan naar aanleiding van schokkende ervaringen in Syrië of in de periode na het vertrek uit Syrië. Psychische klachten kunnen veel leed veroorzaken en leiden tot belemmeringen in het uitvoeren van dagelijkse activiteiten.

Het doel van het STRENGTHS onderzoek is om uit te zoeken of "Problem Management Plus (PM+)" veelvoorkomende psychische klachten, zoals angst en somberheid, bij Syrische vluchtelingen vermindert. Het PM+ programma is ontwikkeld door de Wereldgezondheidsorganisatie (WHO). Eerder onderzoek naar PM+ wijst uit dat het programma effectief is in het verminderen van psychische klachten. Met dit onderzoek willen we uitzoeken of het ook bruikbaar is voor Syrische vluchtelingen in Nederland.

Het doel van dit interview is om uit te zoeken wat de goede kanten zijn aan het PM+ programma, wat er verbeterd zou kunnen worden en welke stappen we moeten ondernemen om het programma beschikbaar te maken voor andere Syrische vluchtelingen met psychische klachten.

115. Wat meedoen inhoudt

U kunt ons helpen door, als PM+ behandelaar bij het onderzoek, uw mening over het PM+ programma met ons te delen. We zullen u niet vragen informatie met ons te delen die persoonlijk of vertrouwelijk is. Dit interview zal ongeveer 30 tot 60 minuten duren.

116. Mogelijke voor- en nadelen

Het is belangrijk dat u de mogelijke voor- en nadelen goed afweegt voordat u besluit mee te doen.

U heeft zelf geen voordeel van meedoen aan dit interview. Uw deelname kan wel bijdragen aan meer kennis over het PM+ programma. We zullen deze informatie gebruiken om het PM+ programma te verbeteren en beschikbaar te maken voor andere Syrische vluchtelingen met psychische klachten.

Het kan zijn dat u sommige vragen onprettig vindt. U doet vrijwillig mee en bent niet verplicht de vragen te beantwoorden. U mag tijdens het onderzoek stoppen.

117. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Als u wel meedoet, kunt u zich altijd bedenken en toch stoppen, ook tijdens het onderzoek. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker.
De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

118. Gebruik en bewaren van uw gegevens

Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet ‘gecodeerd’. Uw naam wordt dan niet meer gebruikt. Het interview wordt opgenomen op audio. Op de audio opname zullen geen namen worden genoemd. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De sleutel voor de code blijft bij de onderzoeker. Ook in rapporten over het onderzoek wordt alleen die code gebruikt.

Sommige mensen mogen uw medische en persoonsgegevens inzien. Dit is om te controleren of het onderzoek goed en betrouwbaar uitgevoerd is. Algemene informatie hierover vindt u in de brochure ‘Medisch-wetenschappelijk onderzoek’. Mensen die uw gegevens kunnen inzien zijn het VU onderzoeksteam, de veiligheidscommissie die het onderzoek in de gaten houdt, een controleur van het Amsterdam Public Health Institute en de Inspectie voor de Gezondheidszorg. Zij houden uw gegevens geheim. Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw medische en persoonsgegevens.

De VU onderzoeker bewaart uw gegevens (geen persoonsgegevens) 15 jaar.

Benadering voor vervolgonderzoek
Mogelijk willen wij u in de toekomst nog benaderen voor vervolgonderzoek naar het PM+ programma. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken.

Dit onderzoek staat ook in een overzicht van medisch-wetenschappelijke onderzoeken, namelijk in het Nederlands Trial Register (http://www.trialregister.nl/trialreg/index.asp). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen. U vindt dit onderzoek onder [studie aanduiding].

119. Vergoeding voor meedoen

Meedoen aan het interview kost u niets. U wordt niet betaald voor uw deelname, maar u krijgt wel een vergoeding voor de reiskosten naar het interview.

120. Heeft u vragen?

Bij vragen kunt u contact opnemen met het VU onderzoeksteam. Voor onafhankelijk advies over meedoen aan dit onderzoek kunt u terecht bij de onafhankelijke deskundige (Prof. dr. M. Huibers). Hij weet veel over het onderzoek, maar heeft niets te maken met dit onderzoek. Bij klachten kunt u het beste terecht bij de klachtenfunctionaris (Prof. dr. A. van Straten). Alle gegevens vindt u in **bijlage A**: Contactgegevens.

121. Ondertekening toestemmingsformulier

Wanneer u voldoende bedenktijd heeft gehad, wordt u gevraagd te beslissen over deelname aan dit onderzoek. Indien u toestemming geeft, zullen wij u vragen deze op de bijbehorende toestemmingsverklaring schriftelijk te bevestigen. Door uw schriftelijke toestemming geeft u aan dat u de informatie heeft begrepen en instemt met deelname aan het onderzoek.
Het handtekeningenblad wordt de onderzoeker bewaard. U krijgt een kopie of een tweede exemplaar van deze toestemmingsverklaring.

Dank voor uw aandacht.

122. Bijlagen bij deze informatie

A. Contactgegevens
B. Toestemmingsformulier
C. Brochure ‘Medisch-wetenschappelijk onderzoek. Algemene informatie voor de proefpersoon’ (versie Maart 2017)

Bijlage A: Contactgegevens

Onderzoekers VU Amsterdam:
Mw. Anne de Graaff, a.m.de.graaff@vu.nl / 020-5983833
Bereikbaar: maandag t/m vrijdag tussen 09.00-17.00 uur

Mw. Dr. Marit Sijbrandij, e.m.sijbrandij@vu.nl

Lokale hoofdonderzoeker i-psy: Mw. Yvette van Son, y.vanson@i-psy.nl / 088-3589200

Onafhankelijk deskundige: Dhr. Prof. dr. M. Huibers, m.j.h.huibers@vu.nl

Klachtenfunctionaris: Mw. prof. dr. Annemieke van Straten, a.van.straten@vu.nl

Bijlage B: Toestemmingsformulier deelnemer

STRENGTHS: Implementatie van Problem Management Plus bij Syrische vluchtelingen

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik weet dat sommige mensen mijn gegevens kunnen inzien. Die mensen staan vermeld in deze informatiebrief.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan.
- Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist
- Ik geef toestemming om mijn gegevens op de onderzoekslocatie nog 15 jaar na dit onderzoek te bewaren.

- Ik geef □ **wel**
  □ **geen**
  toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek.
- Ik wil meedoen aan dit onderzoek.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Ik verklaar dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):

Handtekening: Datum: __ / __ / __

De proefpersoon krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Informatie over het STRENGTHS onderzoek

Nederlandse titel:
Implementatie van Problem Management Plus bij Syrische vluchtelingen

Geachte heer/mevrouw,

U doet mee aan een onderzoek naar de effectiviteit van het PM+ programma. In deze brief willen wij u vragen om mee te doen aan een interview om het PM+ programma te evalueren.
Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Voordat u beslist of u wilt meedoen aan dit interview, krijgt u uitleg over wat het interview inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt ook de onafhankelijk deskundige, die aan het eind van deze brief genoemd wordt, om aanvullende informatie vragen. U kunt er ook over praten met uw partner, vrienden of familie.

123. Algemene informatie

Dit onderzoek is opgezet door de Vrije Universiteit (VU) Amsterdam en wordt uitgevoerd door onderzoekers van de VU. De medisch ethische toetsingscommissie VUmc heeft dit onderzoek goedgekeurd. Algemene informatie over de toetsing van onderzoek vindt u in de brochure 'Medisch-wetenschappelijk onderzoek'.

124. Achtergrond en doel van het onderzoek

Somberheid, stress en angst zijn veelvoorkomende psychische klachten bij Syrische vluchtelingen. Deze klachten kunnen zijn ontstaan naar aanleiding van schokkende ervaringen in Syrië of in de periode na het vertrek uit Syrië. Psychische klachten kunnen veel leed veroorzaken en leiden tot belemmeringen in het uitvoeren van dagelijkse activiteiten.

Het doel van dit interview is om uit te zoeken wat de goede kanten zijn aan het PM+ programma, wat er verbeterd zou kunnen worden en welke stappen we moeten ondernemen om het programma beschikbaar te maken voor andere Syrische vluchtelingen met psychische klachten.

125. Wat meedoen inhoudt

U kunt ons helpen door uw mening over het PM+ programma met ons te delen. We zullen u niet vragen informatie met ons te delen die persoonlijk of vertrouwelijk is. Dit interview zal ongeveer 30 tot 60 minuten duren.

126. Mogelijke voor- en nadelen

Het is belangrijk dat u de mogelijke voor- en nadelen goed afweegt voordat u besluit mee te doen.

U heeft zelf geen voordeel van meedoen aan dit interview. Uw deelname kan wel bijdragen aan meer kennis over het PM+ programma. We zullen deze informatie gebruiken om het PM+ programma te verbeteren en beschikbaar te maken voor andere Syrische vluchtelingen met psychische klachten.

Het kan zijn dat u sommige vragen onprettig vindt. U doet vrijwillig mee en bent niet verplicht de vragen te beantwoorden. U mag tijdens het onderzoek stoppen.

127. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Als u wel meedoet, kunt u zich altijd bedenken en toch stoppen, ook tijdens het onderzoek. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker.
De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

128. Gebruik en bewaren van uw gegevens

Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet ‘gecodeerd’. Uw naam wordt dan niet meer gebruikt. Het interview wordt opgenomen op audio. Op de audio opname zullen geen namen worden genoemd. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De sleutel voor de code blijft bij de onderzoeker. Ook in rapporten over het onderzoek wordt alleen die code gebruikt.

