



INFORMED CONSENT PROCEDURES

DELIVERABLE 9.7



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List of abbreviations and acronyms

DRC	Reference Centre for Psychosocial Support/Danish Red Cross
FUB	Freie Universitaet Berlin
EASE	Early Adolescent Skills for Emotions
IC	Informed Consent
IMC	International Medical Corps UK LBG
ISU	İstanbul Sehir Universitesi
IPSY	I-Psy Midden en Noord Nederland (IPSY)
KIT	The Royal Tropical Institute
LSE	London School of Economics and Political Science
LSHTM	London School of Hygiene and Tropical Medicine
N/A	Not Applicable
PM+	Problem Management Plus
RASASA	Multeciler Ve Siginmacilar Yardimlasma Ve Day Anisma Dernegi
STRENGTHS	Syrian REfuGees MeNTal Health Care Systems
UNSW	University of New South Wales
UZH	Universität Zürich
VUA	Vrije Universiteit Amsterdam
WCH	War Child Holland
WHO	World Health Organization
WP	Work Package

1. STRENGTHS Informed Consent Procedures

This document describes all informed consent (IC) procedures that will be implemented during STRENGTHS in relation to the data collection, storage and protection of personal data.

1.1. Main aims of STRENGTHS

STRENGTHS (*Syrian REfuGees MeNTal Health Care Systems*) is an European Union Horizon2020 funded research project that aims to provide and evaluate effective community-based health care implementation strategies to scale-up the delivery and uptake of effective mental health and psychosocial support interventions for Syrian refugees who are located in Europe and countries bordering Syria.

Research data will be collected in several studies across the STRENGTHS Work Packages involving Syrian refugees and key stakeholders involved in providing mental health and psychosocial support in Syrian refugees.

In STRENGTHS, health system evaluations will be conducted and key informant interviews examining the needs of Syrian refugees and key stakeholders for the provision of evidence-based interventions to reduce psychological distress will be carried out. In addition, pragmatic trials evaluating the effectiveness of low-intensity interventions that aim to reduce psychological distress in Syrian refugees will be conducted across eight sites (Jordan, Lebanon, the Netherlands, Switzerland, Germany, Turkey, Egypt, and Sweden).

1.2. Overview of informed consent procedures implemented

We refer to D.9.1 and D.9.9 for templates for Informed Consent Forms and Information Sheets as used across all studies described below.

In addition, a detailed overview of all datasets to be collected during STRENGTHS and procedures to be implemented for storage and protection of personal data is provided in the Data Management and Protection Plan (D1.1).

On the following pages, we provide an overview of the informed consent procedures that are implemented across the STRENGTHS studies.

1.2.1. WP1 Management and Overall Coordination

Not applicable, no primary data will be collected in this WP.

1.2.2. WP2 Health Systems Evaluation

Study 1	Rapid assessments of health systems responsiveness (T2.1)
Partners involved:	LSHTM, KIT, IMC, WCH, VUA, ISU, IMC, UZH, FUB
Data collected by:	LSHTM (all countries), WCH (Lebanon), IMC (Jordan), VUA (the Netherlands), ISU (Turkey), UZH (Switzerland), FUB (Germany, Sweden and Egypt).
Aim of data collection:	Analyse responsiveness of health systems to scaling up psychosocial interventions for Syrian refugees.
Study participants:	Stakeholders: healthy expert respondents on mental health systems for refugees (policy makers, directors of refugee clinics etc.) in all project countries (Jordan, Lebanon, the Netherlands, Turkey, Switzerland, Germany, Egypt, Sweden).
Ethics approval by:	<p>LSHTM: Ethics approval submitted to London School of Hygiene and Tropical Medicine, approval received September 14 2017.</p> <p>IMC: Jordan Ministry of Health (approval June 11, 2017)</p> <p>WCH: St Joseph University, Beirut, Lebanon (approved dd March 24, 2017)</p> <p>VUA: No objection waiver from VU Medical Center Medical Ethics Committee (dd. April 20, 2017).</p> <p>ISU: Approval from ISU Research Ethics Committee (dd. April 12, 2017)</p> <p>UZH: No objection waiver by Ethics Committee of Canton Zurich KEK-ZH REQ-2017-00404 (dd. June 02, 2017).</p> <p>FUB: Ethics committee of the Department of Education and Psychology at Freie Universität Berlin (dd. June 12, 2017).</p>
Informed consent procedures:	<p>LSHTM: The rapid appraisal work led by LSHTM uses three main methods: (1) reviewing existing publically available published research and routine data and so no informed consent or agreement is required; (2) analysis of qualitative interviews conducted through STRENGTHS partners' formative work (see below); (3) supplementary qualitative work to fill in any knowledge gaps from methods 1 & 2 (along with more in-depth qualitative research later on in the project). The informed consent form and information sheets for this supplementary and more in-depth qualitative research are included in this document.</p> <p>The process for gaining informed consent in the qualitative research will be that the local partners and their community contacts will establish first contact with potential respondents such as Syrian refugees with MHPPS needs, their family members and hospital managers. Policy-makers and other key respondents might be directly approached by WP2 personnel. Snowballing may then be used among key-informants to generate new respondents. Potential respondents will be given an information sheet on the study when they are first approached. This information sheet will either be physically given to them (e.g. in the case of refugees) or sent via email (e.g. in the case of key informants) depending on their preference and internet access permitting. No advertisements, emails, posters etc. will be used.</p> <p>Separate information sheets will be used for each group of participants (i.e. key informants, MHPSS providers, Syrian refugees, family members of Syrian refugees). These contain key elements related to: the purpose of the study and qualitative</p>