Sommige mensen mogen uw medische en persoonsgegevens inzien. Dit is om te controleren of het onderzoek goed en betrouwbaar uitgevoerd is. Algemene informatie hierover vindt u in de brochure ‘Medisch-wetenschappelijk onderzoek’. Mensen die uw gegevens kunnen inzien zijn het VU onderzoeksteam, de veiligheidscommissie die het onderzoek in de gaten houdt, een controleur van het Amsterdam Public Health Institute en de Inspectie voor de Gezondheidszorg. Zij houden uw gegevens geheim. Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw medische en persoonsgegevens.

De VU onderzoeker bewaart uw gegevens (geen persoonsgegevens) 15 jaar.

Dit onderzoek staat ook in een overzicht van medisch-wetenschappelijke onderzoeken, namelijk in het Nederlands Trial Register (http://www.trialregister.nl/trialreg/index.asp). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen. U vindt dit onderzoek onder [studie aanduiding].

129. Vergoeding voor meedoen

Meedoen aan het interview kost u niets. U wordt niet betaald voor uw deelname, maar u krijgt wel een vergoeding voor de reiskosten naar het interview.

130. Heeft u vragen?

Bij vragen kunt u contact opnemen met het VU onderzoeksteam. Voor onafhankelijk advies over meedoen aan dit onderzoek kunt u terecht bij de onafhankelijke deskundige (Prof. dr. M. Huibers). Hij weet veel over het onderzoek, maar heeft niets te maken met dit onderzoek. Bij klachten kunt u het beste terecht bij de klachtenfunctionaris (Prof. dr. A. van Straten). Alle gegevens vindt u in **bijlage A**: Contactgegevens.

131. Ondertekening toestemmingsformulier

Wanneer u voldoende bedenktijd heeft gehad, wordt u gevraagd te beslissen over deelname aan dit onderzoek. Indien u toestemming geeft, zullen wij u vragen deze op de bijbehorende toestemmingsverklaring schriftelijk te bevestigen. Door uw schriftelijke toestemming geeft u aan dat u de informatie heeft begrepen en instemt met deelname aan het onderzoek.
Het handtekeningenblad wordt de onderzoeker bewaard. U krijgt een kopie of een tweede exemplaar van deze toestemmingsverklaring.

Dank voor uw aandacht.

132. Bijlagen bij deze informatie

A. Contactgegevens
B. Toestemmingsformulier

Bijlage A: Contactgegevens

Onderzoekers VU Amsterdam:
Mw. Anne de Graaff, a.m.de.graaff@vu.nl / 020-5983833
Bereikbaar: maandag t/m vrijdag tussen 09.00-17.00 uur

Mw. Dr. Marit Sijbrandij, e.m.sijbrandij@vu.nl

Lokale hoofdonderzoeker i-psy: Mw. Yvette van Son, y.vanson@i-psy.nl / 088-3589200

Onafhankelijk deskundige: Dhr. Prof. dr. M. Huibers, m.j.h.huibers@vu.nl

Klachtenfunctionaris: Mw. prof. dr. Annemieke van Straten, a.van.straten@vu.nl

Bijlage B: Toestemmingsformulier deelnemer

STRENGTHS: Implementatie van Problem Management Plus bij Syrische vluchtelingen

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik weet dat sommige mensen mijn gegevens kunnen inzien. Die mensen staan vermeld in deze informatiebrief.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan.
- Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist
- Ik geef toestemming om mijn gegevens op de onderzoekslocatie nog 15 jaar na dit onderzoek te bewaren.

- Ik wil meedoen aan dit onderzoek.

Naam deelnemer:
Handtekening: Datum : __ / __ / __

Indien deelnemer analfabeet
Naam getuige:
Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):
Handtekening: Datum: __ / __ / __

De proefpersoon krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Informatie over het STRENGTHS onderzoek

Nederlandse titel:
Implementatie van Problem Management Plus bij Syrische vluchtelingen

Geachte heer/mevrouw,

Een familielid/kennis van u doet mee aan een onderzoek naar de effectiviteit van het PM+ programma. In deze brief willen wij u vragen om mee te doen aan een interview om het PM+ programma te evalueren. Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.
Voordat u beslist of u wilt meedoen aan dit interview, krijgt u uitleg over wat het interview inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt ook de onafhankelijk deskundige, die aan het eind van deze brief genoemd wordt, om aanvullende informatie vragen. U kunt er ook over praten met uw partner, vrienden of familie. Verdere informatie over meedoen aan zo'n onderzoek staat in de bijgevoegde brochure 'Medisch-wetenschappelijk onderzoek'.

133. Algemene informatie

Dit onderzoek is opgezet door de Vrije Universiteit (VU) Amsterdam en wordt uitgevoerd door onderzoekers van de VU. De medisch ethische toetsingscommissie VUmc heeft dit onderzoek goedgekeurd. Algemene informatie over de toetsing van onderzoek vindt u in de brochure 'Medisch-wetenschappelijk onderzoek'.

134. Achtergrond en doel van het onderzoek

Somberheid, stress en angst zijn veelvoorkomende psychische klachten bij Syrische vluchtelingen. Deze klachten kunnen zijn ontstaan naar aanleiding van schokkende ervaringen in Syrië of in de periode na het vertrek uit Syrië. Psychische klachten kunnen veel leed veroorzaken en leiden tot belemmeringen in het uitvoeren van dagelijkse activiteiten.

Het doel van dit interview is om uit te zoeken wat de goede kanten zijn aan het PM+ programma, wat er verbeterd zou kunnen worden en welke stappen we moeten ondernemen om het programma beschikbaar te maken voor andere Syrische vluchtelingen met psychische klachten.

135. Wat meedoen inhoudt

U kunt ons helpen door, als familielid van een van de deelnemers van het PM+ onderzoek, uw mening over het PM+ programma met ons te delen. We zullen u niet vragen informatie met ons te delen die persoonlijk of vertrouwelijk is. Dit interview zal ongeveer 30 tot 60 minuten duren.

136. Mogelijke voor- en nadelen

Het is belangrijk dat u de mogelijke voor- en nadelen goed afweegt voordat u besluit mee te doen.

U heeft zelf geen voordeel van meedoen aan dit interview. Uw deelname kan wel bijdragen aan meer kennis over het PM+ programma. We zullen deze informatie gebruiken om het PM+ programma te verbeteren en beschikbaar te maken voor andere Syrische vluchtelingen met psychische klachten.

Het kan zijn dat u sommige vragen onprettig vindt. U doet vrijwillig mee en bent niet verplicht de vragen te beantwoorden. U mag tijdens het onderzoek stoppen.

137. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.
Als u wel meedoet, kunt u zich altijd bedenken en toch stoppen, ook tijdens het onderzoek. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker.
De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

138. Gebruik en bewaren van uw gegevens

Elke deelnemer krijgt een code die op de gegevens komt te staan. Dit heet 'gecodeerd'. Uw naam wordt dan niet meer gebruikt. Het interview wordt opgenomen op audio. Op de audio opname zullen geen namen worden genoemd. Dit doen we voor de verwerking van de informatie. Nadat de informatie verwerkt is wordt het audiomateriaal vernietigd.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Alleen de onderzoekers weten welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de partners in STRENGTHS. De sleutel voor de code blijft bij de onderzoeker. Ook in rapporten over het onderzoek wordt alleen die code gebruikt.

Sommige mensen mogen uw medische en persoonsgegevens inzien. Dit is om te controleren of het onderzoek goed en betrouwbaar uitgevoerd is. Algemene informatie hierover vindt u in de brochure 'Medisch-wetenschappelijk onderzoek'. Mensen die uw gegevens kunnen inzien zijn het VU onderzoeksteam, de veiligheidscommissie die het onderzoek in de gaten houdt, een controleur van het Amsterdam Public Health Institute en de Inspectie voor de Gezondheidszorg. Zij houden uw gegevens geheim. Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw medische en persoonsgegevens.

De VU onderzoeker bewaart uw gegevens (geen persoonsgegevens) 15 jaar.

Benadering voor vervolgonderzoek

Mogelijk willen wij u in de toekomst nog benaderen voor vervolgonderzoek naar het PM+ programma. Op het toestemmingsformulier kunt u aangeven of u hiermee akkoord gaat. U kunt deze toestemming altijd weer intrekken.

Dit onderzoek staat ook in een overzicht van medisch-wetenschappelijke onderzoeken, namelijk in het Nederlands Trial Register (http://www.trialregister.nl/trialreg/index.asp). Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen. U vindt dit onderzoek onder [studie aanduiding].

139. Vergoeding voor meedoen

Meedoen aan het interview kost u niets. U wordt niet betaald voor uw deelname, maar u krijgt wel een vergoeding voor de reiskosten naar het interview.

140. Heeft u vragen?

Bij vragen kunt u contact opnemen met het VU onderzoeksteam. Voor onafhankelijk advies over meedoen aan dit onderzoek kunt u terecht bij de onafhankelijke deskundige (Prof. dr. M. Huibers). Hij weet veel over het onderzoek, maar heeft niets te maken met dit onderzoek. Bij klachten kunt u het beste terecht bij de klachtenfunctionaris (Prof. dr. A. van Straten). Alle gegevens vindt u in **bijlage A**: Contactgegevens.

141. Ondertekening toestemmingsformulier

Wanneer u voldoende bedenktijd heeft gehad, wordt u gevraagd te beslissen over deelname aan dit onderzoek. Indien u toestemming geeft, zullen wij u vragen deze op de bijbehorende toestemmingsverklaring schriftelijk te bevestigen. Door uw schriftelijke toestemming geeft u aan dat u de informatie heeft begrepen en instemt met deelname aan het onderzoek.
Het handtekeningenblad wordt de onderzoeker bewaard. U krijgt een kopie of een tweede exemplaar van deze toestemmingsverklaring.

Dank voor uw aandacht.

142. Bijlagen bij deze informatie

A. Contactgegevens
B. Toestemmingsformulier
C. Brochure ‘Medisch-wetenschappelijk onderzoek. Algemene informatie voor de proefpersoon’ (versie Maart 2017)

Bijlage A: Contactgegevens

Onderzoekers VU Amsterdam:
Mw. Anne de Graaff, a.m.de.graaff@vu.nl / 020-5983833
Bereikbaar: maandag t/m vrijdag tussen 09.00-17.00 uur

Mw. Dr. Marit Sijbrandij, e.m.sijbrandij@vu.nl

Lokale hoofdonderzoeker i-psy: Mw. Yvette van Son, y.vanson@i-psy.nl / 088-3589200

Onafhankelijk deskundige: Dhr. Prof. dr. M. Huibers, m.j.h.huibers@vu.nl

Klachtenfunctionaris: Mw. prof. dr. Annemieke van Straten, a.van.straten@vu.nl

Bijlage B: Toestemmingsformulier deelnemer

STRENGTHS: Implementatie van Problem Management Plus bij Syrische vluchtelingen

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik weet dat sommige mensen mijn gegevens kunnen inzien. Die mensen staan vermeld in deze informatiebrief.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan.
- Ik begrijp dat het audiomateriaal alleen voor analyse wordt gebruikt. Na afloop van het onderzoek wordt dit materiaal gewist
- Ik geef toestemming om mijn gegevens op de onderzoekslocatie nog 15 jaar na dit onderzoek te bewaren.

- Ik geef □ **wel**
  □ **geen**
  toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek.
- Ik wil meedoen aan dit onderzoek.

Naam deelnemer:
Handtekening: Datum : __ / __ / __

Indien deelnemer analfabeet
Naam getuige:
Handtekening getuige: Datum : __ / __ / __

Ik verklaar dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):
Handtekening: Datum: __ / __ / __

De proefpersoon krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

WP5: Community Implementation; Study 2 (Turkey)

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 Problem Management Plus (PM+). The title of our research project is "STRENGTHS".

Site principle investigator: Dr. 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. 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+)".
You were interviewed by a research assistant of our research team and your responses indicated that you are probably distressed. Therefore, we invite you to take part in the next part of our study. In this part, we will test the feasibility of the PM+ program in reducing these feelings of distress.
I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.
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 PM+ sessions. The other half of the participants will be referred to their physician for additional support and will be offered PM+ at the end of the study, if still necessary.

Participant selection
We are inviting all adult patients visiting RASASA between ….. and …… and who have found to be distressed in our earlier interview to participate in this research.

- ***Elucidating question:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

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.

- ***Elucidating question:*** *If you decide not to take part in this research study, do you know what will happen? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

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 PM+ is better than usual care 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 usual care at this association, while the other group will receive usual care along with PM+. The participants in the usual care group will be offered PM+ at the end of the study at four months, if still necessary and if they wish to. This enables us to find out if PM+ is an improvement on usual care.

Outcome assessments
The interviewers do not know whether you are receiving PM+ or usual care 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 – PM+ or usual care - 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: usual care or

PM+ along with usual care. The group to which you are allocated is determined by chance (see *Random group assignment*). In case you are allocated to the PM+ group, the same research assistant will also inform you about therapy group that you will be in and for the time of the first 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 usual care 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 after the first, all participants will again be asked questions similar to the first assessment. This assessment takes approximately 60 minutes. If you were in the usual care group, you will be offered PM+ at this point if you still experience significant distress.

➢ ***Elucidating question:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete research project? And for the PM+ program? When does the study end? Do you have any other questions? Do you want me to go through the procedures again?*

Risks
We do not expect that 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 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 PM+ is helpful, then additional service providers in your area will be trained to deliver 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.

➢ ***Elucidating question:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your costs? Do you have any other*

questions?

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.

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.

- ***Elucidating question:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

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.

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.

- ***Elucidating questions:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information*

about the study?

- ***Question:*** *You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?*

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 participants satisfaction. I confirm that the individual has given consent freely.

Thumb print of participant

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

WP5: Community Implementation; Study 3 (Switzerland)

Universität Zürich[UZH]

UniversitätsSpital Zürich

Klinik für Psychiatrie und Psychiatrie, UniversitätsSpital Zürich

Studieninformation und Einwilligungserklärung (Screening)

STRENGTHS

Scaling-up psychological interventions with Syrian refugees

Diese Studie ist organisiert durch: UniversitätsSpital Zürich und Universität Zürich

Sehr geehrte Dame, sehr geehrter Herr

Wir möchten Sie anfragen, ob Sie an einer Abklärung zu einer Studie teilnehmen wollen. Im Folgenden wird Ihnen dieses Studienvorhaben dargestellt.

Detailliertere Information

1. Ziel der Studie

Bei Geflüchteten besteht eine erhöhte Gefahr von vielfältigen Gesundheitsproblemen, insbesondere auch psychischen Erkrankungen. Diese können durch die Geschehnisse vor, während und nach der Flucht entstehen. Die Weltgesundheitsorganisation (WHO) entwickelte eine neue Methode Namens «Problem Management Plus (PM+)» zur niederschwelligen Behandlung von Stress. Diese Intervention wurde bereits im Ausland erprobt. Allerdings wurde sie noch nicht in der Schweiz getestet. Mit dieser Studie wollen wir untersuchen, ob die Interventionsmethode auch in der Schweiz wirksam ist. Dabei möchten wir neben der Wirkung

auch die Akzeptanz der Methode untersuchen und abklären, wie diese in das lokale Gesundheitssystem implementiert werden kann.

Dafür suchen wir Menschen, welche aus Syrien kommen und einen erhöhten Stresslevel aufweisen. Um dies festzustellen landen wir alle in der Schweiz lebenden Syrerinnen und Syrer, welche nach 2011 ihr Land verlassen haben, am Screening zur Bestimmung ihrer aktuellen psychischen Belastung teilzunehmen. Sollten Ihre Ergebnisse einen erhöhten Wert aufweisen, werden Sie zur Teilnahme an der Hauptstudie eingeladen.

2. Auswahl

Am Screening können alle Personen teilnehmen, die seit dem Beginn des syrischen Bürgerkrieges (2011) aus Syrien in die Schweiz eingereist sind. Sie müssen urteilsfähig und nicht jünger als 18 Jahre alt sein. Sie sprechen Arabisch.

Nicht teilnehmen hingegen dürfen Personen, die unter akuten psychischen Störungen leiden.

3. Allgemeine Informationen

In diesem Abschnitt wird das Wichtigste in Kürze wiedergegeben:

- Die Studie wird in der Deutschschweiz durchgeführt.
- Das Screening wird von Mitarbeitenden des UniversitätsSpitals Zürich durchgeführt.
- Die eingesetzten Fragebogen sind standardisiert und wissenschaftlich erprobt.
- Die Screenings werden zwischen Mitte 2018 bis Mitte 2020 durchgeführt.
- Ca. 2700 Personen werden an Screenings teilnehmen.
- Wir machen diese Erhebung sowie die anschliessende Studie so, wie es die Gesetze in der Schweiz vorschreiben. Ausserdem beachten wir alle international anerkannten Richtlinien. Die zuständige Kantonale Ethikkommission hat die Studie geprüft und bewilligt.
- Eine Beschreibung dieser Studie finden Sie auch auf der Internetseite des Bundesamtes für Gesundheit: www.kofam.ch

4. Ablauf

Sie werden zu einem Screening eingeladen. Es handelt sich um eine einmalige Erhebung und wird mithilfe eines Tablets vorgenommen, welches ein Assessor zum Screening Termin mitbringen wird. Die Dauer für die Ausfüllung der beiden Fragebogen zusammen mit der Erfassung diverser soziodemografischen Fragen beträgt ca. 15-20 Minuten.

Dabei werden folgende Fragebogen eingesetzt:

Name in der Studie	Name des Fragebogens	Was erhebt der Fragebogen
K10	Kessler Psychological Distress Scale (K10)	Erfassung von unspezifischer psychischer Belastung im Alltag
WHODAS 2.0	WHO Disability Assessment Schedule 2.0 (WHODAS 2.0)	Erfasst Schwierigkeiten, die aufgrund von Gesundheitsproblemen entstehen können.

Sollten Ihre Werte im Normalbereich liegen, werden wir Sie darüber informieren. In diesem Fall besteht keine weitere Behandlungsmöglichkeit im Rahmen der Interventionsstudie.
Wenn Sie bestimmte Werte erreichen, werden Sie gefragt, ob Sie an der Intervention teilnehmen wollen. Dazu werden Sie weitere Informationen erhalten, welche Sie mit einer neuen Einverständniserklärung einwilligen können.

5. Nutzen

Wenn Sie bei dieser Erhebung mitmachen, werden Sie Ihren aktuellen Stresslevel erfahren sowie je nach Ergebnissen zur Teilnahme an der Intervention eingeladen.