methods; the process and content of the interviews; potential harms and benefits from the study; confidentiality; anonymity; and freedom of consent. The interviewer will once again give a short verbal explanation on the study before the interview will be commenced. Informed consent will be sought at this time.

All participants will be asked to give written consent to participate. Verbal consent can be given if the individual's literacy is limited, provided that an impartial witness who is appointed by that individual signs the consent form on their behalf. Some interviews may be held by phone or Skype and in these cases the information sheet and consent will be sought through e-mail confirmation. Verbal consent will also be sought prior to the telephone/Skype interview.

One of the groups of participants in this research are refugees seeking MHPSS care due to a mild or moderate common mental disorder such as mild/moderate depression, anxiety, or post-traumatic stress disorder. Informed consent will be sought in the mother tongue of the respondent. It will be ensured that participant understood the process and the intent of the interview before the interview will commence. The respondent will be asked to recall provision of MHPSS and their quality. To avoid potential distress, no questions on past exposure to traumatic events will be asked. Nevertheless, should the respondent get upset or distressed, the interview will be paused or stopped. Interviewers will receive training in dealing with distressed participants. The respondent will have the opportunity to speak with an appropriate member of research staff and can get referred to local psychosocial support services should the respondent wish to access those in addition.

IMC: Verbal and written consent was obtained by all study participants to ensure informed permission to collect and store anonymized data. A consent form was developed which provided information on the purposes of the study, how data will be utilized and ensuring participant anonymity. Participants were informed of their right to withdraw at any time, with no risk to current or future service utilization. The consent form was utilized for community members, mental health and policy maker key informant interviews, and focus group discussions. Illiteracy was accounted for, in that trained interviewers read the consent form, in full, aloud in all interactions with community members. The consent form was reviewed by the Jordan Ministry of Health in the approval process.

WCH: Before taking part in any interview, oral and written information about the study and its purpose is provided by the interviewer to respondents in Arabic. Respondents who decide to participate will be asked to complete a written consent form. The template of the Informed Consent Form has been approved by Ethics Review Committee of the St Joseph University, Beirut, Lebanon.

VUA: Oral and written informed consent is asked to all expert respondents to collect and store data. Information Sheets describe the aims of STRENGTHS and the data collection, pseudonymisation of data, and duration of storage. The template of the Informed Consent Form has been approved by Ethics Review Committee Faculty of Behavioural and has been evaluated by VU Medical Center Medical Ethics Committee (waiver dd. April 12, 2017) (see D9.9 for the Information Sheets and Informed Consent Forms in the Dutch language).

ISU: Oral and written informed consent is asked to all expert respondents to collect and store data. Information Sheets describe the aims of STRENGTHS and the data