6. Rechte

Sie nehmen freiwillig teil. Wenn Sie nicht mitmachen oder später Ihre Teilnahme zurückziehen wollen, müssen Sie dies nicht begründen. Eine medizinische Behandlung/Betreuung ist nicht an die Teilnahme gebunden und unabhängig von Ihrem Entscheid gewährleistet. Sie dürfen jederzeit Fragen zur Studienteilnahme stellen. Wenden Sie sich dazu bitte an die Person, die am Ende dieser Information genannt ist.

7. Pflichten

Als Teilnehmer ist es notwendig, dass Sie sich an die notwendigen Vorgaben und Anforderungen der Erhebung halten.

8. Risiken und Belastungen für die Teilnehmenden

Grundsätzlich ist die Erhebung mit keinen Risiken verbunden. Allerdings kann die Auseinandersetzung mit eigenen Gefühlen und Emotionen die psychische Belastung vorübergehend erhöhen.

Für Frauen, die schwanger werden können

Eine mögliche Schwangerschaft spielt im Rahmen des Screenings keine Rolle. Es besteht keine Kontraindikation. Auch wird das ungeborene Kind in keiner Weise beeinflusst. Dennoch bitten wir Sie, Ihre Kontaktperson darüber zu informieren, falls Sie schwanger sein könnten – die mit einer Schwangerschaft einhergehende Umstellung des Körpers kann stimmungsverändernd wirken und die Ergebnisse beeinflussen. Dies würden wir für unsere Auswertungen gerne berücksichtigen.

9. Andere Behandlungsmöglichkeiten

Beim Screening handelt es sich nicht um eine Behandlung, sondern um die Feststellung des momentanen Zustandes. Sie müssen bei dieser Erhebung nicht teilnehmen. Wenn Sie nicht mitmachen möchten aber eine Behandlung wünschen, sollen Sie sich an Ihren Arzt wenden.

10. Ergebnisse aus der Erhebung

Die zuständige Person aus dem Forschungsteam wird Sie nach der Erhebung über die Erkenntnisse informieren, die den Nutzen der Studie oder Ihre Sicherheit und somit Ihre Einwilligung zur Teilnahme an der Studie beeinflussen können. Sie werden die Information mündlich oder schriftlich erhalten.

11. Vertraulichkeit der Daten und Proben

Für diese Studie werden Ihre persönlichen und medizinischen Daten erfasst. Nur der Projektleiter Herr Dr. Naser Morina und sein Assistent Herr Nikolai Kiselev dürfen Ihre unverschlüsselten Daten sehen, und zwar ausschliesslich, um Aufgaben im Rahmen der Studie zu erfüllen. Beide unterstehen der Schweigepflicht. Bei der Datenerhebung zu Studienzwecken werden die Daten verschlüsselt. Verschlüsselung bedeutet, dass alle Bezugsdaten, die Sie identifizieren könnten (Name, Geburtsdatum), gelöscht und durch einen Schlüssel ersetzt werden. Diejenigen Personen, die den Schlüssel nicht kennen, können daher keine Rückschlüsse auf Ihre Person ziehen. Die Schlüssel-Liste bleibt immer in der Klinik für Psychiatrie und Psychotherapie des UniversitätsSpitals Zürich. Alle Personen, die Einsicht in Ihre Daten haben, unterliegen der Schweigepflicht. Alle Vorgaben des Datenschutzes werden eingehalten und wir werden Ihren Namen weder in einer Publikation noch im Internet öffentlich machen. Sie als teilnehmende Person haben jederzeit das Recht auf Einsicht in Ihre Daten.

Die Daten werden vor Ort gelagert. Dabei handelt es sich um eine Datenbank für Forschungszwecke.

Die Daten können verschlüsselt an andere Forschungsgruppen im In- und Ausland versandt werden, dort für dieses Projekt untersucht und für 5 Jahre aufbewahrt werden. Die Schlüssel-Liste bleibt in der Institution in Zürich und Zugriff haben nur die beiden oben erwähnten Personen. Der Sponsor ist dafür verantwortlich zu sorgen, dass im Ausland die gleichen Standards wie in der Schweiz eingehalten werden.

Möglicherweise wird diese Erhebung durch die zuständige Ethikkommission oder durch die Institution, die die Studie veranlasst hat, überprüft. Der Projektleiter muss eventuell Ihre persönlichen und medizinischen Daten für solche Kontrollen offenlegen. Alle Personen müssen absolute Vertraulichkeit wahren.

12. Rücktritt

Sie können jederzeit aufhören und von der Erhebung zurücktreten, wenn Sie das wünschen. Die bis dahin erhobenen Daten werden gelöscht.

13. Entschädigung für Teilnehmende

Falls zutreffend: Wenn Sie an dieser Erhebung teilnehmen, bekommen Sie dafür keine Entschädigung.

14. Haftung

Die Institution (der Sponsor), die die Studie veranlasst hat und für die Durchführung verantwortlich ist, haftet für Schäden, welche Ihnen im Zusammenhang mit der getesteten Forschungshandlungen (z.B. Untersuchungen) entstehen könnten. Die Voraussetzungen und das Vorgehen dazu sind gesetzlich geregelt. Wenn Sie einen Schaden erlitten haben, so wenden Sie sich bitte an das Forschungsteam.

15. Finanzierung der Studie

Die Studie wird von Staatssekretariat für Bildung, Forschung und Innovation finanziert (SBFI).

16. Kontaktperson(en)

Bei Fragen, Unsicherheiten oder Notfällen, die während der Studie oder danach auftreten, können Sie sich jederzeit hier wenden:

Studien:Handynr (HINWEIS für KEK: zu gegebener Zeit wird eine Handynr für das Projekt gekauft und auch noch eine arabisch-sprechende Person angestellt.)
und e-mail: strengths@usz.ch

Klinik für Psychiatrie und Psychotherapie, UniversitätsSpital Zürich, Culmannstrasse 8, 8091 Zürich, Tel.: zu Bürozeiten: 044-255 52 80

Notfallstation des UniversitätsSpitals Zürich (24 Stunden/Tag an 365 Tagen/Jahr): 044 255 11 11.

Einwilligungserklärung (Screening)

Schriftliche Einwilligungserklärung zur Teilnahme an einem Studienprojekt
Bitte lesen Sie dieses Formular sorgfältig durch. Bitte fragen Sie, wenn Sie etwas nicht verstehen oder wissen möchten. Für die Teilnahme ist Ihre schriftliche Einwilligung notwendig.

BASEC-Nummer (nach Einreichung):	
Titel der Studie (wissenschaftlich und Laiensprache):	Scaling-up psychological interventions with Syrian refugees Testung einer psychologischen Intervention bei syrischen Flüchtlingen
verantwortliche Institution (Sponsor mit Adresse):	Dr. Naser Morina UniversitätsSpital Zürich, Universität Zürich Klinik für Psychiatrie und Psychotherapie Culmanstrasse 8 8091 Zürich
Ort der Durchführung:	Zürich
Verantwortlicher Prüfperson am Studienort: Name und Vorname in Druckbuchstaben:	Dr. MORINA NASER
Teilnehmerin/Teilnehmer: Name und Vorname in Druckbuchstaben: Geburtsdatum:	☐ weiblich ☐ männlich

- Ich wurde von unterzeichnender Prüfperson mündlich und schriftlich über den Zweck, den Ablauf des Screenings zur Implementierung von PM+ über mögliche Vor- und Nachteile sowie über eventuelle Risiken informiert.
- Ich nehme an dieser Studie freiwillig teil und akzeptiere den Inhalt der abgegebenen schriftlichen Information. Ich hatte genügend Zeit, meine Entscheidung zu treffen.
- Meine Fragen im Zusammenhang mit der Teilnahme an diesem Screening sind mir beantwortet worden. Ich behalte die schriftliche Information und erhalte eine Kopie meiner schriftlichen Einwilligungserklärung.
- Ich bin einverstanden, dass die zuständigen Fachleute des Sponsors, der zuständigen Ethikkommission und zu Prüf- und Kontrollzwecken in meine unverschlüsselten Daten Einsicht nehmen dürfen, jedoch unter strikter Einhaltung der Vertraulichkeit.
- Bei Erhebungsergebnissen oder Zufallsbefunden, die direkt meine Gesundheit betreffen, werde ich informiert. Wenn ich das nicht wünsche, informiere ich meine Prüfperson.
- Ich weiss, dass meine gesundheitsbezogenen und persönlichen Daten nur in verschlüsselter Form zu Forschungszwecken für diese Erhebung weitergegeben werden können, auch ins Ausland.

- Ich bin einverstanden, dass die Prüfperson, falls ich ausserhalb des Prüfzentrums weiter behandelt werde, die behandelnden Ärzte kontaktieren darf, um für die Erhebung relevante Nachbehandlungsdaten zu erfragen.
- Ich kann jederzeit und ohne Angabe von Gründen von der Erhebungsteilnahme zurücktreten. Meine weitere medizinische Behandlung ist unabhängig von der Erhebungsteilnahme immer gewährleistet. Die bis zum Rücktritt erhobenen Daten und Proben werden gelöscht.
- Die Haftpflichtversicherung des Spitals/der Institution kommt für allfällige Schäden auf. Ich bin darüber informiert, dass eine Versicherung Schäden deckt, die auf die Studie zurückzuführen sind.
- Ich bin mir bewusst, dass die in der Teilnehmerinformation genannten Pflichten einzuhalten sind. Im Interesse meiner Gesundheit kann mich die Prüfperson jederzeit von der Studie ausschliessen.

Ort, Datum	Unterschrift Teilnehmerin/Teilnehmer

Bestätigung des Prüfarztes bzw. einer von ihm geschulten Prüfperson: Hiermit bestätige ich, dass ich dieser Teilnehmerin/ diesem Teilnehmer Wesen, Bedeutung und Tragweite der Erhebung erläutert habe. Ich versichere, alle im Zusammenhang mit dieser Erhebung stehenden Verpflichtungen gemäss des geltenden Rechts zu erfüllen. Sollte ich zu irgendeinem Zeitpunkt während der Durchführung der Erhebung von Aspekten erfahren, welche die Bereitschaft der Teilnehmerin/ des Teilnehmers zur Teilnahme an der Erhebung beeinflussen könnten, werde ich sie/ ihn umgehend darüber informieren.

Ort, Datum	Name und Vorname der Prüfperson in Druckbuchstaben Unterschrift der Prüfärztin/des Prüfarztes

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Universität Zürich[UZH]

UniversitätsSpital Zürich

SCALING UP PSYCHOLOGICAL INTERVENTIONS WITH SYRIAN REFUGEES
STRENGTHS

Klinik für Psychiatrie und Psychiatrie, UniversitätsSpital Zürich

Studieninformation und Einwilligungserklärung (Intervention)

STRENGTHS

Scaling-up psychological interventions with Syrian refugees

Diese Studie ist organisiert durch: UniversitätsSpital Zürich und Universität Zürich

Sehr geehrte Dame, sehr geehrter Herr

Wir möchten Sie anfragen, ob Sie an einer klinischen Studie teilnehmen wollen. An dem dafür relevanten Screening haben Sie bereits teilgenommen. Im Folgenden wird Ihnen das Studienvorhaben dargestellt.

Detailliertere Information

1. Ziel der Studie

Bei Geflüchteten besteht eine erhöhte Gefahr von vielfältigen Gesundheitsproblemen, insbesondere auch psychischen Erkrankungen. Diese können durch die Geschehnisse vor, während und nach der Flucht entstehen. Die Weltgesundheitsorganisation (WHO) entwickelte eine neue Methode namens «Problem Management Plus (PM+)» zur niederschwelligen Behandlung von Stress. Die Intervention wird von anderen Flüchtlingen durchgeführt, welche dafür ausgebildet werden. Diese Intervention

wurde bereits im Ausland erprobt. Allerdings wurde sie noch nicht in der Schweiz getestet. Mit dieser Studie wollen wir untersuchen, ob die Interventionsmethode auch in der Schweiz wirksam ist. Dabei möchten wir neben der Wirkung auch die Akzeptanz der Methode untersuchen und abklären, wie diese in das lokale Gesundheitssystem implementiert werden kann.

2. Auswahl

Sie haben bereits am Screening teilgenommen. Ihre Werte haben gezeigt, dass das Niveau Ihrer psychischen Belastung möglicherweise erhöht ist. Somit qualifizieren Sie sich für die Zielgruppe der vorliegenden Hauptstudie. Die weiteren Auswahlkriterien sind identisch mit denen vom Screening: an der Studie können alle Personen teilnehmen, die seit dem Beginn des syrischen Bürgerkrieges (2011) aus Syrien in die Schweiz eingewandert sind und einen erhöhten Stresslevel, gemessen während im vorangehenden Screenings, aufweisen. Sie müssen urteilsfähig und nicht jünger als 18 Jahre alt sein. Sie sprechen arabisch.

Nicht teilnehmen hingegen dürfen Personen, die unter akuten psychischen Störungen leiden sowie eine konstante, wöchentliche Teilnahme während der nächsten 5 Wochen nicht gewährleisten können.

3. Allgemeine Informationen

In diesem Abschnitt wird das Wichtigste in Kürze wiedergegeben werden:

- Die Studie wird in der Deutschschweiz durchgeführt.
- Die PM+ Techniken ist eine offizielle von der WHO entwickelte und empirisch untersuchte Methode zur Reduktion von stressbedingter Symptomatik.
- Die eingesetzten Fragebogen sind standardisiert und wissenschaftlich erprobt.
- Die Studie wird zwischen Mitte 2018 bis Mitte 2021 durchgeführt.
- Die Studie ist singlezentrisch, einfachblind, randomisiert – das heisst:
  - singlezentrisch: Sie wird von Mitarbeitenden einer Institution - UniversitätsSpital Zürich vor Ort durchgeführt.
  - einfachblind:Mitarbeitende, welche Sie bei den Erhebungen (vor und unmittelbar nach der Intervention und anschliessend 3 und 12 Monate nach der Intervention) unterstützen, wissen nicht ob Sie eine Behandlung bekommen oder nicht.
  - randomisiert: Sie werden anhand des Zufallsprinzips in die Behandlungsgruppe mit der neuen Methode oder in eine ohne diese Methode eingeteilt.
- Die Teilnehmenden werden zufälligerweise einer der zwei Gruppen (der Interventionsgruppe oder der Kontrollgruppe) zugeteilt. Die Assessoren, welche die Screenings durchführen, wissen bzw. werden nicht wissen, wer welcher Gruppe zugeteilt wurde.
- Die Teilnehmenden der PM+ Gruppe werden während 5 Wochen (einmal wöchentlich) an den Sitzungen à 90 Minuten und ausserdem an 4 Erhebungen (vor und unmittelbar nach der Intervention, 3 Monate und 12 Monate danach) teilnehmen.
- Die Teilnehmenden der Kontrollgruppe werden nur an 4 Erhebungen teilnehmen. Sollten Sie in die Kontrollgruppe eingeteilt werden, werden Sie instruiert im Falle der Zustandsverschlechterung einen Facharzt zu kontaktieren.
- Ca. 350 Personen für beide Gruppen werden an der Studie teilnehmen.
- Wir machen diese Studie so, wie es die Gesetze in der Schweiz vorschreiben. Ausserdem beachten wir alle international anerkannten Richtlinien. Die zuständige Kantonale Ethikkommission hat die Studie geprüft und bewilligt.
- Eine Beschreibung dieser Studie finden Sie auch auf der Internetseite des Bundesamtes für Gesundheit: www.kofam.ch

4. Ablauf

Nachdem Sie alle Informationen zur Studie erhalten haben und alle Ihre Fragen zu Ihrer Zufriedenheit beantwortet worden sind, können Sie die beiliegende Einwilligungserklärung unterschreiben, sofern Sie an der Studie teilnehmen möchten.

Nach Ihrer Unterzeichnung der Einwilligungserklärung werden Sie mehrere Fragebogen an einem Tablet (wie bereits beim Screening) ausfüllen. Die Dauer für die Ausfüllung dieses Fragebogens beträgt ca. 30-40 Minuten.

Dabei werden folgende Fragebogen eingesetzt:

Abkürzung des Fragebogens	Name des Fragebogens	Was erhebt der Fragebogen
HSCL-25	Hopkins Symptom Checklist	Messung der psychischen Belastung
PCL-5	Posttraumatic Stress Disorder Checklist	Erfassung der Symptome der posttraumatischen Belastungsstörung
PSYCHLOPS	Psychological Outcomes Profiles	Überwachung der Therapiedynamik
PTE	Potentially Traumatic Events	Erfragung der erlebten Stresserlebnisse
PMLDC	Post-Migration Living Difficulties Checklist	Erfragung der Lebensschwierigkeiten nach der Immigration
CSRI	Client Service Receipt Inventory	Kosten-Effektivitäts-Analyse psychiatrischer Versorgungssysteme

Unabhängig von den Ergebnissen dieser Erhebung werden Sie von einer unabhängigen Stelle, welche im Forschungsprojekt nicht involviert ist, nach Zufallsprinzip entweder in die Interventionsgruppe oder in die Kontrollgruppe zugeteilt.

Sollten Sie in die Kontrollgruppe eingeteilt werden, werden Sie telefonisch darüber informiert. Sie werden für eine wiederholte Erhebung mittels der gleichen, oben aufgeführten Fragebogen in 6 bis 7 Wochen und dann in 3 und 12 Monaten danach eingeladen. Sollte sich Ihr psychischer Zustand im Laufe dieser Zeit verändern, können Sie sich bei Ihrem Hausarzt melden.

Sollten Sie in die Interventionsgruppe eingeteilt werden, wird Ihnen ein Therapeut zugeteilt, welcher mit Ihnen fünf Sitzungen plant und dann schrittweise durchführt. Diese Sitzungen werden für die fünf aufeinanderfolgenden Wochen geplant – eine Sitzung pro Woche. Jede Sitzung dauert jeweils 90 Minuten. Während dieser Sitzungen werden Ihnen verschiedene Techniken zu Stressmanagement, Verhaltensaktivierung, Stärkung der sozialen Unterstützung etc. vermittelt, welche das Grundkonzept von PM+ bilden. Nach der Beendigung der Behandlung werden Sie zu einer erneuten Erhebung mittels der gleichen, oben aufgeführten Fragebogen und dann in 3 und 12 Monaten danach eingeladen.

5. Nutzen

Wenn Sie bei dieser Studie mitmachen und der PM+ Gruppe zugeteilt werden, kann es zu einer Senkung der stressbedingten Symptomatik führen. Diese Erkenntnissee können auch für andere Personen, die dieselbe Symptomatik aufweisen, sehr nützlich sein. Wenn Sie in die Kontrollgruppe eingeteilt werden, werden Sie keinen persönlichen Nutzen von der Teilnahme an der Studie haben.