	<p>collection, pseudonymisation of data, and duration of storage. The template of the Informed Consent Form has been evaluated and approved by Istanbul Sehir University Ethics Review Committee (waiver dd. April 12, 2017) (see 10.ISU for the Information Sheets and Informed Consent Forms in English).</p> <p>UZH: The participants were identified and contacted through stakeholders. If a person agreed to be contacted by the USZ research team, a research assistant contacted the person for recruitment. The participants were <u>informed orally</u> about the study approach. Since we didn't ask them about any personal or health-related questions there was no necessary to sign the informed consent. This procedure and the template of the Informed Consent Form has been approved by Ethic Committee of Canton Zurich (KEK-ZH REQ-2017-00404, dd June 02, 2017)</p> <p>FUB: All participants will provide initial verbal consent in advance and additional written consent immediately prior to the interview. The informed consent will be based on the following information that are provided in written:</p> <ol style="list-style-type: none"> Which organization is conducting the study The purpose of the study and how the result will be used The conduct of the interview and its estimated duration An explanation of the right to refuse to participate or answer any questions, or withdraw at any time without any adverse consequences Assurance of privacy and confidentiality Instructions on how to contact the study director with any questions or concerns <p>The interview facilitator will make sure that participants had sufficient time to read the document and to ask questions.</p>
Study 2	Community-level surveys with refugees (T.2.2)
Partners involved:	LSHTM, KIT, ISU
Data collected by:	LSHTM (in Germany by party in Leipzig to be subcontracted), ISU (Turkey).
Aim of data collection:	Conduct community surveys in refugees on prevalence of (mental) health systems and help-seeking behaviors
Study participants:	Syrian refugees in Turkey (N=1200) and Germany (N=1200)
Ethics approval by:	<p>Overall ethics approval London School of Hygiene and Tropical Medicine received September 14 2017.</p> <p>Local ethics approval received from Istanbul Sehir University by ISU Research Ethics Committee (dd. June 22, 2017) in Turkey and Germany survey under review at Leipzig university (outcome expected early October 2017).</p>
Informed consent procedures:	<p>Turkey survey:</p> <p>The procedure of informed consent will be explained by researchers to respondents prior to the interview. Potential respondents will receive an information sheet in Arabic containing comprehensive study information. These contain key elements related to: the purpose of the study and methods; the process and content of the interviews; potential harms and benefits from the study; confidentiality; anonymity; and freedom of consent. The researcher will also give a short verbal explanation on the study before the interview will be commenced. Consent will be obtained both verbally and in writing immediately prior to the interview. All consent forms will be provided in Arabic. Signed consent will be sought. However, we also recognize that some respondents may have limited literacy skills. These individuals will be asked to provide verbal consent and appoint another individual to sign on his/her behalf.</p>

Translation of the necessary consent forms into Arabic will be conducted by professional translators fluent in both Arabic and English. The initial translation will be followed by back translation to English to ensure process fidelity. Finally, Turkish, Syrian, and international mental health experts who comprise the study team will review the translated forms to determine their appropriateness for piloting and further testing.

To ensure that consent is properly obtained, trained researchers will be used who are fluent in Arabic and sensitive to the needs of refugees and potential vulnerabilities. The researchers responsible for obtaining consent will ensure that the entire process is explained clearly (including the lack of therapeutic benefit), offer additional time to consider, and highlight that participation is entirely voluntary and consent may be withdrawn at any time. If they feel that the participant cannot adequately understand the survey and its process and so cannot make an informed choice, the interview will not take place.

Germany survey:

The procedure of informed consent will be explained by researchers to respondents prior to the interview. Potential respondents will receive an information sheet in Arabic containing comprehensive study information. These contain key elements related to: the purpose of the study and methods; the process and content of the interviews; potential harms and benefits from the study; confidentiality; anonymity; and freedom of consent. The researcher will also give a short verbal explanation on the study before the interview will be commenced. Consent will be obtained both verbally and in writing immediately prior to the interview. All consent forms will be provided in Arabic. Signed consent will be sought. However, we also recognize that some respondents may have limited literacy skills. These individuals will be asked to provide verbal consent and appoint another individual to sign on his/her behalf.

Translation of the necessary consent forms into Arabic will be conducted by professional translators fluent in both Arabic, German and English. The initial translation will be followed by back translation to English to ensure process fidelity. Finally, German, Syrian, and international mental health experts who comprise the study team will review the translated forms to determine their appropriateness for piloting and further testing.

To ensure that consent is properly obtained, trained researchers will be used who are fluent in Arabic and sensitive to the needs of refugees and potential vulnerabilities. The researchers responsible for obtaining consent will ensure that the entire process is explained clearly (including the lack of therapeutic benefit), offer additional time to consider, and highlight that participation is entirely voluntary and consent may be withdrawn at any time. If they feel that the participant cannot adequately understand the survey and its process and so cannot make an informed choice, the interview will not take place.