6. Rechte

Sie nehmen freiwillig teil. Wenn Sie nicht mitmachen oder später Ihre Teilnahme zurückziehen wollen, müssen Sie dies nicht begründen. Eine medizinische Behandlung/Betreuung ist nicht an die Teilnahme gebunden und unabhängig von Ihrem Entscheid gewährleistet. Sie dürfen jederzeit Fragen zur Studienteilnahme stellen. Wenden Sie sich dazu bitte an die Person, die am Ende dieser Information genannt ist.

7. Pflichten

Als Teilnehmer ist es notwendig, dass Sie

- sich an die notwendigen Vorgaben und Anforderungen der Studie durch den Prüfplan halten
- Ihre Prüf- oder Therapieperson über den Verlauf der Symptomatik informieren und neue Symptome, neue Beschwerden und Änderungen im Befinden zu melden (auch nach Studienende/-abbruch);
- Ihre Prüf- oder Therapieperson über die gleichzeitige Behandlung und Therapie bei einem anderen Arzt und über die Einnahme von Medikamenten informieren.

8. Risiken und Belastungen für die Teilnehmenden

Grundsätzlich ist die Studie mit keinen Risiken verbunden. Allerdings kann die Auseinandersetzung mit eigenen Gefühlen und Emotionen die psychische Belastung erhöhen. Es könnte auch Ihnen schwerfallen, darüber zu reden. Sollte das tatsächlich der Fall sein, sprechen Sie Ihre Kontaktperson darauf an. Auch das Fachpersonal steht Ihnen in solchen Situationen zur Verfügung.

Sollte sich während der Intervention Ihr Zustand massiv verschlechtern werden entsprechende Schritte vorgenommen, um eine notwendige Behandlung zu gewährleisten. Dies ist allerdings ein äusserst unwahrscheinliches Szenario.

Für Frauen, die schwanger werden können

Eine mögliche Schwangerschaft spielt im Rahmen der Studie keine Rolle. Es besteht keine Kontraindikation. Auch wird das ungeborene Kind in keiner Weise beeinflusst. Dennoch bitten wir Sie,

Ihre Kontaktperson darüber zu informieren, falls Sie schwanger sein könnten – die mit einer Schwangerschaft einhergehende Umstellung des Körpers kann stimmungsverändernd wirken und die Ergebnisse beeinflussen. Dies würden wir für unsere Auswertungen gerne berücksichtigen.

9. Andere Behandlungsmöglichkeiten

Sie müssen bei dieser Studie nicht teilnehmen. Wenn Sie nicht mitmachen möchten aber eine Behandlung wünschen, sollen Sie sich an Ihren Arzt wenden.

10. Ergebnisse aus der Erhebung

Die zuständige Person aus dem Forschungsteam wird Sie während der Studie über die Erkenntnisse informieren, die den Nutzen der Studie oder Ihre Sicherheit und somit Ihre Einwilligung zur Teilnahme an der Studie beeinflussen können. Sie werden die Information mündlich oder schriftlich erhalten.

11. Vertraulichkeit der Daten und Proben

Für diese Studie werden Ihre persönlichen und medizinischen Daten erfasst. Nur der Projektleiter Herr Dr. Naser Morina und sein Assistent Herr Nikolai Kiselev dürfen Ihre unverschlüsselten Daten sehen, und zwar ausschliesslich, um Aufgaben im Rahmen der Studie zu erfüllen. Beide unterstehen der Schweigepflicht. Bei der Datenerhebung zu Studienzwecken werden die Daten verschlüsselt. Verschlüsselung bedeutet, dass alle Bezugsdaten, die Sie identifizieren könnten (Name, Geburtsdatum), gelöscht und durch einen Schlüssel ersetzt werden. Diejenigen Personen, die den Schlüssel nicht kennen, können daher keine Rückschlüsse auf Ihre Person ziehen. Die Schlüssel-Liste bleibt immer in der Klinik für Psychiatrie und Psychotherapie des UniverstiätsSpitals Zürich. Alle Personen, die Einsicht in Ihre Daten haben, unterliegen der Schweigepflicht. Alle Vorgaben des Datenschutzes werden eingehalten und wir werden Ihren Namen weder in einer Publikation noch im Internet öffentlich machen. Sie als teilnehmende Person haben jederzeit das Recht auf Einsicht in Ihre Daten.

Die Daten werden vor Ort gelagert. Dabei handelt es sich um eine Datenbank für Forschungszwecke.

Die Daten können verschlüsselt an andere Forschungsgruppen im In- und Ausland versandt, dort für dieses Projekt untersucht und für 5 Jahre aufbewahrt werden. Die Schlüssel-Liste bleibt in der Institution in Zürich und Zugriff haben nur die beiden oben erwähnten Personen. Der Sponsor ist dafür verantwortlich zu sorgen, dass im Ausland die gleichen Standards wie in der Schweiz eingehalten werden.

Möglicherweise wird diese Studie durch die zuständige Ethikkommission oder durch die Institution, die die Studie veranlasst hat, überprüft. Der Projektleiter muss eventuell Ihre persönlichen und medizinischen Daten für solche Kontrollen offenlegen. Alle Personen müssen absolute Vertraulichkeit wahren.

12. Rücktritt

Sie können jederzeit aufhören und von der Studie zurücktreten, wenn Sie das wünschen. Die bis dahin erhobenen Daten werden gelöscht.

13. Entschädigung für Teilnehmende

Wenn Sie bei dieser Studie mitmachen, bekommen Sie dafür folgende Entschädigung: CHF 20.- pro Fragebogenerhebung und zwar für: (1) vor der Intervention, (2) nach der Intervention, (3) drei Monate nach der Intervention und (4) zwölf Monate nach der Intervention.

14. Haftung

Die Institution (der Sponsor), die die Studie veranlasst hat und für die Durchführung verantwortlich ist, haftet für Schäden, welche Ihnen im Zusammenhang mit der getesteten Forschungshandlungen (z.B. Untersuchungen) entstehen könnten. Die Voraussetzungen und das Vorgehen dazu sind gesetzlich geregelt. Wenn Sie einen Schaden erlitten haben, so wenden Sie sich bitte an das Forschungsteam.

15. Finanzierung der Studie

Die Studie wird von Staatssekretariat für Bildung, Forschung und Innovation finanziert.

16. Kontaktperson(en)

Bei Fragen, Unsicherheiten oder Notfällen, die während der Studie oder danach auftreten, können Sie sich jederzeit hier wenden.

Studien:Handynr (HINWEIS für KEK: zu gegebener Zeit wird eine Handynr für das Projekt gekauft und auch noch eine arabisch-sprechende Person hierfür angestellt.)
und e-mail: strengths@usz.ch

Klinik für Psychiatrie und Psychotherapie, UniversitätsSpital Zürich, Culmannstrasse 8, 8091 Zürich, Tel.: zu Bürozeiten: 044-255 52 80

Notfallstation des UniversitätsSpitals Zürich (24 Stunden/Tag an 365 Tagen/Jahr): 044 255 11 11.

Einwilligungserklärung (Intervention)

Schriftliche Einwilligungserklärung zur Teilnahme an einem Studienprojekt

Bitte lesen Sie dieses Formular sorgfältig durch. Bitte fragen Sie, wenn Sie etwas nicht verstehen oder wissen möchten. Für die Teilnahme ist Ihre schriftliche Einwilligung notwendig.

BASEC-Nummer (nach Einreichung):	
Titel der Studie (wissenschaftlich und Laiensprache):	Scaling-up psychological interventions with Syrian refugees Testung einer psychologischen Intervention bei syrischen Flüchtlingen
verantwortliche Institution (Sponsor mit Adresse):	Dr. Naser Morina UniversitätsSpital Zürich Klinik für Psychiatrie und Psychotherapue Culmanstrasse 8 8091 Zürich
Ort der Durchführung:	Zürich
Verantwortlicher Prüfperson am Studienort: Name und Vorname in Druckbuchstaben:	DR. MORINA NASER
Teilnehmerin/Teilnehmer: Name und Vorname in Druckbuchstaben: Geburtsdatum:	☐ weiblich ☐ männlich

- Ich wurde von unterzeichnender Prüfperson mündlich und schriftlich über den Zweck, den Ablauf der Studie zur Implementierung von PM+ über mögliche Vor- und Nachteile sowie über eventuelle Risiken informiert.
- Ich nehme an dieser Studie freiwillig teil und akzeptiere den Inhalt der abgegebenen schriftlichen Information. Ich hatte genügend Zeit, meine Entscheidung zu treffen.
- Meine Fragen im Zusammenhang mit der Teilnahme an diesem Screening sind mir beantwortet worden. Ich behalte die schriftliche Information und erhalte eine Kopie meiner schriftlichen Einwilligungserklärung.
- Ich bin einverstanden, dass die zuständigen Fachleute des Sponsors, der zuständigen Ethikkommission und zu Prüf- und Kontrollzwecken in meine unverschlüsselten Daten Einsicht nehmen dürfen, jedoch unter strikter Einhaltung der Vertraulichkeit.
- Bei Erhebungsergebnissen oder Zufallsbefunden, die direkt meine Gesundheit betreffen, werde ich informiert. Wenn ich das nicht wünsche, informiere ich meine Prüfperson.
- Ich weiss, dass meine gesundheitsbezogenen und persönlichen Daten (und Proben) nur in verschlüsselter Form zu Forschungszwecken für diese Erhebung weitergegeben werden können, auch ins Ausland).
- Ich bin einverstanden, dass die Prüfperson, falls ich ausserhalb des Prüfzentrums weiter behandelt werde, die behandelnden Ärzte kontaktieren darf, um für die Erhebung relevante Nachbehandlungsdaten zu erfragen.