1.2.3. WP3 Adaptation

Study 1	
Partners involved:	DRC, VUA, FUB, WCH, ISU, IMC, UZH
Data collected by:	Data collection was coordinated overall by DRC, but collected by or in collaboration with WCH (Lebanon), IMC (Jordan), VUA (the Netherlands), ISU (Turkey), UZH (Switzerland), FUB (Germany, Sweden and Egypt), with each partner collecting data for the cultural adaptation as part of their overall data collection. For the data collection pertaining to cognitive interviews (for details see D3.1, forthcoming) DRC collaborated on the ground with VUA and ISU to collect data. For this purpose the informed consent procedures and documents for respectively VUA and ISU were used.
Aim of data collection:	To translate and culturally adapt the different versions of the scalable WHO programmes for use in Syrian refugees
Study participants:	<ol style="list-style-type: none"> 1. Healthy Syrians from the refugee population in all project countries (Jordan, Lebanon, the Netherlands, Turkey, Switzerland, Germany, Egypt, Sweden). 2. Stakeholders: local mental health care professionals and policy makers in all project countries (Jordan, Lebanon, the Netherlands, Turkey, Switzerland, Germany, Egypt, Sweden).
Ethics approval by:	<p>DRC: Waiver from Region Hovedstaden (dd. June 28, 2017)</p> <p>IMC: Jordan Ministry of Health (approval June 11, 2017)</p> <p>WCH: St Joseph University, Beirut, Lebanon (approved dd March 24, 2017)</p> <p>VUA: No objection waiver from VU Medical Center Medical Ethics Committee (dd. April 20, 2017).</p> <p>ISU: Approval from ISU Research Ethics Committee (dd. April 12, 2017), The Immigration Authority of Turkey (dd. March 29, 2017)</p> <p>UZH: No objection waiver by Ethics Committee of Canton Zurich KEK-ZH REQ-2017-00404 (dd. June 02, 2017).</p> <p>FUB: Ethics committee of the Department of Education and Psychology at Freie Universität Berlin (dd. June 12, 2017).</p>
Informed consent procedures:	<p>IMC: Verbal and written consent was obtained by all study participants to ensure informed permission to collect and store anonymized data. A consent form was developed which provided information on the purposes of the study, how data will be utilized and ensuring participant anonymity. Participants were informed of their right to withdraw at any time, with no risk to current or future service utilization. The consent form was utilized for community members, mental health and policy maker key informant interviews, and focus group discussions. Illiteracy was accounted for, in that trained interviewers read the consent form, in full, aloud in all interactions with community members. The consent form was reviewed by the Jordan Ministry of Health in the approval process.</p> <p>WCH: Before taking part in any interview, oral and written information about the study and its purpose is provided by the interviewer to respondents in Arabic. Respondents who decide to participate will be asked to complete a written consent form. For the children and adolescents (under 18 years of age), consent by one caregiver was also obtained in order for them to take part. The children and adolescents were asked to give their assent, which is a requirement for participation. The templates of the Informed Consent Form is approved by Ethics Review Committee of the St Joseph University.</p>

	<p>VUA: Oral and written informed consent is asked to all study participants to collect and store data. Information Sheets describe the aims of STRENGTHS and the data collection, pseudonymisation of data, and duration of storage. The template of the Informed Consent Form has been evaluated by VU Medical Center Medical Ethics Committee (waiver dd. April 20, 2017) (see D9.9 for the Information Sheets and Informed Consent Forms in the Dutch language).</p> <p>ISU: Oral and written informed consent is asked to all expert respondents to collect and store data. Information Sheets describe the aims of STRENGTHS and the data collection, pseudonymisation of data, and duration of storage. The template of the Informed Consent Form has been evaluated and approved by Istanbul Sehir University Ethics Review Committee (waiver dd. April 12, 2017) (see 10.ISU for the Information Sheets and Informed Consent Forms in English).</p> <p>UZH: The individuals were identified and contacted through stakeholders. If a person agreed to be contacted by the USZ research team, a research assistant contacted the person for recruitment. The participants were <u>informed orally</u> about the study approach. Since no personal or health-related questions were asked there was no necessary to sign a written informed consent. This procedure and the template of the Informed Consent Form has been approved by Ethic Committee of Canton Zurich (KEK-ZH REQ-2017-00404, dd. June 02, 2017)</p> <p>FUB: All participants provide initial verbal consent in advance and additional written consent immediately prior to the interview. The informed consent is based on the following information that are provided in written:</p> <ul style="list-style-type: none"> a) Which organization is conducting the study b) The purpose of the study and how the result will be used c) The conduct of the interview and its estimated duration d) An explanation of the right to refuse to participate or answer any questions, or withdraw at any time without any adverse consequences e) Assurance of privacy and confidentiality f) Instructions on how to contact the study director with any questions or concerns <p>The interview facilitator will make sure that participants had sufficient time to read the document and to ask questions.</p>
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1.2.4. WP4 Refugee Settlement and Camp Implementation

Study 1	Jordan
Partners involved:	UNSW, IMC
Data collected by:	UNSW and IMC (Jordan)
Aim of data collection:	To evaluate feasibility and effectiveness of implementation of the low-intensity PM+ programmes in Jordan
Study participants:	Adult Syrian refugees
Ethics approval by:	UNSW Human Research Ethics Committee (HREC), dd. July 27, 2017
Informed consent procedures:	The informed consent process entails a two-step procedure; 1. Informed consent for screening, and 2. Informed consent for taking part in the PM+ trial.

	<p>1. Participants will first be orally informed about the project by staff, and will be asked whether they agree that a member of the research team will provide them with further information about the study. Only if permission is given a research assistant will informed consent for study participation be requested. Participants will be free to decline to participate or withdraw at any time. Respondents who decide to participate will be asked to complete a written consent form. For participants who are illiterate, witnessed oral consent and a thumb print in lieu of a signature will be sufficient. The witness will be a member of the research staff and who is willing to act as the witness.</p> <p>Following informed consent for screening, demographic characteristics will be recorded by the research assistant and participants will be invited to complete the K-10, the WHODAS 2.0, and the PM+ manual suicide tool. No identifiable information will be recorded.</p> <p>2. If participants meet the eligibility criteria (K-10 >15.9 and WHODAS 2.0 >16), they will be given oral and written information about participating in the RCT by the research assistant. At least 24 hours after, a research assistant will ask informed consent to participate in the trial (see Screening Consent Form).</p> <p>Following informed consent for participating in the trial, the K10, the WHODAS 2.0, the Psychological Outcome Profiles instrument (PSYCHLOPS), the Life Events Checklist (LEC), the PTSD Checklist for DSM-5 (PCL-5), the Post-Migration Living Difficulties (PMLD), and the Client Service Receipt Inventory (CSRI) will be administered. Also, the Strengths and Difficulties Questionnaire will be completed by the child.</p>
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Study 2	Lebanon
Partners involved:	WCH
Data collected by:	WCH (Lebanon)
Aim of data collection:	To evaluate feasibility and effectiveness of implementation of Early Adolescent Skills for Emotions (EASE) in Lebanon
Study participants:	Young adolescent Syrian refugees (ages 10-14)
Ethics approval by:	The research protocol for this study has been approved by the Ethics Review Committee of St Joseph University, Beirut, Lebanon on September 25, 2017
Informed consent procedures:	<p>Before taking part in any interview, oral and written information about the study and its purpose is provided by the interviewer to respondents in Arabic.</p> <p>Respondents who decide to participate will be asked to complete a written consent form. For the children and adolescents (under 18 years of age), consent by one caregiver will also be required in order for them to take part. The children and adolescents are asked to give their assent, which is a requirement for participation. The templates of the Informed Consent Form has been approved by Ethics Review Committee of the St Joseph University and the Ethics Committee of the WHO. Given high rates of illiteracy and varying developmental stages of young adolescents and their caregivers, the consent form will be read in local, lay language to all caregivers and participants. After providing verbal consent, literate participants and caregivers will be asked to acknowledge the process with a signature. For participants and their caregivers with literacy difficulties, a witnessed thumb print in lieu of a signature will</p>

	be sufficient. It will be ensured that potential participants and their caregivers fully understand what it means to participate and that they can withdraw their consent at any time without having to give an explanation. It will also be made clear that refusal to participate will not have an impact on any type of support they receive.
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1.2.5. WP5 Community Implementation