- Ich kann jederzeit und ohne Angabe von Gründen von der Erhebungsteilnahme zurücktreten. Meine weitere medizinische Behandlung ist unabhängig von der Erhebungsteilnahme immer gewährleistet. Die bis zum Rücktritt erhobenen Daten und Proben werden gelöscht.
- Die Haftpflichtversicherung des Spitals/der Institution kommt für allfällige Schäden auf. Ich bin darüber informiert, dass eine Versicherung Schäden deckt, die auf die Studie zurückzuführen sind.
- Ich bin mir bewusst, dass die in der Teilnehmerinformation genannten Pflichten einzuhalten sind. Im Interesse meiner Gesundheit kann mich die Prüfperson jederzeit von der Studie ausschliessen.

Ort, Datum	Unterschrift Teilnehmerin/Teilnehmer

Bestätigung des Prüfarztes bzw. einer von ihm geschulten Prüfperson: Hiermit bestätige ich, dass ich dieser Teilnehmerin/ diesem Teilnehmer Wesen, Bedeutung und Tragweite der Erhebung erläutert habe. Ich versichere, alle im Zusammenhang mit dieser Erhebung stehenden Verpflichtungen gemäss des geltenden Rechts zu erfüllen. Sollte ich zu irgendeinem Zeitpunkt während der Durchführung der Erhebung von Aspekten erfahren, welche die Bereitschaft der Teilnehmerin/ des Teilnehmers zur Teilnahme an der Erhebung beeinflussen könnten, werde ich sie/ ihn umgehend darüber informieren.

Ort, Datum	Name und Vorname der Prüfperson in Druckbuchstaben Unterschrift der Prüfärztin/des Prüfarztes

WP6: Online Implementation; study 1 (Germany), 2 (Egypt) and 3 (Sweden)

Freie Universitaet Berlin (FUB)

Informed Consent Forms Phase 2 and 4 (all countries)

Participant Information and Consent

"[PM+ App] study"

Part I: Screening

Dear Madam or Sir,

- Do you feel stressed often?
- Do you feel sad a lot?
- Do you have many problems in your life?

The [PM+ App] may help you and offers you a 5-week course on your smartphone that will provide you with information on how to address these problems. Currently, we offer the app as part of a scientific study to see how well it works for refugees from Syria. We kindly ask you to participate in our study and would like to let you know that joining this study is for free and voluntary. This study is conducted by the Freie Universität Berlin in cooperation with several international organizations in a project called STRENGTHS. For more information on this project, please go to: [link to website].

We'll start by asking you some questions about you and how you are feeling lately, so we can tell you whether the app could help you or not. Do you want to answer these questions now? If anything is unclear at this point, please contact us: [contact].

yes [ ] no [ ]

(Screening questions…)

Part II: Study

Screening result: Not eligible participant (under the cut-off)
Thank you very much for answering the questions. It seems that you are coping well enough with things at the moment, and so this intervention is not really something you need. We are very grateful to you for giving us your time and for being so honest with your answers. If you do feel that you require some help in the future, please contact us [contact].

Screening result: Not eligible participant (suicidal)
Thank you very much for answering the questions. It seems you are experiencing difficulties that PM+ would not be able to help you with. You have reported plans to end your life and we therefore highly recommend the following:

- Talk to a trusted family member, friend, or colleague about how you feel.
- If you think you are in immediate danger of harming yourself contact the emergency services or a crisis line, or go there directly [contact information].
- Talk to a professional, such as a doctor, mental health professional, counsellor or social worker.

- If you practice a religion, talk to someone from your religious community who you trust.
- Remember: If you feel like life is not worth living, reach out for help. You are not alone.

If you need assistance with finding a service that is better suited to help you, please contact us [contact].

Screening result: Eligible participant

Thank you very much for answering the questions. Based on your answers, the [PM+ App] may help you. Before we continue, we would like to give you more detailed information on the scientific study and the app itself. Please read the following information and contact us at any time, if you have any questions [contact].

1. The two versions of the app

In this study we want to test a new way of providing help to Syrian refugees with distress and problems. For this purpose, we have taken an approach called "Problem Management Plus" that was developed by the World Health Organization (WHO) and have created two different versions of a smartphone app. The first version will provide you with information on how to get help when experiencing difficult emotions and problems. It will also give you a tool to track your mood. In the second version of the app you will also get these features but in addition, you will also spend 30-40 minutes per week learning and practicing new skills to help you cope with difficult emotions and problems. You will start with one of these versions and we would like you to use it for a minimum of 5 weeks. Which version you start with will be chosen randomly. This is part of the study because we want to compare both versions. However, if you happen to get the version without exercises, you can still get access to the exercises later on. This will happen automatically, three months after you have started using the app. Both versions are designed in a way that allows you to use them on your own and whenever you want. There will be no regular assistance by a human, but if you need additional assistance with managing distress or problems or if you have questions regarding the app, you can contact one of our e-helpers directly within the app. If you don't want to use the app on a smartphone, you can also use a web based version of the intervention [link].

2. Study procedures

The study will start with a questionnaire that will take about 20 minutes to complete. Afterwards you will get to choose one personal narrator for the story that will guide you through the app. You will then be assigned to one of the app versions. A short tutorial will introduce you to all of the features of the app. Afterwards you can start using it. For 5 weeks, you will get one new module (a total of 5 modules) with information and—in the exercise version—with new exercises. Once per week, we will also ask you to answer a short questionnaire. In addition, you can always let us know how you are feeling at the moment, using the mood tracker.

After 5 weeks, we will ask you to answer another 20-minute questionnaire. After answering this questionnaire, you can continue using the app as long as you want. You can still contact your e-helper until 2 weeks after completing the last module of the app. 3 months after you have started using the app, we will contact you again and will ask you to answer another questionnaire. If you got the app version without exercises, you will get access to these from this point on. 12 months after you have started using the app, we would like to ask you to answer the final 20-minute questionnaire.

3. Participation is voluntary

If you decide to participate in this study you will get free access to the app. Your participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and stop using the app. You do not have to give any reasons for stopping participation. The same is true for all questions that will be asked within the app. You don't have to answer them, if you don't want to. If

you decide to stop participating in this study, your personal data will be deleted. Only data that are not associated with your personal information will be used for research. This data is protected in a way that makes it technically impossible to delete for a single user of the app because we cannot know who it belongs to.

4. Possible advantages and disadvantages

With your participation, we will learn more about how to use a smartphone app to assist Syrian refugees with problems and distress. We will use this information to further improve the digital program and we will analyze the study data to write scientific publications that could help to inform similar programs in other parts of the world. Please note that the PM+ App is not about providing direct material support or money, but about giving information and teaching important skills. You will get free access to the app but you will not receive any additional compensation for your participation.

To our knowledge, there are no risks associated with using the app. However, it is possible that something you read or hear in the app might make you feel uncomfortable. Therefore, you are not obliged to answer any questions and you may stop using the app or parts of the app at any time. Please make sure that you protect your privacy by not allowing other persons to access the app on your phone. The app has a password system that will help you protecting access to the app. If you feel uncomfortable with installing the app on your phone or a shared phone, you can use the web version of the app instead [link].

5. Confidentiality and data protection

In order to participate in this study, we will need your personal phone number and your full name. This information are personal data that will be protected through technical measures (encryption) and kept strictly separated from all other data. We will need this information to be able to contact you. We will only contact you in order to remind you to answer a questionnaire or if we are worried about your safety (see below: Your safety).

Within the app, we will ask you to answer questions. We will also track the following user information: times the app was opened, number of modules completed, time spent with the app. This information will be stored with an ID code that cannot be linked to your person. We will store this data for 10 years and use it for scientific purposes only.

Within the app, some exercises will ask you to type, record or take pictures. This data will not be send to us and we cannot read, listen or look at it. It will stay on your phone.

Finally, you can send a message to one of our e-helpers at any time and you will receive an answer within 72 hours after sending it. The messages you sent will be stored together with your personal information. They will be kept strictly separate from all other data. If you ask us, we will delete your personal information and all texts that you have exchanged with your e-helper. All information you share with your e-helper will be treated confidential. We will never share any personal information such as names or contact information.

The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study.

6. Your duties as a participant

If you decide to participate, we ask you to comply with the following points. Please answer truthfully on the questions we ask. If you don’t want to answer, you can always skip a question. Please let us know in case you need additional support and please let us know in case you experience any negative effects or emergencies. Please let us know, in case your contact information change. And finally, please let us know if you decide to stop participating in the study. You don’t have to give us any reason.

7. Alternative ways of getting help

Please know that there are alternative ways of getting help with distress and problems. If you think now or while using the app that you need other or additional help, you will find a list of contact addresses in the help section of the app. You can also always contact one of our e-helpers and ask for assistance with finding additional help.

8. Do you have any questions or concerns?

Please contact one of our e-helpers [contact]

You can also contact our researcher:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Part III: Consent

If you want to participate in the study, please confirm the following points:
I have read the information above. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate. [ ]

I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions. [ ]

I agree that my data will be collected and used in the ways described in the information above. I give permission to store these data for 10 years. [ ]

I want to participate in this study. [ ]

The following statements are optional (you don't have to agree to these):
I give permission to approach me after the study, for an interview on my experiences with the app. [ ]
I want to be informed about the results of the study. [ ]

Information Letters Phase 3 and 5 (all countries – participants, e-helpers, health care providers, policy makers)

Participant Information
- Key Informant Interviews (participants) -

"[PM+ App] study"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

1. Purpose of the study

This research is part of the STRENGTHS research project. In the STRENGTHS program we are investigating the effectiveness of a smartphone app that may help Syrian refugees with distress and problems. We have tested the app in a study in which you have participated. Now we would like to ask you for your feedback and input on the following main questions from your perspective:

m) What is your impression of the app?
n) What may make it difficult to use the app?
o) What may be done to make it easier to use the app?
p) What could be done to make the app widely available to Syrian refugees?