Study 1	The Netherlands
Partners involved:	VUA, IPSY
Data collected by:	VUA and IPSY (The Netherlands)
Aim of data collection:	To evaluate feasibility and effectiveness of implementation of the low-intensity PM+ programme in the Netherlands
Study participants:	Adult Syrian refugees
Ethics approval by:	VU Medical Center Medical Ethics Committee, approval dd. September 6, 2017
Informed consent procedures:	<p>If a participant agrees to participate or when a participant contacts the project (VU Amsterdam or i-Psy) to participate, a VU research assistant will meet with the eligible patient at a later time and will ask informed consent. The VU research assistant will explain the research to the potential study participant and will provide the information letter to the participant (see 'E1. Informatiebrief participanten fase 2 versie 2 dd 01-08-2017' and 'E1. Informatiebrief participanten fase 4 versie 2 dd 01-08-2017'). Participants will be free to decline to participate or withdraw at any time. Respondents who decide to participate will be asked to complete a written consent form (after a minimum consideration time of one week). For participants who are illiterate, witnessed oral consent in lieu of a signature will be sufficient. The witness will be any adult person (not related to the participant) who the participant is comfortable having present during consent, and who is willing to act (and sign) as the witness.</p> <p>If participants meet the eligibility criteria (K10 >15.9 and WHODAS 2.0 >16), they can participate in the study. Participants are allowed to withdraw from the study at any time after they have given their written or witnessed oral consent in case of illiterate participants.</p>

Study 2	Turkey
Partners involved:	ISU, RASASA
Data collected by:	ISU and RASASA (Turkey)
Aim of data collection:	To evaluate feasibility and effectiveness of implementation of the low-intensity PM+ programme in Turkey
Study participants:	Adult Syrian refugees
Ethics approval by:	ISU Research Ethics Committee (dd. April 12, 2017), The Immigration Authority of Turkey (dd. March 29, 2017)
Informed consent procedures:	<p>The participants who meet the eligibility criteria (K10 >15.9 and WHODAS 2.0 >16) in the initial interview will be invited to RASASA. A research assistant from ISU will meet the eligible participant, explain the research and, provide the information letter to the participant (see '5.ISU Informed Consent form for the Trial'). The potential participants do not have to decide whether they will participate in the research on the meeting day. Before they decide, they can talk to anyone they feel comfortable with about the research. Participants will be free to decline to participate or</p>

	withdraw at any time. Respondents who decide to participate will be asked to complete a written consent form (after a minimum consideration time of one week). For participants who are illiterate, witnessed oral consent and the thumb print of participant will be sufficient. The witness will be any adult person (not related to the participant) who the participant is comfortable having present during consent, and who is willing to act (and sign) as the witness.
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Study 3	Switzerland
Partners involved:	UZH
Data collected by:	UZH (Switzerland)
Aim of data collection:	To evaluate feasibility and effectiveness of implementation of the low-intensity PM+ programme in Switzerland
Study participants:	Adult Syrian refugees
Ethics approval by:	Ethics Committee of Canton Zurich [BASEC-Nr.: 2017-01175]), dd. September 08, 2017.
Informed consent procedures:	Interested persons will contact the research team. The research team will inform them orally or in written about the project in general and will ask whether they agree that a member of the research team will provide them with further comprehensive information about the research. Only if permission is given a research assistant will meet with the eligible patient later and will ask written informed consent for screening. If participants meet the eligibility criteria, they will be given oral and written information about participating in the exploratory RCT by the research assistant. At least 24 hours thereafter, a research assistant will request written informed consent to participate in the exploratory RCT.

1.2.6. WP6 Online Implementation

Study 1	Germany
Study 2	Egypt
Study 3	Sweden
Partners involved:	FUB
Data collected by:	FUB
Aim of data collection:	Development and scientific evaluation of a smartphone and internet based psychological intervention for Syrian refugees with common mental health problems.
Study participants:	Adult Syrian refugees
Ethics approval by:	Ethics committee of the Department of Education and Psychology at Freie Universität Berlin (approved dd. August 16, 2017)
Informed consent procedures:	All participants will receive detailed information on the following topics: a) Which organization is conducting the study b) The purpose of the study and how the result will be used c) The intervention and its estimated duration d) An explanation of the right to refuse to participate or answer any questions, or withdraw at any time without any adverse consequences e) Potential risks of participation f) Assurance of privacy and confidentiality g) Instructions on how to contact the study director with any questions or concerns

	<p>The information is presented within the app, will be provided in Arabic, is available in written form and as audio for illiterate users. Before giving consent to participate in the study, every user will have the chance to contact the study team via email or phone in order to ask questions (in Arabic or English). Potential participants are not required to immediately give consent and can always return to the consent form on every restart of the app (until consent was given or refused). At no time will participants be informed incompletely or falsely about the purpose of the study.</p>
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1.2.7. WP7 Economic and Implementation Evaluation

Not applicable, no primary data will be collected in this WP.

1.2.8. WP8 Synthesis and Dissemination

Not applicable, no primary data will be collected in this WP.