In order to get more information on these aspects, we approach participants of our study who have firsthand experience with using the app.

2. The interview

There will be an individual interview conducted by two interviewers. The interview will take approximately one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

3. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of the app for Syrian refugees. For your participation you will receive a compensation of 10€. Apart from that, you will have no personal benefit from participating in this study. To our knowledge, there are not risks associated with participation.

4. Non-participation, not answering questions or stopping participation

Participation in the interview is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any

reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

5. Usage and storage of your data

The study protocol requires that we collect the following personal information: name and profession.
Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGHTS consortium and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study.
If you sign the consent form, you agree to the collection, storage and processing of your personal data (name and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant. However, the website will contain a summary of the results.

6. Compensation for participation

You receive no compensation for your participation.

7. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Participant Information
- Key Informant Interviews (participants) -

"[PM+ App] study"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

1. Purpose of the study

This research is part of the STRENGTHS research project. In the STRENGTHS program we are investigating the effectiveness of a smartphone app that may help Syrian refugees with distress and problems. We have tested the app in a study in which you have participated. Now we would like to ask you for your feedback and input on the following main questions from your perspective:

q) What is your impression of the app?
r) What may make it difficult to use the app?
s) What may be done to make it easier to use the app?
t) What could be done to make the app widely available to Syrian refugees?

In order to get more information on these aspects, we approach participants of our study who have firsthand experience with using the app.

2. The interview

There will be an individual interview conducted by two interviewers. The interview will take approximately one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

3. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of the app for Syrian refugees. For your participation you will receive a compensation of 10€. Apart from that, you will have no personal benefit from participating in this study. To our knowledge, there are not risks associated with participation.

4. Non-participation, not answering questions or stopping participation

Participation in the interview is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

5. Usage and storage of your data

The study protocol requires that we collect the following personal information: name and profession. Each participant will receive a personal code. Only this code will be saved together with the interview

data. This data is called “pseudonymised” because your name will not be stored together with your data.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGHTS consortium and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study.
If you sign the consent form, you agree to the collection, storage and processing of your personal data (name and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant. However, the website will contain a summary of the results.

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For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Participant Information
- Key Informant Interviews (e-helpers) -

"[PM+ App] study"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

1. Purpose of the study

This research is part of the STRENGTHS research consortium. In the STRENGTHS program we are investigating the effectiveness of a psychological intervention for common mental health and psychosocial problems in Syrian Refugees. The intervention is a smartphone based adaptation of Problem Management Plus (PM+), a low-threshold intervention manual developed by the World Health Organization (WHO). We have tested the intervention in a randomized controlled study and would like to ask you for your feedback and input on the following main questions from your perspective:

u) What are barriers to treatment engagement and adherence?
v) What can be facilitators for treatment engagement and adherence?
w) Where you see opportunities for scaling up the intervention within the existing healthcare system?

In order to get more information on these aspects, we approach e-helpers who are or were involved in our research to share their experiences, opinions and their knowledge.

2. The interview

There will be an individual interview conducted by two interviewers. The interview will take approximately one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

3. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of psychological care for Syrian refugees. Apart from that, you will have no personal benefit from participating in this study. To our knowledge, there are not risks associated with participation.

4. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

5. Usage and storage of your data

The study protocol requires that we collect the following personal information: name and profession.
Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGHTS consortium and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study.
If you sign the consent form, you agree to the collection, storage and processing of your personal data (name and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant. However, the website will contain a summary of the results.

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7. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Participant Information
- Key Informant Interviews (health care providers) -

"[PM+ App] study"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

1. Purpose of the study

This research is part of the STRENGTHS research consortium. In the STRENGTHS program we are investigating the effectiveness of a psychological intervention for common mental health and psychosocial problems in Syrian Refugees. The intervention is a smartphone based adaptation of Problem Management Plus (PM+), a low-threshold intervention manual developed by the World Health Organization (WHO). We have tested the intervention in a randomized controlled study and would like to ask you for your feedback and input on the following main questions from your perspective:

x) What are barriers to treatment engagement and adherence?
y) What can be facilitators for treatment engagement and adherence?
z) Where you see opportunities for scaling up the intervention within the existing healthcare system?

In order to get more information on these aspects, we approach mental care providers who were involved in our research (e.g. by referring participants to us or by working at a partner organization) to share their experiences, opinions and their knowledge.

2. The interview

There will be an individual interview conducted by two interviewers. The interview will take approximately one hour. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

3. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of psychological care for Syrian refugees. Apart from that, you will have no personal benefit from participating in this study. To our knowledge, there are not risks associated with participation.

4. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

5. Usage and storage of your data

The study protocol requires that we collect the following personal information: name and profession.
Each participant will receive a personal code. Only this code will be saved together with the interview data. This data is called "pseudonymised" because your name will not be stored together with your data.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGHTS consortium and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study.
If you sign the consent form, you agree to the collection, storage and processing of your personal data (name and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant. However, the website will contain a summary of the results.

6. Compensation for participation

You receive no compensation for your participation.

7. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

Mr. Sebastian Burchert (researcher)
Tel.: +49 30 838 57523
Email: s.burchert@fu-berlin.de

Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Participant Information
- Key Informant Interviews (policy makers) -

"[PM+ App] study"

Dear Madam or Sir,

We kindly ask you to participate in a scientific study. Joining this study is voluntary and if you decide to participate, we will need your written consent. This study is conducted by Freie Universität Berlin. Before you decide whether to participate, we would like to provide you with information on our research. Please read the following information letter and ask the investigator if you have questions.

1. Purpose of the study

This research is part of the STRENGTHS research consortium. In the STRENGTHS program we are investigating the effectiveness of a psychological intervention for common mental health and psychosocial problems in Syrian Refugees. The intervention is a smartphone based adaptation of Problem Management Plus (PM+), a low-threshold intervention manual developed by the World Health Organization (WHO). We have tested the intervention in a randomized controlled study and would like to ask you for your feedback and input on the following main question from your perspective:

aa) Where you see opportunities for scaling up the intervention within the existing healthcare system?

In order to get more information on this aspect, we approach policy makers who are involved in refugee mental health care to share their experiences, opinions and their knowledge.

2. The interview

There will be an individual interview conducted by two interviewers. The interview will take approximately 30 minutes. If you are not available in person, the interview can also be conducted via an online audio/video messaging service.

3. Possible advantages and disadvantages

With your participation, you will contribute to the improvement of psychological care for Syrian refugees. Apart from that, you will have no personal benefit from participating in this study. To our knowledge, there are not risks associated with participation.

4. Non-participation, not answering questions or stopping participation

Participation in the study is completely voluntary. If you decide to participate, you can change your mind at any time and refuse to answer a question or stop your participation. You do not have to give any reasons for stopping participation but we ask you to inform the researcher immediately. The data that was collected up to that point will be used for research, unless you ask us to delete the information.

5. Usage and storage of your data

The study protocol requires that we collect the following personal information: name and profession. Each participant will receive a personal code. Only this code will be saved together with the interview

data. This data is called “pseudonymised” because your name will not be stored together with your data.
All information will be treated confidential. Only the study director will have an encrypted and password protected list of all codes and the related names.
The London School of Hygiene and Tropical Medicine and the Danish Red Cross are our partners in the STRENGHTS consortium and will coordinate the research. For this reason, we will share the information from this interview with these two partners. We will not share any personal information such as names or contact information. All information will be sent anonymized and encrypted.
The survey data will be published in a scientific journal and cannot be traced back to you. If you want, we will inform you about the results of the study.
If you sign the consent form, you agree to the collection, storage and processing of your personal data (name and profession) and the written interview protocols. This data will be securely stored for 10 years and then destroyed.
This research will be described on the STRENGTHS website (www.strengths-project.eu). This website does not contain any information that will allow to identify you as a participant. However, the website will contain a summary of the results.

6. Compensation for participation

You receive no compensation for your participation.

7. Do you have any questions?

For question please contact Mr. Sebastian Burchert (researcher)

Contact:

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Prof. Dr. Christine Knaevelsrud (principal investigator)
Email: christine.knaevelsrud@fu-berlin.de

Thank you very much for your attention!

Consent Forms Phase 3 and 5 (all countries – Participants, e-helpers, health care providers, policy makers)

Informed Consent Form
- Key Informant Interviews -

"[PM+ App] study"

ID: _____

Dear Madam or Sir,

please read the following statements regarding your participation in the study.

1. I have read the information letter. I had the chance to ask questions. My questions have been answered sufficiently and I had enough time to decide whether to participate.
2. I know that participation in this study is voluntary. I also know that I can decide to stop my participation at any time and that I can refuse to answer questions.
3. I agree that my data will be collected and used in the ways described in the information letter. I give permission to store these data for 10 years.
4. I want to participate in this study.

Please mark the following statements with a cross, if you agree.

□ I give permission to approach me after this survey again for a follow-up study.

□ I want to be informed about the results of this study.

Name of participant:

Signature: Date:
____/____/____